Top 10 Hospital C-Suite Watch List

2014

ECRI Institute

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2014 Top 10 Hospital C-Suite Watch List

Introduction

ECRI Institute's 2014 Top 10 Hospital C-Suite Watch List is not a list of "must-haves." Rather, it's a list of "must-think-carefully-about" technologies and health systems issues. We used our Institute's intellectual capital across our 450 interdisciplinary staff to identify new and emerging technologies and health systems issues that have generated – or we believe will be generating – much hype in the next 12 to18 months. Our mission is to help decision makers understand the hype versus the evidence and the important issues to consider when deciding whether to be early adopters, middle adopters, or no-adopters.

Our list may differ from others' top 10 technology lists. That's fine with us. We have no vested interest in the technologies and issues we discuss other than to fulfill our mission to improve patient safety and cost-effectiveness of healthcare. Our decades of experience as an independent evaluator of technologies and our participation in helping solve health systems issues affecting patient safety and cost-effective care drive us to look at the horizon with an eye toward helping the healthcare community understand what to think about before adopting and implementing the next "new" intervention or care strategy.

To compile this list, we looked across the continuum of care at new and upcoming developments in major clinical service lines, such as cancer, cardiovascular, neurosciences, and orthopedics. We also looked at cross-cutting developments that could affect patient care in multiple disciplines. Some of the technologies we chose are commercially available but not yet ready or appropriate, in our opinion, for diffusion beyond the clinical trial setting because important unanswered questions remain about their clinical benefit. Others are not yet available but are on the near horizon and could have a big impact on some aspect of patient care. We also address two health systems topics: geriatric emergency services and some big data implications of electronic health records.

And while cost has been an issue, few want to talk openly and frankly about it. And yet, it is the issue most on people's minds, whether they're a healthcare provider or a consumer. So we offer some straight talk about cost factors with these new technologies.

As always, we welcome discourse and other perspectives. Please feel free to contact ECRI Institute's experts to discuss your unique clinical and technology needs by phone at (610) 825-6000, ext. 5655, or e-mail consultants@ecri.org.

1 Down Under: Will Lower Costs and Higher Patient Satisfaction Offset Brewing Turf Wars over Computer-assisted Sedation Systems?

Get ready for the big waves being generated by the new Sedasys® computer-assisted personalized sedation system (Ethicon Endo-Surgery, Inc., Somerville, NJ). If health systems adopt it, the system could theoretically be used during millions of endoscopic gastrointestinal (GI) procedures (esophagogastroduodenoscopy and colonoscopy) performed on adults and reduce use of nurse anesthetists and anesthesiologists (and thereby lower costs).

The American Society of Anesthesiologists (ASA) isn't happy about it. As soon as the device approval was announced, ASA outlined a three-pronged strategy to deal with the situation and the U.S. Food and Drug Administration (FDA).[1] Read on to understand its patient safety implications and the issues you'll need to contend with as you decide whether and when to adopt this potentially big cost saver.

WHAT TO DO

- Include the affected clinical and patient-safety stakeholders in your health system in the decision-making process about acquisition and implementation plans. Training is a critical part of the plan. Ethicon Endo-Surgery announced plans to diffuse the technology in a carefully controlled, limited fashion in 2014 and is using nurse anesthetists to train clinical personnel who expect to use the system.
- Carefully adhere to the requirement for an anesthesiologist to be immediately on-call for emergencies that could arise during these procedures.
- Ensure that medical staff leaders work with your risk management team to verify the facility's current bylaws are being adhered to regarding safety precautions for these procedures.
- Make a plan to collect and closely monitor outcomes data for all procedures performed using the system to ensure that risks to patients are not increasing from system use.

Sedation Safety and Endoscopic GI Procedure Turf Issues

During endoscopic GI procedures, patients undergo light to moderate sedation, which an anesthesiologist or nurse anesthetist has traditionally provided—not gastroenterologists or their nurses untrained in anesthesia administration. In most cases in the United States, a benzodiazepine (e.g., midazolam, diazepam) and an opioid analgesic (e.g., fentanyl, meperidine) have been used for patients undergoing these endoscopic procedures.[2] However, propofol use is growing, especially for colonoscopy—at least 25% of procedures in recent estimates.[3] Until the recent Sedasys approval, propofol administration by anyone other than an anesthesiologist or nurse anesthetist had been contraindicated by propofol's labeling. Furthermore, ASA and the American Association of Nurse Anesthetists have historically recommended against propofol administration by any medical personnel not trained to administer general anesthesia.[3]

Propofol's rapid onset and rapid termination of the sedative effect (compared with benzodiazepine and opioid combinations) usually lead to faster patient recovery from sedation.[2] For GI procedures, its use for light to moderate sedation can increase patient throughput. However, propofol also has higher potency than benzodiazepines/opioids and, therefore, carries an increased potential for the unintended induction of deep sedation (general anesthesia) and/or hemodynamic and respiratory depression.[4] Also, no drugs are available to reverse propofol's effects, but drugs are available to reverse the effects of benzodiazepines and opiates. These safety issues are why the anesthesiology community is raising objections. But for GI centers, procedure costs could be significantly lowered by not needing an anesthesiologist or nurse anesthetist present for each patient and procedure.

