

the Reporter

In the past decade, bacteria have become more resistant to antibiotic treatment, causing the Centers for Disease Control and Prevention (CDC) to name antimicrobial resistant bacteria as one of its top concerns. ¹ Methicillin-resistant *Staphylococcus aureus* (MRSA) currently plagues hospitals. ² Cases of community associated MRSA (CA-MRSA) have emerged in areas of close contact, including correctional facilities, child care centers, and gyms. ³ MRSA infections led to four pediatric deaths in Minnesota and North Dakota. ⁴

Even more ominous, since 1997 there have been 16 recorded cases in the United States of antibiotic resistance to Vancomycin — the antibiotic of last resort. ⁵ Fortunately, both Vancomycin-resistant *Staphylococcus aureus* (VRSA) and Vancomycin-intermediate *Staphylococcus aureus* (VISA) have so far been susceptible to other FDA-approved drugs. ⁶ The emergence of a bacterium resistant to all existing antibiotics may be inevitable.



by William Malamon

Resistance Factor

Physicians change prescribing practices as antimicrobial-resistant bacteria spread

Cause and effect

When penicillin was first mass-produced in the 1940s, antibiotics were perceived as an “almost magical medicine, capable of curing almost any disease.” ⁷ Instead, the result has been described as “The use and misuse of large quantities of antibiotics are the driving force behind the worldwide resistance phenomenon.” ⁷

Antibiotic over prescription and inappropriate prescription remain a problem. Between 20% and 50% of antibiotic prescriptions in community settings are believed to be unnecessary. ⁸ Though a 1999 study showed that antibiotics were unnecessary to treat upper respiratory infections (URI), the medications were still prescribed for more than 40% of the URIs in the United States. ⁹

Nevertheless, a more positive trend is emerging. A study published in the *Journal of General Internal Medicine* showed that between 1995 and 2002, “there was a significant decline in the proportion of outpatient visits that resulted in antibiotics prescribed for U.S. adults.” The study also showed that the

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decline was in proportion to prescriptions written for acute respiratory infection which are “overwhelmingly viral in origin and do not respond to antibiotic therapy.”¹⁰

Along with the decline in the number of antibiotic prescriptions comes a new challenge for physicians — changing their patients’ overconfidence in the power of antibiotics. Often patients expect, even demand, antibiotics. Many patients come to health care offices assuming that antibiotics will cure any ailment.

Patients’ persistence often gets them the antibiotics that they want. According to a study published in *Pediatrics*, physicians are 30% to 45% more likely to prescribe antibiotics if they perceive patients want them. In the same study, 71% of family physicians and 53% of pediatricians said they would immediately prescribe antibiotics for an infant exhibiting symptoms of a URI for only one day. For older children, 50% of the family physicians and 24% of pediatricians would prescribe antibiotics.¹¹

Patient expectations may also account for the reason that antibiotics are prescribed for viral infections. Researchers found that nearly one-third of patients diagnosed with a cold receive antibiotics.¹²

“Patients want antibiotics and physicians continue to prescribe them in situations where antibiotics may be withheld for many reasons. The act of prescribing an antibiotic has social and medical implications. From the patient’s point of view, the prescribing of an antibiotic validates that the patient does have an illness, that a diagnosis has been made and that the illness is amenable to treatment. The fact that there is a ‘cure’ for their problem reassures them that the illness is not serious.”¹³

While physicians may try to resist patients’ demands for antibiotics, there are several reasons they may prescribe them anyway. Physicians must weigh a number of factors when diagnosing an infection. They may fear the infection will turn out to be bacterial, and prescribe an antibiotic for peace of mind. If the infection turns out to be bacterial, the prescription was appropriate. If not, the physician can then diagnose the problem having ruled out a bacterial infection.¹⁴ Physicians may also fear a lawsuit if a misdiagnosed viral infection turns out to be disastrous bacterial infection. In the patient’s eyes, a simple antibiotic prescription may have avoided an uncomfortable and costly illness.¹⁴

Guidelines to prevent bacterial resistance

The CDC has implemented guidelines to prevent resistance to antibiotics and change patient attitudes. It has undertaken the task of advising local and state health agencies, health care facilities, and laboratories on identifying resistant bacteria and educating patients on risks.¹⁵ In this effort, the CDC has promoted programs that encourage the appropriate use of antibiotics. One program, the Campaign to Prevent Antimicrobial Resistance, centers on four strategies physicians can use.

1. Prevent infections. Encourage your staff and patients to receive regular influenza and pneumococcal vaccinations. Prevent the conditions that lead to infection. Use IV devices only when essential and with minimal exposure.
2. Diagnose and treat infections effectively. Consult infectious disease experts for complicated infections and potential outbreaks.
3. Use antibiotics wisely. Know when to say “no” to patients. Stop antibiotic treatment when cultures are negative and infection is unlikely.
4. Prevent the transmission of infections. Isolate the pathogen and break the chain of contagion. Cover your mouth when you cough or sneeze. Insist your employees do the same. Promote wellness among your staff. Insist they stay home when they are sick.”¹⁵

According to an article published in the *American Family Physician*, education is crucial to changing patient attitudes. The authors rec-

ommend that physicians take time to, “explain when antibiotic use is appropriate and when it is not.”⁸ The Alliance for the Prudent Use of Antibiotics states that it may only take “two or three minutes” to educate a patient on why antibiotics are or are not an appropriate therapeutic option.¹⁶

Recent studies show that the amount of time spent educating patients, and not necessarily the receipt of an antibiotic prescription, correlate with patient satisfaction. “One survey indicated that while 65 percent of patients expected to receive an antibiotic for treatment of a URI, there was no correlation between patient satisfaction and receipt of an antibiotic prescription. Instead, patient satisfaction correlated highest with the quality of the physician-patient interaction. Results from focus groups indicate that patients would be satisfied if an antibiotic was not prescribed as long as the physician explained the reasons for this decision.”¹³

Resources are available to help physicians educate patients. The CDC offers brochures that, in clear language, explain to patients the difference between viruses and bacteria and why antibiotics are not effective against viral infections. Most importantly, they explain that the misuse of antibiotics can endanger the patient and others in the community. Brochures are available at www.cdc.gov/drugresistance/community/healthcare_provider.htm. Physicians can also order fact sheets, laminated cards, notepads, and posters from the CDC web site, www.cdc.gov.

