



SAME-DAY SURGERY

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AHC Media

Printing 3D medical devices comes with substantial liability risk

Just a few years ago, 3D printing was a futuristic breakthrough that seemed to have endless potential for manufacturing and other industries. The future is here, and surgery is one of the fields in which professionals are using 3D printing to create models and even surgical devices that are otherwise unavailable.

The medical community is excited about all the ways 3D printing can be incorporated into patient care, but managers might need to be the ones who pull back on the reins and consider the potential liability. Creating a device in-house opens up the healthcare facility

to an area of potential liability that previously affected only commercial medical device manufacturers. Normally, when a device is blamed for an adverse outcome, the healthcare facility can direct the plaintiff to the manufacturer and escape liability, but not when you made the device yourself.

Healthcare providers use 3D printing in two principle ways: either creating a 3D model that helps physicians plan and practice surgery and other procedures, or making temporary tools. Some of the tools are templates affixed to bone to guide the surgeon in shaping the patient's bone structure to

Next month: Best cost-saving and revenue ideas

The February issue will include the best cost-saving and revenue-generating ideas for outpatient surgery managers. We'll tell you about a source of “free” money. We'll also tell you how to improve your on-start times and reduce your turnover times so you can perform more cases. We'll talk to facilities that have seen dollar savings from supply and “green” efforts. We'll give you a quick tip that one facility used to reduce its expenses immediately by several percentage points.

We'll have free benchmarking information, resources, and more. Don't miss this special issue!

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accommodate an implant of standard size. Other tools are drill guides that help the surgeon place screws in the right place based on the patient's unique dimensions.

Other tools are being made in healthcare facilities, including spinal cages, hip prosthetics, and artificial bone structure for repairing facial injuries or birth defects.

Healthcare facilities that are making their own surgical devices are assuming the risk of their failure, says **Max Gaujean**, JD, a malpractice attorney and founding member in the White Plains, NY, office of the Brown, Gruttadaro, Gaujean & Prato law firm. In addition to the possibility of immediate failure, healthcare facilities don't test their homemade devices for long-term wear and tear, he notes.

Healthcare facilities "are also removing a deep pocket, namely the manufacturers, exposing themselves to enormous economic risk," Gaujean says. They also might be "assuming any risk that the doctor may expose them to since the physician may not have been trained to install the custom device."

Physicians also are exposed to the usual malpractice complaints: that they did the procedure incorrectly, that they were not properly trained to handle the surgery or the device,

or that they failed to provide informed consent with regard to risks associated with the device.

Gaujean recommends that managers require informed consent for use of any facility-made device. It also would be a good idea to obtain the opinion of the facility's medical ethics board, he says.

The biggest risk from 3D printing, also known as additive manufacturing, is lack of education and unrealistic expectations by healthcare professionals, says **Adam Clark**, the founder of Tangible Solutions in Matthews, NC, a consultancy and provider of 3D printing/additive manufacturing and engineering design services.

"Sticking a printer in a hospital, and letting a doctor or nurse print stuff, is currently very risky because there is a serious knowledge gap in additive manufacturing methods, materials, and finishing processes," Clark says. "Currently levels of expectations of the technology from the general population are relatively unrealistic. Healthcare professionals are really good at what they do: taking care of people when they are sick or injured. This does not mean they are qualified to print a new device off a [3D printer] the hospital decided to buy because they got pulled into the hype."

EXECUTIVE SUMMARY

- Healthcare facilities are adopting 3D printing for a variety of uses without fully exploring the potential risk. Creating a medical device brings substantial liability exposure.
- 3D modeling does not pose the same risks as creating a device to be used on a patient.
- Managers should weigh the potential risks of any 3D printing project before allowing it to proceed.
- A surgical device created in the facility will bring product liability potential.

Nevertheless, Clark says 3D printers are in healthcare facilities and will play a bigger role in the future. Healthcare facilities should, at least, consult with a company specializing in 3D printing and possibly partner with one in the same way facilities outsource diagnostic or scanning services. “Education will enable an understanding of what additive manufacturing is and how it can be implemented, not just from the user perspective, but how additive manufacturing fits into the organization from an enterprise level,” Clark says. “This will help manage risk, and the technology can be exploited for the good of their patients.”

Tort liability in 3D

Tort liability is a primary concern with 3D printing in healthcare, notes **Colleen T. Davies**, JD, partner with Reed Smith in San Francisco. The firm recently launched the white paper titled *3D Printing of Medical Devices: When a Novel Technology Meets Traditional Legal Principles*. (The paper is available online at <http://tinyurl.com/pr8dlgr>.) If a 3D-printed medical device is at issue in a lawsuit, Davies says, a key question will be who the manufacturer of the device is.

“Is it the 3D printer company? Is it the creator of the software used to make the design? Or it the surgeon? Or the hospital?” she says. “That is as of now an unresolved issue. It’s not clear in the law yet, so it definitely has to be considered when assessing risk.”

That question has not yet been tested in the courts, Davies says. There are many unanswered questions regarding the technology and healthcare, but it is clear that managers should be involved in overseeing its use in the healthcare facility, she says. As with other

technologies, there must be a process for quality control with the machine, maintenance, and supply chain, she notes.

There is a possibility that healthcare facilities will have some protection from liability related to 3D items. State laws vary, but in general, they do not impose strict liability on healthcare facilities for medical devices, says **Paven Malhotra**, JD, partner with the law firm of Kecker & Van Nest in San Francisco. States are more concerned with commercial sellers of a product and are not likely to see the healthcare facility in that way for 3D printed devices, he says.

“That could change if a hospital were printing these devices in bulk, using them in the hospital, and selling them as well,” Malhotra explains. “That could push them over the line so that the courts see the hospital as a commercial seller. If you stay with printing the item as needed or in small batches to use in the hospital, you’re unlikely to be held strictly liable.”

However, courts would be likely to accept a claim of negligence, he notes. But what is negligence in 3D printing of medical devices? The practice is so new that it would be difficult to prove a standard of care or bring in expert witnesses to testify, he says.