System and Safety Concerns

FDA approved the Sedasys system for marketing in 2013 after a long, circuitous route through the premarket approval pathway. The company planned a limited initial diffusion to start in early 2014. According to product labeling, the system is intended to allow nonanesthesiologist clinicians to administer propofol, so gastroenterologists and their nurses can use it during colonoscopy and esophagogastroduodenoscopy procedures. The approved labeling requires that an anesthesiologist be immediately available should the need arise, but an anesthesiologist will not be required to be present

in the room during a procedure. During propofol administration, the system is intended to continually monitor the patient using the following built-in monitoring capabilities:[2]

- Pulse oximetry
- Noninvasive blood pressure
- Capnometry
- Electrocardiography
- Assessment of patient responsiveness

By continuously adjusting the rates of propofol infusion and oxygen flow rates in response to patient vital signs and responsiveness, the Sedasys system purportedly can avoid administering too much or too little sedation. In particular, the system is designed to interrupt propofol infusion if the patient's oxygen saturation level or respiration rate falls below certain levels. Upon return of the patient to normal ventilation, the system is designed to resume propofol administration at a lowered dose or, in the case of more severe deficits in ventilatory function, prompt the clinician to decide whether to resume propofol administration. In addition to monitoring the automated administration of propofol, the clinician may transiently increase sedation in response to patient discomfort. After infusion of such a transient increase, the system is designed to prevent administration of a second such bolus for 90 seconds.[5]

FDA's required safety stipulations include use only for mild to moderate propofol sedation in patients age 18 years or older and use only for colonoscopy and esophagogastroduodenoscopy procedures. FDA also recommended that patients who fall outside ASA's physical status I to II range receive sedation only with an anesthesiologist present. When an anesthesiologist is not present, FDA requires that healthcare facilities have one on-call or immediately available for consultation. Also, approval is required from a clinician for sedation levels before infusion begins and before it resumes after an automatic system shutdown, which occurs if a patient's monitored levels fall below a specific threshold. Clinicians also have the option to manually override the system and reduce/increase sedation levels depending on patient discomfort.

Even with these stipulations, concerns remain about procedure risks. Among ASA's concerns are that because of the system's ability to deliver supplemental oxygen, clinicians untrained in anesthesia may not recognize airway obstruction due to the delay in oxygen desaturation. This is seen as especially challenging during esophagogastroduodenoscopy procedures because the endoscope blocks much of a patient's throat and mouth. Sparked by these concerns, ASA stated that it will undertake studies to assess the risk of these computer-assisted sedation systems, but as of late 2013, no new trials have been registered with the National Clinical Trials database (ClinicalTrials.gov).

Photo courtesy of Ethicon Endo-Surgury

The evidence base thus far consists of 1 manufacturer-sponsored multicenter, randomized, comparative trial of 1,000 patients undergoing sedation during routine colonoscopy or esophagogastroduodenoscopy.[5,6] Endoscopist/nurse teams at four ambulatory surgery centers, three endoscopy centers, and one academic center in the United States participated. The reported results were "patients were predominately minimally to moderately sedated in both groups," and Sedasys patients were "significantly more satisfied" than patients receiving the standard sedation method. Study authors also reported greater clinician satisfaction with use of Sedasys than standard sedation methods and faster patient recovery. However, in this study, a higher percentage of colonoscopy patients receiving Sedasys-administered propofol sedation experienced deep sedation/general anesthesia (3%) than patients receiving standard benzodiazepine/opiate sedation (1%). Deep sedation/general anesthesia may elevate the risk of cardiopulmonary complications or interrupted breathing; however, the Sedasys clinical trial reported no such incidents.

The Cost Equation

About 8,200 physician practices performed about 14.2 million colonoscopies in the United States in 2002, according to the latest available figures from the U.S. Centers for Disease Control and Prevention (CDC). This estimate includes all types of providers performing colonoscopy. With the aging population, these providers indicated they could perform an additional 8.2 million colonoscopies per year, if needed. The average estimated cost of colonoscopy is $3,000 per procedure, although in many European countries the cost estimates are around $400 per procedure.

A study funded by Ethicon Endo-Surgery estimated that the U.S. healthcare system has the potential to save approximately $160 million by 2015 just by utilizing these systems on 80% of colonoscopy procedures. In addition, cost savings might likewise be achieved in esophagogastroduodenoscopy procedures, which are often performed in patients presenting with abdominal pain, black or tarry stools, chronic liver disease/cirrhosis, Crohn's disease, feelings of early satiety, gastroparesis, heartburn, narrowing of the esophagus/tumors of the esophagus, difficulty swallowing, unexplained anemia, unexplained weight loss, or who are vomiting blood or continuously vomiting.

Currently, reimbursement for sedation during endoscopy procedures is typically handled in one of two ways. If the endoscopist performing the procedure administers the sedative (typically a benzodiazepine), reimbursement is bundled into payment for the endoscopy procedure itself. However, if an anesthesiologist gives the sedative (typically propofol), the anesthesiologist is reimbursed under a second procedure code, termed "monitored anesthesia care." This is billed separately from the endoscopy procedure and cannot be billed by the clinician performing the endoscopy. While third-party payers typically reimburse endoscopy procedures and the associated endoscopist-delivered sedation, several third-party payers have begun to limit which patients can receive reimbursement for a procedure with monitored anesthesia care. At this time, payer policies have not yet been developed specific to Sedasys, so it is unclear whether system use would be reimbursed separately or would need to be absorbed by the reimbursement rate for endoscopy procedures.

Related ECRI Institute Publication

- **Health Technology Forecast:** Sedasys Computer-assisted Personalized Sedation System, June 2013

2 The Pressure Is On: Is Catheter-based Renal Denervation for Treatment-resistant Hypertension a New Cash Cow or More Fuel for the Fire?

Catheter-based renal denervation is an emerging treatment for a pervasive problem affecting millions of Americans: uncontrolled or treatment-resistant hypertension, which is associated with high morbidity and mortality. This technology is expected to become available in the U.S. market by mid-2015, and Medicare is already reviewing it to prepare a coverage determination by the time it gains FDA approval. Plan now, because it will herald a paradigm shift in care from medical therapy to a hospital-based minimally invasive procedure. The technology has been on the market in Europe for several years and is also under development for other prevalent conditions, so it may have long-term staying power. If you plan to offer this new technology and have robust catheterization labs in your health system, you probably won't need major infrastructure changes—though you might need to plan for adding capacity. You will also want to clarify which physician specialties you let perform the procedure in your facilities to avoid potential internal strife and competition among clinical specialists. Read on to learn what your health system will need to consider to prepare for this technology.