At the 1999 Summit of Antimicrobial Resistance, researchers developed a plan to educate physicians and the public about antibiotic-resistant bacteria. For physicians, they recommend:

- “Do not accommodate patients’ or parents’ demands for unneeded antibiotics.
- Clarify to patients and parents that antibiotics put them at risk for a multi-resistant bacterium.
- Educate patients and parents on the prudent use of antibiotics, including the importance of completing the full course of prescribed antibiotics.
- Educate patients and parents on preventative measures such as vaccines, frequent hand washing, and proper hygiene.
- Make use of all diagnostic methods to identify the proper pathogen.”¹⁶

The CDC also offers guidelines for the appropriate use of antibiotics in adults. The American College of Physicians follows the CDC guidelines, described below.

Upper respiratory infections

1. The diagnosis of nonspecific upper respiratory tract infections or acute rhinopharyngitis should be used to denote acute infection that is typically viral in origin, and in which sinus, pharyngeal, and lower airway symptoms, although frequently present, are not prominent.
2. Antibiotic treatment of nonspecific URI in adults does not enhance illness resolution or prevent complications, and is therefore not recommended.
3. Purulent secretions in the nares and throat (commonly reported and seen in patients with an uncomplicated, upper respiratory tract infection) neither predict bacterial infection nor benefit from antibiotic treatment.
4. Throat cultures are not recommended for the routine primary evaluation of adults with pharyngitis, nor for the confirmation of negative rapid antigen tests. Throat cultures may be indicated as part of investigations of outbreaks of GABHS [Group A beta hemolytic streptococcus] disease, for monitoring the development and spread of antibiotic resistance, or when pathogens such as gonococcus are being considered.
5. The preferred antibiotic for treatment of acute GABHS pharyngitis is penicillin, or erythromycin for a penicillin-allergic patient.”¹⁷

Bronchitis

“1. The evaluation of adults with an acute cough illness, or with presumptive diagnosis of uncomplicated acute bronchitis, should focus on ruling out pneumonia. In the healthy, non-elderly adult, pneumonia is uncommon in the absence of vital sign abnormalities or asymmetrical lung sounds, and chest radiography is usually not indicated. In patients with cough lasting 3 weeks or longer, chest radiography is warranted in the absence of other known causes.

2. Routine antibiotic treatment of uncomplicated bronchitis is not recommended, regardless of duration of cough. In the unusual circumstance when pertussis infection is suspected, a diagnostic test should be performed and antimicrobial therapy initiated.

3. Patient satisfaction with care for acute bronchitis is most dependent on the doctor-patient communication rather than on whether or not an antibiotic is prescribed.”¹⁷

Pediatric patients

The most common reason for prescribing antibiotics in children is acute otitis media (AOM).¹⁸ To prevent the over prescription of antibiotics in children, the American Academy of Pediatrics (AAP) has published the following guidelines for AOM:

“1. careful diagnosis;

2. use of narrow-spectrum antimicrobial agents; and

3. the initial observation of nonsevere cases of acute otitis media in selected children, including children up to 2 years old with mild ear pain, without high fever, and for whom the physician believes that prompt follow-up is assured should symptoms worsen.”¹⁸

A watchful waiting policy for AOM has been adopted by the AAP and the American Academy of Family Physicians (AAFP).¹⁹ Watchful waiting involves deferring antibiotic treatment for up to 72 hours. During this time, analgesics are prescribed. If the infection is not bacterial, the patient’s condition will likely improve on its own. If the patient’s condition persists or worsens, the physician can prescribe antibiotics.¹⁸ The AAP and AAFP guidelines are described below.

“1. Accurately diagnose AOM and differentiate it from otitis media with effusion (OME), which requires different management.

2. Relieve pain, especially in the first 24 hours, with ibuprofen or acetaminophen.

3. Minimize antibiotic side effects by giving parents of select children the option of fighting the infection on their own for 48-72 hours, then starting antibiotics if they do not improve.

4. Prescribe initial antibiotics for children who are likely to benefit the most from treatment.

5. Encourage families to prevent AOM by reducing risk factors. For babies and infants these include breastfeeding for at least six months, avoiding ‘bottle propping,’ and eliminating exposure to passive tobacco smoke.

6. If antibiotic treatment is agreed upon, amoxicillin is recommended for most children.”¹⁹

As a follow up to the recommendation for AOM, the AAFP, AAP, and the American Academy of Otolaryngology published recommendations for otitis media with effusion (OME). OME is also a common diagnosis in children, with 2 million cases in the U.S. per year.²⁰ The guidelines state:

“• Physicians should manage children with OME who are not at risk with ‘watchful waiting’ for at least three months before recommending other treatment.

• Antibiotics and corticosteroids are not recommended for routine management of OME.”²⁰

Looking ahead

Adherence to guidelines for the prudent use of antibiotics has proven to be effective. A Finnish study published in the *New*

England Journal of Medicine demonstrated that erythromycin resistance among *group A streptococci* decreased from 16.5 to 8.6 percent over four years during implementation of national guidelines to limit the use of erythromycin.²¹ “Other studies in the United States show that decreased use of antibiotics for prophylaxis and treatment correlated with decreasing rates of colonization with resistant organisms.”¹³

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patient safety news

FDA proposes labeling changes to OTC pain relievers

In December, the Food and Drug Administration (FDA) proposed changes to the labeling regulations on over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drugs to include information about the potential for stomach bleeding and liver damage and when to consult a doctor. The changes affect drug products commonly known as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, naproxen and ketoprofen. The FDA proposed these labeling changes.

For products containing acetaminophen:

- to require new warnings that highlight the potential for liver toxicity, particularly when using acetaminophen in high doses, when taking more than one product with acetaminophen, and when taken with moderate amounts of alcohol; and
- to require that the ingredient acetaminophen be prominently identified on the product's principal display panel (PDP) of the immediate container, and the outer carton (if applicable).

For products containing NSAIDs:

- to require new warnings that highlight the potential for stomach bleeding in persons over age 60, in persons who have had prior ulcers or bleeding, in persons who take a blood thinner, when taking more than one product containing an NSAID, when taken with moderate amounts of alcohol, and when taken for longer time than directed; and
- to require that the name of the NSAID ingredient and the term "NSAID" be prominently identified on the product's PDP of the immediate container and the outer carton (if applicable).

