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Covering Hospitals, Surgery Centers, and Offices for More than 30 Years

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IN THIS ISSUE

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Are you Twittering, getting friends on Facebook, and YouTube?

Social media embraced as marketing, educational, and recruitment tools

How would you like to get more than 9,000 people to view a procedure at your facility? Methodist University Hospital in Memphis recently accomplished this feat during the live webcast of a surgical procedure. The broadcast paid off with 20 requests for more information and three requests for appointments.

"We have found that most patients are quite willing to participate in events that will help educate others with their medical condition," says **Ruth Ann Hale**, APR, director of media and community relations at Methodist University.

Many surgery providers and others are responding to economic pressures and competition by using social media, according to a recent article in *The New York Times*.[1] Facilities use Twitter, YouTube, and patient blogs to market to and educate patients, recruit staff, and even obtain donations, the article says.

At Scripps Health, which manages four hospitals in San Diego, web technology director **Marc Needham** searches Twitter every workday for mentions of the health system, and he responds to many of them via "tweets." As a result of these Twitter saved searches, he has "seen

EXECUTIVE SUMMARY

Progressive outpatient surgery programs are using social media to market their programs, educate patients, and recruit patients and staff.

- Caveats include potentially negative comments posted online, as well as exposure to malicious software.
- Fully educate patients if their procedures will be broadcast. Broadcast the positive and negative aspects of the surgery.
- When a procedure is being broadcast, have a response plan in place in the event something goes wrong.

dozens of people talking about their surgical and clinical experiences with Scripps," he reports.

He says the "unofficial" social media policy is to attempt new things, be nice, and don't say anything that the health system's legal department would object to. "As such, I generally steer well clear of anything clinical in nature," Needham says. "The only times that I ever reach out to people through social media channels are when I feel like it would be an appropriate use of the Scripps brand and when it can improve that person's situation in some marked way. Those situations, thus far, have generally related to finding a new physician, billing questions, and the odd question about facilities."

In fact, more than 250 hospitals and an unknown number of surgery centers use Twitter, Facebook, YouTube, or blogs, according to **Ed Bennett**, web strategy director for the University of Maryland Medical System in Baltimore. *(Editor's note: See partial list at ebennett.org/hsnl/now.)*

Children's Mercy Hospitals and Clinic, Kansas City, MO, uses Facebook to announce upcoming events, place photos, and post published articles. Additionally, it uses YouTube to post television commercials. "The advantage is that it gets the Children's Mercy brand out there," says **Jessica Salazar**, manager of media relations. Children's Mercy also uses YouTube as an outlet for in-house physician interviews in which it provides a one- to two-minute monologue on a specific topic, Salazar says. Additionally, the YouTube site includes employee testimonials, she says.

Don't overlook these caveats

Despite the plusses, there are some negative aspects to online exposure, say social media experts interviewed by *Same-Day Surgery.* There's the potential for viruses and other malicious software (malware). Also, some health care managers report "shocking" tweets that fall into the TMI (too much information) category, such as "Sexy nurse just shaved my _____. Ready for surgery!"

Needham says, "A more pressing concern of mine than Twitter is what people post up on review sites such as Yelp.com." Former patients have posted some scathing and completely inappropriate items on those sites, he says, while other facilities report that incorrect information about their facilities have been put online. "People are posting incredibly graphic descriptions of their experiences in our facilities," Needham says. "They're that much more wont to share the negative experiences, and that presents a serious brand management issue for us — and every other health care [organization] in the country."

Also, the search indexes on those web sites are more efficient than Twitter's, Needham adds. Once information is posted online, it's there forever, sources point out. Needham's health system is considering adding a customer service position to focus on online channels, he says.

Same-Day Surgery reviewed Yelp comments regarding health care providers across the country

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and found these:

How can I let people who are so utterly incompetent be the people I entrust my health and life to? . . . They are the type of incompetents that would call you to schedule a visit to discuss your high cholesterol levels the day after you were buried.

