

# Medicine Health RHODE ISLAND

PUBLICATION OF THE RHODE ISLAND MEDICAL SOCIETY



## Risk Management

# What's in a Name???

GOOD - authentic, honest, just, kind, pleasant, skillful, valid

NEIGHBOR - friend, near

ALLIANCE - affiliation, association, marriage, relationship

CORPORATION - company, business establishment

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VOLUME 90 No. 6 June 2007

PUBLICATION OF THE RHODE ISLAND MEDICAL SOCIETY

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## Commentaries

### “...But I can still sue you, can’t I?”

“Sure you can. This is America. Anyone can sue anyone else. But you couldn’t win. I’m doing you a favor.”

“If I can’t sue you, then I won’t take it.”

**Mr X was a 35 year-old man in a very** unfortunate situation. I met him in the forensic unit of the state hospital. He had been arrested after he stabbed a close relative because he thought the relative was involved with his girl friend. Since the patient suffered from paranoid schizophrenia, I had no idea whether this was a real concern or not, but it hardly mattered. To get transferred from the jail to the Institute of Mental Health required a severe degree of mental illness.

I was evaluating Mr X because of a severe movement disorder induced by his antipsychotic medication. The medication he required to control his paranoia had caused **tardive dystonia (TD)**. With the drugs available to treat his psychosis at the time this occurred, TD was not uncommon, and all had the potential for causing the problem. In most cases, the TD was so mild that it was not even noticed by the patient. In cases where it was noticed it was not usually disabling, but on rare occasion it was. The tardive dystonia was, in fact, disabling for Mr X. He had involuntary spasms that caused him to look up at the ceiling, grimace violently and close his eyes. The spasms occurred about every 10 seconds or so. He was a living figure from a Breughel painting.

As a result of this disorder he had sued his doctors. Since he was on Medicaid, his options for doctors were even more limited than the choices his doctors had for treating him. His doctors had quite generously arranged for him to be treated at a different mental health center so as to avoid the conflicts of treating a patient who was suing his treating physicians.

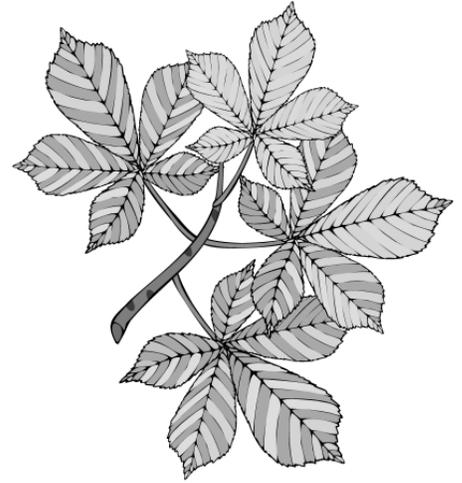
At the time that I met him there were no good treatment options. Treat

the psychosis and make the movement disorder worse, or don’t treat the psychosis and hope that the movement disorder resolved. I, however, had a compassionate use protocol for clozapine, not yet approved by the FDA, an antipsychotic more effective than any other, and completely free of movement disorder side effects, a drug that might treat the psychosis without worsening the TD. But it was considered experimental in the 1980s and required informed consent. Obviously a patient in the forensic unit is incapable, by definition, of providing informed consent.

I told Mr X to see me in my outpatient office after discharge so he could be treated with clozapine. When he showed up, he was better than he had been, psychiatrically, but still a long ways from normal. His facial and neck spasms were painful to watch. When we discussed the advantages of the drug he was quiet. “But what about the side effects?”

There used to be a “problem patient clinic” at Rhode Island Hospital. It was for patients who complained a lot, and didn’t have identifiable medical problems to explain their symptoms. Or they had an organic disorder but uncontrollable symptoms. I’m unsure if the “problem” part of the “problem-patient” was the problem of the patient or the problem caused by the patient. A somatoform disorder clinic, if you will. A lot of smoke, not much fire.

There are lots of types of problem patients. A famous article in the *New England Journal of Medicine* many years ago was entitled, *The Hateful Patient*. There are hateful patients, ungrateful patients, demanding patients, drug-seeking patients, hopelessly depressed patients. Mr X was not a hateful patient. He was not seeking drugs and he wasn’t depressed. He did not have a somatoform disorder, complaining of dizziness, back pain, headache, nausea, diarrhea, tin-



gling, chest pain and shortness of breath. He had the unfortunate concurrence of severe psychiatric and neurological diagnoses, one interfering with the other. Patients with personality disorders suffer from these difficulties all the time. Their personalities make them untreatable.

When mentally ill patients seek treatment, their mental illness sets the stage for treatment options. In the case of a paranoid person, since the paranoia is irrational, one can’t convince a patient, one can only hope that the psychiatrist will eventually control the problem so that the medical illness can be treated. This is, of course, a paradox for advocates for the mentally ill, the reluctance to force treatment in someone who is legally competent but clearly, by choosing to not treat an illness, endures severe and long-term suffering. Witness the mentally ill homeless who choose no treatment over a stable, physically comfortable life.

In the case of Mr X, one of life’s miracles occurred. I lost track of him (but that was not the miracle), until a few years later when my secretary received a call. “This is Mr X. Please tell Dr Friedman that I got put on clozapine when the FDA approved it. My movement disorder went away and my schizophrenia got better too. I got my life together. Tell him that I thank him for trying to help me.”

Would all life’s stories end so well. Although a true story, it remains apocryphal as well. You never know what your next “problem patient” may metamorphose into.

— JOSEPH H. FRIEDMAN, MD

# A Brief Chronicle of Appendicitis

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*Ehrich Weiss was born on March 24, 1871, in Budapest, Hungary, one of seven Weiss children. His father, a rabbi, was recruited by a congregation in Appleton, Wisconsin; and so, in 1889, the family left Europe and migrated to the American Midwest. Ehrich, called Harry by his family, was short, five feet and five inches, but otherwise physically active with a love of sports and a fascination for traveling circuses. When the family moved to New York City, a youthful Ehrich worked briefly as a locksmith's apprentice; and in his free time he sought employment as a trapeze-artist with one of the local circuses.*

**In 1892, at age 21, Ehrich Weiss, declared himself to be a magician and, accordingly, changed his name to Harry Houdini after the renown 19th Century French magician, Jean Robert-Houdin.**

Houdini's career blossomed, particularly because of his inventive escape acts, freeing himself from jails, chains, handcuffs, straitjackets and even from locked, water-filled tanks.

By 1914 Houdini had reached the pinnacle of his career as an illusionist and escape artist, performing to enthusiastic audiences throughout Europe and North America. He now added two parallel vocations: He shared his prestidigitational secrets with both the British and American Secret Services during the first World War; and, by 1920, he invested his energies and resources in debunking so-called psychics and mentalists. This pursuit cost him the friendship of Arthur Conan Doyle, who was an implacable believer in spiritualism.

Houdini's final performance took place in Detroit's Garrick Theater on October 24, 1926. After a strenuous performance he retired to his dressing room couch. A student from McGill University, J. Gordon Whitehead, entered and asked Houdini if it was true that his abdominal muscles were strong enough to withstand blows of a human fist. Without waiting for a reply, Whitehead struck Houdini's abdomen repeatedly with his fists until others restrained him. On the following day Houdini complained of nausea and abdominal pain. He sought admission to Grace Hospital. A diagnosis of appendicitis was made and surgery revealed an inflamed, ruptured appendix. Peritonitis developed and Houdini died on the afternoon of October 31 [Halloween], 1926. He was 52 years old. Most physicians declared that the blows to his abdomen played little if any role in his encounter with appendicitis.

During the last few centuries, appendicitis [inflammation of the appendix] has been a common occurrence. In the United States, the lifetime risk of developing acute appendicitis is about 8.6% in males and 6.7% in females. Thus approximately one in 400 Americans develops appendicitis each year with a total of close to 700,000 Americans who are its annual victims. Fewer than 400 per year, however, die of the disease.

The human appendix, a vestigial structure with no known current function, is an inconspicuous worm-like extension of the ascending segment of the large intestine. It is rarely more than three inches in length. And while the appendix was clearly illustrated in the anatomical drawings of da Vinci [1492] and in the anatomy texts of Vesalius [published in 1543], the structure was not specifically named in any anatomy publication until the writings of the Italian anatomist, Berengario Da Carpi in 1521.

The first clinical recognition of disease of the appendix is assigned to an 1812 scientific paper written by a London physician, James Parkinson [1755 - 1824], who described a five year-old boy suffering from acute abdominal pain associated with nausea. The child died within two days of the onset of the pains. An autopsy disclosed intense inflammation confined to the appendix and Parkinson coined the word appendicitis to give the disease an identity. This was the same physician who wrote extensively on the need for democratic reform in England [he was charged with high treason by King George III]. He also published extensively on geology, paleontology and authored, in 1817, *An Essay on the Shaking Palsy*, now commonly known as Parkinson's disease.

A brief paper by Francois Melier added further autopsy-derived verification of appendiceal inflammation as a cause for pain in the right lower quadrant of the abdomen. But it wasn't until June, 1886, when Reginald Heber Fitz, MD, [1843 - 1913], Professor of Pathological Anatomy at Harvard, offered a scientific paper, "Perforating Inflammation of the Vermiform Appendix: With Special Reference to its Early Diagnosis and Treatment," that the disease became widely recognized. The recognition was not total, however. In 1897, Dr. Harvey Cushing, then in training in surgery at Johns Hopkins Hospital in Baltimore, made the diagnosis of acute appendicitis on himself. Few of his superiors believed it and Cushing, after 22 hours of searching, finally found a surgeon brave enough to operate. The diagnosis was confirmed and Cushing went on to become this nation's most prominent surgeon in the early decades of the 20th Century.

Well-documented epidemiological studies indicate that the frequency of acute appendicitis is gradually diminishing. Despite this, an estimated 2,300 Rhode Islanders will require surgery for the disease in the coming twelve months. Fortunately, few will be inconvenienced more than the usual four days of hospital stay.

— STANLEY M. ARONSON, MD

# Risk Management: Introduction

Patricia R. Recupero, JD, MD, and Lawrence W. Vernaglia, JD, MPH

**“Risk management” in medicine means** different things to different people. To some physicians, it represents a hospital-imposed bureaucratic hassle interfering with time that should be spent in direct patient care activities. Other physicians have come to recognize that risk management is not just about avoiding legal liability, but about improving patient care by optimizing procedures and avoiding certain known or anticipated risks. Risk management means better patient care and improved outcomes, with better results for all.

This issue, which we guest edited at the request of the *Journal*, represents several perspectives on risk management in medicine. These are far from the only issues facing modern healthcare. Rather, they represent what we believe are voices and approaches worthy of serious consideration, and which also provide some insights into other ways that risk management may prove helpful in the healthcare setting.

In these pages, you will find discussions about risk management strategies relating to new models of physician-patient communications and the impact of new technology on practice patterns. These articles focus on industry-driven as well as technology-driven changes to medical practice. We have also included a thoughtful piece on the dangers of prescribing for oneself or one’s associates – not a new problem, but one which has special implications for risk management in the increasingly-regulated healthcare market. Finally, as the courtroom is the real overlap between law and medicine in “risk management,” we focus on an important decision from the Rhode Island Supreme Court that challenges many commonly-held notions about the breadth of the “peer review” privilege.

These articles not only showcase several valuable specific topics in risk management; they each offer insights into how thoughtful risk management practices *improve* patient outcomes and quality of

care. We hope you find these articles helpful to your practice. We look forward to continuing this dialogue in the *Journal* as well as in the community.

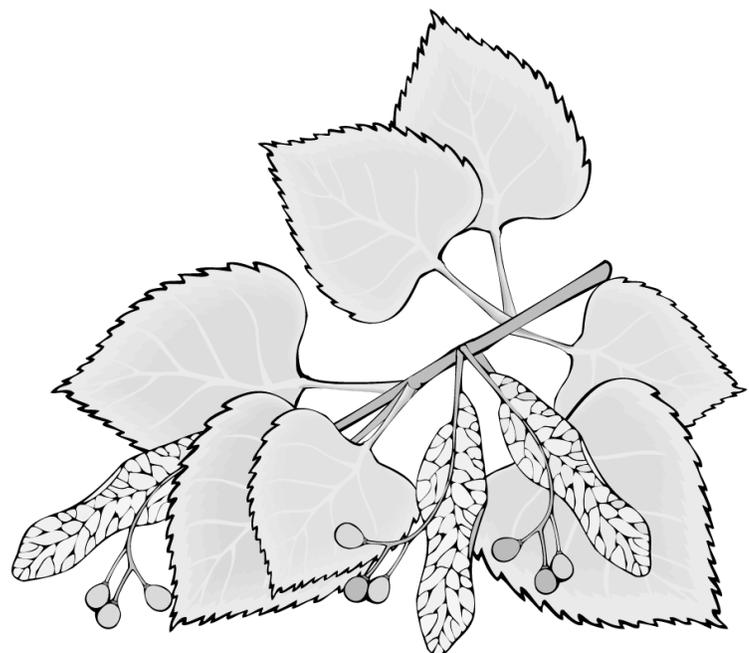
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# Websites and E-mail In Medical Practice: Suggestions for Risk Management

Patricia R. Recupero, JD, MD, and Samara E. Rainey

**Increasing numbers of patients seek** information online before consulting their physicians.<sup>1</sup> Over 70% of American internet users go online for health information; 90% of them find the information reliable.<sup>2</sup> Some health organizations, such as Dartmouth-Hitchcock Medical Center in Lebanon, NH, offer online consultations for patients frustrated with the difficulties of phone tag.<sup>2</sup> Some physicians, too, now have websites, and many physicians e-mail their patients. With the benefits of new technology comes the necessity for newer safeguards and strategies to reduce risk. This article aims to present some of the legal risks associated with the use of websites and e-mail in clinical practice, along with some suggestions for risk management.

## WEBSITES IN MEDICAL PRACTICE

In 2004, 28% of internet users had researched a specific doctor or hospital online.<sup>2</sup> Websites may be an inexpensive marketing tool, attracting new patients. On websites providers can post information about their practices, links to health information sites, and resources to increase patients' and families' understanding of health issues.

When designing a website, the physician should consider the complex legal ramifications. Typically, the more interactive a website is, the greater the number of legal risks and concerns its owner should anticipate. We begin with a discussion of the classification of websites under the law.

## Website Design and Interactive Features

In cyberspace, activities normally governed by state law, such as business transactions, may frequently cross state boundaries. The courts have adopted a "sliding scale" test for determining whether a particular state court may exercise jurisdiction over a website's owner.<sup>3</sup> According to this test, a website may belong to one of three categories: passive websites, interactive websites, and business websites. These categories differen-

tiate websites according to their levels of interactivity, ranging from minimal to extensive, and the likelihood of sufficient contacts for jurisdiction correspondingly increases. Passive websites amount to little more than advertisements. Interactive websites might contain feedback forms or self-screening tests. Business websites, such as online pharmacies, facilitate financial transactions or contracts online. The degree of interactivity on a site, aside from possibly subjecting it to the jurisdiction of a distant court, may also affect the perception of a physician-patient relationship and the corresponding duty of care.