Healthcare facilities should think of best practices in general and how they can apply to 3D printing, Malhotra says. “Explain it all to the patient, everything: the risks, how new this item is, the fact that there is no liability record to draw on, and you explain the benefits as well,” he says. “If you end up in court, you want to show that the patient was well-informed and you didn’t hide anything about this new device.”

Follow usual safeguards

Managers should be very cautious

with 3D printing and insist on at least the same safeguards that would be required for any other item used in the facility, says **Amy Alderfer**, JD, a products liability attorney with the law firm of Cozen O’Connor in Los Angeles. The FDA has approved about 85 3D printing products for use in healthcare, and confirming that approval for any particular device is a good starting point, Alderfer suggests.

The risk manager might have to be the one who says no to a surgeon who has printed a device and is planning to use it on a patient, she says. Just because it is created through 3D printing doesn’t make it different from any other medical device in regard to ensuring safety and quality. After all, Alderfer says, you wouldn’t let a surgeon use a device that he made in his garage and brought to the hospital, at least not before getting the proper clearances and quality assurances.

“If I have surgeon who announces he has this hot new item that he printed at home or on the hospital’s 3D printer, I’m going to say ‘Whoa!’ and slow this down. There are a lot of things we need to step back and evaluate,” she says. “This is always a challenge in risk management, having to temper the excitement of clinicians who are eager to do something new and innovative.”

Is modeling different?

When 3D printing is used for modeling rather than with a patient, the manager need not apply such strict review, she says. However, the managers should remind surgeons and others that the same approval process for medical devices still applies to 3D printing. FDA approval is available on an emergency basis for any medical device, she notes.

“Just because you have a new technology doesn’t mean that you

don't have any regulations or we're going to develop new regulations," Alderfer says. "The existing framework you have for ensuring that you use approved medical devices still applies here. The danger is that a surgeon will think it doesn't because this technology is so different and exciting, and not take his or her device through the approval process."

Large liability

If that happens, the potential liability is huge, Alderfer says. A plaintiff's attorney would see

many avenues to pursue and many defendants.

The facility "doesn't want to be in a position of being sued and asked how you allowed this to happen, how you let somebody make their own medical device and use it on a patient without all the appropriate safeguards," Alderfer says.

Reimbursement also becomes an issue with 3D printing, notes **Farah Tabibkhoei, JD**, an attorney with the law firm of Reed Smith in Los Angeles.

"Reimbursement continues to be

an obstacle because 3D printing is such a new technology. In order for it to be reimbursed, you have to show that it is medically necessary and provides a substantial clinical benefit," Tabibkhoei says. "While it's been said that 3D printing will shorten procedure times and offer benefits to the patient, there isn't enough long-term data to show that. So at the moment, we're seeing a lot of 3D printing used in academic medicine, where they have grant funding, but we haven't seen it be eligible for reimbursement." ■

Doctor reveals dirty secret about how OR patients are treated

(In this second part of a two-part series on bad behavior in the OR, we give you details about a report in the Annals of Internal Medicine as well as details from a specific incident involving an anesthetized patient who was ridiculed. In last month's issue, we gave you an overview of the problem and provided potential solutions.)

An essay in the *Annals of Internal Medicine* received the attention of not just the medical community, but also the general public, when it revealed how anesthetized patients sometimes are treated with disrespect and even subject to what could be considered assault.

Titled "Our Family Secrets," the physician author recounts incidents of misogyny, racism, and sexual assault in the operating room. In an accompanying editorial, the editors of the journal said that they debated whether to publish the sensational essay, but they said they did so to underscore that it's important that doctors not remain silent when they

witness misconduct.

The author of the essay was teaching a medical humanities course to senior medical school students. During the course, he asked the students if any of them had something happen during their medical school experience that troubled them deeply.

One student expressed regret at not standing up to a surgeon's inappropriate behavior while a patient was under anesthesia for a vaginal hysterectomy. While the surgeon was prepping the unconscious patient's vaginal area for the procedure, he looked at the student and said, "I bet she's enjoying this," accompanied with a laugh and wink.

The student called the surgeon a "dirtball" when recounting the incident, but expressed remorse that he had laughed along with the surgeon. He felt intimidated by the senior physician and didn't know what to do other than play along with the joke.

The anonymous author also told

his class of an incident that occurred when he was a third-year medical student. He had helped deliver a baby, but the mother experienced severe bleeding immediately after. The resident instructed the anesthesiologist to put the patient under and then proceeded with an internal bimanual uterine massage, which involves placing a hand inside the vagina and pressing a fist against the uterus to stop the blood flow. Once the bleeding was controlled, the doctor said "Atta girl. That's what I like. A nice, tight uterus." Then he raised his free hand in the air and started singing "La Cucaracha," shuffling so it looked like he was dancing. (The patient was Latina.)

The essay author laughed and hummed along to the song until the anesthesiologist yelled at both of them to stop. (*Access to the essay is available at the Annals of Internal Medicine website at <http://tinyurl.com/ooov85m>. The cost is \$32. See story in this issue of another example of bad behavior in the OR.*) ■

OR staffers invite others to laugh at patient

An incident involving an out-of-control OR team illustrates how undignified and abusive behavior can occur even at facilities with high standards.

R. Stephen Trosty, JD, MHA, ARM, CPHRM, president of Risk Management Consulting in Haslett, MI, and a past president of the American Society for Healthcare Risk Management (ASHRM) in Chicago, was a risk manager at a hospital when he learned of the incident. A patient was about to undergo surgery, and when the OR staff undraped him, the man was found to have an extremely large penis and scrotum.

“Not only was this mentioned and laughed about by the people in the room, but other hospital personnel

were invited to come into the operating room to witness this. It was referred to as a ‘true gift of nature,’” Trosty recalls. “All sorts of comments were made about how fortunate his wife was and how talented he must be.”

When Trosty learned of the incident from staff members who were bothered by it, he conducted an investigation to determine exactly what happened. Then he went to the chief of staff, the head of the department, the vice president of nursing, and the CEO to insist that it be dealt with immediately and effectively.