Dried blood on stainless steel instrument tables in my room. Yes, dried blood. Human fluids on the floors of vacant rooms as well as on the waiting room furnishings. Seriously, OSHA, CDC, and HHS would have way too much fun with this place. Instruments handled by staff WITHOUT GLOVED HANDS. You can bet your sweet little _____ that I had them resterilize and glove up before probing me with ANYTHING.

In a perfect world, providers would have the resources to reach out to each potentially wronged patient to make sure action is taken to correct the negative parts of their experience and to ensure they never happen again, Needham says. "As an organization, we provide incredible high-quality care for almost universally grateful patients," he says. "The vocal minority of dissatisfied customers leave a very visible smear across search results that a potential new patient might be running across." **[For more information on social media, see "Surgeons 'Twitter' Surgery on Social-Networking Site,"** ***Same-Day Surgery Weekly Alert*****, Feb. 27, 2009. For a free subscription to the weekly alert, contact customer service at (800) 688-2421 or customerservice@ahcmedia.com.]**

Reference

1. Belluck P. Webcast your brain surgery? Hospitals see marketing tool. *The New York Times;* May 24, 2009. Accessed at www.nytimes.com/2009/05/25/health/25hospital.html?_r=1&ref=global-home. ■

Examples of using social media

- At **Children's Mercy Hospitals and Clinic**, Kansas City, MO, one physician performed surgery on a child from Mongolia while another physician updated the facility's Twitter site for viewers, which included family and friends abroad and the child's mother in the waiting room. "She said before the doctor came out to say everything was OK, she knew five minutes ago everything was OK," says **Jessica Salazar**, manager of media relations. **(Not everyone embraces the idea of twittering from the OR. See story, p. 108.)**
- At **Children's Mercy Hospital and Clinic** in Kansas City, MO, had a seventh-grade patient undergoing a laparoscopic procedure. Her mother twittered about the surgery pre-operative experience, the wait during surgery, and the postoperative time.
- **Henry Ford Hospital** in Detroit uses Twitter from the operating room. In one procedure, three surgeons participated. Two were scrubbed in at a time, while a third Twittered.
- **Genesis Health** in Davenport, IA, has bariatric surgical patients, as well as pregnant patients, blog about their experiences at www1.genesishealth.com/weblogs. ■

Consider these 5 tips for social media

To ensure that your presence on social media is as effective as possible, consider these suggestions:

• Make sure patients whose procedures will be broadcast are fully educated.

Methodist University Hospital in Memphis has Webcast and Twittered during surgery.

Ruth Ann Hale, APR, director of media and community relations, says, "Every patient that participates in a public webcast is carefully chosen and have full awareness of the scope of the event that they are participating in. Our organization, from our board of directors to our physicians, is vehement protectors of patient privacy, and this type of event would not take place unless we had taken every possible step to ensure that the patients were fully engaged and positively on board." **(For more information on taping of surgical procedures, see "Should you allow live broadcasts of cases? Some answer definitive 'no,'"** ***Same-Day Surgery*****, June 2008, p. 61.)**

• Show the positive and negative aspects of surgery.

E. Haavi Morreim, an ethicist at the University of Tennessee College of Medicine, was quoted in

a recent article in *The New York Times* as saying that showing the positive aspects of surgery, while ignoring the negative, can result in patients who are "misinformed or with excessively optimistic expectations."[1]

• If Twittering or broadcasting, have a plan in place in the event something goes wrong during surgery.

In addition to obtaining the appropriate patient consents, have a backup plan, say experts interviewed by *Same-Day Surgery.*

Children's Mercy Hospitals and Clinic, Kansas City, MO, "had a plan in place if something went wrong in OR" that involved a stop to the tweeting, says **Jessica Salazar**, manager of media relations.

Methodist University Hospital in Memphis has recorded an identical surgery to the one being webcast so the camera can cut away from the procedure, if needed.[1]

• Encourage satisfied staff and patients to post positive comments online.

On one web site with negative comments against a hospital, including verbal attacks on the homeless patients, a doctor identified himself and explained the facility's mission to care for the less fortunate. He explained the high caliber of the staff and added that they have "way more heart than anywhere else in the city." He added: "If you want outstanding medical care, you won't find it better anywhere else." He added the he and several members of his family had undergone surgeries at the facility.

