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Kathy Ferrell: Medical-Legal Consulting Newsletter March 2006

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Greetings!

I hope you find my newsletters useful and informative. As always, I welcome your suggestions for future monthly newsletters, including topics you would like for me to address. Also, I would appreciate your forwarding my newsletter to other attorneys who may need assistance in medical malpractice, personal injury or product liability cases. I look forward to being of service to you.

WRONG SITE SURGERY – HOW CAN THAT HAPPEN?

How can a physician operate on the wrong hip or amputate the wrong limb? The trend for performing wrong site surgeries has risen every year that statistics have been calculated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The rise in these errors continues in spite of sentinel event alerts by JCAHO which were first issued in 1998, then again in 2001. A Wrong Site Surgery Summit was conducted in 2003. Yet, the trend continues to rise.

Wrong site surgery most often occurs during orthopedic surgery, followed by urologic procedures and neurological surgeries. Several risks factors have been identified that may contribute to these errors.

- More than one surgeon involved in the case, either because of multiple procedures were contemplated or because the care of the patient was transferred to another surgeon.
- Multiple procedures were conducted on the same patient during a single trip to the OR, especially when the procedures were on different sides of the patient.
- Unusual time pressures, related to an unusual start time or pressure to speed up the preoperative procedures.
- Unusual patient characteristics such as physical deformity or massive obesity that might alter the usual process for equipment set-up or positioning of the patient.

Root cause analysis was conducted on all 455 errors in wrong site surgery which were reported from 1995 – 2005. The following reasons are listed in the order of their occurrence:

- Communication (between surgeons, patient and surgeon, hospital personnel)
- Orientation/training (reversing the pre-op x-ray on the viewer, wrong equipment set-up, performing surgical scrub on wrong limb)
- Procedural compliance (not marking the correct limb with permanent marker)
- Patient assessment (not confirming surgical site with patient prior to induction of anesthesia)
- Availability of information (incomplete consent form, pre-op assessment form not complete, x-rays not available)
- Leadership (no formal policies and procedures in place)
- Competency/credentialing (surgeons not board certified and competent in hospital policies and procedures)
- Environment safety/security
- Organization culture (some members of the surgical team excluded from the verification process and feel they are not permitted to point out a possible error; some surgeons have attitude that they should never be questioned; coupled with the attitude by other team members that the surgeon should never be questioned)
- Staffing
- Continuum of care
- Care planning

Several strategies for reducing the risk of wrong site surgeries were recommended by JCAHO:

- Clearly mark the operative site and involve the patient in the marking process to enhance the reliability of the process
- Require an oral verification of the correct site in the operating room by each member of the surgical team.

<http://www.jointcommission.org/>

As part of the discovery process in any case involving wrong site surgery the attorney should request the following documents:

- Policies and procedures for verification of the correct surgical site on all surgical patients
- Staffing logs for the date of the error
- Complete medical records including operative consent form, pre-operative nursing and anesthesia assessment, pre-operative x-rays, nursing checklist used to ensure that all appropriate documents are included in the patient chart which goes with the patient to surgery
- Nursing care plan
- Credentials of the operating surgeon
- Dates of all orientation and training schedules as well as all educational seminars attended by each member of the surgical team

ADHD DRUGS AND CARDIOVASCULAR RISKS

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 An article will be released in the April 6, 2006 New England Journal of Medicine warning physicians of the cardiovascular risks produced by medication prescribed for ADHD.

On February 9, 2006 the Drug Safety Risk Management Advisory Committee of the Food and Drug Administration (FDA) voted by a narrow margin to recommend a "black box" warning describing the cardiovascular risks of stimulant drugs used to treat attention deficient-hyperactivity disorder (ADHD). The drugs under review were primarily amphetamines (Adderall and other brands) and methyl-phenidate (Ritalin, Concerta, and other brands). The compounds in the drugs exert potent stimulant efforts on the cardiovascular and central nervous systems.

The concern of the possible effects of these drugs is heightened not only because of the numbers of prescriptions that are written for these drugs, but also because illicit use of these drugs has become an increasing public health problem. Nearly 2.5 million children now take stimulants for ADHD, including nearly 10 percent of all 10-year old boys in the United States. Even more strikingly, 1.5 million adults now take such stimulants on a daily basis, with 10 percent older than 50 years of age.

The action of drugs used for ADHD is similar to that of ephedra and PPA (sympathomimetic amines); these drugs increase the heart rate and blood pressure. Documents presented to the FDA described cases of myocardial infarction, stroke, and sudden death in children and adults taking ADHD stimulants. Based on these findings, the FDA acted preemptively to recommend strong regulatory action concerning these drugs. <http://www.nejm.org>

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