Suppose that Dr. Smith creates a passive website that displays her curriculum vitae, a brief biography, a description of her practice, directions to her office, and contact information. The following activities may directly affect the level of interactivity and risk in her website:

- posting hyperlinks to other health information websites, especially those designed to promote particular treatments or practices
- hosting, and receiving money for, banner advertisements or other advertisements or implied endorsements of pharmaceutical companies or other health companies
- posting a hyperlink to her e-mail address, such that patients can click on the link and e-mail her directly
- encouraging, or soliciting, requests for advice
- self-screening tests (e.g., "Am I at risk for skin cancer? Take our free, confidential online screening.")
- invitations for site visitors to purchase her books (with a link to the website selling the books)
- a form through which patients or visitors can message her directly

When she adds an "intake form" to her website, and individuals from distant states contact her for advice, her liability risk may increase. Laws regulat-

ing telemedicine and cybermedicine change frequently, and state laws are not uniform. Staying current on the relevant laws would require additional research and time. When designing a website, it would be prudent to investigate your state's law, ethical obligations, professional society requirements, and general health law principles applicable to the website you are planning, in order to understand how different features might affect levels of risk.

## Advertising

In many cases, websites are advertisements. Because they can be more interactive than simple media advertisements (e.g., television ads, brochures, etc.), and because they are usually accessible through internet search engines, they may be an attractive networking tool for professionals. However, like other forms of advertising, websites are subject to regulation by the **Federal Trade Commission (FTC)** and other regulatory bodies, such as the **United States Food and Drug Administration (FDA)**, if they contain claims regarding particular medicines or treatments. The FTC has taken action against advertisers for false claims on websites about health treatments and false representations about privacy policies.<sup>4</sup> The presence of hosted advertisements, as well as the choice of domain or "domain extension" (for example, whether it is a .com, .org, or .edu site) may affect the credibility of the website.<sup>5</sup> When creating a website, physicians should be conscious of the advertising laws and avoid unsubstantiated claims, misleading statements, and trademark or copyright infringement. For more information about legal risks related to advertising, see Professor Ronald L. Scott's review, "Cybermedicine and Virtual Pharmacies."<sup>6</sup>

## Disclaimers and Click-Wrap Agreements

Many websites contain disclaimers to discourage unrealistic expectations on the part of the visitor. Dr. Smith's website,

for example, might offer the following disclaimer above a hyperlinked e-mail address: "Please note that not all e-mails will receive replies. If you are not a patient, please call our office at [phone number] to set up an appointment. If you are an existing patient, and this is an urgent matter, please call [phone number] immediately." Physicians should not assume, however, that a disclaimer will necessarily protect them from liability, nor reduce their ethical duties to patients. Simply posting a disclaimer may not prevent a malpractice action if the physician provides advice upon which the patient relies to his detriment, or if the physician disregards communications concerning existing patients. However, disclaimers may clarify for patients and visitors the purposes and limits of the physician's website.

Websites may also use **click-wrap agreements (CWAs)**: electronic contracts in which a visitor indicates his acceptance to the terms by clicking an "I accept" button. CWAs may be legally binding and are typically enforceable.<sup>7</sup> However, CWAs, like other contracts, may be invalidated by courts if they contain objectionable terms or do not sufficiently warn the reader of rights or privileges he may be surrendering. For example, in *Sanchez v. Sirmons*,<sup>8</sup> the Supreme Court of New York invalidated a contract (not a CWA) requiring arbitration for medical malpractice claims against a physician, since the contract had not adequately alerted the patient that she was surrendering her right to a jury trial. Although the contract had warned that claims would have to be addressed through arbitration, the court found that the patient had not been afforded adequate time to fully consider and agree to the contract's terms, and that the contract did not call sufficient attention to the arbitration clause. While click-wrap agreements may help to add an additional layer of protection and may provide a forum to warn patients or visitors of some risks, they cannot prevent lawsuits or insulate providers from all liability. For some activities, thorough informed consent is more appropriate, and physicians are cautioned to recognize that CWAs and disclaimers cannot substitute for a complete informed consent discussion.

## **E-MAIL IN MEDICAL PRACTICE**

In a recent study of family physicians and their patients, e-mail communication between patients and physicians was found to improve satisfaction by both physicians and patients without affecting the time required for physician-patient communication.<sup>9</sup> Some commentators have even speculated that increased patient involvement through e-mail might lessen the practice of medical paternalism and its associated legal risks.<sup>10</sup> In the early days of medicine, physicians often corresponded with distant patients by mail and frequently relied on patients' written descriptions of their conditions in formulating diagnoses and treatment plans.<sup>11</sup>

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### **Simply posting a disclaimer may not prevent a malpractice action if the physician provides advice upon which the patient relies to his detriment...**

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#### **Confidentiality**

The duty to protect a patient's confidentiality has its roots in the Hippocratic Oath. Confidentiality is a significant concern with websites, e-mail, and electronic medical records. Scholars have noted an increasing number of tort lawsuits for breach of confidentiality,<sup>12</sup> and stories of privacy violated as a result of computing errors and hackers have attracted considerable attention from the media.<sup>13</sup>

Confidentiality risks abound when using e-mail with patients. While these risks do not necessarily outweigh the potential benefits of e-mail, sound risk management stresses the importance of obtaining patients' understanding and consent to these risks prior to corresponding with them by e-mail. Among some of the risks to patient confidentiality are the following:

- family members may read patients' e-mail if the computer is shared

- a patient may check his e-mail at work, not considering the possibility that his employer may be monitoring his e-mail
- a patient, or the physician, may be using an insecure internet connection and may be vulnerable to hackers, viruses, worms, or other technological errors or problems that may lead to breached confidentiality
- e-mails may be misdirected to unintended recipients
- e-mails may be intercepted by software or surveillance
- "deleted" e-mails frequently remain accessible on servers or hard drives long after users believe they have completely deleted them
- e-mails may be subject to disclosure through legal process, such as through search warrants or subpoenas
- e-mails sent through a patient's employer's computer system may be accessible to the employer

HIPAA<sup>14</sup> applies to e-mail containing protected health information (PHI), and additional state laws may also apply. Patients should be informed that there is no way to guarantee patient confidentiality when transmitting PHI online, and that there is always a risk of breached confidentiality. Patients may then choose whether to consent to this risk, and with their physicians they can discuss safeguards, such as firewalls, encryption, and other safe practices, to help reduce risk. Physicians can then document the patient's understanding and consent in the patient record.

Many physicians are accustomed to presenting themselves as experts, but a distinction must be drawn between expertise in medicine and expertise in information technology. Physicians should not be afraid to admit that their knowledge of technology and technological risks is limited; understanding this, patients may be able to help physicians to improve safeguards for the confidentiality of e-mail communications.

#### **"Matters of Business"**

E-mail communication may not be suitable for some patients, or for some subjects. As one scholar explains, "...a

paranoid schizophrenic who has delusions of thought insertion through the TV is definitely not a good candidate [for telemedicine].”<sup>15</sup> Similarly, a patient undergoing treatment for carpal tunnel syndrome may not be the best candidate for correspondence via computer keyboards. Physicians should exercise special caution regarding the communication of test results and other sensitive information by e-mail. Some tests warrant face-to-face counseling about the meaning of the results. With the patient’s written permission, pre-test HIV counseling may benefit from additional e-mail communication, such as sending patients links to webpages with general information about HIV and HIV testing. With the patient’s informed consent, follow-up e-mails can provide a written record to help patients remember advice, questions, and information communicated during an office visit and, in some cases, may result in improved patient compliance and quality of care. Communicating the actual test results for conditions such as HIV, however, is not ideally suited to a perfunctory e-mail. Nor is e-mail thread the best substitute for discussions that would otherwise take place in the office or on the phone, in part because e-mail removes many of the cues that signal patient distress or clinician compassion.

### **Unsolicited E-Mails**

Surprisingly, some physicians cannot resist temptation when receiving e-mail requests for advice from non-patients.<sup>16,17</sup> Prudence suggests, however, that providing medical advice to an individual who is not already a patient may increase risk. Physicians receiving such requests should be wary of providing information that might foster the perception of a physician-patient relationship and the corresponding duty of care. Physicians may also receive e-mails from third parties, such as a patient’s family members. Special risks may apply to these e-mails. Providing information to third parties, answering their questions without the patient’s consent, and corresponding with them without informing the patient may increase risk. E-mail creates a written record of the content of the communications, a factor absent from most phone conversations. E-mails concerning existing or possible future pa-

tients (e.g., initial e-mails requesting an appointment or consultation and describing a complaint or presentation) can be saved in the patient’s medical record. Keeping e-mails in the medical record may reduce risk. If the practice uses electronic medical records, the process of saving e-mails to the record may be done automatically.

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## **Keeping e-mails in the medical record may reduce risk.**

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### **Unavailability & Unanswered E-Mails**

Physicians should not assume that all patients understand that e-mail is an inappropriate means to communicate urgent matters. Furthermore, patients might have different expectations about the timeliness of replies or message receipt. It may be useful to create a policy with respect to timeliness for e-mails, and to adhere to it. Physicians may wish to create a separate e-mail account for use with patients and to apply settings that send automatic replies to patients, including the expected response time and a phone number patients may call if a concern is urgent, or if it takes longer than expected for them to receive a reply. When traveling, an “out of office” auto-reply message may alert patients how to contact the covering physician. One may also encourage patients to request “read receipts” on e-mails so that patients may know whether or not their doctor has read a message. You may wish to avoid using this feature if there is a chance that the receipt could be triggered inadvertently, such as by office staff.

Additional risks with e-mail are numerous and may grow more complicated. However, if patients understand the risks, they may consent to them, and in many cases the benefits will outweigh the risks. Allowing patients to decide whether these risks are acceptable, which safeguards they want and what benefits they will enjoy as a result of e-mail communication, may facilitate a dialogue and a cooperative approach to risk management that involves the patient in the process, thereby further reducing risk through a stronger treatment alliance. With his

physician’s help, the patient who takes steps to protect his own safety may be less likely to blame the physician if a disclosed risk occurs.

### **IMPORTANT CONCERNS Licensing, Advice, and the Physician-Patient Relationship**

If Dr. Smith provides advice to a stranger, there is a risk that patients, and possibly courts, may view this as creating a physician-patient relationship, giving rise to additional responsibilities and risks. If the “patient” resides in a state where Dr. Smith is not licensed, she might be argued to be practicing medicine without a license. In such a case, her malpractice liability insurance may not reimburse her defense counsel fees and may not reimburse her for any judgments associated with a malpractice action in a distant state. Even if Dr. Smith is licensed in the distant state, being sued in another state for malpractice proceedings or other legal issues can be costly and time-consuming. Even when fully licensed in the state, physicians should be sensitive to laws and regulations that apply specifically to telemedicine or cybermedicine practices within that state; such regulations may specify activities which may not be conducted online.

### **Treating and Communicating with the Wired Patient**

Scholars have noted both benefits and risks associated with the disinhibiting effect of internet communication.<sup>18</sup> The volume of “spam” from online pharmacies advertising medicines for erectile dysfunction suggests that some patients may feel uncomfortable requesting such medicines in the physician’s office; indeed, the Harris Poll found that among the six million US adults who had bought prescription medicines online, Sildenafil (a drug for treating erectile dysfunction) was one of the most frequently purchased.<sup>19</sup> Some patients may feel more comfortable broaching uncomfortable subjects in the context of an e-mail discussion with their physicians.

Also, some patients purchase medicines online without prior prescriptions and without informing their doctors. In *The Lancet* physicians report treating a 64-year-old woman for bilateral cataracts and glaucoma resulting from overuse of

oral steroids she had purchased online after diagnosing herself with myalgic encephalomyelitis.<sup>20</sup> Further complicating this problem is the prevalence of counterfeit medicines sold online<sup>21</sup> and the patients who self-diagnose through the information and diagnostic tools on the world-wide web.<sup>22</sup> These developments underscore the importance of obtaining a full history of a patient's use of prescription and over-the-counter medicines, including nutraceuticals and supplements. Additional questions about patients' experience with web-based health and drug information may improve communication between physicians and web-savvy patients.

### Practicing Online?

Some activities, such as online prescribing, carry a very high degree of risk. Indeed, penalties have ranged from warning letters to disciplinary action by medical boards, loss of license, and even, in some cases, prison terms.<sup>23</sup> However, even providing advice often constitutes the practice of medicine, so experts advise physicians to exercise caution in their internet activities. Some physicians knowingly provide medical services over the internet or through other telecommunications technology. While doing so is not, in itself, illegal or unethical, circumstances vary greatly. Such practices are common in radiology, for example, but "questionnaire prescribing" online to patients not examined in person has subjected physicians to sanctions. While the practices of cybermedicine and telemedicine are beyond the scope of this article, we encourage readers to consult their malpractice insurance providers for guidance regarding practice-related activities online.

### ETHICAL GUIDELINES AND FURTHER READING

For physicians seeking to enhance their practice through the use of websites or e-mail with patients, there are many helpful guidelines. The AMA's Code of Ethics, which is accessible at the AMA's website (<http://www.ama-assn.org/ama/pub/category/2498.html>), has sections specifically applicable to e-mail and websites. With respect to websites, the AMA urges informed consent for interactive features, as well as minimization of

conflicts of interest and commercial bias.<sup>24</sup> Physicians might go about these safeguards by clearly disclosing sponsorship and being sure that their website sponsorship (such as advertisements) does not trump patient interests. The AMA also stresses the importance of technological safeguards for patient privacy and confidentiality on sites where patient-specific information is involved. For physicians seeking to develop practice websites, the AMA has additional resources to help guide decisions and decrease risk.<sup>25,26</sup>

With respect to e-mail, the AMA's Code of Ethics cautions that "E-mail correspondence should not be used to establish a physician-patient relationship" and that physicians should adequately notify patients of e-mails' "inherent limitations," such as risks to confidentiality or privacy, "difficulties in validating the identity of the parties," and delayed responses.<sup>27</sup> The American Medical Informatics Association also has a helpful white paper on the use of e-mail with patients.<sup>28</sup>

The Federation of State Medical Boards has also produced a helpful guide for the use of the internet in clinical practice.<sup>29</sup> This general guide covers aspects of both e-mail and websites, as well as other areas of the internet that may apply to different physicians.