Such comments can go a long way toward addressing negativity, sources say.

• If you don't have the time to explore use of social media, hire someone.

Genesis Health System in Davenport, IA, hired a web site vendor, Geonetric (www.geonetric.com) to set up Facebook, Twitter, and YouTube accounts, says **Marcie Fleischman**, coordinator of electronic communications at Genesis Health. The health system also set up a patient blog web site.

"There were not any specific costs for us to set up our blog as it was a 'module' in the content management software from our web site vendor," Fleischman says. "Our other social media outlets are all free."

Reference

1. Belluck P. Webcast your brain surgery? Hospitals see marketing tool. *The New York Times;* May 24, 2009. Accessed at www.nytimes.com/2009/05/25/health/25hospital.html?_r=1&ref=global-home. ■

OR tweets aren't sweet, some commenters say

Public debates pros, cons of Twittering

While some managers tout the benefits of having someone on the staff Twitter during surgical procedures, the public has mixed ideas. Consider these comments posted with a recent article in *The New York Times* about OR Twittering:[1]

• *Twittering from the OR brings to mind the California railroad engineer who was texting just before his train crashed. Sorry, guys, this is just plain dumb!* — JM

• *This is, if you'll excuse me, a no-brainer. If I ever need surgery, brain or otherwise, I will definitely ask if anyone will be Twittering my operation. If they say yes then I'll find another doctor/hospital. I know it's a quaint notion but I feel that everyone in the room should be concentrating on keeping me alive and healthy, not Twittering: "I just opened up the skull!"* — hank

• *Some things are mundane, others are not. . . . The nonmundane was when I had to have a needle breast biopsy. The hospital had video of exactly what would happen. I watched beforehand and felt calmer going in. It turned that the doctor performing the biopsy was the same one as on the video.* — issy

• *Every day I drive past . . . the main medical center where I live . . . For the last year, there have been large signs covering the skywalk between the hospital and clinic encouraging people to log on to the website to watch a live 'lap band procedure' or knee surgery or cyberknife procedure. While I find it fascinating, and I wouldn't mind reading about it, believe me, I don't need the ENTIRE tour.* — Jonathan

• *I read the sample Twitter feed posted by the article. My reaction was immediate and visceral. There were words but there was no humanity. It took something, brain surgery, that is both complex and wondrous and made it seem like preparing an omelet. It was dry and soul-deadening. It convinced me that Twitter is worse than useless. By removing all feelings it coarsens our existence.* — hugh

• Perhaps one commenter, concerned about his privacy, said it best in a calypso song he composed about gastroenterology:

When I get my gastro gift this year
My tube's insides will be unfurled—!
And HIPAA assures that
MY tube won't be posted
–On YouTube 'round the world!

Reference

1. Nytimes.com. Accessed at roomfordebate.blogs.nytimes.com/2009/05/24/one-tweet-over-the-line/?apage=3#comments. ■

Same-Day Surgery Manager

At the end of the day . . . what really matters

By **Stephen W. Earnhart**, MS
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Everything seems to be about health care these days. Everyone has an agenda on what is best, for whom, and how much it will cost whom.

I am in a unique position this month to share *my* views with you from several aspects. But before I do, I want to remind all who read this, that at the end of the day, we provide care and comfort to those who need it the most: our patients. They are the only reason why we are here. More on that later.

As a consultant, I have the opportunity to provide hospitals, surgery centers, recovery centers, and other health care facilities to other countries that currently have "socialized medicine." The systems we set up are for those of means who can afford the luxury of seeing a quality physician of their choosing and have their surgery done or ailments treated quickly and professionally. The centers we establish are all "cash up front," and the word "insurance" is never spoken. There is no need for insurance when you pay out of pocket. Interestingly enough, we are setting up these facilities in the United States for the same reasons.