The new labeling would be required for all OTC drug products that contain only an IAAA ingredient, and for products that contain an IAAA ingredient with other ingredients, such as cold symptom relievers. A number of manufacturers of OTC analgesic drug products already have voluntarily implemented labeling changes to identify these potential safety concerns.¹

FDA identifies contributing factors

In a paper published in 2004, the FDA identified the following factors that contribute to IAAA adverse events.

Unintentional acetaminophen overdoses in adults:

- failure by consumers to recognize the ingredients in the OTC drugs and/or the potential for harm due to exceeding the recommended dose;
- the wide variety and availability of both OTC and prescription drugs that contain acetaminophen;
- the lack of consumer awareness for the potential to develop adverse events from taking two or more different drug containing acetaminophen concomitantly; and
- the failure of prescription container labels to list acetaminophen as an ingredient.

Unintentional acetaminophen overdoses in children:

- administering the wrong pediatric formulation (substituting the concentrated infant drops for the less concentrated children's suspension);
- administering the adult instead of the age-appropriate children's formulation;
- incorrectly calculating the weight-appropriate dose of acetaminophen; and
- using the wrong measuring device (tablespoon instead of teaspoon, dropper versus syringe).

Risk factors for GI bleeding for OTC and prescription NSAIDs:

- use with other medications such as anticoagulants and/or corticosteroids;
- use with low dose aspirin and other NSAIDs;
- increasing age (over 60);
- increasing dose;
- previous history of GI bleeding; and
- use with alcohol.

The following at-risk populations for NSAID-induced nephrotoxicity were identified:

- patients with volume depletion;
- underlying kidney disease;
- congestive heart failure;

- age 65 or older;
- hypertension; and
- diabetes.

The FDA recommends physicians educate their patients about the following:

- that any OTC analgesic is a drug and appropriate safety precautions need to be taken when using or storing it;
- the wide variety of different strengths, formulations, and combinations of acetaminophen- and NSAID-containing products that are available OTC and by prescription;
- the correct dosing frequency for each acetaminophen or NSAID formulation;
- the correct weight-based dose for each child;
- the use of the correct measuring device for liquid formulations;
- drinking more than 3 alcoholic drinks every day is not compatible with safe acetaminophen or NSAID use;
- risk of taking OTC analgesics with other prescription or OTC medications;
- signs and symptoms of self-recognizable side effects; and
- the potential problems associated with using more than one pain reliever product simultaneously.

"Most importantly, health care professionals should remind their patients to always read their OTC and prescription medication labels and carefully follow the directions."²

Sources

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A sleepy nation: diagnosing and treating sleep disorders

Course author

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Disclosure

Stacey Agnew has no commercial affiliations/interests to disclose related to this activity.

Target audience

This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

CME credit statement

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This course has been designated by TMLT for 1 hour of education in medical ethics and/or professional responsibility.

Directions

Please read the entire article and answer the CME test questions. To receive credit, submit the completed test and evaluation form to TMLT. All test questions must be completed. Please print your name and address clearly. Allow four to six weeks from receipt of test and evaluation form for delivery of certificate.

Estimated time to complete activity

It should take approximately one hour to read this article and complete the questions.

Release/review date

This activity is released on February 2, 2007 and expires on February 2, 2009. Please note this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.



Introduction

According to the National Institute of Neurological Disorders and Stroke, there are approximately 40 million people in the United States who suffer from sleeping disorders and an additional 20 million have occasional sleeping problems. Sleep disorders account for an estimated \$16 billion in health care costs each year, not including the indirect costs associated with the loss of productivity and other contributing factors. Sleep disorders and sleep deprivation interfere with everyday functions such as driving, working, and other social activities. Lifestyles have changed significantly over the last few decades, contributing to the increase in sleep problems. We work longer hours, and are constantly connected to the outside world through the Internet, cell phones, and digital assistants. Stress combined with 24/7 accessibility creates difficulty for our internal clocks to regulate sleep cycles resulting in sleep deprivation or disorders. Doctors have identified more than 70 sleep disorders, with the most common including insomnia, sleep apnea, restless leg syndrome, and narcolepsy.¹

Insomnia

At some point in time, almost everyone has suffered from insomnia. Insomnia includes having trouble falling asleep, trouble getting back to sleep, and waking up too early.² Stress, diet, jet lag, shift work, or other factors can contribute to this problem. Job performance and well-being are almost always affected the

Objectives

At the conclusion of this educational activity, the physician should be able to:

1. describe the most common sleep disorders that affect patients;
2. identify symptoms and treatment options for the four most prevalent sleep disorders; and
3. explain the health and safety issues associated with sleep disorders.

next day. Each year, approximately 60 million Americans experience insomnia frequently or for extended periods of time.¹ Insomnia is more common in people over the age of 60, women, and people with a history of depression.²

Short-term insomnia lasts only a few days and is usually treated with sleep medications. Most medications stop working after several weeks of nightly use, and if used long-term can actually interfere with good sleep. Mild insomnia can often be prevented and cured by following these good sleep habits:

- Keep a regular sleep-wake cycle. Try to go to bed and wake up at the same time every day.
- Avoid caffeine, alcohol, and nicotine in the four to six hours before bedtime.
- Don't exercise within two hours of bedtime. Exercising five or six hours before bedtime may help you sleep more soundly.
- Don't eat large meals within two hours of bedtime.
- Don't nap later than 3 p.m.
- Sleep in a dark, quiet room with a comfortable temperature.
- If you can't fall asleep within 20 minutes, do a quiet activity somewhere else and return to bed when sleepy.
- Wind down in the 30 minutes before bed with a relaxing pre-sleep ritual such as a warm bath, soft music, or reading.³

Insomnia is considered chronic when it lasts for more than a few weeks. Traditionally, long-term insomnia has been viewed as a symptom of an underlying medical or psychiatric illness. Thyroid disorders, anxiety, depression, arthritis, and asthma can cause insomnia. About 85% of people with insomnia can be helped with a combination of medicine and behavioral therapy.²

Sleep apnea

Apnea literally means "without breath" in Greek.⁴ Sleep apnea is a disorder of interrupted breathing during sleep and usually occurs with fat buildup or a loss of muscle tone with aging. These changes cause the windpipe to collapse during breathing when muscles relax during sleep.¹ The most common form of sleep apnea is obstructive sleep apnea, which is usually associated with loud snoring, although not everyone who snores has this disorder. During an episode of obstructive apnea, efforts to inhale air create a suction that collapses the windpipe, and blocks airflow for 10 seconds to a minute while the person sleeping tries to breathe. When the oxygen level falls, the brain awakens the person enough to tighten the upper airway muscles and open the windpipe. The person may

snort, gasp, or resume snoring and repeat this cycle hundreds of times per night. The frequent awakenings prevent the deepest stages of sleep from being reached, which causes a person to be sleepy during the day.