### CONCLUSION

This article presents only some of the legal risks associated with passive websites and incidental e-mails with patients. Numerous additional risks arise with respect to more interactive sites and business websites, and with more extensive use of e-mail. Readers interested in a more thorough discussion of these issues with respect to websites,<sup>30</sup> e-mail,<sup>31</sup> or internet-based treatment activities<sup>32</sup> are encouraged to consult references from the literature, malpractice insurance providers, professional organizations or affiliations (e.g., the AMA), state licensing boards, and official policies or guidelines of their employers, institutions, and other professional memberships.

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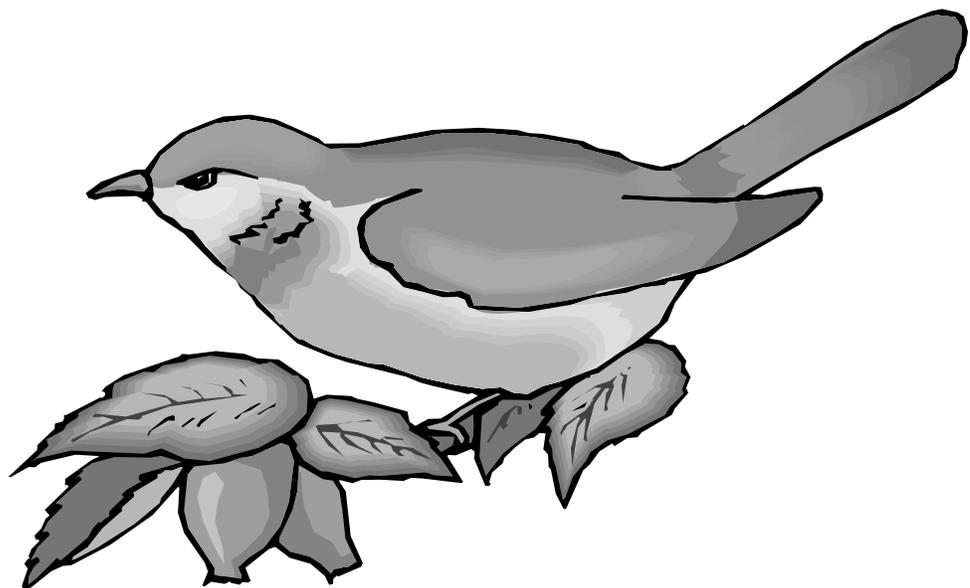
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# Dangers of Self-Prescribing and Prescribing for Family Members

Marilyn Price, MD, and Bruce W. McIntyre, JD

**Physicians prescribe for themselves** and their family members despite ethical guidelines that discourage the practice and stress the need to avoid treatment situations in which objectivity may be compromised.<sup>1</sup> Many physicians are unaware that state medical licensing boards have regulations vis a vis treating and/or prescribing for themselves and family members absent an emergency. Additional regulations govern the prescribing of controlled substances. While many jurisdictions do not have explicit prohibitions, there will be regulations related to the doctor/patient relationship such as those requiring that a history and physical exam be performed and documented. Rhode Island law and regulation do not explicitly prohibit self-prescribing, although a number of legal requirements place restrictions on the practice.<sup>2,3</sup>

In spite of the ethical considerations and regulations discouraging the practice, Toyry noted that self-treatment was common and physicians begin self-prescribing early in their careers.<sup>4</sup> A survey of internal medicine residents demonstrated that 52% had self-prescribed in the past year. Convenience and the ready availability of medication have been viewed as factors promoting this practice.<sup>5</sup> Christie and colleagues noted that 42% of the residents who had self-prescribed medications, obtained the medications from a sample cabinet; and 11% had obtained medications directly from a pharmaceutical representative.<sup>5</sup>

Self-prescribing appears to extend beyond the first years of practice. Hem et al) surveyed all the medical graduates from all 4 medical schools in Norway at one-year post graduation and then again at 4 and 10 years post graduation.<sup>6</sup> Of the physicians who had used any prescription medications over the past year, 90% of those who were one year post graduation, 86% of those 4 years post graduation and 84% of those who were 10 years post graduation had self-prescribed. The most frequently prescribed medications were antibiotics, contraceptives, analge-

sics and hypnotics. Those who had a mental health problem needing treatment were more likely to self-prescribe hypnotics and sedatives than those without perceived health problems. In the study by Christie the most commonly self-prescribed medications included antibiotics, allergy medication and contraceptives.<sup>5</sup> Westfall et al found that only 2 of 55 physicians or staff members in a resident training setting had not taken samples for their personal or a family member's use in the past year.<sup>7</sup>

Self-prescribing can result in a delay in obtaining appropriate treatment. This can be seen as especially problematic when a mental illness could be affecting the judgment of the physician. While only 2% of the residents in Christie's sample admitted to self-prescribing psychotropic medications, Toyry reported that two thirds of the physicians who acknowledged having a mental disorder had self-treated.<sup>4</sup> McCauliffe et al found that 25% of their sample of physicians in practice had treated themselves with a psychotropic medication in the past year.<sup>8</sup> Reinhardt and colleagues found that 5% of their sample of house staff admitted using a sedative or hypnotic without a prescription in the previous year. While the prevalence of recent depressive symptoms was 30%, only 11% had consulted with a mental health professional during that same time period.<sup>9</sup>

The American Medical Association's Code of Ethics, Opinion E-8.19 articulates the very real dangers inherent in prescribing for self or family members.<sup>1</sup> The AMA recommends that: "Physicians generally should not treat themselves or members of their families." The rationale is that:

Professional objectivity may be compromised when an immediate family member or the physician is the patient; the physician's personal feelings may unduly influence his or her professional medical judgment,

thereby interfering with the care being delivered. Physicians may fail to probe sensitive areas when taking the medical history or fail to perform intimate parts of the physical exam. Similarly patients may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the physician is an immediate family member.

These factors are seen as especially pertinent when the patient is a child.<sup>1</sup> There are further fears that when treating themselves or family members, physicians may be more likely to treat problems outside expertise. Physicians are warned that if problems arise as a result of a negative medical outcome, there could be ramifications in the personal relationship. In addition Opinion E-8.19 points out that the process of informed consent is significantly impacted. Family members may feel that by seeking a second opinion they are insulting the physician or indicating a lack of confidence in his/her ability.

The AMA does allow for exceptions. "In emergency settings or isolated settings where there is no other qualified physician available, physicians should not hesitate to treat themselves or their family members until another physician becomes available. In addition while physicians should not serve as a primary or regular care provider for immediate family members, there are situations in which routine care is acceptable for short-term, minor problems. Except in emergencies, it is not appropriate for physicians to write prescriptions for controlled substances for themselves or immediate family members (I, II, IV)."

The medical licensing boards have taken various approaches in dealing with physicians who prescribe for themselves or family members. The College of Physicians and Surgeons of Ontario recently revised the policy about treating self and

family members.<sup>10</sup> The provincial regulation states that:

Physicians should not treat either themselves or family members, except for a minor condition or in an emergency situation, and only when another qualified health care professional is not readily available. Where it is necessary to treat themselves or family members, physicians must transfer care to another qualified health professional as soon as is practical. Physicians are advised that if they do not comply with this policy, they may be subject to allegations of professional misconduct.

Even in states such as Rhode Island that do not explicitly ban this practice, the prescribing physician must meet practice guidelines set by the state and the United States **Drug Enforcement Agency (DEA)**. A physician may not prescribe for a non therapeutic purpose and there needs to be an adequate medical record justifying the use of the medication. Rhode Island has a medical record regulation, R5-37 MD/D0 sec 11.4 which requires that the course of treatment be justified.<sup>11</sup> There needs to be documentation of the history, test results, drug prescribed or administered, reports of consultations and hospitalizations.<sup>11</sup> Physicians need to consider that the adequacy of their documentation will be an important issue should there be a complaint. Documentation requirements are rarely considered by physicians prescribing for themselves or a family member.<sup>12</sup>

When the prescribed medication is a controlled substance there could be further requirements or restrictions. The Rhode Island Board of Medical Licensure and Discipline has issued guidelines for the administration of controlled substances that require the following be provided; history and physical examinations, treatment plan and objectives, informed consent, periodic review of plan and treatment, consultations with experts, accurate and complete records, and compliance with State and Federal Laws (Rhode Island-225 ILCS60/Medical Act of 1987).

There are usually grounds for disciplining a physician who prescribes a controlled substance other than for a legitimate medical purpose. Under Rhode Island General Laws § 21-28-3.04 (2006) one of the conditions for suspension or revocation of registration includes “possessing, using, prescribing, dispensing, or administering controlled substances except for a legitimate medical or scientific purpose.”<sup>2</sup> In addition, in defining unprofessional conduct of a physician, R.I. General Laws §5-37-5.1 (2006) one of the behaviors noted is “violating any state or federal law or regulation relating to controlled substances.”<sup>3</sup>

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### **Physicians who self-prescribe controlled substances such as sedatives and narcotics raise suspicion of drug abuse/dependence.**

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In Kentucky prescribing to self or to family members is not a violation of Kentucky law, but KRS 311.597 (1) states that “self-prescribing and prescribing to immediate family members is contrary to the law when the physician knows or has reason to know that an abuse of controlled substances is occurring, or may result from such a practice.”<sup>13</sup>

The College of Physicians and Surgeons of Ontario also makes it clear that physicians should never write a prescription for themselves or family members for narcotics, controlled drugs, psychotropic drugs, or any drugs that are addicting or habituating, even when another physician is in charge of managing those medications.<sup>10</sup>

In 2001, The Commonwealth of Massachusetts Board of Registration in Medicine issued “Prescribing Practices: Policy and Guidelines.” Physicians are advised to “maintain records that are detailed enough in nature that the physician’s clinical reasoning is implicit in his or her documentation. Treatment plans should be explicitly recorded. All patients visit and telephone calls relating to treatment should be documented. Prescriptions should be documented and

changes in medication dosage should be explained.”<sup>14</sup> The Massachusetts guidelines (2001) warn:

Prescribing to immediate family members is frequently associated with problems of self-medication and chemical dependency by physicians and is therefore carefully scrutinized by the Board. Treatment of immediate family members with controlled substances over a sustained period of time may indicate a lack of objectivity and clinical detachment on the part of the physician. Physicians who prescribe controlled substances for family members must take extra precautions to insure that this privilege is not abused.

The guideline/policy further cautions that “[t]he same examination requirements applicable to patients who are not related to the physician apply when the physician is prescribing controlled substances to the physician’s immediate family. Physicians should document examination results carefully and accurately.”

Massachusetts prohibits the prescription of Schedule II Controlled Substances to family members. “Schedule II controlled Substances, because of their high potential for abuse, may not be prescribed to a member of a licensee’s immediate family, including a parent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, or spouse or equivalent, except in an emergency.” This prohibition includes other relatives permanently residing in the same residence as the licensee. The Board suggests that physicians consider refraining from prescribing all controlled substances for family members and significant others in non-emergency situations.<sup>14</sup>

The Board of Registration in Medicine in Massachusetts has even graver concerns about self-prescribing.<sup>14</sup> The same document advises:

Physician self-prescribing presents even deeper concerns than prescribing to family members. The prescription of drugs to oneself creates an enormous

potential for abuse and places a difficult burden on the pharmacist, who is equally responsible under the law to determine whether a prescription is valid. The Board has concluded that the potential for abuse of lower schedule drugs far outweighs the relatively minor inconvenience that is caused by requiring physicians to obtain prescriptions for their own use from other physicians. For this reason, the Board has prohibited physicians from prescribing controlled substances in Schedule II through IV for their own use.

Massachusetts is not alone in the absolute prohibition of self-prescribed controlled substances. In Georgia self-prescribing of controlled medication is prohibited as a violation of Board Rule 360-3-.02(7).<sup>15</sup>

Of course physicians in all states are required to adhere to the DEA regulations. According to DEA regulation 21 CFR 1306.04 (a)<sup>16</sup> the physician must determine that there is a legitimate medical purpose for the patient to be prescribed the controlled substance and the individual practitioner must be acting in the usual course of his/her professional practice as described in *U.S. v Moore*, U.S. 122, 1975.

The DEA has developed a Practitioner's Manual that offers guidance on how the DEA determines that the prescribing practice meets that the legal standard that a controlled substance may only be prescribed, administered, or dispensed for a legitimate medical purpose. The Manual provides examples of recurring patterns that may be indicative of inappropriate prescribing or diversion.<sup>17</sup> Many of these factors had been articulated in *US vs. Rosen*, 1978,<sup>18</sup> a Fifth Circuit Decision in which the court upheld the conviction of a Louisiana Physician on charges of dispensing and distributing controlled substances, a violation of 21 U.S.C.S. §841 (a) and were reviewed again in *U.S. vs. Rottschaef* 2006 a Third Circuit decision.<sup>19</sup> These include

- An inordinately large quantity of controlled substance prescribed or large numbers of prescriptions is-

sued compared to other physicians in the area;

- No physical exam was given;
- Issuing prescriptions knowing that the patient was delivering the drugs to others;
- Issuing prescriptions in exchange for sexual favors or for money;
- The use of street slang rather than medical terminology for the drugs prescribed
- No logical relationship between the drugs prescribed and the treatment of the condition allegedly existing

States can track prescriptions in the event of a complaint. "Prescription Monitoring Programs" are state programs that collect prescription information electronically from the pharmacies. States vary in the extent of information received and whether or not they perform trend analysis in a proactive approach. In Rhode Island a report to the Board can generate an investigation using the database to verify that there is a pattern and to determine the extent of the diversion or abuse.<sup>20,21</sup> Rhode Island's Electronic Data Transfer System, initiated in 1997, allows the tracking of controlled substance prescribing by patient, by prescribing physician or by pharmacy. This can be a valuable tool when there has been a complaint or inquiry concerning prescribing practices.

The following vignette describes a situation that led to a complaint brought before the Board. It was created for illustrative purposes only and is not intended to refer to any actual individual, event or outcome.

Dr. A had always been very close to his younger brother who was an excellent student and always dependable. Dr. A was aware that his brother had been in a car accident 6 months earlier. His brother had complained of back pain following the accident but had not been admitted to hospital. His brother reported to him that he still had severe residual pain. Because of his exam schedule he had missed an appointment with his own physician and had run out of Oxycontin. He asked Dr. A if he would be willing to write a prescription for a one-month supply. Dr. A. was hesitant but nevertheless agreed to prescribe the medication. Dr. A was not aware that his brother was abusing Oxycontin as well

as other medications. The following month his brother demanded that he fill the prescription again. When Dr. A. refused, his brother threatened to report him to the Board. Dr. A. felt trapped and gave his brother another prescription on condition that this would be the last time. When Dr. A. subsequently refused to continue the Oxycontin and suggested that his brother seek treatment for an addiction, his brother filed a complaint with the Board.