American Heart Association (AHA) defines uncontrolled hypertension as:

- Blood pressure (BP) levels that are not maintained below 140/90 mm Hg through use of three medications that have pharmacologically complementary mechanisms, one of which is an appropriately dosed diuretic; all three drugs have been given at maximum tolerated doses

WHAT TO DO

- Start now to define the numbers of patients with treatment-resistant hypertension in your patient populations, and form consensus on criteria for patient eligibility for renal denervation.
- Identify which clinical specialty areas in your health system are treating these patients now.
- Convene a stakeholder meeting with these clinical specialists to discuss the technology and adoption plans; update your strategic plan for cardiovascular services to ensure smooth adoption. Considerations include appropriate infrastructure planning and training and credentialing of the specialty groups that will be allowed to perform the procedure. Discuss the data about suboptimal medical therapy, procedure safety/risks, and criteria that payers will likely expect before they authorize approval for the procedure.
- Keep in mind:
  - Another new technology in development for the same condition may compete with this procedure in a few years. It's called baroreflex stimulation, which involves permanent implantation of an electronic medical device for treatment-resistant hypertension.
  - Indications for renal denervation technology may expand in a few years to several other conditions now under study (i.e., sleep apnea, heart failure, diabetes), if clinical researchers gain sufficient understanding of the role the sympathetic nervous system plays in these diseases.

Enter Minimally Invasive Renal Denervation

In 2013, AHA reported that about 77.9 million Americans have hypertension—about 1 in 3 Americans age 20 years or older. AHA also states that hypertension is inadequately controlled in about 48% of those with the condition. AHA stated that 61,762 deaths were attributed to hypertension in 2009.[7]

Suboptimal medical therapy may be the reason for about half of apparent treatment-resistant hypertension cases, according to a recent large community practice study (n = 468,877).[8] The study found that only about one in seven patients with uncontrolled hypertension and only one in two with apparent treatment-resistant hypertension are prescribed ≥3 BP medications in optimal regimens. So there appears to be significant room for improvement for medical therapy. Yet, even if optimal therapy could be achieved for those affected, as many as 20 million Americans could still experience treatment-resistant hypertension.

The underlying theory for this new minimally invasive technology is that the sympathetic nervous system contributes

to increases in BP, and certain nerves (afferent renal sensory nerves) carry signals from the kidneys to the central nervous system. These nerves are considered additional contributors to hypertension. For decades, the idea that surgery could be used to disrupt this signaling pathway has been explored as an approach to treatment-resistant hypertension. Early approaches involved open surgery; while surgery reduced BP in some patients, undesirable rates of perioperative and long-term complications, including bowel and bladder injury, erectile dysfunction, and postural hypotension, occurred.

The Symplicity™ Renal Denervation System (Medtronic, Inc., Minneapolis, MN) is the first minimally invasive catheter-based renal denervation system expected to gain FDA approval for the U.S. market. The system has been available for several years in Europe and Australia. The system uses radiofrequency (RF) energy delivered through a catheter to the patient percutaneously to selectively ablate the desired renal artery nerves. The system is intended to avoid the serious side effects and lessen risks associated with open surgery. It comprises a generator that automatically controls the RF energy delivery and a catheter that the clinician uses to apply RF energy to the renal artery.[9-11] Thus, adopting the system will involve a capital purchase and purchase of disposables used for each procedure. Other manufacturers—St. Jude Medical (St. Paul, MN) and Boston Scientific (Boston, MA)—also have renal denervation systems in earlier phases of development for the U.S. market.

The Evidence Story

In May 2013, Medtronic announced it had completed enrollment in its pivotal trial, Symplicity HTN-3, to support its FDA marketing application. Two-year data on 40 of 106 enrolled patients from Symplicity HTN-2, the first randomized, controlled, crossover trial on renal denervation were reported in March 2013, and the safety profile looks promising so far.[12] The average drop in BP at two years was statistically significant, although its degree of clinical significance is less clear. BP reductions were not low enough, on average, to obviate the need for all medical therapy. Also, BP was measured in the physician's offices rather than outside the office, so the "white-coat" influence (elevated BP readings in physician offices) may have affected results. No device-related serious adverse events, no late vascular complications, and no significant declines in kidney function occurred compared with patients' baseline values. Longer-term data are available outside the United States. Six-month safety results from 617 patients in the Global Symplicity Registry (which includes patients outside the United States) were reported in May 2013.[13] No major treatment-related complications or serious adverse events were reported. However, one problem clinicians will face is predicting which patients will benefit, because reductions were achieved by about 84% of patients, but uncontrolled hypertension persisted for others. The reasons why aren't clear but might include physician learning curve and technique. Given the emphasis on tying patient satisfaction to reimbursement, this could be an issue for those who don't achieve expected results.

The Cost Equation

A health economics cost-effectiveness model published in *Journal of the American College of Cardiology* in 2012 reported that catheter-based renal denervation appeared to be cost-effective over a wide range of assumptions and may lower cardiovascular morbidity and mortality in patients with treatment-resistant hypertension.[14] Medtronic has not yet announced costs for its system, but the FDA-Centers for Medicare & Medicaid Services (CMS) Parallel Review Program is evaluating the system so that CMS can begin a national coverage determination process while FDA conducts its safety and efficacy review. So, the reimbursement picture holds promise and could propel diffusion relatively quickly. However, payers will likely create coverage policies

Photo courtesy of Medtronic

with conditions requiring rigorous attempts at optimal medical therapy in light of recent data from Egan et al. (2013), indicating wide prevalence of suboptimal medical therapy.[8] If catheter-based renal denervation yields long-term cost-savings by decreasing hospitalizations and reduces need for hypertensive medications, it may become a preferred option, and payers might loosen requirements for coverage.

Costs for new infrastructure may not be necessary for hospitals with one or more cardiac catheterization laboratories, though it might attract enough patients to require adding catheterization laboratories. But first hospitals will need to consider which clinical specialists they will allow to perform the procedure. Clinicians who treat hypertension medically, cardiac interventionalists, and interventional radiologists may all want to offer the procedure. Hospitals can also expect to see some patient care shift from office-based medical management to management that includes hospital-based, short-stay procedures. Whichever physicians perform the procedure, hospitals will want to closely monitor catheterization lab and interventional suite utilization rates to ensure they maintain capacity for these procedures. The procedure involves conscious sedation of the patient and typically takes about 40 minutes to complete. The manufacturer states that patients typically recover and return to normal activities quickly.