The health complications associated with sleep apnea can lead to headaches, decline in mental functioning, high blood pressure, irregular heartbeats, and an increased risk for heart attack and stroke. Patients with severe, untreated sleep apnea are two to three times more likely to be involved in automobile accidents than the general public. High-risk individuals with sleep apnea can suffer respiratory arrest or sudden death during sleep.¹

An estimated 18 million Americans suffer from sleep apnea. However, the majority have gone undiagnosed. Typical features of sleep apnea include loud snoring, obesity, and excessive daytime sleepiness. For diagnosis, polysomnography may be performed at a sleep center to record brain waves, heartbeat, and breathing patterns throughout the night. Mild sleep apnea can be treated with weight loss or by preventing the person from sleeping on their back. More severe cases need special devices such as the continuous positive airway pressure (CPAP) mask, which pushes air through the airway at a sufficient pressure to keep the airway open while sleeping.² Surgery is also an option to treat sleep apnea and snoring, including removal of the tonsils or adenoids. Uvulopalatoplasty is performed to enlarge the airway by reshaping the palate and the uvula, making them less likely to vibrate which improves snoring. Uvulopalatopharyngoplasty is used to remove the excess tissue in the back of the throat, which assists in relieving sleep apnea.

Restless legs syndrome

Restless legs syndrome (RLS) affects as many as 12 million Americans and leads to constant movement during the day and insomnia at night. This disorder is hereditary and causes unpleasant crawling, prickling, or tingling sensations in the legs and feet and an urge to constantly move them for relief. Severe cases of RLS occur most commonly in the elderly, but symptoms can occur at any age. Health conditions such as anemia, pregnancy, or diabetes can also cause symptoms.¹

More than 80 percent of people with RLS also experience periodic limb movement disorder (PLMD), which causes repetitive jerking movements of the limbs, especially the legs. These movements occur every 20 to 40 seconds and cause repeated awakening resulting in poor sleep. Unlike RLS, the movements caused by PLMD are involuntary. Although most patients with RLS develop

PLMD, most people with PLMD do not experience RLS.⁵

Diagnosing RLS is difficult and health care providers must rely largely on the patient's description of the symptoms and information from their medical history, including past medical problems, family history, and current medications.⁵ Blood tests, electromyography, nerve conduction studies, and Doppler sonography may be used to document disease and damage to any nerves and nerve roots. Negative results from these tests may indicate the diagnosis is RLS.

Moderate RLS symptoms can be treated by making lifestyle changes including eliminating caffeine and alcohol; adding supplements such as folate, iron, and magnesium; maintaining regular sleep cycles and patterns; exercising; massaging; or using hot and cold therapy. More severe symptoms can be treated with dopaminergics, benzodiazepines, opioids, and anticonvulsants. Unfortunately, no one drug is effective for RLS sufferers. What may help one person may worsen symptoms for another. Additionally, these medications lose their effectiveness when taken regularly, requiring medications to be changed periodically.⁵ RLS is typically a lifelong condition for which there is no cure. However, current therapies, minimizing triggers that cause symptoms, and increasing restful sleep can help control the disorder.

Narcolepsy

Narcolepsy affects about one in every 2,000 Americans for a total of more than 135,000 individuals. After sleep apnea and restless legs syndrome, narcolepsy is the third most prevalent sleep disorder in patients seeking treatment at sleep clinics.⁶ Narcolepsy is caused by the brain's inability to regulate sleep-wake cycles. People who suffer from this disorder experience sudden urges to sleep at various times of the day, even if they had a normal amount of sleep the night before. These urges to sleep can last from a few seconds to several minutes and can severely affect their lives. People may fall asleep at work or school, eating a meal, while having a conversation, or most dangerously, while driving an automobile or operating machinery.⁶

In addition to daytime sleepiness, there are three other major symptoms associated with narcolepsy: 1) cataplexy, or sudden loss of voluntary muscle tone; 2) vivid hallucinations; and 3) brief episodes of total paralysis inhibiting speech or movement. These symptoms seem to be features of rapid eye movement (REM) sleep that appear during waking which may suggest that narcolepsy is a

disorder of sleep regulation.⁶ The symptoms of narcolepsy typically appear during adolescence and often take years to correctly diagnose. This disorder can be hereditary, but occasionally is associated with head injuries, neurological diseases, stress, and hormonal changes such as those occurring during puberty or menopause.

Treatment for narcolepsy includes stimulants, antidepressants, and other drugs to help control the symptoms and the embarrassing and dangerous effects of falling asleep at inappropriate times. Napping throughout the day can also assist with reducing excessive daytime sleepiness.¹

How much sleep do we need?

Sleep needs vary among individuals and many factors are associated including age. Infants generally require 16 hours per day and teenagers need approximately 9 hours per day. Most healthy adults need 7 to 9 hours of sleep each night, although some adults require as little as 5 hours or as many as 10 hours. As people age, they tend to sleep more lightly and for shorter periods of time, although they still need the same amount of sleep as they did in early adulthood. About half of all people over the age of 65 have frequent sleeping problems such as insomnia, and deep sleep stages tend to become very short or stop completely. This may be a normal part of aging or it may be the result of medical problems, medication use, or other treatment modalities.¹

During sleep, we usually pass through five phases of sleep: stages 1, 2, 3, 4 and REM sleep.¹ Adults spend almost 50 percent of their total sleep in stage 2; 20 percent in REM sleep; and the remaining 30 percent in the other stages. Infants start out spending about half their sleep time in REM sleep.