“Disciplinary action was taken at all levels, up to and including the firing of non-physician staff. The

physician who was most responsible had his privileges revoked,” Trosty says. “I am not sure that this actually permanently stopped the behavior, but I do believe it was a major deterrent to it happening again. All levels of the institution gave the message that this type of behavior would not be tolerated, and it was explicitly stated that anyone who participated in this type of behavior in the future faced equally serious consequences.” The incident was used as a teaching example for staff and physicians. *(Editor’s note: Do you have an example of bad OR behavior that you can share and address how it was handled? Please note if you want to share anonymously. Send to joy.dickinson@AHCMedia.com.)* ■

Newly developed surgical ‘black box’ is similar to airplane device used to analyze data after crash

An adverse event investigation typically must rely on a mix of people’s imperfect memories and incomplete data. However, there is growing interest in using systems during surgery that record a wealth of information — not just videotape, but data from the devices used in the operation and other information such as the correct timeout procedure.

Proponents say such a system would be akin to the “black box” recordings that crash investigators use after an airplane disaster, which provide valuable information about what happened when people’s memories are unavailable or insufficient. However, such recordings also pose important questions for healthcare managers about patient safety, privacy, and the potential use

of the information in malpractice litigation.

A system developed by **Teodor Grantcharov**, MD, PhD, FACS, professor of surgery at the University of Toronto and the Canada research chair in simulation and surgical safety, is gaining attention as the most advanced model so far, and the one most likely to be available for general

use soon. Grantcharov is a surgeon specializing in advanced minimally invasive surgeries at St. Michael’s Hospital in Toronto, which has been using the recording system for more than a year.

Since April 2014, Grantcharov has recorded all of his procedures with the unit, which is about the size of a box of tissues or a thick book and

EXECUTIVE SUMMARY

There is growing interest in videotaping and recording other data routinely during surgery. A system similar to an airplane’s “black box” recorders might be available soon.

- Some state legislators are pushing for mandatory recording in surgery.
- Recordings could be used in malpractice litigation.
- In a review of surgical recordings, 75% of the problems found were not noticed at the time by the surgical team.

looks like any other electronic unit used in laparoscopy.

It records almost everything that goes on in the OR, such as video from the laparoscopic camera, hundreds of data points from around the OR, physiologic details of the patient, conversations between members of the surgical team, temperature and decibel levels in the room, and a gallery view of the operating theater.

Safety advocates push it

The drive for surgical black boxes comes mostly from patient advocacy groups rather than the healthcare community.

In 2005, members of the American Medical Association adopted a policy that encouraged recording during clinical care for educational purposes, but the policy mostly addressed patient privacy and emphasized that patients must consent to the recording.

State legislators more recently have pushed for recording systems. There is a bill in the Wisconsin legislature that would require cameras in every operating room in the state. The bill is known as the “Julie Ayer Rubenzer Law” for a Wisconsin woman who died after she was given excessive amounts of propofol during a breast augmentation procedure. Her brother Wade Ayer founded the National Organization for Medical Malpractice Victims and helped draft the bill. The legislation has been assigned to the Assembly Committee on Health.

In Massachusetts, a bill was introduced in recent years that would require hospitals to allow recording by a licensed videographer, at the patient’s expense.

The system designed by Grantcharov is intended to improve patient safety by helping surgeons improve their performance, not to

generate evidence for use in litigation, he says.

As the system is used at St. Michaels, the data from a procedure are analyzed within 48 hours, and then the video and audio files are destroyed. The other data are retained for 30 days so that they can be used in documenting the 30-day outcome of patients. After 30 days, the data are de-identified and anonymized.

“We use the data on a system level and also to provide feedback to individuals,” Grantcharov says. “The information on a single procedure is not useful for us. We use the data to identify trends and deficiencies within our hospital, but we don’t use it to blame and shame people or in court.”

When the black box was introduced at St. Michael’s, Grantcharov was the only one using it, and it was available in just one OR. Over time, the system was adopted by more surgeons and made available in more ORs. After the successful trial at St. Michaels, the system is being introduced for beta testing at other hospitals in Canada, the United States, and South America.

In a pilot project involving 54 procedures, surgeons reviewing data from the black box found adverse events in 38 of the cases, and 75% of the problems were not noticed at the time by the surgical team.

Surgeons skeptical

Grantcharov acknowledges that surgeons and managers will be wary of creating such a detailed record of the procedure that might be used against them in court.

After he presented research from his use of the system at the 2015 annual meeting of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), the question-and-answer session included attendee surgeons who voiced

concerns that a black box would be weaponized by plaintiffs’ attorneys.

Grantcharov points out, however, that the Healthcare Quality Improvement Act (HQIA) protects data collected for peer review and quality improvement from discovery. That protection is justified when the system is intended to improve performance, he says, not to augment the patient record. Additionally, the information would not be available to attorneys if it were destroyed and/or anonymized after a short period, as is done at St. Michael’s. However, Grantcharov says that even if the data did make its way to the courtroom, he believes it would be beneficial to the hospital and the surgical team in a malpractice case.

“The data would most often work to their favor in proving what did and did not happen,” he says. “We did not design it with the courts in mind, but I think more documentation in surgery will lower malpractice claims by improving team performance in surgery.”

Court use is possible

Though the HQIA protects information generated as part of a formal peer review process from use in litigation, that protection is not ironclad, says **M. Daria Niewenhaus**, JD, an attorney with the law firm of Mintz Levin in Boston. Efforts to keep such information out of the courtroom often are challenged, Niewenhaus says.

Increased data collection would help with the increasing pressure from payers and governmental authorities who are looking for ways to measure quality, she says, but managers should proceed carefully.

“This could be a useful tool, but safeguards must be put into place to ensure the confidentiality of patient information and to control how such

information is used,” Niewenhou says. “The black box data has a place as a training tool and may well result in better-trained surgeons and clinicians. Care must be taken to de-identify information used, much as how medical school and other training programs de-identify X-rays shown in lectures.”