Related ECRI Institute Publication

- **Health Technology Forecast:** Percutaneous Renal Denervation for Treating Refractory Hypertension, March 2013

3 Emergency Departments Just for Elderly Patients: Fad or Wise Planning?

We've all heard that the proportion of the U.S. population that is aged 65 years or older is increasing as baby boomers age. CDC estimates that between 2010 and 2050, the number of adults aged 65 years or older will double, reaching 89 million.[15] Older adults average 45.4 emergency department (ED) visits per 100 individuals per year compared with 38 ED visits per 100 individuals per year for younger patients. Overall, older adults account for 12% to 25% of all ED attendances worldwide.[16] This patient population has unique needs not addressed by general ED services—needs that if not addressed often lead to complications, longer stays, repeat ED visits, and readmissions for the same conditions within short time frames.

Older adults use ED services more than younger patients because of the increasing prevalence of chronic and degenerative diseases that require care and ongoing management. Atypical presentations, altered laboratory values, comorbidities, multiple medication use, communication problems, and altered mental status contribute to longer ED visits for older adults.[16] The ED's physical layout may pose a risk for falls for elderly patients, narrow and thin mattresses increase the risk of developing pressure ulcers, florescent lights and a lack of windows foster disorientation in cognitively impaired older adults, and noise pollution from alarms, staff, and patients contributes to communication difficulties in elderly patients who may be more likely to have hearing impairment than younger patients.[17] After an ED visit, seniors are at greater risk for medical complications, functional decline, and poor health-related outcomes than they were before the ED visit.[17] ED services that are designed to cater specifically to the geriatric population have been proposed to help address these challenges.[17]

WHAT TO DO

- If your health system serves a significant number of patients age 65 years or older, incorporate strategic planning to create geriatric ED processes, staffing, and infrastructure for optimally managing seniors using your ED services.
- Get buy-in from hospital leadership, and include all stakeholders.
- Not all geriatric patients are the same: identify community dwellers, assisted-living, and nursing home patient populations to determine your target populations.
- Figure out optimal location and whether it should be carved out of the general ED space by repurposing an area or be built as a new separate space; whatever the choice, a quiet environment well separated from the general ED is best.
- Determine whether structural modifications are financially and logistically feasible.
- Identify geriatric ED clinical champions—a physician and nurse, at least—to run the program.
- Plan for staff training in geriatric ED care and referral to geriatric ED employees.
- Include prescription management and counseling.
- Plan for geriatric-focused discharge care planning and patient follow-up.

Process, Staff, and Infrastructure Approaches

Health systems and facilities leading the way in addressing senior-specific ED issues have identified two types of approaches that are used singly or, ideally, in combination to improve geriatric patient outcomes and reduce intensive care unit (ICU) stays and readmissions: 1) infrastructure/structural redesign of EDs, and 2) new protocols/care processes for ED services to geriatric patients, including training ED staff in geriatric patient care.

A model described by clinical researchers at the Brookdale Department of Geriatrics and Adult Development at Mount Sinai School of Medicine (New York, NY) provides an example: the Geriatric Emergency Department Interventions (GEDIs) model.[17] Structural GEDI modifications intended to make an ED more "senior friendly" include reclining chairs or padded/lined stretchers to improve patient comfort and reduce pressure ulcers; large-face clocks, calendars, and boards with the names of hospital and clinical staff to reduce risk for patient delirium; nonskid floor surfaces, handrails, aisle lighting, and bedside commodes to reduce patient risk for falls and injury; and visual and lighting aids that may also reduce risk

for delirium. Protocol interventions include training staff to screen for cognitive impairment and delirium as part of regular clinical practice to identify early those patients at risk for these conditions and to assist in disposition, treatment, or discharge planning. Protocols are implemented to screen for risk of adverse health outcomes, return visits, and hospitalization. Care processes strive to minimize use of urethral catheters and other "tethering" devices that reduce patient mobility and increase risk for nosocomial infection and delirium. Protocols also create a staff position for a nursing discharge coordinator to improve continuity of care, decrease risk of return visits, and increase patient satisfaction.

The first "Seniors Emergency Center" implemented in the United States (Holy Cross Hospital, Silver Spring, MD) illustrates how these interventions may be put into practice. The hospital created a separate, enclosed area of the ED for seniors.[18] Structural and environmental modifications included the use of special lighting, soft colors, noise-abatement features, handrails, flooring that is less likely to cause falls, thicker bed mattresses, telephones with larger buttons, and speakers in the bed pillows.[18] The clinical care team that works in the center includes (in addition to physicians) a geriatric nurse practitioner, registered nurses trained in geriatrics, and a geriatric social worker. The hospital states that unit staff receive training in both geriatrics and communication with elderly adults.[19]

Senior-specific EDs are intended to be staffed by clinicians, nurses, assistants, social workers, and other healthcare professionals who specialize in geriatric care. Hospitals that implement these EDs typically need to train staff on the use and purpose of the structural and protocol-based modifications. Ongoing education that focuses on geriatric medicine and strategies for communicating with senior patients could be incorporated. Mount Sinai Hospital, for example, has implemented a training program for volunteers who assist patients in the geriatric ED called Care and Respect for Elderly.[20]

Patient referral to senior-specific EDs varies. For example, at Mount Sinai Hospital, all patients are first screened in the general ED. Patients are referred to the geriatric ED if they are age 65 years or older, know their name, could walk before the ED visit, and rank 2 to 5 on a standard emergency severity index of 1 to 5 (1 signifies the sickest patients).[21] At other senior-specific EDs, patients come directly to that ED, not to the general ED.

The prevalence of these EDs appears to be growing steadily. Although no specific registry of senior-specific EDs in the United States exists, reports from health systems and healthcare news articles indicate that more than 50 have opened across the United States since 2011, with an estimated 150 in development.