The question I am always asked is, "Is the service and treatment better in these cash-only facilities." The answer is obvious: unquestionably! There is virtually no comparison between the "socialized" programs and the "cash programs." This is not a political statement on my part. It is simply the fact. What we do in these new centers is simply eliminate the insurance company who —- by the way — contributes no care whatsoever in the system. In this two-class health system, the money goes straight from the patient's wallet to the surgeon's wallet. Ultimately, it is cheaper because there is no middle person involved to muck it up. There will always be those who can afford it and sadly, there will always be those who cannot. No one ever said life is fair.

So with all this being said, what can we do? Nothing. Absolutely nothing, except to do the job for which we are all paid, in one way or another. There is too much money at stake, too much special interest, too much greed, and not enough desire to make it happen. So, let it work itself out, and let's do our job and take care of the patient.

About four weeks ago, I developed a pain in my arms and shoulders following a minor bicycle accident. I ignored it and lived with the pain. However, it soon got worse, and my left arm started getting "heavy" and "clumsy." The right side of my body was tingling. Cold water felt hot, and hot felt cold. Within a couple of days, I couldn't sign my name, and I noticed that I was keeping my hand in my pocket so it wouldn't stray. About nine days ago, everything started going from bad to worse. I couldn't type, and I couldn't use e-mail except with one finger. The pain was now intolerable and untreatable. My left arm was numb and essentially useless, the right side of my body was living its life without me, and I was walking with a decided canter.

Ever the business owner, I continued to work and travel. A little over a week ago, I was having dinner in Los Angeles with — as luck would have it — an orthopedic surgeon and a spine surgeon. And after dropping everything in sight, one of the surgeons asked me if I was OK. (I'm sure he thought I was drunk.) I spilled it all out. Early the next morning, I was inside an MRI tube. An hour later, I heard the words that no one ever wants to hear, "I have never seen a compressed spinal cord as bad as yours."

I wanted to have the emergency cervical surgery in Texas for family reasons. That trip back home was harrowing. I feared every bit of turbulence even though I was wearing a protective neck brace. Thanks to my referral from California, I was seen immediately upon arrival in Texas and underwent a C6-C7 cervical fusion with donor graft and a plate and screws in my spinal cord. I was released in two days, and

suddenly everything works again. I take my first plane trip in the morning and cannot wait to see how interesting getting through security is going to be.

But again, with all that is happening in health care right now, I had great surgeons, outstanding nurses, great anesthesia care, and a new sense of appreciation for what all of you do that makes a difference. Here's a sincere and grateful thank-you to every nurse, surgeon, tech, front office staff, nurse's aides, med nurse, aftercare specialist, surgical fellow, and all the other people who made a difference to another human being.

For what it is worth, not a single politician was involved in my care.

(Earnhart & Associates is a consulting firm specializing in all aspects of outpatient surgery development and management. Contact Earnhart at 1000 Westbank Drive, Suite 5B, Austin, TX 78750-2254*. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.)* ■

Should you let surgeons use devices off label?

Your surgeon says she wants to use a medical device in a different manner than it was approved by the Food and Drug Administration (FDA). She says he has the data to ensure it will be used safely, and the patient already has given informed consent.

What should you do?

"In some circumstances, good evidence may have accumulated that off-label use of a device may be in a specific patient's interest, even though the use of that device for that indication is not approved by the FDA," says **Dan Berry**, MD, professor of orthopaedics, College of Medicine at Mayo Clinic, chair in the Department of Orthopaedic Surgery at Mayo Clinic, Rochester, MN, and second vice president of the American Academy of Orthopaedic Surgeons. "In other words, sometimes medical knowledge and practice may advance ahead of regulatory approval."

EXECUTIVE SUMMARY

Surgeons can decide to use a medical device in a manner that has not been approved by the Food and Drug Administration (FDA), if steps are taken to protect themselves, their patients, and their facilities.

- Read FDA guidance issued earlier this year on unapproved new uses of cleared medical devices.
- Ensure that the data support off-label use of the device and that surgery with an approved device is not an option.
- Ensure that informed consent and documentation is thorough.