Challenging questions

Niewenhou notes that with more widespread use, the information could become a part of the patient’s medical record and therefore no longer under peer review or other protections. Also, some of the state legislation that is pending or under consideration would require that

the recordings be made a part of the patient record.

“There are challenging questions to be addressed. For example, should a patient or his/her legal representative have the right to watch the video and, if so, under what circumstances?” Niewenhou says. “We are becoming more used to having our activities recorded and, with technology readily available to enable patients to view the information, will patients call for the option to have their procedures recorded?”

Ensure that the legal and ethical issues surrounding use of these black boxes and the use, storage, and retention of the information they collect are addressed before their use

becomes more popular, Niewenhou says. Too often, she says, policies and procedures have to catch up to technology that is already in use.

Grantcharov urges healthcare leaders not to let the legal concerns overshadow the potential for improving patient safety.

“We as healthcare providers need to be aware of our deficiencies and be able to improve them, and I have no doubt in my mind that this is a tool that can help in that regard,” he says. “Once we have shown this in a multi-center trial, we hope that this will lead to a change in the way we practice surgery and a change in the way we critically reflect on our performance.” ■

Many patients prefer postop care to be online

Study points to a greater role for patient-generated data in the future of postop care

Most patients who undergo routine, uncomplicated operations prefer online postoperative consultations to in-person visits, according to results from a study published online in the *Journal of the American College of Surgeons*.

In this prospective pilot study from Vanderbilt University Medical Center in Nashville, TN, researchers tracked 50 patients who completed both online and in-person visits after their operations. The patients underwent elective laparoscopic cholecystectomy, laparoscopic ventral hernia repair, umbilical hernia repair, or inguinal hernia repair. Seventy-six percent of this group said that online visits were acceptable as the only form of follow-up care.

“This is beneficial not just for those far away, but those who are busy and don’t want to take time off work and whatever else they’re

doing, go to an appointment, and wait in room, especially for a postop visit, which takes 5-10 minutes to see the surgeon,” says lead study author **Kristy Kummerow Broman**, MD, MPH, resident physician in general surgery.

The surgeons conducting the study said that for 68% of patients, online and in-person visits were equally effective, which indicates that offering an option for online care might have largely impacted patient preferences. Also, while clinic visits took an average of 10 minutes, the online visits took only five minutes, says Kummerow Broman. “Theoretically, it opens up clinics to see more patients,” she says.

The research team approached the study by questioning whether all aspects of perioperative care need to take place in person. Members of the team thought that there might be a

role for moving some postoperative care for certain operations to an online environment. The study authors wrote, “To date, there has been minimal incorporation of these new care delivery modalities into general surgical care, and patients have been less frequently relied upon to generate their own data in the form of digital images.”

An online patient portal was used for the study that had previously been established at Vanderbilt as a way for patients to access health data and communicate with their care providers. The system used for the survey was REDCap (Research Electronic Data Capture). (*For more information, go to <http://www.projectredcap.org>.)*

As a prerequisite for participating, all study patients were required to have internet access and be able to take and upload digital images to the

online portal. Patients were asked to upload digital wound images using a smartphone, tablet, digital camera, or computer to the online portal. Surgeons then responded to patients about their symptom reports and wound images. The surgeons and patients did not need to be online at the same time, but they uploaded and accessed information at their own convenience.

“That makes a difference,” Kummerow Broman says. With video or telephone, both people have to be communicating at the same time, she points out.

Images of patient wounds previously have been used more for provider-to-provider interaction, but having patients generate images for patient-to-provider consultation is a relatively new concept, according to Kummerow Broman. “By the end, all of our surgeons saw utility in the concept of online care,” she says.

Despite the optimism from patients and surgeons, the researchers acknowledged certain limitations to the study. “The data revealed potential advantages of online postoperative care, including convenient access for patients, decreased patient travel times, and surgeon efficiency gains; however, these [benefits] must be carefully weighed against potential detriments of using patient-generated data to provide clinical assessment, including concerns about liability, provider work burden, and modified patient-provider relationships,” study

authors noted.

Another potential disadvantage is that patients must have access to a smartphone, tablet, or computer and have the ability to use them, Kummerow Broman says. Also, some providers might be concerned about whether they are obtaining all of the information they need when it is conveyed online, she says.

One patient in the study had a seroma under the wound, Kummerow Broman says. “This patient’s online visit suggested the possibility of a seroma, and it was confirmed on physical exam,” she says. “This supports our conclusion that online visits should be used as a triage tool to determine which patients require in-person care for complete assessment. . . . We think the key is designing our tools for online care and developing appropriate standards for adequate online assessment so that providers can determine when online care is adequate and when in-person care may be needed.”

The study was designed to measure patient acceptance and not to measure safety or quality of care, Kummerow Broman emphasized. “We wanted to first establish whether this method is something that patients wanted, and now that we feel we have done so, we are continuing our research in this area trying to develop ways to measure safety and quality,” she says. (*Access the study abstract at <http://bit.ly/1X95bxI>.*)

Kummerow Broman also

participated in a Veterans Administration (VA) study that allowed surgery patients to have follow-up visits on the phone, in person, or by video inside the VA facility to determine if remote follow-up was feasible and if patients preferred it. All veterans in the study had all three visit types. The researchers found most veterans preferred follow-up visits using one of the remote methods: phone or video. (*Access the research letter at bit.ly/1FfNg0j.*)

Society already is moving in the direction of using technology such as smartphones to bank and shop, Kummerow Broman says. “Consumers are expecting to be able to use these basic tools, like take picture with a smartphone, and integrate that into clinical care,” she says. “They’re expecting we can take their electronic responses. It’s time for the surgical community to develop the quality standards and infrastructure to make this accessible to patients.”

Sherry Wren, MD, FDACS a professor of surgery at Stanford University and a physician with the Palo Alto Veterans Affairs Health Care System in California, has studied using phone follow-up with patients.

“Finding alternative ways to follow patients can be very patient-centric and can be very helpful to them,” Wren says. (*Read an abstract of Wren’s study at <http://bit.ly/1PVxHNB>.*) ■

OIG will focus on these areas in 2016

The *Work Plan* of the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) lists projects to be addressed during the fiscal year. The plan includes projects planned in each

of the Department’s major entities, including the Centers for Medicare and Medicaid Services (CMS).