Dr. A. could not produce a medical record documenting that he had taken an appropriate history, performed a physical exam, considered a treatment plan, ordered or reviewed diagnostic test results, or monitored the response to treatment. He had never documented why he had arrived at the decision to treat his brother with Oxycontin. His brother admitted in his letter to the Board that he had abused Oxycontin. The Electronic Data Transfer System indicated that his brother had filled numerous prescriptions of Oxycontin from other providers. Dr. A. could not produce documentation that he had prescribed for a legitimate medical purpose. He was asked to meet with the Board.

Physicians are well advised to have their own treating physicians. Self-treatment has been viewed as a symptom of poor health care for physicians.<sup>22</sup> Physicians who self-prescribe controlled substances such as sedatives and narcotics raise suspicion of drug abuse/ dependence. Self-prescribing of controlled substances including pain medication, stimulants and sedatives can influence the development of drug abuse and dependence on these medications.

While self-prescribing may be convenient and time-saving, the lack of objectivity may result in inappropriate and even dangerous self-treatment. Diagnosis may be delayed affecting prognosis. The lack of objectivity and concerns about the absence of proper informed consent should be considered when treating a family member. It is important for training programs to foster discussion about this issue which will allow trainees to consider the implications when prescribing for themselves or for family members and to learn to maintain appropriate professional boundaries.<sup>5</sup>

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# Patient Safety Efforts Target Communication at Rhode Island Hospitals

Melinda Morin, MD

The 1999 Institute of Medicine (IOM) report, *To Err Is Human*,<sup>1</sup> sparked a public outcry over patient safety in US hospitals. This has resulted in attention to system factors as well as accountability at an individual level. Although technologic advances have soared in many of our hospitals, communication - a basic tenet of patient care - has suffered. This article advocates for a change in procedures around patient "hand-offs" and describes the efforts at Rhode Island Hospital to reduce iatrogenic injury and liability for practitioners and the hospital. These efforts include standardizing the process, improving communication, and minimizing reliance on the memory of patients, families and practitioners.

The accurate transfer of information between teams of caregivers is essential for the seamless continuity of care. However, "hand-off" communication has been identified as the major cause of sentinel error events and delay in treatment within US hospitals.<sup>2</sup> Too often key information is misstated or misunderstood. Five-year data from CRICO/RMF, the medical malpractice company for the Harvard Medical Institutions, indicate that handoffs were involved in 268 claims and suits, with more than half involving a high severity patient injury.<sup>3</sup> As a result, the Joint Commission has included the implementation of a standardized approach to hand-off communications, with an opportunity to ask and respond to questions, as one of the required goals for 2006 and 2007.<sup>4</sup>

Communication strategies successful in other high risk settings are being introduced into the setting of medical care. Patterson et al<sup>5</sup> evaluated communication methods at NASA Johnson Space Center, nuclear power plants in Canada and railroad and ambulance dispatch centers. Techniques found to be effective included: 1) Face-to-face verbal updates with interactive questioning; 2) Unambiguous transfer of responsibility; 3) Overhearing others' updates; and 4) Limiting interruptions during update. Al-

though logical, these methods are rarely utilized in current medical practice and should be mandatory in sign-out at all levels.

## Studies of the physician sign-out process reveal it to be a haphazard event with great variation in information content and process.

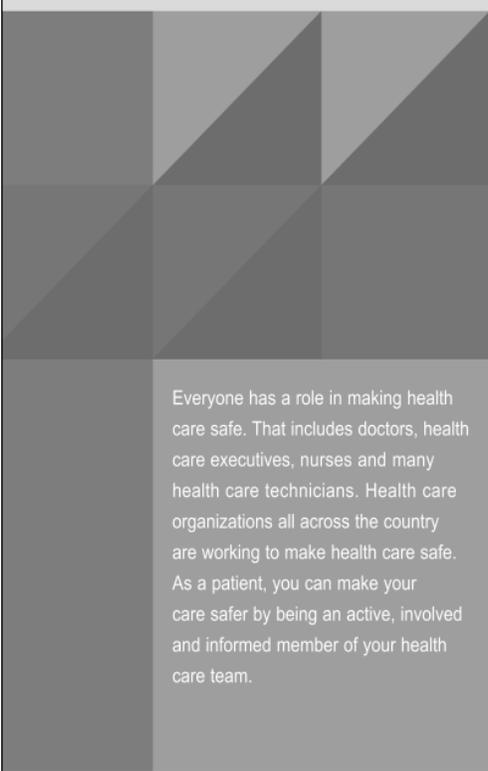
In the United States, resident-physicians provide much of the direct patient-care. Previous work has identified coverage by house staff not primarily responsible for the patient (cross-coverage) as a significant correlate of risk for preventable adverse events.<sup>6</sup> Cross-coverage by a different physician, principally at night, was a far better predictor of hospital complications and errors than was the severity of the patients' illness. With the 2003 mandate of an 80-hour work-week for residents, the number of handoffs has substantially increased. While targeting fatigue-related errors, this change has exacerbated communication problems involving the handoff of patient information.

SBAR report to physician about a critical situation	
<b>S</b>	<p><b>Situation</b>            I am calling about &lt;patient name and location&gt;.            The patient's code status is &lt;code status&gt;            The problem I am calling about is _____            I am afraid the patient is going to arrest.</p> <p><b>I have just assessed the patient personally:</b>            Vital signs are: Blood pressure _____ / _____, Pulse _____, Respiration _____ and temperature _____</p> <p><b>I am concerned about the:</b>            Blood pressure because it is over 200 or less than 100 or 30 mmHg below usual            Pulse because it is over 140 or less than 50            Respiration because it is less than 5 or over 40.            Temperature because it is less than 96 or over 104.</p>
<b>B</b>	<p><b>Background</b>            The patient's mental status is:            Alert and oriented to person place and time.            Confused and cooperative or non-cooperative            Agitated or combative            Lethargic but conversant and able to swallow            Stuporous and not talking clearly and possibly not able to swallow            Comatose. Eyes closed. Not responding to stimulation.</p> <p><b>The skin is:</b>            Warm and dry            Pale            Mottled            Diaphoretic            Extremities are cold            Extremities are warm</p> <p><b>The patient is not or is on oxygen.</b>            The patient has been on _____ (l/min) or (%) oxygen for _____ minutes (hours)            The oximeter is reading _____ %            The oximeter does not detect a good pulse and is giving erratic readings.</p>
<b>A</b>	<p><b>Assessment</b>            This is what I think the problem is: &lt;say what you think is the problem&gt;            The problem seems to be cardiac infection neurologic respiratory _____            I am not sure what the problem is but the patient is deteriorating.            The patient seems to be unstable and may get worse, we need to do something.</p>
<b>R</b>	<p><b>Recommendation</b>            I suggest or request that you &lt;say what you would like to see done&gt;.            transfer the patient to critical care            come to see the patient at this time.            Talk to the patient or family about code status.            Ask the on-call family practice resident to see the patient now.            Ask for a consultant to see the patient now.</p> <p><b>Are any tests needed:</b>            Do you need any tests like CXR, ABG, EKG, CBC, or BMP?            Others?</p> <p><b>If a change in treatment is ordered then ask:</b>            How often do you want vital signs?            How long to you expect this problem will last?            If the patient does not get better when would you want us to call again?</p>

Table 1. SBAR Method of Communication SBAR Tool, Institute for Healthcare Improvement, Copyright Institute for Healthcare Improvement, 2007.

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Everyone has a role in making health care safe. That includes doctors, health care executives, nurses and many health care technicians. Health care organizations all across the country are working to make health care safe. As a patient, you can make your care safer by being an active, involved and informed member of your health care team.

**S**peak up if you have questions or concerns. If you still don't understand, ask again. It's your body and you have a right to know.

**P**ay attention to the care you get. Always make sure you're getting the right treatments and medicines by the right health care professionals. Don't assume anything.

**E**ducate yourself about your illness. Learn about the medical tests you get, and your treatment plan.

**A**sk a trusted family member or friend to be your advocate (advisor or supporter).

**K**now what medicines you take and why you take them. Medicine errors are the most common health care mistakes.

**U**se a hospital, clinic, surgery center, or other type of health care organization that has been carefully checked out. For example, The Joint Commission visits hospitals to see if they are meeting The Joint Commission's quality standards.

**P**articipate in all decisions about your treatment. You are the center of the health care team.



Table 2. SPEAK UP - Poster, The Joint Commission, 2007

Studies of the physician sign-out process reveal it to be a haphazard event with great variation in information content and process.<sup>7</sup> The typical resident sign-out is a “one-liner” including diagnosis and the clinical impression, e.g. the patient is all right. It is often purely task-oriented. Thus, effectiveness of sign-out is currently restricted by its inadequate content, particularly regarding the plan of care for patients.

Six Sigma is a process-focused business strategy aimed at improving quality, reducing costs and improving efficiency. The sigma level indicates the defect rate in a given production or service process. In an

effort to achieve Six Sigma performance and diminish the incidence of errors, the Lifespan Health System, including Rhode Island Hospital, Miriam Hospital and Newport Hospital, is currently utilizing CPOE (**computerized provider order entry system**). CPOE is the portion of a clinical information system that enables a patient's provider to enter an order for a medication, laboratory or radiology test, or procedure using a computer system that provides some level of clinical alerts. CPOE allows rapid, up-to-date, intra-hospital information transfer that is available, and HIPAA protected, at any computer terminal within any

of the hospitals. Rhode Island Hospital is implementing a standardized sign-out system for resident sign-out that is electronically linked to CPOE. This system offers a readily available, cost-effective and user-friendly sign-out method, which could be instrumental in decreasing reliance on vigilance and memory, while communicating the plan of care.

Another identified area of frequent communication failures centers around the nurse-physician interaction. SBAR (Situation-Background-Assessment-Recommendation) is a situational briefing technique that conveys only the most critical information and is one of several communication models gaining momentum in American healthcare. The SBAR model, which has proven successful in the nuclear submarine industry, has been adopted by the Kaiser Permanente system. (Table 1). SBAR requires that information be communicated in a standardized, consistent manner. This method emphasizes the anticipation of what information the other person will need, the use of critical thinking and assessment skills and, of particular import, the goal of reaching a mutually acceptable plan.

Undoubtedly, the change to an effective model of communication requires an enormous change in the very culture of medicine. It requires a change to concerns about an abnormality seen, not the performance of specific tasks. It requires a team approach, where nurses are not afraid to be wrong and are not afraid to state that they are worried. It requires change in the hierarchy of medicine. Physicians would still be the *de facto* leaders in patient management, but would need to be more accepting of nursing input. Successful implementation would ablate the current system of hinting and hoping by non-physicians. The use of SBAR could also be expanded to the other healthcare settings (e.g. outpatient office or nursing home settings); incorporation into other practice situations (daily rounds, discharge summaries); or incorporation into other types of hospitals outside of academic medicine (community hospitals).

SBAR is being introduced into another vital area of communication at Rhode Island Hospital: nursing sign-out. Traditionally, shift change sign-out has relied on taped or written report while physically separated from the patient.





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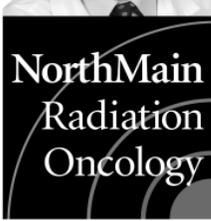
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There is minimal opportunity to ask questions and the content is highly variable and inconsistent. It is an inefficient method, frustrating to both nurses and their patients. The Joint Commission National Patient Safety Goal #2<sup>4</sup> includes the opportunity to ask questions during sign out; thus, listening to taped report after the previous shift of nurses has departed will no longer be adequate.<sup>8</sup> The principles of SBAR communication, including a standardized content, use of critical thinking and an emphasis on plan of care, offer the promise of decreased adverse events as well as improved patient satisfaction. The focus for nursing sign-out becomes the anticipated patient course and what should be done, not simply a description of what has already happened. Paid time for handoffs involving both participants is already included in the RN budgets at many hospitals (personal communication).

There are additional hurdles to the introduction of a standardized model of nursing sign-out. Nurses traditionally use a narrative style and are not trained to make diagnoses. Nurses are often not comfortable discussing difficult or sensitive issues in front of patients. Sign-out time is often utilized as a time for social interaction. These differences must be considered when SBAR is introduced and staff must be involved in addressing these barriers.

Although the use of SBAR in US hospitals is growing, there is minimal published data of its effectiveness. Hos-

pitals utilizing SBAR report increased satisfaction from all participants and hospital-wide use of the technique has been shown to improve medication reconciliation and decrease the rate of adverse events.<sup>9</sup> Although SBAR is likely to result in improved information transfer, long-term advantages remain ill defined.

Communication between medical professionals and their patients and families has also suffered. In the hectic pace of today's hospital medicine, the simple act of updating patients is too often overlooked. Patient satisfaction data routinely cites communication with the healthcare team as problematic.<sup>10</sup> A recent study evaluating communication in the outpatient setting revealed that physician-patient communication errors were associated with a lack of patient participation in the decision-making process in terms of voicing expectations or responses to their doctor's recommendations.<sup>11</sup> In response to the Joint Commission recommendation, Rhode Island Hospital has launched a Speak Up™ (Table 2) campaign urging patients to participate actively in their healthcare. Posters and brochures in multiple languages throughout the hospital advertise these efforts.

A laudable practice gaining momentum in the United States is nursing sign-out at the patient bedside, including a discussion with the patient to make sure s/he understands the discharge plan and post-discharge treatment plan. Such a standard would not only improve patient satisfaction, but also patient safety. Bedside rounds in the ICU with the entire healthcare team<sup>12</sup> have had an equally positive impact and is the practice at Rhode Island Hospital.

Although nursing and physician leadership recognizes the importance of communication, the front-line worker is often unaware of its role in patient safety. Education remains the key to successful implementation of any change in practice; thus, efforts must be aimed at improving communication at all levels to affect a change to a culture of patient safety. This represents a significant change in the culture of medicine, nationally, as well as locally in Rhode Island. Incorporation into daily practice will be a slow, but ultimately successful process.



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# Rhode Island Supreme Court Affirms Limited Nature of Peer-Review Privilege

Lawrence M. Kraus, JD, and Lawrence W. Vernaglia, JD, MPH

In its recent opinion in *Pastore v. Samson*<sup>1</sup>, the Rhode Island Supreme Court reaffirmed its view that the “peer-review privilege” offers a *limited* protection to certain information created by properly constituted peer-review boards. The opinion provides useful guidelines as to the type of information that may be protected from disclosure to plaintiffs and other parties seeking information presented at and created by peer-review boards. As will be discussed, the principle message from *Pastore* is that the peer-review privilege is quite limited, and that physicians and hospitals should be mindful that not everything they may consider as “peer-review privileged” material actually is protected from discovery.