Custom-tailored care

Off-label use clears the way for surgeons to custom-tailor treatment so that they can treat the unique signs and symptoms of each patient, says **Patrick J. Hurd**, attorney at law with LeClairRyan in Norfolk, VA. "Off-label use of medical devices keeps the focus on healing and not rigidity and conformity, permitting the physician to practice the art and science of medicine," Hurd says.

Sometimes it's not in the best interest of the patient to wait for FDA approval, says Hurd, adding that "if patients had to await FDA approval of every medical device before receiving treatment, their health and well-being would suffer." Some outpatient surgery providers are "guided by very conservative legal advice stating that no off-label use can be permitted," Hurd says. "In my opinion, such policies ignore the realities of the patient mix such entities serve and belittle the professional competence and expertise of the physicians treating such patients."

Off-label use, in and of itself, doesn't imply that the surgery is illegal or clinically improper, says **Madelyn S. Quattrone**, Esq., senior risk management analyst at ECRI Institute, a Plymouth Meeting, MA-based nonprofit organization that uses applied scientific research to identify approaches to improving patient care.

"Physicians are permitted by law to use medical devices and drugs in an off-label manner," she says. "Congress did not authorize the FDA to regulate the practice of medicine. That is a function of state medical boards."

Guidance issued earlier this year

Still, fear runs rampant among outpatient surgery providers, including fear of lawsuits, Hurd notes.

"Having the off-label use become the recruiting tool for attorneys seeking class-action plaintiffs via commercials and other media advertising," he says. Class-action lawsuits have been filed against

manufacturers that involved clinicians and health care facilities as co-defendants, Quattrone says.

She says researchers have claimed "many off-label uses lack supporting scientific and clinical evidence of safety or efficacy, that physicians may rely to their patient's detriment solely on manufacturers' data and information concerning off-label use."

There have been reports of data manipulation, fraud, and conflict of interest, she says. Hurd says, "If [hospitals or ambulatory surgery centers] receive remuneration for promoting certain off-label uses to their medical staff, receive entertainment/money from device/drug companies, etc., then, like physicians, they can be subject to allegations of fraud."

Does the patient understand?

Quattrone says another problem is that many patients undergoing surgery with an off-label device "may erroneously believe that a medical device has been approved by the FDA as safe and effective for use for their condition — a false assumption that may lead patients to overestimate a device's safety."

Still, providers don't have to ban off-label use, sources say. Their fears might be calmed somewhat by FDA guidance issued earlier this year on unapproved new uses of cleared medical devices. **(For information on how to access, see resource box, p. 112.)** These recommendations attempt "to set a science-based standard for disseminating off-label information to physicians," Quattrone says. While the guidance is directed toward drug and medical device manufacturers, "the guidance should be 'must reading' for physicians and staff at every hospital and outpatient surgery center," Hurd says. "It clarifies what information can be exchanged between manufacturers/suppliers and providers and, over time, provides a measure of comfort to those reluctant to permit such off-label use." **(See tips for using devices off label, below.)** ■

Tips for using devices off label

Outpatient surgery centers and hospitals should have a policy for the off-label use of medical devices, says **Patrick J. Hurd**, attorney at law with LeClairRyan, Norfolk, VA.

"In my experience, physician input into the policy is key in ensuring its effectiveness," Hurd says.

The policy doesn't have to be elaborate, he says. However, it should address informed consent, documentation, basis for use of the device, and tracking and follow-up of postoperative complications, Hurd says. "Some [facilities] require that information on the safety and efficacy of the off-label use be made a part of the patient's record," he says. "Frequent off-label use of the same device by a surgeon or practice may be subject to IRB [institutional review board] or products committee review by some health care entities."

Consider involving the clinical engineering departments in developing a policy for off-label use, advises **Madelyn S. Quattrone**, Esq., senior risk management analyst at ECRI Institute in Plymouth Meeting, MA. Ensure that clinicians are familiar with the indicated uses, contraindications and warnings related to off-label use, she says. Determine if there is an FDA-approved alternative device available, she suggests.

Will the device be used safely?