Outcomes

Several institutions that have implemented senior-specific EDs have informally reported positive results. Holy Cross Hospital reported in January 2012 that one-ninth of patients in the geriatric ED had been prescribed five or more medications, and pharmacist referral revealed that 20% of them were taking inappropriate medications or doses. The hospital also reported that inpatient volume increased, signifying appropriate admissions and return ED visits within 72 hours decreased to 3%.[22] St. Joseph's Regional Medical Center (Paterson, NJ) reported that 1 year after it opened its geriatric ER in 2009, the hospital's 30-day post-ED return rate for seniors (for the same condition) decreased

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from 20% to less than 1%.[23] Mount Sinai Hospital ED reported no falls had occurred in its GEDI, whereas previously up to eight elderly patients a month had fallen in the general ED.[21]

Cost, Funding, and Reimbursement Considerations

The cost of constructing/updating the ED to address geriatric needs varies according to the institution's needs and resources. For example, Newark Beth Israel's facility (NJ), composed of eight beds, reported costs of $3.2 million.[24] However, Holy Cross Hospital stated that it spent $150,000 to create its senior-specific ED and that it raised the money through an annual fundraising event.[19] The hospital states that patients do not pay an extra fee to use the ED and expected the initial financial outlay to be recovered by reducing the rate of hospital readmissions.[19] Reimbursement rates are no different in a senior-specific ED than a general ED; however, reduced admissions to ICUs, reduced readmissions, and improved outcomes are anticipated to bring a return on investment. However, published evidence for that has not yet accumulated.

Related ECRI Institute Publication

- **Health Technology Trends:** Are geriatric EDs the wave of the future? October 2013

4 Copper Surfaces: How Many Are Needed in a Hospital Room to Prevent Hospital-acquired Infections?

Copper's antimicrobial properties have been known for a couple thousand years. The idea of using them in healthcare settings to reduce infection is not new. However, the conversation has evolved given the very high stakes today for reducing healthcare-associated infections (HAIs), costs of treating infections, costs of copper, and concern about reducing risks for the most vulnerable hospitalized patients. The conversation also focuses on how many copper surfaces need to be installed in a patient room to achieve desired effects.

About 80% of infectious diseases are transmitted by touch, according to the International Copper Association. The association asserts that about 2 million HAIs are documented in the United States annually and result in 100,000 deaths. CDC estimates that treating HAIs adds between $28 billion and $45 billion to annual U.S. healthcare costs. On average, HAIs add an estimated 19.2 hospital days and $43,000 in additional costs for each affected patient.[25] Further, patients contracting an HAI have a 1-in-20 chance of dying if the infection is acquired while hospitalized and a 1-in-4 chance of mortality if the infection is contracted in an ICU.[26] Given these staggering numbers, is Antimicrobial Copper worth the investment? Which and how many surface areas in a room should be copper?

The Real Thing

Antimicrobial Copper is the only hospital touch surface with a U.S. Environmental Protection Agency (EPA) public health registration, allowing manufacturers to claim that copper surfaces can kill specific bacteria (*Staphylococcus aureus*, methicillin-resistant *Staphylococcus aureus* [MRSA], vancomycin-resistant *enterococci* [VRE], *Enterobacter aerogenes, Pseudomonas aeruginosa*, and *Escherichia coli* O157:H7) that cause infections and pose a threat to human health.[27] The literature has shown that copper might also be effective against viruses, other bacteria, and fungal pathogens.[28,29] More than 479 Antimicrobial Copper alloys are EPA-registered public health antimicrobial products available to address both practical and aesthetic demands.[30]

Hospital surfaces in patient rooms, including the ICU, typically consist of stainless steel and plastics that serve as environments for disease transmission between disinfection procedures in many healthcare settings. In some cases, these surfaces have become colonized with live microbes that live for days or weeks, providing a contamination source to the hands and equipment of healthcare workers, professionals, visitors, and patients. The

WHAT TO DO

- Introducing Antimicrobial Copper touch surfaces into ICUs and bed linens and patient gowns woven with copper-spun threads could have large implications for infection control practices and capital budgets. Hospitals with plans for new or remodeled ICUs should employ evidence-based design and consider where to introduce copper surfaces and materials to reduce HAIs. Reducing HAIs could decrease patient length of stay, hospital readmission rates, and costs in targeted patient areas. In addition, administrators could see a return on investment due to fewer infections within their own staff. Implementation of copper and copper alloy surfaces might not only improve patient health outcomes, but might also save the healthcare system significant funds.
- Facilities and infection control departments of healthcare facilities should work with their value analysis and technology assessment groups when considering whether and where to implement copper surfaces in hospital rooms, especially in the ICU. While Antimicrobial Copper is still not widely used, early adopters may be pleasantly surprised—sooner rather than later—by the return on their investment.
- Be prepared for a short-term rise in costs to outfit rooms, as copper and copper alloy raw materials, bed linens, and hospital gowns are more expensive than stainless-steel, plastic, and regular sheets and gowns. Additionally, ICU rooms and other hospital rooms may have to temporarily close during installation of copper and copper alloy surfaces. However, hospitals could see a return on investment for employment of Antimicrobial Copper in ICU and other hospital rooms within 12 months.

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intrinsic antimicrobial properties of copper and copper alloys (brasses and bronzes) for touch surfaces on hospital hardware and equipment could add another safeguard against disease transmission between cleanings.[29]

How Much to Use and Where?

Antimicrobial Copper touch surfaces can be incorporated into a wide variety of components, including bedrails, handrails, door handles, grab bars, intravenous (IV) poles, food trays and carts, sinks, faucets, shower and lavatory components, work surfaces, computer keyboards, equipment adjustment knobs, face plates, and yes, even bed sheets and blankets. Copper's antimicrobial properties remain in effect for the product's lifetime and do not rely on coatings or impregnated surfaces that can wear off or wash away. The Copper Development Association claims that copper touch surfaces work continuously, achieving 99.9% reduction of gram-negative and gram-positive bacteria within two hours of exposure and that the surface delivers continuous antibacterial activity between routine cleaning and sanitizing steps.