## A “Discovery Melee”

Pastore’s estate commenced this lawsuit against Dr. Samson, a fellow doctor, and Kent County Memorial Hospital following Mr. Pastore’s death on July 12, 1998. The plaintiff’s complaint alleged that Pastore died as a result of negligent care delivered by the defendant doctors. In addition to the medical malpractice claims against the doctors, the plaintiff alleged that the Hospital had negligently credentialed and granted privileges to Dr. Samson.

The lawsuit descended in what the Court termed a “discovery melee,” in which the “discovery phase stalled as plaintiff and the hospital engaged in a lengthy battle over certain hospital documents concerning Dr. Samson.” At issue were 750 pages that the Hospital claimed were protected by the peer-review privilege, as well as other confidentiality protections. The dispute reached the Supreme Court after numerous proceedings in the lower court, stretching out over more than two and a half years. The specific ruling on appeal was the trial court’s order rejecting the Hospital’s claims of privilege, and ordering that all 750 pages be turned over to plaintiff.

The Supreme Court affirmed the production of all but one page of the documents—and even that one page was ordered to be produced with certain information removed.

## THE PEER-REVIEW PRIVILEGE IS “STRICTLY CONSTRUED” AND LIMITED

In its analysis, the Court first reviewed the Rhode Island statutes that create the peer-review privilege as well as its past opinions interpreting the privilege. The Court noted that “two similar yet distinct Rhode Island statutes afford providers of health care the peer-review privilege,” “which create a privilege for the ‘proceedings’ and ‘records’ of peer-review boards, such that those documents shall not be subject to discovery or be admissible in evidence.” The Court identified the principle underlying the peer-review privilege as “the social importance of open discussions and candid self-analysis in peer-review meetings to ensure that

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**You should not believe that extensive documentation or information can be protected merely because it is labeled “peer-review privilege.”**

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medical care of high quality will be available to the public.” Based on this principle, the Court has ruled in the past that—in the proper circumstances—a hospital is entitled to withhold “all records and proceedings before a peer-review board,” even as pertaining to the allegedly negligent treatment delivered to a plaintiff himself.

Having done so, however, the Court focused the bulk of its opinion on just how limited this protection is. Relying

in part on past precedent, the Court stressed that this privilege is to be “strictly construed” because it prevents potentially relevant evidence from being brought to light.<sup>2</sup> “The privilege must not be permitted to become a shield behind which a physician’s incompetence, impairment, or institutional malfeasance resulting in medical malpractice can be hidden from parties who have suffered because of such incompetence, impairment, or malfeasance.” In doing so, the Court explicitly rejected the Hospital’s argument that because the privilege serves the socially beneficial “remedial” purpose of improving the quality of medical care, it should be broadly interpreted and applied.

## SPECIFIC EXAMPLES OF APPLICATION OF PEER-REVIEW PRIVILEGE

Having interpreted the scope of the privilege in general, the Court then turned to the specific examples presented by the case.<sup>3</sup> The results are instructive as to how limited the privilege is.

The first document considered was a 51-page transcript of the proceedings of a committee meeting “arising from a complaint about Dr. Samson’s bedside manner while working in the emergency room[,]” much of which focused on interactions with the patient and family members. Despite conceding that the transcript was from a proceeding before a hospital committee—a necessary prerequisite for the privilege to apply—the Court examined “whether a committee investigating the bedside manner of a doctor qualifies as a peer-review board.”

It does not. The Court held that the bedside manner of the Doctor was insufficiently related to the purposes of the statute to protect the transcript by the privilege. “The [lower court’s] distinction between a doctor’s bedside manner and the actual medical care that a doctor administers strikes us as sensible. The peer-review privilege was designed to alleviate an increase in medical malpractice lawsuits for substandard health care,

not to reduce the number of rude or uncompassionate health-care professionals – although the latter is certainly a commendable objective.” Because the committee was not engaged in the sort of investigation that sufficiently met the objectives of the statute, the Court agreed that it was not a “peer-review board,” and ordered the transcript to be produced.

The second document considered was a one-page report from a peer-review board that “focused not on Dr. Samson’s bedside manner, but on whether or not he timely responded to a patient who needed care.” This document therefore clearly constituted a “record” of a peer-review board, and certain information in it was therefore protected by the peer-review privilege.

Notably, however, even here the Court did not say that the entire single page document could be withheld. Instead, it held that any restriction of the physician’s privileges, as well as the list of doctors attending the meeting, were all subject to disclosure. “Accordingly, this report is not privileged, and is discoverable, so long as it is redacted to cloak the summary of key items discussed in the meeting.”

## GUIDELINES REGARDING SCOPE OF PRIVILEGE

Pastore highlights the limited nature of the peer-review privilege. The following are some guidelines to be aware of:

- While the peer-review privilege exists, it is strictly construed. You should not believe that extensive documentation or information can be protected merely because it is labeled “peer-review privilege.”
- Only “records” and “proceedings” of peer-review boards are protected, and not “documents or records otherwise available from original sources.” In other words, materials that were created outside the peer-review body – including, for example, patient records – are not protected merely because they have been brought into peer-review.<sup>4</sup>
- Similarly, the privilege only applies to information generated by peer-review bodies, and not, for example, “records made in the regular course of business by a hospital.”
- The identities of persons participating in peer-review are discoverable.

- The privilege prevents peer-review participants from testifying as to “findings, recommendations, evaluations, opinions, or other actions of the board,” but the imposition of a restriction of privileges or a requirement of supervision is not privileged and is subject to discovery.

In short, Pastore demonstrates that the peer-review privilege is alive in Rhode Island—it just might not be as protective as you think.

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2. The Court noted that “[p]rivileges, by their nature, ‘shut out the light’” on “the ascertainment of the truth.”
3. The Court noted with some chagrin the fact that 750 pages of materials were at issue, the hospital’s lawyers only discussed 2 documents, as a result limiting the Court’s analysis to those two documents.
4. In fact, the Court ruled that if the hospital has such original documents in its possession, it should be required to produce them, and that the Plaintiff was not required to seek them from another original source.

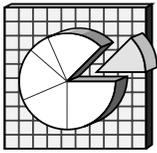
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## Trends In Tobacco Use (1990-2006) and Patterns of Tobacco Use Among Rhode Island Adults in 2006

Jana Hesser, PhD, Yongwen Jiang, PhD, and Seema Dixit, MS, MPH

**Tobacco use is the single leading cause of preventable illness and death in the United States and in Rhode Island.<sup>1</sup>** Each year, more than 435,000 Americans and approximately 1,900 Rhode Islanders die prematurely from smoking-related diseases. Annual health care costs in Rhode Island directly caused by smoking are estimated to be \$506 million,<sup>2</sup> not counting costs linked to exposure to secondhand smoke, smoking-caused fires, spit tobacco use, or cigar and pipe smoking.<sup>2</sup>

This report presents survey data on the trend in cigarette smoking among Rhode Island adults from 1990 – 2006, and on the patterns of adult tobacco use and associated health risks in Rhode Island in 2006.

### METHODS

Tobacco use rates were calculated using self-reported data from Rhode Island's **Behavioral Risk Factor Surveillance System (BRFSS)**, a telephone survey administered in all 50 states and 4 US territories with funding and specifications from the **Centers for Disease Control and Prevention (CDC)**.<sup>3</sup> The BRFSS monitors the population ages 18 and older for access to health care, certain health conditions, and behaviors that contribute to the leading causes of disease and death in the US, including tobacco use. Rhode Island has participated in the BRFSS since 1984.

From 1990 to 1997, Rhode Island's BRFSS had an annual sample size of approximately 1,800. Between 1998 and 2005, RI's BRFSS sample size varied between 3,600 and 4,500. Each year's data are weighted to be representative of the age, sex and race composition of Rhode Island's adult population.

The BRFSS has asked the same "core" tobacco questions each year since 1990. A person is identified as a "current smoker" if he/she had ever smoked 100 cigarettes and now smokes every day or some days. "Sedentary lifestyle" is defined as engaging in no leisure time physical activity or exercise in the past 30 days. "Chronic drinking" is defined for men as consuming 2 or more alcoholic drinks each day; for women, 1 or more alcoholic drinks each day. Indicators of poor quality of life or poor mental health include: 14 or more days in the past month of pain-related activity limitations, lack of sleep, lack of energy, poor mental health, feeling sad/blue/depressed, and feeling worried/tense/anxious.<sup>4</sup> Two other mental health indicators are having "ever been told you have an anxiety disorder", and having "ever been told you had a depressive disorder". "Error" bars on the charts represent the 95% confidence limits around the estimates.

### RESULTS

#### Smoking trend, 1990 - 2006

From 1990 to 2006, smoking rates among RI adults dropped from 25.6% to 19.2%. (Figure 1) Between 1992 and 2001, annual rates fluctuated between 22% and 25%. Since 2001 smoking rates have dropped in each successive year.

#### Current smoking in 2006

About 1 of every 5 adults in Rhode Island, or roughly 160,000 persons, is a current cigarette smoker. There is no significant difference in smoking rates between men and women. Smoking rates are highest among adults ages 18 – 24 (35%), non-White non-Hispanics (26%), adults who are not college graduates (25%), adults in households with incomes less than \$25,000 (28%), never married and divorced/separated adults (28%), and among persons either unemployed (28%) or unable to work (37%). The lowest smoking rates are associated with being 65 or older (9%), being a college graduate (10%), or having a household income of \$50,000 or more. (Figure 2) More than half (60%) of all smokers reported that they quit smoking for one day or longer during the past year. (Figure 3)

Smokers are at greater risk than non-smokers for having a sedentary lifestyle (35% vs 22%). Eleven percent of smokers are chronic drinkers compared with 5% of other adults. A greater proportion of smokers than non-smokers lack access to dental care (29% vs 17%) and to a regular medical provider (25% vs 11%). (Figure 3)

Smokers have higher rates than non-smokers for each of 8 indicators of poor quality of life and poor mental health. (Figure 3) Almost one-third of smokers had been told they had a depressive disorder at some time in their lives; nearly one-quarter had been told they had an anxiety disorder at some time in their life.

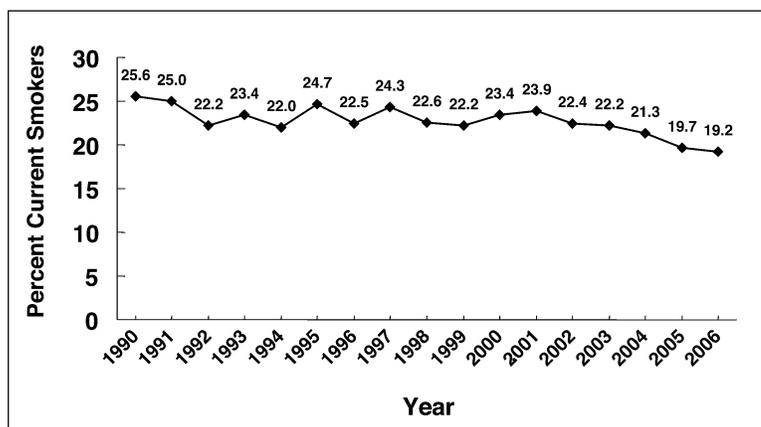


Figure 1. Annual current smoking prevalence, ages 18 and older, Rhode Island, 1990 – 2006.

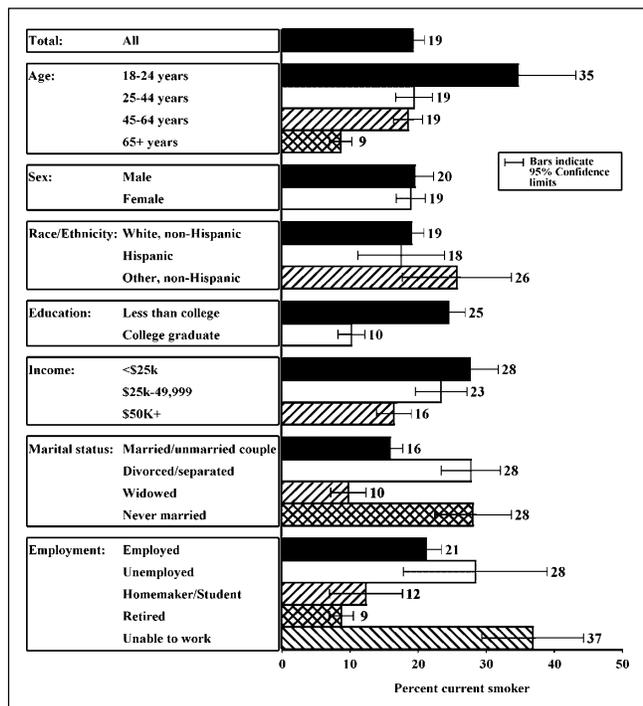


Figure 2. Current smoking among Rhode Island adults (ages 18 and older) within demographic subgroups, 2006.

More than a third of smokers, compared with about a quarter of non-smokers, reported not getting enough sleep for 14 or more days in the past month or not feeling very healthy or full of energy. (Figure 3)

## DISCUSSION

The state of Rhode Island has enacted measures to discourage tobacco use. The state has increased cigarette taxes each year since 1994. The most recent increase of \$.75 per pack, enacted in 2004, brought the retail price to \$6.10 per pack in 2005 (compared to \$1.84 in 1994). The Rhode Island Smoke Free Public Place and Workplace Law, which went into effect March 1, 2005, banned smoking in all public and workplaces. Rhode Island was the seventh state to do so. In 2006 the legislature mandated tobacco treatment coverage by all state health insurers, both public and private. During February 2005, just prior to implementation of the public and workplaces smoking ban, and during March 2005, the Health Department's 1-800-Try-To-Stop line received about 1,500 calls each month, an eight-fold increase in the number of calls received from people wanting to stop smoking.

Although smoking rates in Rhode Island's adult population overall have been decreasing since 1990, smoking rates among some demographic groups remain high. Smokers are at increased health risk due to sedentary lifestyles, chronic drinking, and poor mental health. The poor mental health of smokers observed in the BRFSS data is substantiated by other studies.<sup>5</sup> One report estimates that "the mentally ill carry the burden of nearly half of all US tobacco consumption".<sup>5</sup>

Using nationally proven best practices, the **Rhode Island Tobacco Control Program (RITCP)** works in partnership with community based organizations, voluntary agencies, health care providers, and state-wide partners to prevent and control to-

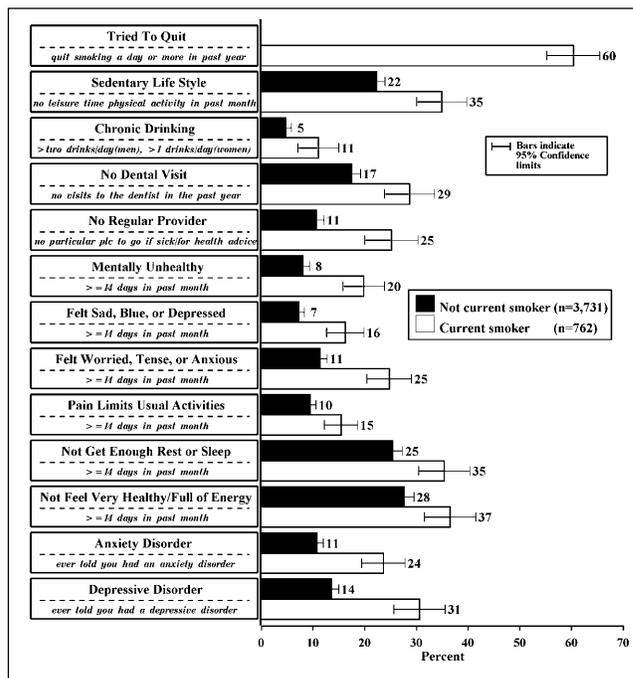


Figure 3. Health risks among Rhode Island adults by smoking status, 2006.

bacco use, aiming specifically to reduce youth initiation of tobacco use, to eliminate exposure to second hand smoke, and to promote cessation.