The *Work Plan* for 2016 includes the following:

- **Ambulatory surgery centers**

(ASCs): Quality oversight.

The OIG will review Medicare’s quality oversight of ASCs. Previous OIG work found problems with Medicare’s oversight system, including finding spans of five or more years

between certification surveys for some ASCs, poor CMS oversight of state survey agencies and ASC accreditors, and little public information on the quality of ASCs.

• **ASCs: Anesthesia services – non-covered services.**

OIG will review Medicare Part B claims for anesthesia services to determine whether they were supported in accordance with Medicare requirements. “Specifically, we will review anesthesia services to

determine whether the beneficiary had a related Medicare service,” the OIG said. Medicare will not pay for items or services that are not “reasonable and necessary.”

• **Hospitals: Medical device credits for replaced medical devices.**

The OIG will determine whether Medicare payments for replaced medical devices were made in accordance with Medicare requirements. Medical devices might require replacement because

of defects, recalls, mechanical complication, etc. Federal regulations require reductions in Medicare payments for the replacement of implanted devices (42 CFR §§ 412.89 and 419.45). Prior OIG reviews have determined that Medicare administrative contractors have made improper payments to hospitals for outpatient and inpatient claims for replaced medical devices. (To access the entire work plan, go to <http://1.usa.gov/1OfHdcz>.) ■

SDS Manager

Help your employees find work meaningful, productive, and stable

By *Stephen W. Earnhart, MS*
CEO
Earnhart & Associates
Austin, TX

An ever-growing issue with all healthcare facilities is employee satisfaction, relations, and interaction with the business.

I always have claimed that every facility I visit is overstaffed. I still believe that statement to be true. When I bring up that belief to the administrator, vice president, or director of human resources/ personnel, each is inclined to agree with me to some degree, but all defend the practice to compensate for staff turnover and the need to have experienced employees on board. That’s a good argument, for sure, but there is a dark side to that argument.

If you need extra employees as “insurance” against turnover, you might have a bigger problem than you think. More and more, I am finding *fewer* licensed personnel jumping the fence to greener grass. It’s as if there is calm acceptance that,

“Well, this job may not be what I had hoped, but it is still a good job with the benefits I need.” Not the strongest endorsement.

However, what if you could engage your staff to make their employment meaningful, productive, and stable? Most professionals have a need to accomplish something every day. It might be as trivial as their cases starting on time or handling a difficult situation in their home life. Most of us feel a need to make a difference, every day!

One way to deal with these individuals is to challenge them. Give them an opportunity to accomplish *something* outside of their normal, sometime mundane, and yes, even boring, job.

Delegate!

Every individual where you work has a role in the success of the facility. There are many moving parts to all, and each part is screaming, “Pay attention to ME!” The days are long gone when the administrator

or department head can handle all the nuances of running a healthcare facility.

Just to name a few, the important, but time-consuming, parts are:

- infection control;
- compliance;
- medical records;
- patient satisfaction;
- state reports;
- federal reports;
- certification;
- materials management;
- physician office liaison;
- in-services.

The list goes on.

Assign each member of your staff, or each can ask to be assigned, to oversee one task. Give them training and resources to excel. Require all to provide a written update of their activities. Depending upon the nature of the task, have them give a brief update at your staff meeting.

Next, periodically rotate them! Keep them challenged with new goals and responsibilities. I promise that you will be amazed at the renewed

energy you will see in your facility. What about the staff member who really doesn't want to participate? If you have decided that by doing these assignments, you are going to build a team within your organization and

not just employ a group of people, then maybe you don't need that staff member any longer. With less staff turnover, you gradually will realize that you no longer need the "insurance" of extra staff. [Earnhart & Associates

is a consulting firm specializing in all aspects of outpatient surgery development and management. Contact Earnhart & Associates in Austin, TX. E-mail: searnhart@earnhart.com. Web: www.earnhart.com.] ■

Price increases compared for ASCs, hospitals

The proliferation of ambulatory surgery centers (ASCs) has not led to a decrease in hospital outpatient surgery department prices, according to a new study funded by the Agency for Healthcare Research and Quality (AHRQ).

The study examined ASC growth and revenues using a large national claims database that contains information on actual prices paid. The author found that for six common outpatient surgical procedures, prices paid to ASCs remained stable during 2007–2012, while prices paid to hospital outpatient surgery departments (HOPSDs) for the same procedures

increased sharply. The six procedures were:

- cataract surgery with intraocular lenses;
- colonoscopy;
- knee arthroscopy with debridement;
- knee arthroscopy with meniscectomy;
- post-cataract surgery;
- upper gastrointestinal endoscopy.

The study also found that private insurers paid ASCs more than Medicare paid ASCs for the same procedures. Medicare pays ASCs a legislated percentage of what it pays HOPSDs for the same services, but there is a considerable discrepancy

between this ratio and the ratio of payments by private insurers across provider types and procedures, AHRQ said.

"These findings question the use of a single ratio for ASC payments to HOPSD payments and suggest that ASCs and HOPSDs do not currently compete on price," according to AHRQ. "The findings support the argument for increased price transparency and narrow or tiered insurance network designs that reward high-value providers."

The study was published in the October issue of the journal *Health Affairs*. To access the abstract, go to <http://1.usa.gov/1PAyeFQ>. ■

Recall of automated scope reprocessors ordered

(We tweeted about this recall on Nov. 16. To keep up with breaking news as it happens, join more than 1,000 individuals who keep up with our breaking news on Twitter @SameDaySurgery.)

The Food and Drug Administration (FDA) has ordered Custom Ultrasonics to

recall all of its automated endoscope reprocessors (AERs) from healthcare facilities due to what the FDA says is "the firm's continued violations of federal law."

"The identified violations could result in an increased risk of infection transmission," according to the FDA.

The agency recommends that healthcare facilities using Custom

Ultrasonics AERs transition away from their use to alternative methods to reprocess flexible endoscopes as soon as possible. Custom Ultrasonics was required to provide a written recall proposal to the FDA within seven business days of the announcement.