Antimicrobial Copper consists of copper alloys such as brass and bronze, copper nickels, and copper with nickel and zinc. Manufacturers intend these alloys to have strength comparable to stainless steel. Copper alloys are purportedly durable. Natural tarnishing does not impair the surface's efficacy, and copper touch surfaces have been deemed to not be harmful to people and the environment.[31,32] Copper allergy is relatively rare, although awareness of patient metal allergies would need to be considered because of the alloys used in copper surfaces. We identified no research addressing how to manage copper allergies in copper-fitted rooms. The surfaces are not supposed to wear, so the risk of contact dermatitis would likely be very low. Allergies to nickel are more common, and some copper alloys contain nickel; therefore, the amount of nickel in such alloys used in patient rooms would need to be considered.

Antimicrobial Copper use is intended to supplement, not substitute for, standard infection control practices. Users are advised to continue to follow all current infection control practices.[27] At least 13 companies have reported positioning themselves to manufacture products containing the Antimicrobial Copper mark, so it's a competitive market from which hospitals can choose.

Determining the number of copper-fitted items to place in a room is a big question and should be based on evidence-based design—that is, clinical evidence. A recent randomized controlled trial (RCT) studied 650 patients admitted to 3 ICUs in the United States.[33] These patients were randomly assigned to rooms fitted with six copper alloy surfaces (bedrails, overbed tables, IV poles, arms of the visitor's chair, and any two of the following items: nurses' call button, computer mouse, bezel of the touchscreen monitor, or palm rest of a laptop computer) or standard surfaces. Patients admitted to copper-fitted rooms had a 45% reduction in HAI or colonization with MRSA or VRE compared with infection rates in patients placed in standard rooms ($p = 0.020$). Additionally, patients assigned to rooms with copper surfaces had a 58% reduction in HAIs alone compared with patients placed in standard rooms ($p = 0.013$).

In another study, investigators sampled 282 copper-containing objects in 32 ICU rooms and 288 noncopper-containing objects in 27 ICU rooms to determine whether Antimicrobial Copper lowered the microbial burden (MRSA and VRE) on commonly touched objects and mitigated the acquisition of HAIs.[34] Using copper significantly reduced the total mean microbial burden in the ICU room by 87.4% ($p = 0.003$). Copper was also effective in reducing the mean microbial burden on four of the six objects: bedrails, call buttons, IV poles, and chair arms. However, using copper showed no

reduction in microbial burden for trays or monitors. *Staphylococcus* was the predominant organism isolated from each object regardless of the surface composition. According to investigators, MRSA and VRE were frequently isolated from noncopper-containing objects but were not isolated from copper-containing objects.

An October 2013 study reported that dry copper alloy surfaces showed rapid inactivation of murine norovirus, the main cause of viral gastroenteritis worldwide, with alloys containing 60% or more copper at room temperature.[35] Researchers said the inactivation rate was initially very rapid and proportional to the copper content of alloy tested. Viral inactivation was less rapid on brass, but copper-nickel alloy proved effective.

In July 2012, the David Geffen School of Medicine at the University of California, Los Angeles (UCLA), UCLA Fielding School of Public Health, and UCLA Henry Samueli School of Engineering and Applied Science announced that the U.S. Agency for Healthcare Research and Quality (Rockville, MD) had awarded them $2.5 million to conduct a four-year, randomized study to determine whether reductions of surface bacteria from use of copper surfaces lead to decreased HAI rates, improve treatment outcomes, and reduce costs. The study will evaluate copper, plastic, and sham stainless-steel surfaces to determine their role in HAI transmission.[36]

The Cost Equation

In the big picture, equipping every U.S. hospital room with antimicrobial copper products could cost from $1.5 billion to $2.5 billion, and a return on investment might be realized within 1.0 to 1.5 years after implementation, according to the Copper Development Association. Building and outfitting new rooms with Antimicrobial Copper is typically easier and less costly than retrofitting. The additional cost of manufacturing a copper sink for a hospital room is estimated at $40 to $60 each, which might be considered marginal considering a hospital sink costs approximately $7,500.[37] Copper rails add about $100 to the cost of a standard $30,000 hospital bed.

Antimicrobial Copper trials are ongoing in several U.S. ICUs, including at Memorial Sloan-Kettering Cancer Center (New York, NY), Medical University of South Carolina (Charleston, SC), and Ralph H. Johnson VA Medical Center (Charleston, SC).

Related ECRI Institute Publication

- **Health Technology Forecast:** Copper Surfaces in the Intensive Care Unit for Preventing Hospital-acquired Infections, April 2013

5 Roboman, Arise: Should You Offer Wearable Powered Exoskeleton Rehabilitation for Individuals with Paraplegia?

Fans of the TV show *Glee* may be familiar with the powered exoskeleton from an episode in which a lead character, confined to a wheelchair, donned a powered exoskeleton to walk upright for the first time. Wearable powered exoskeletons are a new $100,000+ ticket to standing upright for patients who are paraplegic from a spinal cord injury (SCI), but less expensive options are also on the horizon.

The devices are used in two ways: rehabilitation after SCI and personal, at-home use as an assistive device. About 30 U.S. rehabilitation hospitals (as of late 2013) offer them as part of rehabilitation for patients with paraplegia. A personal, at-home version is also emerging but awaiting FDA marketing clearance. The personal version is intended to serve as an assistive device to improve access (e.g., stairs) and health complications stemming from SCI. Interest in exoskeletons is high because wheelchair users often experience other complications related to confinement that contribute to significant morbidity, cost, and increased mortality.

Will getting wheelchair-bound patients up on their feet help reduce morbidity and improve overall survival after SCI? Is this a technology your health system should use in its rehabilitation facilities? Will you need specialized technical expertise to maintain the computerized devices? Read on to find out.