Determine whether peer-reviewed literature supports the off-label use, Quattrone says. Also, "weigh the relative risk of harm from the off-label use with anticipated clinical benefit to the particular patient," she says.

Be certain that the device has been approved by the Food and Drug Administration (FDA) for on-label use, says **Dan Berry**, MD, professor of orthopaedics, College of Medicine at Mayo Clinic, chair in the Department of Orthopaedic Surgery at Mayo Clinic, Rochester, MN, and second vice president of the American Academy of Orthopaedic Surgeons. However, you can't rely on the FDA "to have carefully evaluated the safety and efficacy of the device for that specific application," Berry says. "This puts a greater burden on the treating physician to carefully evaluate the available data, in an unbiased manner, to determine the benefits vs. the risks of using that device for the specific patient," he says.

Before going off label, the surgeon must be certain that the evidence is solid that the patient will be safe and that off-label use of the device is in the patient's best interest, Berry says. "The responsibility to use the device responsibly lies on the surgeon," he says.

RESOURCE

Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices is available at www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm.

However, off-label use is not forbidden, sources emphasize. Hurd says, "The law does not restrict a physician from practicing his/her art." The surgeon can make a decision based on his or her training and experience, he says. "Such use cannot be wanton and reckless; it should be based on a deliberate and studied review of available scientific evidence on the safety and effectiveness of the device for the intended use, including his or her own personal experience with prior similar uses for similar conditions/patients," Hurd says.

Is it worth the risk?

Carefully consider the risks and benefits, Quattrone says. "It's one thing to use a device off label for a serious condition when there is no FDA-approved device, especially when reliable evidence supports the off label use," she says. "It's another thing to use a device off-label where there is a safe and effective FDA-approved alternative or where the patient's condition is not sufficiently serious to warrant risks of an unproven use or treatment."

Ensure that informed consent and documentation is thorough, and ensure the discussion is documented, say sources interviewed by *Same-Day Surgery.* Hurd says, "In general, my advice is 'document, document, document.'"

Surgeons should provide an opportunity for the patient to ask questions to ensure adequate understanding of off-label use, "as well as the risks and benefits of alternatives," he says. "This dialog should be memorialized in the patient record."

The surgeons also should document the "rationale and basis for the off-label use," Hurd says. "From the initial H&P to the pre-op work-up to the surgery itself, all the way through post-op assessment and follow-up visits, the patient record should reflect the facts supporting the selection, deployment, and outcome of the off-label use," he says. ■

GUEST COLUMN

Unnecessary mastectomy: $6.5 million verdict in NY

By **Radha V. Bachman**, Esq.
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After a 31-year-old student and part-time clerk underwent an excisional biopsy on her left breast, the physician diagnosed the woman with cancer and recommended commencement of chemotherapy. About six months later, the woman came under the care of a hospital breast clinic and was evaluated by a general surgeon employed by the hospital who recommended a mastectomy. The pathology studies from the removed breast did not reveal any evidence of cancer in the breach or the 28 lymph nodes that were removed at the time. The surgeon conducted further testing, all of which revealed no cancerous tissue.

The woman sued the physician who made the cancer diagnosis and claimed that he failed to properly perform the biopsy.[1] She alleged that the biopsy did not clearly indicate the margins of the cancerous tissue and that the physician should have made a second incision. The woman also sued the surgeon, an employee of the hospital,

EXECUTIVE SUMMARY

A woman underwent an excisional biopsy on her left breast. The physician who performed the surgery diagnosed cancer and began chemotherapy. Later, other physicians evaluated the woman and recommended a mastectomy and removal of lymph nodes in the woman's breast.

- After the mastectomy, no evidence of cancer was found.
- The woman claimed that the mastectomy was unnecessary and sued various hospitals and physicians. The jury awarded $6.5 million.

alleging that she failed to obtain the necessary informed consent, because no alternative treatment options were provided, and alleging that the mastectomy was, in fact, unnecessary.