The stages of sleep

Stage 1

Described as light sleep, drifting in and out, and one can be awakened easily. The eyes move slowly and muscle activity slows. If awakened, one can often remember fragmented visual images.

Stage 2

Eye movements stop and brain waves become slower with occasional bursts of rapid waves called sleep spindles.

Stage 3

Described as deep sleep when extremely slow brain waves called delta waves appear, interspersed with smaller, faster waves.

Stage 4

Deep sleep in which the brain produces delta waves almost exclusively. There is no eye movement or muscle activity.

Stage 5

REM sleep. Breathing becomes more rapid, irregular, and shallow. Eyes jerk rapidly, limb muscles become temporarily paralyzed, heart rate increases, and blood pressure rises. Dreams almost always occur during this stage, but can occur in other stages of sleep as well.¹

Experts agree that those who have trouble staying alert or feel drowsy during the day, including during boring or monotonous situations, probably are not getting enough sleep. If you routinely fall asleep within 5 minutes of lying down, then sleep deprivation or possibly even a sleep disorder can be to blame. Other signs that you are not getting enough sleep include irritability, difficulty concentrating or remembering facts, and problems with relationships among co-workers, family, or friends.³

Health and safety consequences associated with sleep disorders

The cumulative effects of sleep deprivation and sleep disorders have been associated with a wide range of health consequences such as hypertension, diabetes, obesity, mental illness, respiratory problems, heart attack, and stroke. For example, problems such as stroke and asthma tend to occur during the night and early morning, possibly due to changes in hormones, heart rate, and other characteristics associated with sleep. Sleeping problems are associated with many other health disorders such as Alzheimer's disease, cancer, and head injuries. Once sleeping problems occur, they can add to a person's impairment and cause confusion, frustration, or depression.¹

In addition to health problems, sleep deprivation is associated with public safety issues. Almost 20 percent of all serious motor vehicle accidents in the U.S. are associated with fatigued drivers.⁷ According to the National Highway Traffic Safety Administration, driver fatigue is responsible for an estimated 100,000 motor vehicle accidents and 1,500 deaths per year.¹ Drivers age 25 or younger tend to be the most affected by this problem. Tests with a driving simulator have shown that sleep deprived people may perform just as badly as intoxicated individuals.² The National Sleep Foundation indicates that if you have trouble keeping your eyes

focused, you cannot stop yawning, or if you cannot recall driving the last few miles, then you are probably too tired to drive safely.

Pilots and truck drivers have been accustomed to working long hours, and federal regulations were passed years ago to limit their work hours for safety reasons. Pilots must limit their flight time to eight hours within a 24-hour period, whereas truck drivers cannot drive more than 10 hours without a mandatory break. Physician advocacy groups are currently pursuing the passage of the Patient and Physician Safety Protection Act. This would set limits nationwide on the number of hours worked by medical residents. The American Medical Student Association estimates that residents sometimes work 100 to 120 hours per week in 24-36 hour shifts. Research indicates the excessive hours worked by physicians lead to higher rates of medical errors, falling asleep while driving home, and health problems such as depression. This bill was introduced in 2005 and is still in committee at both the House and Senate. If passed, residents would be limited to 80 hours per week with at least 10 hours off between shifts, among other provisions.²

Children and sleep

The words sleep and children are not typically synonymous. From middle of the night feedings when they are infants, to awakenings to soothe them after a nightmare when they are toddlers or school age, most households with children suffer sleep problems. According to a poll from the National Sleep Foundation, people without kids in the house rated their sleep as "excellent" or "very good," compared to those with children. Sleep interruptions come with the territory for parents, but experts say the best thing people can do for themselves and their children is to develop a regular bedtime sleep routine so children become accustomed to falling asleep on their own. Experts advise that school-age children generally need 9 to 12 hours of sleep each night.²

Childhood sleep problems are numerous and include talking during sleep and bedwetting. Many children outgrow these problems, but if it is suspected a child has a sleep problem, the National Sleep Foundation has developed a simple set of sleep questions called BEARS. Each letter stands for a different potential sleep problem area.

- Bedtime: Does the child have problems going to bed or falling asleep?
- Excessive daytime sleepiness: Is the child difficult to wake up in the morning? Does the child seem sleepy or groggy dur-

ing the day? Does he or she seem overtired (moody, hyperactive, as well as sleepy)?

- Awakenings during the night: Does the child awaken frequently during the night or have trouble falling back to sleep?
- Regularity and duration of sleep: What time does the child go to bed and get up on weekdays? Weekends? How much sleep does he or she get? Need?
- Snoring: Does the child snore loudly? Does he ever stop breathing, choke or gasp during sleep?⁸

Recognizing the signs of sleep disorders in children is difficult because unlike adults, children get through the daytime sleepiness and keep going. A child with a sleep disorder may not be noticeably tired, but may perform poorly in school.²

Case study

In the following closed claim study, allegations include failure to assess a pediatric patient for sleep apnea.

Presentation

A seven-year-old girl was referred to an otorhinolaryngologist by her pediatrician. The patient had a history of Strep throat and she complained of trouble breathing in the mornings.

Physician action

A physical exam revealed a red throat, enlarged tonsils, and significant material within the crypts. The physician prescribed antibiotics.

Three weeks later, the patient returned. The antibiotics had alleviated some symptoms, but the patient still had enlarged tonsils and symptoms of sleep apnea. The otorhinolaryngologist recommended tonsillectomy and adenoidectomy.

One month after this office visit, the patient was admitted to a regional medical center for tonsillectomy and adenoidectomy. The surgery began at 7:45 a.m. and was completed without complication. The patient was extubated in good condition and transferred to the recovery room.

At 9:10 a.m., the patient was received in the PACU, and she was discharged to the pediatric unit at 10:09 a.m. Her respirations were unlabored on room air for the last 20 minutes in recovery without signs of distress. Oxygen saturation was 97%. An EKG indicated a normal sinus rhythm. Vital signs at discharge were: blood pressure 159/98 mm/Hg; pulse 132 bpm; respirations 12 breaths/minute. The floor nurses' notes indi-

cated that the patient was asleep and exhibiting no signs of distress. Her color was good.