WHAT TO DO

- Decide whether you want your health system to join the leading edge of rehabilitation therapy now for your patients with SCI or whether you want to wait for more market entrants.
- Participate in patient outcomes data collection to build the body of evidence and help define which candidates might benefit to provide data to inform coverage and reimbursement decisions.
- You don't need to plan for different staffing. Manufacturers provide all needed technical support for the equipment when used in rehabilitation settings. Less clear is what would happen in the home care or community use setting if a patient using a system has problems.
- If you adopt the technology at this early stage, plan fundraising initiatives to support acquisition, maintenance, and training.
- Stay attuned to developments in brain-controlled walking systems for this patient population; the technology is quickly evolving.

Systems in Play for the Population in Need

According to the National Spinal Cord Injury Statistical Center (NSCISC), in 2012, an estimated 270,000 people in the United States were living with SCI. Extrapolating from NSCISC discharge-by-diagnosis data, about 43% of patients experiencing an SCI each year have complete or incomplete paraplegia. Patients with paraplegia after SCI experience paralysis of part or all of the trunk, legs, and pelvic organs. The candidates for the powered exoskeleton devices would be drawn from this patient population. NSCISC reports incidence of about 12,000 new patients with SCI per year and that most SCIs occur in males, who are 4 times as likely as females to incur an SCI, says NSCISC. Worldwide, the reported incidence of SCIs ranges from 10.4 to 83.0 per million people per year.

Medically appropriate candidates for the systems have sufficient upper-body strength, sufficient bone density, good cardiovascular health, body weight at or below 200 lb, good skin integrity for contact with device surfaces, spinal stability, good cognitive functioning, and no medical issues that could pose serious risks during device use (e.g., unresolved deep vein thrombosis).

Two companies have systems available in the United States now for use in rehabilitation settings. Three other U.S. developers could eventually enter the market: Florida Institute for Human and Machine Cognition (Pensacola, FL), University of Michigan at Ann Arbor, and Vanderbilt University (Nashville, TN). New development directions also include using the brain to control the device movement.

Systems available in the United States:

- ReWalk™ Rehabilitation (Argo Medical Technologies, Ltd., Yokneam Illit, Israel)

- Ekso™ system (rehabilitation version) (Ekso Bionics, Richmond, CA)
- Vanderbilt University, which stated plans to commercialize in 2014 its 27 lb compact system that fits in a wheelchair backpack when not being worn

Systems available outside the United States:

- ReWalk Personal (Argo Medical Technologies) in the European Union
- Rehab Rex (rehabilitation centers) and Rex (personal use) in Canada and New Zealand (Rex Bionics, Ltd., Auckland, New Zealand)
- Robot Suit Hybrid Assistive Limb® (HAL®) (rehabilitation centers) in Japan (Cyberdyne, Inc., Tsukuba, Japan)

The systems differ in some ways. For example, the 35 lb ReWalk system includes wearable computer-controlled, motorized leg braces that require patients to use crutches. The system uses an array of sensors and proprietary computer algorithms that analyze body movements and manipulate the motorized leg braces to help users maintain proper gait using crutches. A backpack, which the user wears, contains the system's onboard computer, sensor array, and rechargeable batteries.

The 45 lb Ekso system is intended for lower-extremity paresis due to neurologic conditions, including SCIs, multiple sclerosis, amyotrophic lateral sclerosis, or Guillain-Barré syndrome. It incorporates technology similar to that of the ReWalk system. The system is based on the Human Universal Load Carrier™ that the U.S. military uses. The motorized exoskeleton is designed to enable users to continuously carry up to 200 lb. The manufacturer states that transfer to and from a patient's wheelchair and the powered exoskeleton device takes under five minutes and requires little to no assistance. Battery life is estimated to be three hours.

FDA classifies these devices as powered exercise equipment (product code BXB) for medical purposes (e.g., physical therapy), thus making the technology exempt from 510(k) premarket notification or premarket approval application processes when used for rehabilitation. Personal use devices may be treated differently, and one manufacturer is seeking 510(k) clearance for its personal use device.

Is It Just to Improve Quality of Life?

Not quite. The hope is that health will improve, too. The systems are used for both functional improvement and locomotion. Profound muscle atrophy and bone loss often occur from degradation or loss of walking ability and mechanical unloading of the lower extremities. Although several assistive devices can be used to facilitate standing or locomotion (e.g., standing systems, knee-ankle foot orthoses, reciprocal gait orthoses, functional electrical stimulation systems), most affected individuals use conventional manual or powered-assisted wheelchairs for locomotion. Wheelchair users have limited access in many places and often experience secondary complications related to confinement that contribute to significant morbidity, cost, and increased mortality. The hope is that getting patients on their feet will help reduce morbidity and improve overall survival after SCI.

Data are available on several patients trained to use the ReWalk system. Two ongoing trials enrolling 70 patients are expected to wrap in 2014 and may help clarify the systems' clinical utility. The ReWalk pilot study results were reported at the meeting of the Association of Academic Physiatrists and

Photo courtesy of ARGO Medical Technologies

published in November 2012. The authors reported that "after training, all [12] subjects were able to independently transfer and walk, without human assistance while using the ReWalk, for at least 50 to 100 m continuously, for a period of at least 5 to 10 minutes continuously and with velocities ranging from 0.03 to 0.45 m/sec (mean, 0.25 m/sec)."[38] Ekso Bionics reported that it tested its system with patients at 12 U.S. rehabilitation hospitals in 2011 and early 2012; no published study results are available, and no ongoing trials are yet registered.[39]

Photo courtesy of Ekso Bionics

The Cost Equation

In the near term, you may need fundraising initiatives to adopt the systems because third-party payer support does not look strong right now in the absence of clinical evidence. In the future, competition may drive down pricing and help accumulate more evidence. The ReWalk Rehabilitation system costs about $105,000, according to the manufacturer; the ReWalk Personal use system (used only in Europe currently) reportedly costs about $20,000. The Ekso institutional system costs about $130,000, and the anticipated cost for a personalized Ekso exoskeleton is between $50,000 and $75,000. Acquisition includes comprehensive technical service, financing, and training programs. Ekso Bionics has also established the EksoHope program to help interested facilities raise funds for the device and share resources. That assistance is needed.