Facilities using the AER should report any infections that might be related to the recalled reprocessors to the company and the FDA MedWatch program. (Access MedWatch at <http://1.usa.gov/1ghByT7>. For the announcement, go to <http://1.usa.gov/1SfhLEW>. For background, see "Custom Ultrasonics resumes manufacturing," SDS, September 2007.) ■

COMING IN FUTURE MONTHS

- Be survey-ready with these tips
- Response protocol for medication shortage
- Advice on contracting with ACOs
- Research on using texting to notify family

Elective surgery risk factor: post-hospital syndrome

A condition known as post-hospital syndrome (PHS) is a significant risk factor for patients who undergo elective outpatient surgery, according to a study from Loyola in Maywood, IL.

PHS is defined as having been hospitalized during the previous 90 days. The first-of-its-kind study found that among patients with PHS, 7.6% had to be readmitted to the hospital within 30 days of undergoing elective outpatient hernia surgery. By comparison, only 1.6% of non-PHS patients had to be readmitted following hernia surgery.

Also, 8.3% of PHS patients were admitted to the emergency department within 30 days of hernia surgery, compared with 4.3% of non-PHS hernia surgery patients.

“Surgeons must consider all recent inpatient admissions when risk-stratifying patients for ambulatory, elective surgery,” the

researchers concluded.

PHS was first identified in an article in *The New England Journal of Medicine* by Harlan Krumholz, MD, of Yale University School of Medicine. He is the Harold H. Hines, Jr. professor of medicine (cardiology) and professor of investigative medicine and of public health (health policy) in the Institute for Social and Policy Studies. Krumholz defined PHS as “an acquired condition of vulnerability.”

During hospitalization, patients often are sleep-deprived and in pain or discomfort. They receive medications that can alter their mental and physical abilities. They become deconditioned, with loss of muscle mass, reduced cardiac output, etc. Also, patients might not obtain sufficient nutrition if, for example, they are on a ventilator or have to fast before surgery or tests. These problems can impair their recovery

and make them more prone to disease and mental errors, Krumholz wrote.

The Loyola researchers analyzed records of 57,988 California patients who underwent hernia repair in 2011, including 1,332 patients who had PHS. Data sets came from the Agency for Healthcare Research and Quality.

Among the PHS patients, the most common reason for their previous hospitalization was gastrointestinal problems (25.1%), followed by cardiovascular problems (12.3%), hip fractures and other injuries (8.2%), and pregnancy-related complications (7.1%). The average length of time between their previous hospitalization and their elective hernia surgery was 48.7 days.

Loyola researchers are doing a follow-up study to determine what measures healthcare providers could take to reduce the negative impact of PHS. ■

Supplement to anesthesia consensus statement

SmartTots has issued a supplement to its recent revised consensus statement on anesthesia and young children in response to a clinical trial’s preliminary outcome that found no difference in the developing brain between 2-year-olds who had undergone general anesthesia and those who had received regional anesthesia as infants.

In October, SmartTots, a partnership of the International Anesthesia Research Society and the FDA, released a revised consensus statement that cited growing evidence of potential risk of general anesthesia and sedatives for children younger than age 4. The statement urged continued research to determine

whether these medications are safe and to seek alternative medications.

Soon after, preliminary results of the first prospective clinical trial showed no difference in cognitive function at age 2 between children who had been given general anesthesia for less than one hour as infants and those given regional

anesthesia during hernia repair. The international trial is ongoing. (*To see the supplement to the revised statement, go to <http://smarttots.org/consensus-statement-supplement>. For more information, see “Updated consensus statement: Research on anesthesia for babies and children,” Same-Day Surgery, December 2015.*) ■

CNE/CME OBJECTIVES

After reading *Same-Day Surgery*, the participant will be able to:

- identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care;
- identify how current issues in ambulatory surgery affect clinical and management practices;
- incorporate practical solutions to ambulatory surgery issues and concerns into daily practices.



SAME-DAY SURGERY

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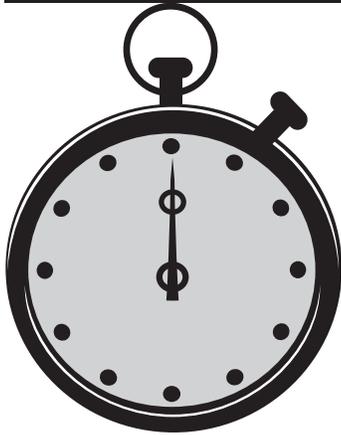
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CNE/CME QUESTIONS

1. According to Colleen T. Davies, JD, Partner, with Reed Smith, in regard to tort liability, who would be considered the manufacturer of a device 3D printed in a hospital?
 - A. The 3D printer company
 - B. The creator of the software used to make the design
 - C. The hospital
 - D. It is, as of now, an unresolved issue.
2. What does his hospital do with the data from the surgical black box system developed by Teodor Grantcharov, MD, PhD, FACS, professor of surgery at the University of Toronto?
 - A. The video and audio files are destroyed after 48 hours, and remaining data are de-identified and anonymized after 30 days.
 - B. All data are destroyed after 48 hours.
 - C. All data are destroyed after 30 days.
 - D. The video and audio files are maintained indefinitely, but only the other data become part of the patient record.
3. In a pilot study from Vanderbilt University Medical Center, researchers tracked 50 patients who completed both online and in-person visits after their operations. What percent of this group said that online visits were acceptable as the only form of follow-up care?
 - A. 16%
 - B. 29%
 - C. 48%
 - D. 76%
4. According to a study from Loyola, a condition known as post-hospital syndrome is a significant risk factor for patients who undergo elective outpatient surgery. Post-hospital syndrome is defined as having been hospitalized when?
 - A. In the previous 30 days
 - B. In the previous 60 days
 - C. In the previous 90 days
 - D. In the previous year



SAME-DAY SURGERY

With staff shortages projected, you'll need to stand out among surgery providers

Winners of award for 'Best Places to Work' share recruitment and retention advice

Do you want to hear the good news or the bad news first? The good news is that the nursing shortage is not as bad as predicted several years ago. The bad news is that there still is a shortage projected.