Vital signs taken at 11:15 a.m. were: blood pressure 112/67 mm/Hg; pulse 135 bpm; respirations 18 breaths/minute; and temperature 98.1 degrees. According to the nursing notes, the patient appeared to be asleep displaying no signs of distress. There were no concerns or complaints voiced at this time.

At 11:55 a.m., the patient's mother came out of the room crying for someone to check on her daughter. The nurses found the patient to be unresponsive and lying on her side. She was cyanotic with no pulse or respirations. A code was called. Before the code team arrived, a nurse gave a quick breath and the patient returned coffee ground emesis. Despite oral suctioning and defibrillation, the patient remained in asystole. She was pronounced dead at 1:26 p.m.

The otorhinolaryngologist's death summary for the patient indicated that at 11:55 a.m., the patient's mother reported that the patient was resting comfortably and then seemed to stop snoring suddenly. An autopsy conducted the next day revealed a dilated right ventricle with normal wall thickness. Pathological findings included myocarditis, chronic pericarditis and pulmonary edema.

Allegations

Lawsuits were filed against the otorhinolaryngologist, his practice association, the anesthesiologist, the CRNA, and the hospital. The allegations included:

- failure to assess the patient for sleep apnea (otorhinolaryngologist);
- failure to take precautions to include ordering closer monitoring with pulse oximetry (otorhinolaryngologist);
- failure to conduct a complete physical exam and assessment of the patient during preoperative visits (practice association);
- failure to obtain respiratory rate, temperature, and history during preoperative visits (practice association);
- administration of too high a dose of morphine (CRNA, anesthesiologist);
- failure to monitor the patient postoperatively (hospital); and
- failure to communicate abnormal vital signs to the physicians (hospital).

Legal implications

The plaintiff's experts concluded that this patient had clinically significant upper airway obstruction. Further, since obstructive sleep apnea had not been ruled out by polysomnography, the perioperative management of the patient should have reflected the possibility that it existed. It was asserted that the

otorhinolaryngologist should have communicated these issues to the care team and ordered closer monitoring of the patient. The plaintiffs also argued that the dose of sedating medications would have been smaller or the anesthesiology team would have changed medications if they had known about the sleep apnea.

A significant weakness in this case was the otorhinolaryngologist's failure to order postoperative pulse oximetry on the patient. A number of defense consultants said that a patient who has severe sleep apnea should be placed on pulse oximetry postoperatively. The defendant stated in his deposition that the patient did not have a confirmed case of sleep apnea. However, in his operative note he stated that the patient had severe sleep apnea and this was one of the reasons for performing the surgery.

Another issue that adversely affected the defense of this case involved the poor care provided by the hospital nurses. The plaintiffs argued that the otorhinolaryngologist should have ordered closer monitoring. However, after the nurses were deposed, it was evident that they did not know the difference between normal and abnormal vital signs, did not know when to report abnormal vital signs, and failed to do hands-on physical assessments on this post-surgery patient. However, the plaintiffs still contended that if pulse oximetry had been ordered, the patient would not have died.

Disposition

Given the facts of this case, the defense felt the chance of a successful jury verdict was 50%. With the consent of the otorhinolaryngologist, this case was settled before trial. The outcome of the lawsuits against the anesthesiologist, the CRNA, and the hospital is unknown.

Risk management considerations

The otorhinolaryngologist indicated in his operative note that the patient had severe sleep apnea. While it is speculative as to whether a postoperative order for pulse oximetry would have altered the outcome, it would have placed the defendant in a better defensive posture. The defendant testified that sleep apnea had not been confirmed, but the credibility of this statement was reduced in view of his operative note.

Additionally, the otorhinolaryngologist could have ordered closer postoperative monitoring, given the sleep apnea issue. However, that may not have altered the outcome, as there was significant evidence of poor nursing care. However, it would have

greatly assisted the physician in his own defense.

Solutions to the sleep deprivation epidemic

Recognizing the health consequences of sleep disorders and deprivation, the American Academy of Sleep Medicine, the National Center on Sleep Disorders Research at the National Institutes of Health, the National Sleep Foundation, and the Sleep Research Society requested that the Institute of Medicine:

- review the public health significance of sleep, sleep loss, and sleep disorders;
- examine gaps in research, education, and training in the public health system and academia; and
- provide a comprehensive plan for enhancing sleep medicine and research.⁷

The report titled, *Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem* concluded that although scientific opportunities and clinical activities in the field are expanding, the human resources and infrastructure to improve patient care and expand scientific research are insufficient. The report also concluded that increased awareness among the general public and health care professionals is imperative, along with a coordinated strategy to ensure continued advancement.

The strategies to advance sleep medicine and research include:

- Increase awareness among the general public by developing a multimedia, comprehensive education campaign on the health and economic impact of sleep loss and sleep disorders.
- Expand awareness among health care professionals through education and training.
- Establish the workforce required to meet the clinical and scientific demands of the field.
- Develop and validate new and existing diagnostic and therapeutic technologies.
- Expand accreditation criteria to emphasize treatment, long-term patient care, and chronic disease management strategies.
- Increase the investment in interdisciplinary sleep programs in academic health centers that emphasize long-term clinical care, training and research.
- Create a national research network that connects individual investigators, research programs, and research centers.⁷

The Institute of Medicine report acknowledges the problem of large numbers of people who have undiagnosed sleep disorders that negatively affect their health and performance. The lack of public awareness of sleep disorders and sleep deprivation, along

with the lack of recognition by primary care health professionals, serve as major obstacles for people getting the care they need.⁹ Perhaps a comprehensive patient health history could include questions regarding hours, pattern, and quality of sleep. This information is relevant, but busy patients and their physicians may not routinely discuss sleep.

Sleep specialists are trained to diagnose sleep disorders and provide treatment. The number of sleep specialists increases by more than 350 per year, and the number of accredited sleep centers by more than 200 per year.⁹

Adequate sleep is believed to be just as essential to health and performance as exercise and nutrition. Understanding the factors that affect sleep may lead to revolutionary new therapies for sleep disorders.¹ Continued research will assist in helping the public and health care professionals become more aware of sleep disorders and ultimately improve lives.

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CME test questions

Instructions: Using black ink, read each question, select the answer, and then clearly mark your selection. Please fax the completed test and evaluation forms to the Risk Management Department, attention Rebecca Henson 512-425-5996. You can also mail the test and evaluation forms to the TMLT Risk Management Department, attention Rebecca Henson, P.O. Box 160140, Austin, Texas 78716-0140. A certificate of completion will be mailed to the address you provide on the CME evaluation form.