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## ACKNOWLEDGEMENT

Data Source: Rhode Island Behavioral Risk Factor Surveillance System, 1990 - 2006, Center for Health Data and Analysis, Rhode Island Department of Health, and supported in part by the National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention Cooperative Agreements U58/CCU100589 and U58/CCU122791.

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# Atypical Antipsychotics for the Treatment of Dementia-Related Behaviors: An Update

Lori A. Daiello, PharmD

**Dementing illnesses are frequently associated with agitation, hallucinations, delusions and aggression.** While loss of cognitive and functional abilities is distressing both to patients with **Alzheimer's Disease (AD)** and their caregivers, the psychiatric aspects are often cited as the precipitating factor for nursing home placement.<sup>1</sup>

The most frequently used, but least descriptive, term for the behavioral symptoms of dementia is "agitation." Cohen-Mansfield describes agitation as inappropriate verbal, vocal, or motor activity that does not result from identified need.<sup>2</sup> "Agitated" behaviors may include aggression, anxiety, phobias, diurnal rhythm disturbance, and motor restlessness.

Antipsychotic drugs have been the primary treatment for psychosis, agitation, and aggression in AD and other dementias for decades, although it was never clear if the drugs improved the behavior or provided a "chemical straitjacket" that reduced *all* behavior. The conventional antipsychotics such as haloperidol have been supplanted by four of the newer or "atypical" antipsychotic drugs (risperidone, olanzapine, quetiapine, aripiprazole), although no medication has an FDA indication for the treatment of behavioral symptoms in patients with dementia.

The prescribing of antipsychotics for neuropsychiatric symptoms was stimulated by observations that psychosis is present in many patients with AD who exhibit agitated and aggressive behaviors. However, the biological basis of psychotic symptoms in dementia is not well understood and likely differs from underlying mechanisms hypothesized for psychotic disorders such as schizophrenia.<sup>3</sup>

Widespread use of atypical antipsychotics for psychosis and other dementia-related behaviors preceded the availability of an evidence base because of the perception of superior effectiveness and safety of these drugs over the older antipsychotics. Over the past 3 years, some placebo-controlled clinical trials of atypical antipsychotics for behavioral symptoms reported small treatment effects coupled with troubling adverse effects at rates that exceeded those observed in placebo-treated patients. Reports of increased risk of mortality and cerebrovascular accidents in some trials of atypical antipsychotics in dementia populations resulted in FDA-mandated changes to product labeling for all atypical antipsychotic medication despite the fact that not all of drugs in the class have been studied in dementia populations.<sup>4,5</sup> Controversies sparked by these changes and recent clinical trial results fuel debate about the appropriate prescribing of these medications.

Other classes of psychoactive medications (typical antipsychotics, antidepressants, benzodiazepines, and anticonvulsants) are utilized in the treatment of neuropsychi-

atric symptoms, but have not been as well studied as atypical antipsychotics in dementia patients.<sup>6</sup> In light of the FDA warnings, potential medico-legal implications, and new clinical data, clinicians should understand the current data for atypical antipsychotic prescribing in patients with dementia. This article summarizes the 2 most recent publications on the efficacy and safety of atypical antipsychotic medications used in the treatment of agitation, psychosis and other behavioral symptoms.

### CLINICAL ANTIPSYCHOTIC TRIALS OF INTERVENTION EFFECTIVENESS – ALZHEIMER'S DISEASE (CATIE-AD)

CATIE-AD is the first head-to-head, prospective, randomized, double-blind, placebo-controlled effectiveness trial of antipsychotic therapy in AD. The unique design measured outcomes associated with real-world prescribing of these medications to treat behavioral symptoms.<sup>7</sup> In the initial, 36-week phase of the study, community-dwelling patients with mild-severe AD and behavioral symptoms (delusions, hallucinations, aggression,

**Table 1.**

#### Outcomes-Effectiveness

Overall effectiveness (as measured by the time to drug discontinuation) was similar for olanzapine, risperidone, quetiapine, and placebo

- Time to discontinuation for lack of efficacy was significantly longer for olanzapine (22.1 weeks) and risperidone (26.7 weeks) groups than in the placebo group (9.0 weeks)
- Discontinuation for intolerance of study drug, adverse effects or death was greater for all groups receiving active treatment (olanzapine (24%); risperidone (18%); quetiapine (16%)) than placebo (5%) treated patients
- Except for quetiapine (56.5 mg), mean daily dosages for olanzapine (5.5 mg) and risperidone (1.0 mg) at endpoint were within the usual dose range for treatment of neuropsychiatric symptoms in dementia studied in earlier trials. The optimal therapeutic dose of quetiapine remains unclear. While daily doses of 75-150mg are often prescribed, the dose range in 3 dementia clinical trials varied from 25-600mg.<sup>8</sup>

#### Outcomes-Safety

- Confusion and psychotic symptoms were observed at significantly higher rates with olanzapine than with placebo or the other antipsychotics.
- Treatment emergent Parkinsonism was more common in patients receiving olanzapine or risperidone.
- Sedation occurred more frequently with active treatment than with placebo for all antipsychotics.
- Despite higher rates of Parkinsonism and sedation in the treatment groups, there were no differences in the incidence of falls, fractures or injuries across all treatment groups.

**Table 2. Pooled Adverse Events Occurring With Atypical Antipsychotics in Placebo-Controlled Dementia Trials - Moderate or Strong Evidence**

Adverse Event	Drug	Number of studies	Pooled Odds Ratio	95% Confidence Interval
CVA*	Olanzapine	2	2.09	(0.32, 23.27)
	Risperidone	3	3.88	(1.49, 11.91)
Edema	Olanzapine	4	3.31	(1.27, 10.91)
	Risperidone	4	2.33	(1.48, 3.78)
EPS**	Aripiprazole	3	2.53	(1.34, 5.01)
	Risperidone	4	2.82	(1.81, 4.51)
Gait Abnormality	Olanzapine	4	2.75	(1.52, 5.79)
	Risperidone	3	3.04	(1.32, 7.84)
Tardive Dyskinesia	Risperidone	3	.31	(0.07, 1.03)
Increased Appetite/Weight Gain	Olanzapine	4	6.12	(1.49, 54.04)
Anticholinergic Effects	Olanzapine	4	3.29	(1.62, 7.17)
Sedation	Aripiprazole	3	6.68	(3.19, 15.72)
	Olanzapine	5	4.26	(2.66, 7.08)
	Risperidone	6	2.50	(1.89, 3.34)

\*Aripiprazole trials did not report increase in CVA; quetiapine trials did not report CVA

\*\* Insufficient extrapyramidal symptom (EPS) data for olanzapine and quetiapine

(Adapted from Reference 11)

agitation) of at least moderate severity were randomized to either olanzapine (N=100), risperidone (N=85), quetiapine (n=94) or placebo (N=142). Aripiprazole and ziprasidone were not included in the study because they were not available in the US at the time the trial was designed. The multi-center trial was funded by the National Institutes of Mental Health.

Physicians could adjust the dosage throughout the trial. Participants who adequately responded could continue the trial up to 36 weeks. If the patient's response assessed as inadequate for any reason after the initial 2 weeks of therapy, treatment could be discontinued. Patients whose therapy was discontinued could enter phase 2 of the trial to be randomized to one of the other antipsychotics or citalopram under double-blind conditions. To date, only phase 1 data have been published.

The primary outcome was time to discontinuation of treatment for any reason in Phase 1 of the study. This type of novel outcome allowed the composite effect (efficacy, tolerability, caregiver burden) of the interventions to be evaluated and compared.

The study population was moderately cognitively impaired (MMSE 15±5.8) with a mean age of 77.9 ±7.5 years. Baseline behavioral symptoms were moderately severe and 60% of the subjects received adjunctive cholinesterase inhibitor therapy upon study entry.

Treatment of psychiatric illness such as schizophrenia or bipolar disorder with some atypical antipsychotics has been associated with weight gain and metabolic abnormalities such as hyperglycemia, hyperosmolar coma, Type 2 diabetes, and hyperlipidemia in younger individuals. It is unknown whether this phenomenon is a class effect, or a consequence of an inter-

action of antipsychotics with the complex diathesis of psychiatric illness, genetics, and dietary factors. Clozapine and olanzapine appear to be most commonly associated with metabolic adverse effects and aripiprazole and ziprasidone the least implicated. In schizophrenia and bipolar disease trials, risperidone and quetiapine have intermediate effects on weight gain and metabolic parameters.<sup>9</sup>

CATIE-AD was the first head-to-head trial to explore the association between atypical antipsychotic treatment and development of metabolic adverse effects in older adults with AD. Subjects receiving olanzapine, quetiapine, or risperidone averaged a monthly weight gain of 1.0, 0.7 and 0.4 pounds on treatment, compared to weight loss among placebo-treated patients. Neither the changes in weight nor the mean changes in blood glucose, total cholesterol, or triglyceride levels were statistically significant for the active treatment groups compared with changes in

the placebo group. The modest weight gain and lesser changes in metabolic indices are consistent with data from other placebo-controlled clinical trials of atypical antipsychotics in dementia and may reflect the dementia-related changes in protein and carbohydrate metabolism that blunt antipsychotic effects on appetite, weight, and lipid metabolism.<sup>10</sup>

Analyses of pooled clinical trial data have linked atypical antipsychotic treatment of behavioral symptoms in patients with dementia to an increased risk of **cerebrovascular adverse events (CVAE)** and increased mortality. The discovery of the increased risk of mortality in pooled data from risperidone, olanzapine, quetiapine, and aripiprazole placebo-controlled dementia trials led the FDA to add a black box warning to the product labeling for all atypical antipsychotics in 2005. The labeling for olanzapine and risperidone also includes a warning about the increased risk of CVAE.

There were no observed differences in the rates of stroke or sudden death between the groups receiving atypical antipsychotic treatment and placebo-treated patients in CATIE-AD. The lack of a signal for increased incidence of stroke or risk of mortality with atypical antipsychotic therapy is not surprising when considering the differences between the dementia population studied in CATIE-AD and the populations under study in the short-term (6-12 week) antipsychotic dementia trials. Many of the atypical antipsychotic trials included dementia patients with significant cardiovascular risk factors; some included frail nursing home patients who were likely at higher risk of adverse medication-related outcomes.<sup>8</sup>

**AGENCY FOR HEALTHCARE RESEARCH AND QUALITY  
(AHRQ) EFFICACY AND COMPARATIVE  
EFFECTIVENESS OF OFF-LABEL USE OF ATYPICAL  
ANTIPSYCHOTICS**

This AHRQ analysis, published online in January 2007, retrospectively reviewed efficacy and safety data related to the 4 most common off-label uses for the atypical antipsychotics - treatment of agitation in dementia, depression, obsessive-compulsive disorder, posttraumatic stress disorder, personality disorders, and Tourette's syndrome.<sup>11</sup>

Data for the agitation in dementia analysis were drawn from randomized, controlled trials in dementia, including the CATIE-AD trial. Conclusions about the relative effectiveness of risperidone, olanzapine, quetiapine, and aripiprazole were in general agreement with results of a recently published meta-analysis of 15 placebo-controlled atypical antipsychotic trials that reported small but significant benefits on agitation and psychosis for risperidone and aripiprazole. A trend favoring the effectiveness of olanzapine for psychosis in dementia that did not reach statistical significance was also noted. The 3 quetiapine trials were too different in design and outcome measures to be analyzed and compared. There were no trials of ziprasidone in patients with dementia.

Table 2 summarizes the AHRQ analysis of safety data. The group did not analyze trial-related mortality data, but cited a recently published meta-analysis that included 15 placebo-controlled trials

of risperidone, olanzapine, quetiapine, and aripiprazole. Risk of death was increased relative to placebo (odds ratio = 1.54 (95% CI 1.06-2.23)) for patients with dementia randomized to one of the four antipsychotics. The authors concluded that a small, but statistically significant increase in risk of death is associated with use of atypical antipsychotics in dementia; however, there is insufficient evidence to determine differential risk between antipsychotics.

Conventional antipsychotics may also increase the risk of death in older adults. AHRQ's **Developing Evidence to Inform Decisions (DEcIDE)** program analyzed health care utilization data for British Columbia adults  $\geq 65$  years to study the association between use of conventional and atypical antipsychotics and death. Those who were prescribed conventional antipsychotics had a 35% greater mortality risk from fatal outpatient cardiac events, pneumonia, and stroke compared to patients who were prescribed atypical antipsychotics.<sup>11</sup>

**PARSING POTENTIAL BENEFITS VERSUS RISKS**

Subgroup analyses across atypical antipsychotic trials indicate that larger effect sizes are associated with greater cognitive impairment, residence in nursing home, and the presence of severe agitation without psychosis. These results concur with older studies of conventional antipsychotics in hospitalized patients with dementia which reported that more robust treatment effects were associated with greater severity of agitation and aggression at baseline.<sup>8</sup>

A post hoc analysis of pooled data from 6 trials comparing olanzapine to placebo, risperidone, or haloperidol is the only publication that has attempted to identify the patient-specific risk factors associated with mortality and CVAEs in dementia clinical trials.<sup>5</sup> Kryzhanovskaya et al reported that advanced age (age=80), treatment emergent sedation, benzodiazepine use, and treatment-emergent pulmonary conditions were additional risk factors for mortality in olanzapine-treated patients.

The group's analysis of the CVAE data revealed that for patients receiving either olanzapine or placebo, age  $\geq 80$  years and diagnosis of mixed or vascular dementia were significantly associated with CVAE. Orthostatic hypotension and gender were not significant risk factors.

**SUMMARY**

Atypical antipsychotics will continue to be prescribed for the behavioral symptoms of dementia in the absence of more effective, better tolerated, and safer alternatives. The evidence base, although incomplete, suggests that modest treatment effect sizes are offset by risk of considerable adverse effects. How might this information be best applied to clinical practice?