The woman's counsel argued that the woman's cancer was eradicated by chemotherapy, and he claimed that chemotherapy typically resolves 15%-30% of cancerous masses. He contended that the woman's medical records indicated that the cancerous mass had been "resolved," and he also contended that the woman's records indicated that a pre-surgical evaluation did not reveal the presence of a "palpable mass." The woman maintained that the surgeon should have suggested a less invasive surgery, such as lumpectomy or a sentinel-node biopsy, rather than a mastectomy, which would have revealed that the woman's cancerous mass had been resolved. The woman's expert stated that the mastectomy was "like shooting a fly with a cannonball." The woman further claimed that the surgeon never discussed any alternative procedures.

The woman also sued the hospital-employer, the hospital's operator, and many other doctors and hospitals that were alleged to have been involved in her care. Her claim maintained that the hospital and the hospital operator were vicariously liable for the actions of the surgeon.

The defendants countered the woman's argument and claimed that the woman had failed to attend all her pre-surgical evaluations, which they said made her partially liable for the failure to properly diagnose her condition.

The woman underwent a mastectomy and reconstruction of her left breast. The reconstruction included the use of a flap that was harvested from her abdomen. The woman claimed that her left breast is horribly disfigured and scarred. She also claimed to suffer from residual lymphedema, which is painful swollenness caused by the body's retention of fluid. She contended that the condition stems from the surgeon's removal of some of her lymph nodes. The woman sought recovery of damages for her past and future pain and suffering.

The jury rendered a mixed verdict. It found that the woman was not offered the option of undergoing less invasive alternatives to the mastectomy that the surgeon performed. It further found that a reasonable, properly informed patient would have declined to undergo the mastectomy. It also found that the mastectomy was not necessary. Thus, it concluded that the surgeon was liable for the woman's injuries. The physician performing the biopsy was not assigned liability. The jury determined that the woman's damages totaled $6.5 million: $3 million for past pain and suffering, and $3.5 million for future pain and suffering. **(For information on what this case means for providers, see story, below.)**

Reference

1. Case No. 14520/01, Bronx (NY) County. ■

What mastectomy case means for providers

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Inverness, FL

Two of the pivotal points in the case of an unnecessary left mastectomy on a 31-year-old involve informed consent without specifying or discussing alternatives to the mastectomy and appropriate pre-surgical evaluation.[1]

The Joint Commission defines informed consent as the *"Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment."* The Joint Commission requires that the hospital's written policy describes the process used to obtain informed consent and how informed consent is documented in the patient record *(Joint Commission Standard RI.01.03.01, EP 4,5).*

It is imperative that informed consent is properly executed. It is the responsibility of the physician or surgeon to explain the risks, benefits, and alternatives of a procedure in a clear and concise manner to assist the patient and/or patient's representative in understanding what they are agreeing to and giving consent for. Key to informed consent is the inclusion of a list of risks, benefits, and alternatives to the procedure. Failure to offer

information regarding any of these three components is a failure to achieve true informed consent. A patient is not fully enabled to make a good decision if information is lacking. In this case, the patient being duly informed of alternatives to the recommended surgery might have resulted in more desirable outcomes.

Physicians and surgeons work within a busy schedule and might feel rushed. They might view informed consent as a task to be accomplished rather than an opportunity to educate, to entertain patient questions, address concerns, and to engage in discussion regarding a procedure. The process of obtaining informed consent also is an opportunity to develop a trust relationship between physician and patient, thus reducing the risk of litigation. Patients who trust in their physician or surgeon and who believe they have a good relationship with their practitioner are less likely to consider litigation in the event there is a negative outcome as a result of a procedure.

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Health care organizations must invest in educating medical staff in the content, importance, and ramifications of informed consent. While informed consent remains the full responsibility of the physician or surgeon, the facility also must work to ensure that informed consent is properly defined by policy and executed by the medical staff for the safety and well-being of their patients.

In this case, the jury also found the mastectomy was not necessary. Contributing to this decision was the fact that "a pre-surgical evaluation did not reveal a palpable mass." It was contended that the patient's record indicated "that the cancerous mass had been resolved" post-chemotherapy.