1. According to the National Highway Traffic Safety Administration, driver fatigue is responsible for an estimated 1,500 deaths per year.

- True
 False

2. What is the third most prevalent sleep disorder in patients seeking treatment at sleep clinics?

- Sleep Apnea
 Narcolepsy
 Restless Legs Syndrome
 Insomnia

3. The number of accredited sleep centers increases by 350 per year.

- True
 False

4. Insomnia is more prevalent in people over the age of:

- 40 50 60 70

5. Which of the following is not a typical feature of sleep apnea?

- Loud snoring
 Cataplexy
 Excessive daytime sleepiness
 Obesity

6. Adults spend 50 percent of their total sleep in stage 2.

- True
 False

Statement of completion

I attest to having spent _____ hours in this CME activity.

Physician signature _____ Date _____

CME evaluation form

Please complete the following regarding the article, "A Sleepy Nation: diagnosing and treating sleep disorders."
Please fax the completed evaluation with the CME test questions.

1. The objectives for this CME were met. Yes No

2. The material will be useful in my practice. Yes No

3. Did you perceive any evidence of bias for or against any commercial products? If yes, please explain.
 Yes No

4. How long did it take you to complete this learning activity?
 .5 hr .75 hr 1 hr 1.25 hrs 1.5 hrs

5. On a scale of 1 to 5, with 5 being the highest, how do you rank the effectiveness of this activity as it pertains to your practice?
 1 2 3 4 5

6. What will you do differently in your medical practice after reading this article?

7. Suggestions for course improvement are:

8. Suggestions for future topics include:

Contact information

Name _____

Address _____

Phone _____

TMLT policyholder? Yes No

closed claim studies

Failure to diagnose and notify ED physician

by Barbara Rose and Anna Tausin

The following closed claim studies are based on actual malpractice claims from Texas Medical Liability Trust. These cases illustrate how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physicians' defensibility. The ultimate goal in presenting these cases is to help physicians practice safe medicine. An attempt has been made to make the material more difficult to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.

Presentation

A 38-year-old woman came to the emergency department (ED) with complaints of headaches, nausea, and vomiting. She also described vision problems such as flashing lights. She indicated that she had vomited several times over the past seven hours, but she did not have diarrhea. She reported regular use of oral contraceptives.

Physician action

An ED physician first saw the patient one hour after she arrived. The patient described her pain as the worst headache of her life. The physician ordered Phenergan and Toradol intravenously. He also ordered a head CT.

Radiologist 1 interpreted the scan in a hand written report that states "high density appears to correspond to internal cerebral veins, torcula, and dural sinuses. Suspect merely dense appearance of blood within vessels. Subdural blood difficult to completely exclude. Follow up recommended in one to two days. Otherwise negative."

A lumbar puncture ordered by the ED physician was negative. The patient was released with instructions to follow up with her primary care physician or return to the ED if her symptoms did not improve.

The next morning, Radiologist 2 reviewed the patient's CT results and dictated the final report as follows. "Examination demonstrated a hyperdense appearance of the internal

cerebral veins, vein of Galen as well as dural sinuses bilaterally. Suspect acute venous thrombosis." He felt that this was the same diagnosis that Radiologist 1 made, simply worded differently. Thinking that his diagnosis was redundant, Radiologist 2 did nothing further with the report except to put a copy in the patient's chart.

Two days after her initial visit, the patient returned to the ED complaining of disorientation, nausea, and incapacitating frontal headaches. An MRI was ordered and the results confirmed that the patient had a venous thrombosis.

The patient was transferred to another hospital and a tissue plasminogen activator was administered. She developed a seizure and experienced respiratory difficulty. The patient was intubated and ventilated. After remaining in the hospital for several weeks, the patient was transferred to another hospital for rehabilitation and recovery.

As a result of the venous thrombosis, the patient requires the assistance of a walker and wears ankle braces daily.

Allegations

In her lawsuit against Radiologist 1, the patient alleged that he failed to appropriately and accurately diagnose venous thrombosis, and did not properly inform the ED physician of the diagnosis. Radiologist 2 was also named in the suit for failing to contact the patient about the proper diagnosis of venous thrombosis.

Legal implications

Consulting physicians agreed that Radiologist 1 correctly read the CT scan, but failed to document and report that his findings could be due to venous thrombosis. They also agreed that Radiologist 2 made the correct diagnosis but failed to inform anyone or document the discrepancy between the two reports. Consultants also noted that Radiologist 2 failed to notify any of the treating physicians or the patient when he diagnosed intracerebral venous thrombosis.

Disposition

This case was settled with the consent of the radiologists. The inability of the defense to find supportive expert testimony led to the decision to settle this case.

Risk management considerations

One reviewer acknowledged the impossibility of determining if a 2-day delay of the diagnosis would have altered the outcome, but further opined it is possible there could have been a better outcome with fewer complications had treatment been initiated earlier. Radiologists are expected to notify a patient's attending physician(s) when discrepancies are noted between the initial and final interpretations.

Physicians are expected to follow a reasonable course of action based on patient needs to deliver effective and safe medical care.¹ According to guidelines released by the American College of Radiology (ACR), "documentation of communication of any discrepancy should be incorporated into the final report."¹

A policy on communication for radiologists and imaging departments "can be an effective tool to promote patient care . . . To be effective, however, any written policy must be followed and shared with others within the institution where the diagnostic imagers provide their services."¹

Reference

1. American College of Radiologists. ACR Practice Guideline for Communication of Diagnostic Imaging Findings. Effective October 1, 2005.

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Improper performance of laser skin treatment

by Barbara Rose and Anna Tauzin

Presentation

A 53-year-old woman came to her family physician complaining of what she thought were age spots on her upper chest. These spots were later discovered to be dilated blood vessels.

Physician action

The patient, who was a dentist, asked about laser treatment for the spots. At that time, the family physician was considering purchasing a KTP laser, which is used to treat vascular and pigmented lesions and for skin rejuvenation and hair removal. The laser was eventually purchased, and the physician received nominal training on the machine. Each time a representative from the manufacturer visited the office to provide training, the scanner was not working.