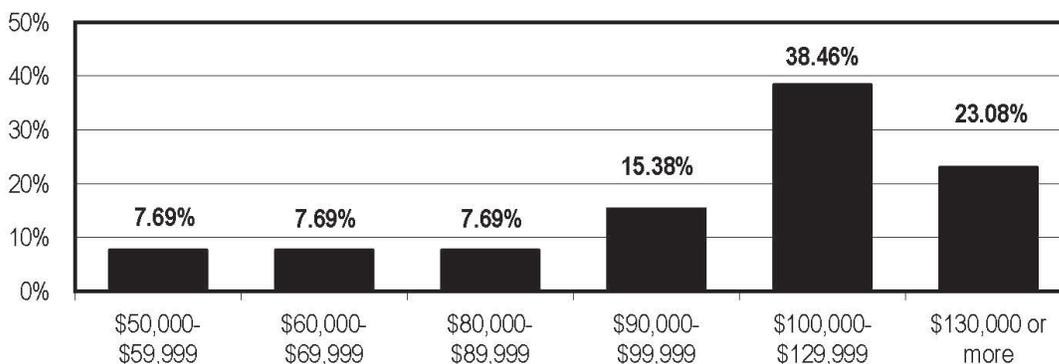
If nurses continue to enter the workforce at the same rate as now, our country will have about 4% fewer RNs than it needs by 2025, according to a study published in the October issue of *Medical Care*.

"It's important to keep in mind that this doesn't get us out of the woods; the woods just are not as dark and scary

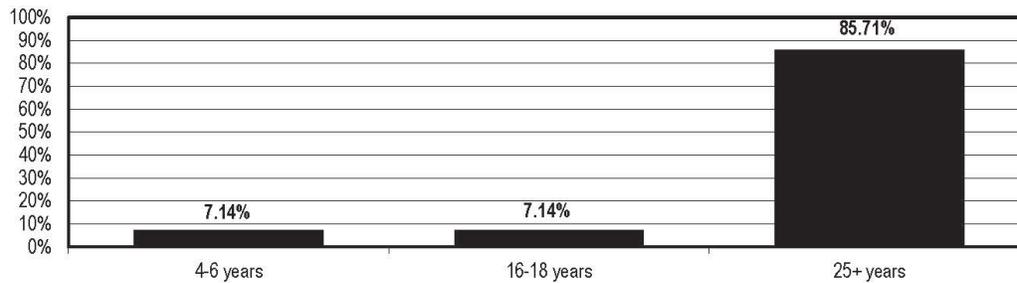
as they appeared," said **Peter Buerhaus**, PhD, RN, FAAN, coauthor of the nursing shortage study and Montana State University nursing economist. "We still project the nation will have a shortage of around 130,000 nurses by 2025, which is by no means a small number, but not the overwhelming shortage that we had once anticipated."

A shortage also is predicted for physicians. *The Washington Post* reported that by 2025, the United States will need 90,000 more physicians. (To read more, go to <http://wapo.st/1LEyKGy>.)

What is your annual gross income from your primary healthcare position?



How long have you worked in healthcare?



To be able to recruit and retain the best employees and surgeons, you must stand out. *Same-Day Surgery* interviewed two facilities recently named “Best Places to Work in Healthcare in 2015” by *Modern Healthcare*. Consider their suggestions:

- **Establish a positive culture, and find people who fit in it.**

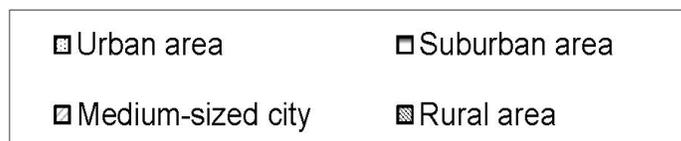
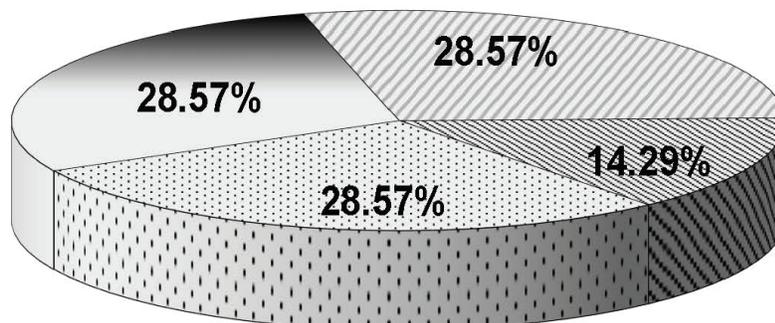
At Lafayette (LA) Surgical Specialty Hospital, the culture was set from the beginning by the physician owners, says **Stephanie Talbot**, RN, MS, OR manager. “When

the physicians originally opened, they wanted high quality patient care,” Talbot says. “They also wanted a place that physicians would be proud of and a place patients wanted to come to, and where the staff would be proud of working there.”

The 20-bed hospital, which has 8,000 annual cases, is a four-time winner of the Women’s Choice Award, given by WomenCertified, for being voted one of “America’s Best Hospitals for Patient Experience” by women.

Laser Spine Institute, an organization with seven

Where is your facility located?



regional surgery centers with headquarters in Tampa, FL, has been named a top employer by the *Tampa Bay Times*, *Tampa Bay Business Journal*, *Philly.com*, and *okc.BIZ*, in addition to *Modern Healthcare*, and has been named a Most Admired Company by *BestCompaniesAZ*. The company has more than 1,100 corporate and healthcare professionals.

Its recruiters are very particular, says **Diane DiRocco**, senior director of human resources. While other healthcare organizations hire “en masse,” recruiters at Laser Spine Institute take more time. “We look for someone who is a good culture fit and has a good skill set,” DiRocco says.

The company, which has treated more than 50,000 patients, has a culture that focuses on patient satisfaction. “We encourage them to develop a relationship with the patients,” DiRocco says.