This finding begs the question, how extensive was the pre-surgical exam? A complete history and physical preoperatively would take into account the biopsy results and subsequent course of chemotherapy. It would be prudent to complete additional testing to verify the continued presence or resolution of cancer in the left breast. The Joint Commission, in its introduction to Standard *PC.01.02.01*, states, "The goal of assessment is to determine the care, treatment, and services that will meet the patient's initial and continuing needs. Patient needs must be reassessed throughout the course of care, treatment, and services." This assessment includes collecting and analyzing information regarding the patient's health history, followed by care and treatment decisions appropriate for the patient based on the information obtained.

Given the jury findings in this case, it is evident the pre-surgical evaluation did not meet the assessment goal as defined by The Joint Commission. It behooves managers to ensure that their history and physical policies meet Joint Commission standards and that the medical staff adhere to such policies in order to provide safe and appropriate patient care.

Reference

1. Case No. 14520/01, Bronx (NY) County. ■

COMING IN FUTURE MONTHS

- Tip for surviving when revenues decline
- Thrive as your quality and cost data go transparent
- Should price for surgery include all pre-op, post-op care?
- Avoid being sued over a surgical fire

Is patient angry? Take these steps

Patients may arrive for outpatient surgery, only to find out the bill is estimated to be more than $10,000.

At Monroe Carell Jr. Children's Hospital at Vanderbilt in Nashville, TN, insurance management staff provide upfront liability information in advance. "The patient access staff then collect the amount that insurance management loads in the system," says **Tina Williams**, director of access services.

If insurance management is unable to reach the family, access staff work with patients directly. This includes obtaining financial assistance for uninsured or underinsured patients. All staff can hand out $5 vouchers for the gift shop and cafeteria. Williams says, "Access staff are trained to listen to the patient, empathize, acknowledge the concern, respond in a calm manner, and thank them for voicing their concerns." Staff members also involve a manager as soon as they think their efforts at resolution are not working.

Staff tell patients that they want their insurance to pay as much of the liability as possible, and so they must verify benefits, ensure pre-certifications, etc.

Cheri S. Kane, MSA, FHFMA, CHFP, FACMPE, division president of The Outsource Group in St. Louis, says if a patient is angry, take that individual to a secluded quiet room, ask the patient to sit down, and request assistance. "If necessary, the first person may need to leave. The replacement handles the situation," she says. ■

CNE/CME instructions

Physicians and nurses participate in this CNE/CME program by reading the issue, using the references for research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to the answers listed in the answer key to test their knowledge. To clarify confusion on any questions answered incorrectly, consult the source material. After completing this semester's activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CNE/CME *questions*

- **Identify** clinical, managerial, regulatory, or social issues relating to ambulatory surgery care.
- **Describe** how current issues in ambulatory surgery affect clinical and management practices.
- **Incorporate** practical solutions to ambulatory surgery issues and concerns into daily practices.

17. What does Methodist University Hospital in Memphis plan to do in the event something goes wrong during a webcast of a surgery?
A. Go to a blank screen.
B. Go to a previously recorded tape of the same procedure.
C. Go to a previously recorded tape of the surgeon explaining the procedure.
D. None of the above

18. Guidance was issued earlier this year from the Food and Drug Administration (FDA) on unapproved new uses of cleared medical devices What does it address, according to Patrick J. Hurd, attorney at law with LeClairRyan.
A. Whether devices can be used off label.
B. For what procedures devices can be used off label.
C. What information can be exchanged between manufacturers/suppliers and providers.

19. What pieces of information should be included in a policy on off-label device use, according to Hurd?
A. Informed consent
B. Documentation
C. Basis for use of the device
D. Tracking and follow-up of postoperative complications
E. All of the above

20. In a lawsuit over an unnecessary left mastectomy on a 31-year-old, what is/are the pivotal point(s), according to the columnists?
A. Informed consent without specifying or discussing alternatives to the mastectomy
B. Appropriate pre-surgical evaluation
C. Both A and B
D. Neither A nor B

Answers: 17. B; 18. C; 19. E; 20. C.

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