A few months after her office visit, the patient came for a laser treatment. A representative from the laser manufacturer was present, but the scanner was not working. The physician used the Dermastat handpiece for the first time to apply the laser.

The settings used for the patient's treatment were from a list of suggested settings provided by the manufacturer. This list did not include settings for the neck or chest area. The representative and the physician approximated the settings to be used in that area. The physician, assuming that the face was the most sensitive area, used settings suggested for the face to configure settings for the neck and chest. (The physician now knows that the chest and neck area are more sensitive than the face.)

During treatment, the patient complained of pain and the physician immediately lowered the settings and continued. The procedure lasted less than an hour. At the end of the treatment, the patient's treated areas were raised and red, as expected. Aloe ointment was applied, and the patient left 20 minutes later.

The family physician did not hear from the patient until six weeks later. The patient stated that she developed blisters on her neck and chest the night of the procedure, but she did not seek treatment. She also reported that one week after the procedure the treated areas developed a Staph infection. The patient self-prescribed Keflex for the infection, and used Medermantemorate lotion on the area. She complained that the blisters had turned into painful scars.

The family physician and the patient discussed using steroid injections to reduce the scarring, and a referral was made to a

plastic surgeon. The family physician last saw the patient three months after the initial treatment. The scar on her chest appeared flatter but with increased vascularity.

The patient continued to seek treatment to relieve the pain and tightness of the scars and improve their appearance. She underwent additional laser treatments with a V-beam pulse dye laser. She also had steroid and botox injections, massage therapy, and physical therapy. Additionally, the patient needed treatment for GERD and a mild MI, all of which she attributed to the burns. The patient also received treatment from a pain management specialist due to an alleged eleventh cranial nerve injury, which she also attributed to the initial laser burn.

Allegations

A lawsuit was filed against the family physician, alleging negligence because he was not properly qualified to operate the laser; did not obtain adequate informed consent; and used an improper laser setting that caused severe burns and injury to the patient's eleventh cranial nerve. The manufacturer of the laser device was also named in the suit.

Legal implications

It was determined that the defendant was not properly trained to use the laser, and the setting on the laser during the procedure was too high, causing the burns. However, early efforts to settle the case were unsuccessful because of the patient's claims that the laser burned deep enough in her neck to cause a permanent eleventh cranial nerve injury. The injury allegedly made it impossible for the patient to work as a dentist and caused a substantial loss of future earnings.

The defense was unable to locate expert support for the family physician on liability issues. However, there was no difficulty in obtaining an expert to refute the cranial nerve allegation and assist with the causation and damage aspects of the case. Likewise, the patient was able to locate experts to support her position on liability, causation, and damages. The manufacturer of the laser device took the position that the machine functioned properly but the defendant was negligent in using their product.

Disposition

This case was settled during mediation on behalf of the family physician. The defendant's lack of training and the obvious nature

of the patient's injuries led to the decision to settle the case. The manufacturer of the laser device did contribute to the settlement.

Risk management considerations

When physicians add services in their practices that were not a part of their residency and training, it is incumbent on them to be trained and to practice new procedures until their skill and competence is verified. If a medical device is a part of the new service, the physician is expected to verify the proper and safe operation of that device.

In this case, the patient may have been inconvenienced, but the physician would have been wise to delay offering any laser treatments until the device was fully functional and its safe operation demonstrated to his satisfaction. This physician was not a skin specialist as reflected in "guessing" about the laser settings. Most patients trust that a physician is highly trained and competent in his or her practice of medicine.

Informed and signed consent, though not required by law in this case, is always prudent practice as there are risks associated with any procedure. This patient would not have been less angry about her situation, but perhaps a signed consent indicating a risk of burns, scarring, etc., and evidence of her informed choice with a signature may have aided in this physician's defense.

Because it was the first time for a laser treatment by the defendant and subsequent to the plaintiff's complaints of pain during the procedure, it seems advisable to schedule a return appointment. Evidence of close follow up, conscientious care, and timely referral to a specialist may have altered the outcome.

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IHI initiates “5 Million Lives Campaign”

Following the success of their 100,000 Lives Campaign, the Institute for Healthcare Improvement (IHI) has begun a new patient safety initiative. The 5 Million Lives Campaign is asking participating hospitals to prevent 5 million incidents of medical harm over the next two years.

The 100,000 Lives Campaign enrolled 3,100 hospitals in an 18-month effort to prevent 100,000 unnecessary deaths by instituting six evidence-based interventions to prevent avoidable deaths. The 5 Million Lives Campaign is asking hospitals to carry out an additional six interventions:

- prevent pressure ulcers by reliably using science-based guidelines for prevention of this serious and common complication;
- reduce Methicillin-Resistant *Staphylococcus aureus* (MRSA) infection through basic changes in infection control processes throughout the hospital;
- prevent harm from high-alert medications starting with a focus on anticoagulants, sedatives, narcotics, and insulin;
- reduce surgical complications by reliably implementing the changes in care

recommended by the Surgical Care Improvement Project;

- deliver reliable, evidence-based care for congestive heart failure to reduce readmission; and
- get Boards on board by defining and spreading new and leveraged processes for hospitals Board of Directors, so that they can become far more effective in accelerating the improvement of care.

All 3,100 hospitals who signed on to the 100,000 Lives Campaign have been carried over to the 5 Million Lives Campaign. In Texas, 149 hospitals have enrolled. IHI hopes to enroll a total of 4,000 hospitals.

The IHI estimates there are 15 million “incidents of harm” each year. The incidents include preventable adverse events, medical errors, and injuries contributed to by medical care or the absence of indicated care.

As part of the campaign, the IHI offers support and resources for enrolled hospitals. Detailed information about the interventions, improvement methods, tools, and other resources are all available for free at www.ihi.org/IHI/Programs/Campaign/.

Clarification

In the November-December 2006 issue of *the Reporter*, statistics and information from the Texas Medical Board were presented in an inexact manner. The paragraph should have stated:

“According to the TMB web site, between 2000 and 2006 the number of disciplinary decisions nearly tripled. At one recent meeting, the Board disciplined a record 99 physicians for violations ranging from failure to meet the standard of care to maintaining inadequate medical records. This was the largest number of actions taken at any single time in the TMB’s history.”