Recruiters examine applicants to see how much they focus on patient care. Other important factors of their company culture are integrity, commitment, and fun, DiRocco says. The fun part is “not true of a lot of healthcare organizations,” she says. “A lot of the time, it’s about the numbers.”

The recruiters also look for applicants who are able to get along with others. Hiring managers are included in the recruitment process, DiRocco says.

Their efforts are paying off. While the Department of Labor reports that the healthcare field has a turnover rate of about 7%, DiRocco reports that her turnover rate is no higher than 3%.

• **Encourage positive communication.**

Encourage a positive culture by thanking employees when they do a good job, and be specific, Talbot says. For example, say, “Thank you for staying late today to help do that case. It’s really appreciated,” she says.

Every hospital employee makes an effort to talk positively to coworkers and surgeons, Talbot says. For example, occasionally a surgeon will have a new person in the OR, Talbot says.

“I say to him or her, ‘You’ll see this person in your room. You’ll like her. She’s new to our facility, but she came from another facility, where she worked with Dr. So-and-So. She’s done cases like this before,’” she says.

Such communication contributes to a team atmosphere, she says.

• **Offer a good benefits package.**

Laser Spine Institute offers the usual health benefits, but it also offers tuition reimbursement, DiRocco says.

According to a recent salary survey by the Ambulatory Surgery Center Association (ASCA), the benefit showing the biggest increase among respondents is tuition support. ASCA reports that 52% of respondents offer some form of tuition support, which is up from 28% in 2012.

That tuition support can be used to obtain the certified ASC (CASC) credential. The ASCA survey indicated that 14% of respondents work for surgery providers who require its administrators to hold that credential. Also, the median salary for ASC administrators who work for facilities that require the certification is 19% higher than for those who work in an ASC where it isn’t required. (*For more on the ASCA salary survey results, go to www.ascassociation.org/salarysurvey.*)

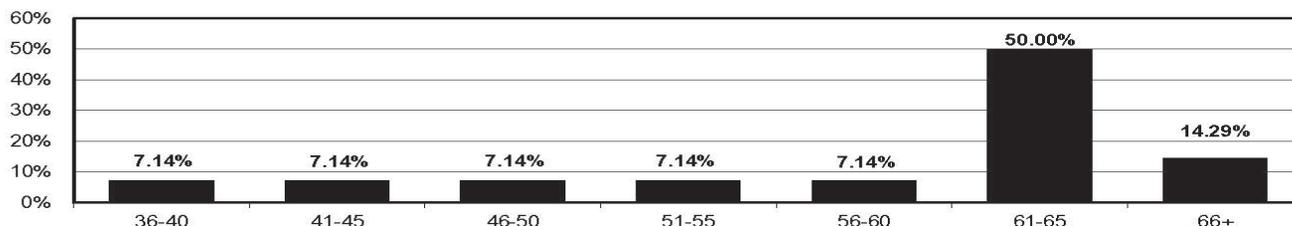
Laser Spine Institute also offers a range of employee discounts including child care initiatives, tickets to local theme parks, clothing stores, and cell phones. “All it takes is for an employee to call and ask, ‘Why don’t we have this?’” DiRocco says. “We jump on it and add it.”

The Institute also offers ancillary benefits including hospital indemnity, short-term disability, and pet insurance. The company also picks up 100% of the tab for telemedicine services provided by Healthiest You. (*For more information, go to <http://www.healthiestyou.com/#/>.*)

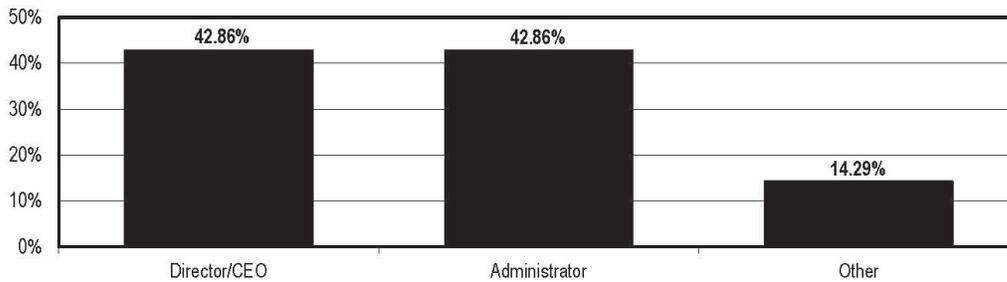
Offering good benefits is one factor that has helped attract individuals who are focused on the patients, DiRocco says. The result has been a 97% patient satisfaction rate.

“That’s what it’s all about: Shooting for the best outcomes possible, and taking care of patients,” DiRocco says. Such efforts will impact your recruitment and retention and result in a stronger healthcare workforce, she says. “They went into this field to take care of patients,” Di Rocco says. “If you give them a platform to do that, they will stay and be happy.” ■

What is your age?



What is your title?



Survey Snapshot

In responding to the 2015 *Same-Day Surgery Salary Survey*, more than one-third (38.46%) of respondents saw pay increases of 1% to 3%.

More than half (53.85%) saw no change to their salary. (See *“In the past year, how has your salary changed?” graphic in this issue.*)

About 62% of respondents make \$100,000 or more. (See *“What is your salary level” graphic.*) One reason for the salary level might be the number of years that most respondents have worked in healthcare. More than 85% of respondents have worked in healthcare for 25 years or more. (See *“How long have you worked in healthcare” graphic in this issue.*) While half (50%) of respondents report having a BSN degree, more than 28% report having an MSN or other

master’s degree. (See *“What is your highest academic degree?” graphic.*)

More than one in five (21.43%) saw an increase in staffing last year.

The location of respondents was diverse, with the numbers evenly divided among the following:

- urban areas;
- suburban areas;
- medium-size cities (28.57% each).

A slightly lower percentage responded from rural areas (14.29%). (See *the graphic enclosed in this issue, “Where is your facility located?”*)

The *Same-Day Surgery Salary Survey* was mailed in September 2015. ■

What is your highest academic degree?