Non-pharmacologic strategies should be implemented in routine clinical practice. Placebo-controlled clinical trials of individual antipsychotic agents have historically reported high placebo response rates; CATIE-AD reported that the sum total of the risk/benefit equation of atypical antipsychotic therapy was no greater than that achieved by placebo.

CATIE-AD was designed to study the effectiveness of atypical antipsychotic treatment in community dwelling patients with AD. It is uncertain whether the results can be generalized to the populations of dementia patients residing in nursing homes with more severe cognitive and behavioral impairment. There is some suggestion that nursing home patients with dementia complicated by severe behavioral symptoms, particularly agitation and aggression without accompanying psychosis, might achieve greater benefit from atypical antipsychotic treatment than patients with milder behavioral symptoms. The finding that dementia patients without psychosis may respond more robustly to antipsychotic treatment seems counterintuitive, but may support the hypothesis that the neurobiology of the "psychosis of AD" differs from the psychosis of schizophrenia or bipolar disease.<sup>3, 8</sup>

Adverse effects associated with antipsychotic therapy should be aggressively monitored throughout therapy. Treatment-emergent sedation was associated with all of the atypical antipsychotics in CATIE-AD and is probably an important mediator of mortality risk in patients with dementia. Sedation exacerbates pre-existing cognitive impairment and increases the risk of complications such as aspiration pneumonia, so concomitant use of benzodiazepines should be discouraged or limited to short periods with careful observation.<sup>5</sup>

Once initiated, the effectiveness and tolerability of antipsychotic therapy should be evaluated routinely. In Alzheimer's disease, the severity and frequency of behavioral symptoms of-

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ten decreases as illness progresses. In a stable patient, it is prudent to attempt to taper and discontinue the antipsychotic after 2-8 months of therapy.<sup>12</sup>

Better understanding of the potential adverse effects of antipsychotic therapy has increased interest in the effects of the dementia-specific medications on behavioral symptoms. Reductions in neuropsychiatric symptoms have been reported from trials of individual cholinesterase inhibitors, memantine monotherapy, and memantine combined with donepezil in AD patients.<sup>13,14</sup> Studies of small numbers of patients in open trials of cholinesterase inhibitors (donepezil, rivastigmine, galantamine) and one double-blind placebo controlled trial (rivastigmine) have reported varying degrees of improvement of behavioral symptoms and psychosis of dementia with Lewy bodies (DLB).<sup>15</sup> Delusions, hallucinations, apathy, and agitation/aggression are cited as the symptom categories most likely to show significant improvement.<sup>13</sup> Since few of these studies were prospectively designed to study behavioral symptoms, results must be interpreted cautiously.

Treatment of behavioral symptoms in AD and other dementias is challenging. The limitations of current approaches drive the search for effective, well tolerated therapies.

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## The Management of Insomnia in the Older Adult

Ana C. Tuya, MD

**An 88 year-old man contacts the on-call physician on a Saturday afternoon with a chief complaint of being unable to fall asleep for three nights; he requests a new prescription to help him sleep. He has been on trazodone 75 mg for several years and takes it nightly, but it has not been effective for sometime. He has a medical history of hypertension and hyperlipidemia, for which he takes metoprolol, aspirin, atorvastatin, and a daily multivitamin. He is active, walks 2-miles daily, drives and is independent in ADL and IADL. He does not smoke or drink alcohol. What should the on-call physician do—increase the trazodone? Start a new sleep medication? Ask the patient to wait until Monday when he can talk to his physician?**

Insomnia is exceedingly common in the older adult population; up to 33% use over the counter or prescription sleep aids, and close to 40% describe difficulty falling asleep.<sup>1</sup> Contributing factors include changes in sleep architecture and circadian rhythm, increased incidence of sleep disorders, and life stressors unique to the older adult. As with so many other decisions in geriatrics care, the treatment must consider patients' multiple co-morbid diagnoses and long medication lists.

The first step in evaluating a patient with insomnia is to take a detailed sleep history—duration of symptoms, nap history, life situation at start of symptoms, wake up times, bedtime, caffeine/alcohol/fluid intake, activities done in bed before and after trouble sleeping, sleep room characteristics, medication use, and detailed review of systems and family history. Also useful is a review of the sleep hygiene “do’s and don’ts”.<sup>2,3</sup> Important medical diagnoses to rule out by history and/or workup include sleep disorders (sleep apnea, restless leg syndrome, REM sleep behavior disorder) that are more common with aging. This evaluation may point toward focused interventions to improve sleep hygiene, or the need for diagnostic workup to treat a sleep disorder. If neither of these results obtains, the next step is to decide whether to treat. If treatment is indicated, the choice is non-pharmacological versus pharmacological.

Studies showing that non-pharmacological treatment is effective and long lasting abound. Interventions that have been proven effective include stimulus control, bright light therapy, regular exercise, bathing before bed, cognitive therapy, sleep hygiene improvement, warm milk, back rub, and relaxation techniques. One particularly interesting study evaluated patients with Alzheimer’s dementia and insomnia. In this randomized trial, one group of patients and caregivers received extensive training and support on sleep hygiene interventions, while the other group received one information session only, at the start of the study. After six months, the intervention group showed a significant trend toward increased satisfaction, with 50% reporting substantial benefit. The benefit continued throughout the follow up period.<sup>4</sup> The benefit was not only in satisfaction and self-reported benefit, but also in caregiver reports of time awake and number of nighttime awakenings.

When non-pharmacologic therapy fails, or when urgent intervention is required to temporarily alleviate sleeplessness while non-pharmacologic therapy is being instituted, medications are often prescribed. There are several drug classes from which to choose; adverse reactions, efficacy, safety and interactions vary significantly. These sedative hypnotic medications are for short-term use. Most studies follow patients for only a few months—long-term use by any group has not been evaluated in detail. One meta-analysis demonstrated that effectiveness of the benzodiazepines waned after two weeks.<sup>5</sup> Older, but still often used, these drugs are plagued by adverse reactions in the older adult population; for example, next-day somnolence, dependence, dizziness, drug interactions, and increased risk of falls. This group is one of the drug classes listed among the Beer’s criteria of drugs to avoid using in the elderly due to unacceptably high adverse effects.<sup>6</sup> For patients who have been on them for years, it is recommended to wean them gradually.

Another popular choice among sedative hypnotics for sleep has been trazodone. Its use has exceeded that of zolpidem (Ambien), which is estimated at over 27 million prescriptions.<sup>7</sup> It is reputed to be safe, effective, non-habit forming and more cost-effective. Of note, the use of trazodone (and mirtazepine, mentioned later) is off-label. A systematic review published in 2005<sup>8</sup> found 18 studies in the literature for the period of 1980-2003 and included all 18, regardless of inclusion or exclusion criteria, because of the small number. Of the studies included, only one was a randomized placebo control trial on the use of trazodone in patients with primary insomnia. The majority of the remaining studies evaluated its use in depression, and revealed improvement of insomnia as a secondary outcome.

The primary insomnia study examined 306 patients ages to 65 who were randomized to zolpidem 10 mg, trazodone 50 mg, or placebo. The effect of the drug was measured using a subjective sleep questionnaire; follow up was for two weeks. At week one, there was improvement in both the zolpidem and trazodone group, compared with placebo. By week two, zolpidem was better than placebo, but trazodone improvement was not statistically significant compared with placebo.<sup>8</sup> In this study, follow up was short; and no patients over age 65 were included. The remaining studies evaluated in this systematic review had small sample sizes, used much higher doses of trazodone (>150 mg) and were in depressed patients. These results may not apply when trazodone is prescribed for primary insomnia, especially in view of the much lower doses used. Safety analysis revealed several important side effects in significant proportions of subjects: drowsiness in 29%, dizziness in 21% and next day fatigue in >10%. Less common but still disturbing adverse reactions included orthostatic hypotension, priapism and QT interval prolongation. The question of tolerance, and whether increasing the dose would restore the initial effect, was not addressed by this or

any study reviewed. Therefore, the evidence does not support the benign profile that providers and the public have accepted.

Another commonly used medication is mirtazapine, an antidepressant found to have significant sedation effect when used in depressed patients. It is similar to trazodone, and is used for insomnia to capitalize on its side effect profile. It has also become a popular choice among those who care for dementia patients who suffer from both insomnia and anorexia – increased appetite was another side effect noted when the drug was used in depressed patients. Of note, the side effects of increased appetite and sedation are typically seen with the lowest doses (7.5 mg or 15 mg). Case reports have demonstrated clinical improvement in both insomnia and anorexia when the medication is used in Alzheimer's patients.<sup>9</sup> However, more rigorous studies of mirtazapine's tolerance and safety profile in elderly patients are limited. A small study, examining its efficacy, noted that 11% of patients discontinued use due to adverse events, 18% of which were falls.<sup>10</sup> Caution should be used when prescribing this agent for insomnia in older adults.

The newer drugs that capture the most media attention, and that patients request by name, are the "Z drugs," which include zaleplon (Sonata), zolpidem, and eszopiclone (Lunesta). One randomized trial compared zaleplon at 5 mg and 10 mg doses to zolpidem 10mg and to placebo in 549 patients, all over the age of 65.<sup>11</sup> The results demonstrate better sleep quality in both groups as compared to placebo. Adverse events were similar in the four groups, with no increased adverse effects as compared to placebo. However, the follow up time was only two weeks. Another group of authors reviewed the literature to compare the effectiveness of the Z drugs to placebo, and included 24 trials.<sup>12</sup> Their final conclusions reflected disappointment: most studies had small sample size, poor methodologic quality, and in most, pharmaceutical funding. They recommended further studies in the elderly, with more rigorous methodologic adherence before drawing clinical conclusions.<sup>12</sup>

Finally, ramelteon (Rozerem) warrants discussion. In the limited but promising existing studies, this melatonin receptor agonist was found to produce improvements in all sleep components (latency, efficiency, and duration).<sup>13</sup> The agent has been found to be effective and safe, with no concerns of dependence or next day somnolence. It is best used for patients who have difficulty initiating sleep. However, as a newer agent, more time and study in post-marketing surveillance must be awaited before recommendations can be made in vulnerable very old persons. Yet, among the options, this one seems preferable for use in the older adult population, and some studies have demonstrated that elderly patients can use it safely without increased risk of falls or drowsiness the following day.<sup>14</sup> Only time and clinical use will tell how truly safe and effective it is. This agent has recently been added to the formulary at the Lifespan hospitals.

In summary, the evidence supports the use of non-pharmacologic treatments as first line due to their proven efficacy, and for the long-term effects. Pharmacologic therapy has an important role, but only for the short-term, and carries with it significant risk of adverse reactions. The newer agent ramelteon is promising, but will require further study and use in practice. Trazodone did not prove to be as safe and harmless as initially thought, and its efficacy is also in question. The newer Z drugs also proved efficacious, but had limited data in the older adult

population, are expensive, and are scheduled drugs, making use in long-term care settings more troublesome.

For the patient presented at the beginning of this article, the first assessment the clinician must make is whether the situation is a sleep emergency or not. If the patient can wait, it would be better for him to discuss the problem and options with his primary physician, who knows him and his history best. This patient has had three days of symptoms, but is retired and able to nap during the day; he should continue his current regimen until Monday, when he can call his primary care doctor. Options at that point include a more detailed review of sleep hygiene and recommendations to discontinue drinking coffee after breakfast, to decrease caffeine intake and substitute a glass of warm milk or herbal tea after dinner. He should avoid napping during the day and evaluate the quality of his bedroom for sleep promotion. The trazodone dose can remain the same, since there is no evidence base for increasing the dose to regain initial effect, and strong consideration should be given to discontinuing it altogether due to the poor evidence base for its use in primary insomnia

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**THE ANALYSES UPON WHICH THIS PUBLICATION IS BASED** were performed under Contract Number 500-02-R102, funded by the Centers for Medicare & Medicaid Services, an agency of the U.S. Department of Health and Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. The author assumes full responsibility for the accuracy and completeness of the ideas presented.



# Images In Medicine

## Ocular Melanoma

*Ikue Shimizu, MD, Richard Gold, MD, and Edward Feller, MD*

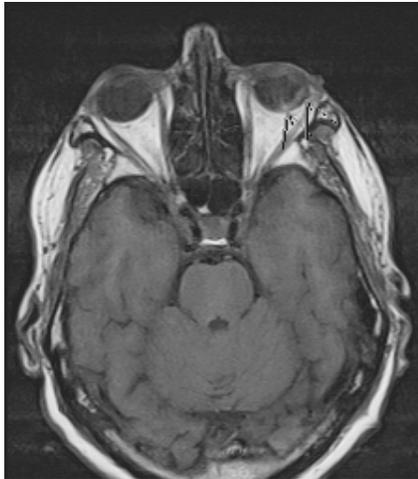


Figure 1a.

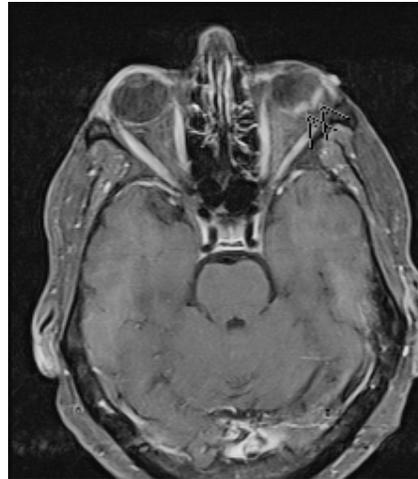


Figure 1b.



Figure 1c.

**A 71 year-old man presented with severe nausea and vomiting** for several days. He had no visual complaints. Physical exam was normal except for an enlarged, tender liver. Abdominal CT scan revealed a 12cm mass in the right liver lobe, shown to be melanoma by biopsy. Skin exam did not reveal a primary cutaneous lesion. An ophthalmologic consult to evaluate for ocular melanoma demonstrated a lesion in the left choroid. Magnetic resonance imaging of the orbit showed two choroidal masses in the left eye consistent with melanoma: slightly hyperintense on the T1-weighted image (Figure 1a), hypointense on the T2-weighted image (Figure 1b), and enhancement on the T1 post-gadolinium image with fat saturation (Figure 1c). The patient received right hepatic artery chemoembolization, and was discharged on anti-emetics.

The eye and orbit are the most common non-skin sites of primary or metastatic melanoma.<sup>1</sup> The most frequent location is uveal, the majority are choroidal. Presentation of ocular melanoma is diverse, including visual disturbance, ocular mass, cra-

nial nerve palsy, orbital myopathy, or uveitis or vitritis. Severe pain is uncommon. Some are detected by routine exam or discovered during evaluation of known extra-ocular melanoma. Uveal melanomas tend to spread hematogenously, most often to the liver; as many as 60% of these melanomas have liver metastases at presentation. Diagnosis of uveal melanoma is usually established by an indirect fundoscopic exam. Fluorescein angiography and ultrasound studies are also used to diagnose uveal melanoma.<sup>2</sup> Magnetic resonance imaging can be helpful in uveal melanoma staging and the evaluation of prognostic factors such as tumor pigmentation, size, shape, location, retinal detachment, extrascleral extension.<sup>3</sup>

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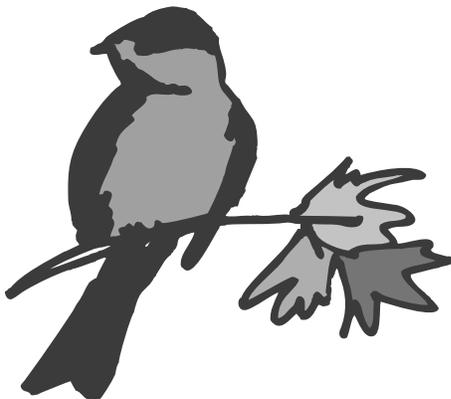
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# Physician's Lexicon

## The Vocabulary of Pathogenic Bacteria

The binomial words defining the various genera and species of bacteria pathogenic to humans derive from two principal sources: first, as eponyms of the scientists who laid claim to their initial identification; and second to a series of Greek roots serving to describe some morphological feature of the microbes.

The numerous eponyms include Brucella, Ehrlichia, Escherichia, Klebsiella, Listeria, Neisseria, Nocardia, Pasteurella, Salmonella, Shigella, and Yersinia. Curiously, the discoverer of the tubercle bacillus and cholera vibrio, Robert Koch, has no genus bearing his name.

The word, bacterium, derives from a Greek word meaning little staff or rod and gave rise to the Latin *baculum* meaning grape-like [but is only remotely related to the word, bacciferous, meaning bearing grapes which is directly related

to Bacchus, the Greek god of grapes.]

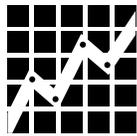
Coccus is yet another Greek word meaning berry-like. A number of Greek prefixes define it further: *gono-* meaning sexual or reproductive [as in the word, gonad], *crypto-* meaning hidden [as in cryptogram], *diplo-* meaning double [as in diplopia or diplomat; it should be hastily stressed that diplomat does not mean double-dealing but rather one who carries a sanctioned diploma, which is a folded, or doubled, document], *staphylo-* meaning clustering or grape-like, *strepto-* meaning pliant or chain-like, and *meningo-*, meaning membranous.

Diphtheria was coined from a Greek root meaning leather-like referring to the characteristic pharyngeal pseudo-membrane. Corynebacterium stems from a Greek root meaning club-like. Clostridium uses a Greek root meaning

spinning or thread-like; the Greek Fate, *Clotbo*, is a spinner of fabric. Botulism stems from a Latin word meaning sausage [from whence the bacteria were first isolated.]

Proteus is the name of the Greek sea-god who had the skill of easily changing form. Vibrio comes from a Latin word meaning to vibrate. Anthrax is from a Greek word meaning coal [as in anthracosis or anthracite]; and Chlamydia is derived from the Greek word for cloak or upper garment.

– STANLEY M. ARONSON, MD



RHODE ISLAND DEPARTMENT OF HEALTH  
DAVID GIFFORD, MD, MPH  
DIRECTOR OF HEALTH

## VITAL STATISTICS

EDITED BY COLLEEN FONTANA, STATE REGISTRAR

### Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Underlying Cause of Death	Reporting Period			
	June 2006	12 Months Ending with June 2006		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	201	2,712	253.5	3,828.5
Malignant Neoplasms	176	2,270	212.2	6,239.0
Cerebrovascular Diseases	23	436	40.8	615.0
Injuries (Accidents/Suicide/Homicide)	34	427	39.9	6,512.5
COPD	28	476	44.5	367.5

Vital Events	Reporting Period		
	December 2006	12 Months Ending with December 2006	
	Number	Number	Rates
Live Births	948	12,831	12.0*
Deaths	894	9,885	9.2*
Infant Deaths	(16)	(89)	6.9#
Neonatal Deaths	(4)	(64)	5.0#
Marriages	443	6,974	6.5*
Divorces	229	3,169	3.0*
Induced Terminations	491	4,788	373.2#
Spontaneous Fetal Deaths	120	802	62.5#
Under 20 weeks gestation	(109)	(743)	57.9#
20+ weeks gestation	(11)	(59)	4.6#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 1,069,725

(c) Years of Potential Life Lost (YPLL)

*Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.*

\* Rates per 1,000 estimated population

# Rates per 1,000 live births



## MEDICAL MALPRACTICE TOPICS

INFORMATION FOR RHODE ISLAND PHYSICIANS FROM BABCOCK & HELLIWELL

# PREPARING YOUR PRACTICE FOR A NATURAL DISASTER

John Tickner, CPCU, President, Babcock & Helliwell

The hurricane season is here. The specialists at Colorado State University recently issued their updated forecast for the 2007 season. They anticipate 17 named storms; this includes nine hurricanes, five of which they predict will be Category 3 storms with winds of at least 111 mph.

Preparing contingency plans can make a significant difference in how well your practice survive a disaster. A checklist is an efficient loss-prevention measure. Spend time discussing these questions with your staff to help avoid confusion, reduce your exposure to loss, and maintain patient safety if and when you're faced with a serious storm.

### Patients

- Do you have adequate backup for paper/electronic files?
- How could these records be protected in the event of a hurricane or other natural disaster?
- How could you access electronic files if the power were out for several days? Could they be restored?
- How will your patients contact the practice in the event of a disaster? What if phone lines are not functional?
- What impact will the lack of a phone and the Internet have on the practice?
- Is the practice prepared to handle injured walk-in patients during or after a disaster?
- Are arrangements in place to facilitate continued care for homebound patients with chronic conditions?

### Employees and Staff

- Do you maintain current contact information, landline and cell phone numbers, for all employees and staff?
- Do all staff members have access to this information?
- Has your practice administrator compiled the phone numbers of the applicable agencies that you would need to contact during and after a disaster?

### Physical Assets, Equipment, and Supplies

- If a third party handles billing records, do they have adequate recovery plans?
- Are contact numbers for equipment and supply vendors available and accessible?
- What basic equipment would be needed for the practice

to be functional during and immediately after a disaster?

- Is electronic data backed up? Is off-site access to such data available?
- Does the practice maintain an adequate inventory of essential supplies such as gloves, syringes, etc.?
- Is there a source for replacement units if equipment is destroyed?
- How will pharmaceuticals that require refrigeration be stored if there's a power failure?
- In the event that the office is damaged severely, is there an alternate site that can be used to see patients?

### Business Associates

- What alternatives are there for services such as x-ray and laboratory if these are unavailable for several days?
- Have arrangements been made with colleagues out of the area whom you use for consultations?
- How will on-call responsibilities be handled?

### Insurance Coverage

- Are all property and casualty insurance policies up to date, and are coverage limits adequate?
- Does the practice carry business interruption coverage?
- Are the facility and property covered for flood loss?
- Are copies of all insurance policies and your insurance agent's landline and cell phone numbers available?

Most Rhode Island towns have model preparedness plans and reference material available at little or no cost. For additional information or assistance in establishing a preparedness plan, go to the Hurricane Preparedness section of the Babcock & Helliwell Web site.

*John Tickner, CPCU, is president of Babcock & Helliwell, a privately held independent insurance agency established in 1892 that provides professional insurance-related services of all kinds. Babcock & Helliwell is an agency for ProMutual Group, New England's largest medical malpractice insurance provider and the second-largest provider in Rhode Island.*

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**NINETY YEARS AGO, JUNE 1917**

In "The Liver," Charles F. Peckham, MD, discussed specifics, including liver cells, bile, enzymes, parasitic microorganisms, and dead protein.

H.P. Lovewell, MD, in "A Study of Cardiorenal Types," presented a review of 250 cases from a course in "Medicine and Pathology" at the Massachusetts General Hospital, using a classification of Dr. R. Cabot, from a paper read before the American Medical Association in 1914. [Dr. Cabot had found that 93% of "failing hearts" fell into 4 groups: rheumatic, arteriosclerotic, nephritic, syphilitic.] Of the 250 cases reviewed, Dr. Lovewell would put 70 under one of the 4 types.

An Editorial urged "More Men for the Medical Reserve Corps." "It is evident that the local profession is not sufficiently impressed with the fact that we are engaged in a real war." The Editorial warned that an army of 2 million soldiers would need 20,000 physicians. "It should be a patriotic duty for us to [volunteer]."

A Second Editorial, "Scientific Feeding of the People in Waiting," cautioned readers that because of the war, Americans were receiving less food from Europe (less acreage devoted to crops, poor crops, submarines). Consequently, physicians needed to counsel patients on how to achieve better nutrition with less food. Physicians should "...offer gratuitous advice on the proper feeding of the family in every home we visit."

**FIFTY YEARS AGO, JUNE 1957**

Herbert Fanger, MD, YS Song, MD, and Thomas H. Murphy, MD, contributed "Uterine Cancer: A Report of the First 2000 Cases of the State Cytology Program for Uterine Cancer." The report drew from 2000 patients, submitted by 210 physicians. In the first 3 months of testing, 40 tested in the "positive and suspicious group;" 152, in the "atypical group." Most (83.6%) tested negative.

Charles L. Farrell, MD, president, Rhode Island Medical Society, in "Retrospect and Prospect - 1957," in describing Medicare, warned: "National Socialism is being fed to you piecemeal."

Francis P. Catanzaro, MD, and Anthony Merlino, MD, in "Adenomatous Polyps of the Gastrointestinal Tract," summarized data from 49 patients, seen at St. Joseph's from 1946-1957.

**TWENTY-FIVE YEARS AGO, JUNE 1982**

Joseph R. Salvatore, MD, and LR Jenkyn, MD, in "Progress in Neurology," contributed "Prophylactic Cranial Irradiation in Small Cell Carcinoma of the Lung," which they called "a controversial treatment."

Irving A. Beck, MD, in "The Providential Visits of Dr. Osler: The Great Master Keeps Alive Rhode Island Connections," drew from the papers of Dr. Frank T. Fulton, including his correspondence with Dr. Osler.

Frank M. D'Allessandro, MD, in "Diabetes Mellitus - Practical Aspects," discussed the "serial determination of plasma insulin levels" as a way to delineate the type of diabetes.

Michael G. Pierik, MD, in "Fatal Staphylococcal Septicemia Following Acupuncture: Report of 2 Cases [from St. Joseph's Hospital]" emphasized the "need for thorough medical evaluation before such procedures."

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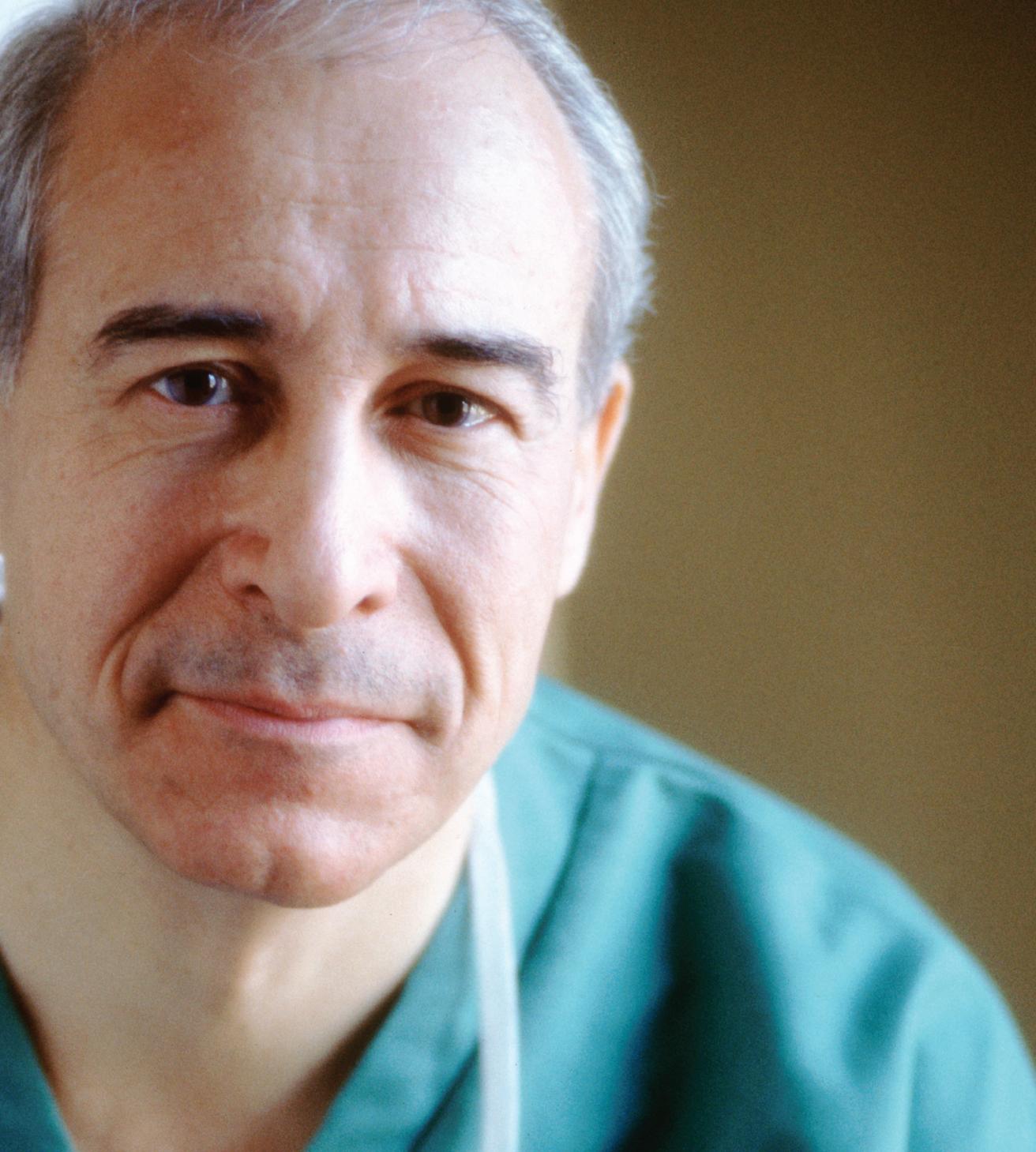
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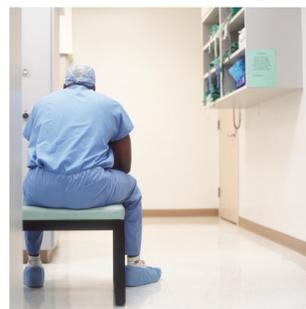
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