While these systems are costly, if they're eventually available for home use they may initially eliminate the need for manual standing devices, stair lifts, bed lifts, and other assistive-mobility devices that either cost a significant amount or require costly household renovations. For qualified patients, long-term costs associated with comorbidities stemming from chronic sitting in assistive devices could be significantly reduced.

Related ECRI Institute Publications

- **Emerging Technology Evidence Report:** Wearable Powered Exoskeleton Use after Spinal Cord Injury, November 2013
- **Health Technology Forecast:** Reciprocating Gait Orthoses (Computerized Walking Systems) for Managing Paraplegia from Spinal Cord Injury, August 2012

6 Magnetic Resonance-guided Focused Ultrasound for Bone-crushing Cancer Pain: A New Use for an Old Technology?

The most common cause of cancer pain is from bone metastases, so effective pain management is critical to improving patient quality of life and functioning. Bone is a common site of cancer metastases, especially in breast cancer and prostate cancer, with most of these patients having bone metastases by the time they die. Given the prevalence of these two cancers alone, bone metastases can be expected to affect several hundred thousand patients each year. Current treatments are mainly palliative and include localized therapies, chemotherapy, hormone therapy, radiopharmaceuticals, bisphosphonates, and pain medication. But these treatments are not effective in about one-third of patients, so new options have been sought.

Magnetic resonance-guided focused ultrasound (MRgFUS) has been available in the United States since 2004 for uterine fibroids and available abroad for many years for this and other applications (e.g., benign prostate hyperplasia, prostate cancer) with relatively low utilization. In the United States, it has reemerged as a recently FDA-approved option for bone metastases pain and is under study for treating certain cancers. The body of evidence of its effectiveness for bone pain is small and limited by lack of comparative evidence to other options at this time. The FDA-approved system (ExAblate® 2000/2100, InSightec Ltd, Tirat Carmel, Israel) costs about $750,000 to $1.5 million to acquire if you already have a compatible MR system and from about $2.0 million to $3.5 million if you don't. Two other systems are available in other countries but are not approved yet in the United States for any indication.

Should you take the plunge to offer this new option now or at all? Should you wait until more evidence accumulates or until more than one player is in the market to decide?

WHAT TO DO

- Decide whether you want to be an early adopter of a technology that may have many additional oncologic applications in a few years but has limited clinical applications now.
- For now, it offers another option for an important unmet patient need, but the clinical evidence and reimbursement climate are still developing. Publication of results of the pivotal RCT that was part of the submission to FDA for marketing approval may improve coverage, although the study is small (n <200) and does not provide the comparative-effectiveness data that payers, clinicians, and patients most want—comparisons to other treatments for bone metastases. FDA required postapproval studies and a patient registry to provide "real-world" data on adverse events. So, getting a return on investment might take time while awaiting results of further studies to inform payer decision making regarding coverage policies.
- If you plan to acquire the ExAblate, a magnetic resonance imaging (MRI) system will be needed. If you have a compatible MRI system, assess its current utilization to ensure you can accommodate an increased patient load. However, given the procedure time required, it's more likely that you will need the MRI scanner to be allocated exclusively for oncologic use, especially if you are planning for possible future oncology applications.

Is It Prime Time for MRgFUS?

ExAblate 2000/2100 received FDA approval in late 2012 for treating bone metastases as the first MRgFUS system to be approved for this indication in the United States. Eight U.S. centers in seven states (CA, FL, MA, NY, PA, TX, VA) have systems installed. The system is also available in Canada, Europe, Australia, Brazil, and several countries in the Middle-East, Southeast Asia, and Far East Asia.

Two other systems are in clinical trials for treating early-stage prostate cancer (Ablatherm®, EDAP TMS S.A., Lyon, France; Sonablate® 450 [U.S. product] or Sonablate 500 [outside U.S. product], SonaCare Medical, Charlotte, NC). ExAblate is also in trials for treating breast cancer, prostate cancer, and Parkinson's tremor. These potential future indications might pique health system interest for those treating many patients with cancer but are likely a few years away from entering the U.S. market.

The ExAblate and the other systems integrate with compatible MRI systems to deliver high-intensity focused ultrasound (HIFU) energy to local tumor sites while sparing healthy surrounding tissue to try to provide better and longer-term pain relief. Unlike imaging ultrasound, which exposes tissue to biologically insignificant energy levels, HIFU energy acts on bone primarily through thermal effects. HIFU energy rapidly heats tissue to the point at which irreversible thermal ablation and coagulative necrosis occurs. Bone tumors are particularly conducive to this ablation method because they have significantly higher ultrasound energy absorption, lower thermal conductance, and less penetration of ultrasound waves than soft tissue. As a result, the absorption pattern by bones allows wider surface areas of the bone to be treated with each energy pulse, shortening treatment duration.[40-42]

MRgFUS is typically an outpatient procedure that requires conscious sedation and analgesia. A standard MRI patient table is replaced with an MRgFUS procedure table fitted with a focused ultrasound transducer. The patient lies on the table with the target lesion positioned over the ultrasound transducer, and a clinical team member places a coupling gel pad between the patient and table. The ultrasound transducer is housed within a water-bath cooling system to prevent overheating and unwanted tissue damage during sonication. MRI both localizes the tumor and monitors real-time tissue temperature. Images are uploaded to the MRgFUS workstation for treatment planning. Initial, low-energy pulses are performed to confirm accurate targeting of the lesion before therapeutic-level sonication. Clinicians monitor the temperature of the tissue adjacent to targeted bone regions and can adjust treatment parameters (e.g., power, frequency, sonication duration, sonication target size) to ensure thermal ablation or prevent overheating. Treatment requires about one hour per lesion but may vary with tumor size and location. Contrast-enhanced MRI scans are performed immediately after the procedure to verify ablation and assess potential damage to tissues adjacent to the target bone sites.

Not all patients with bone metastases pain are eligible for the procedure; contraindications include standard contraindications for MRI, pregnancy, need for pretreatment stabilization of the affected bone, impending fracture of the affected bone, and obstruction of the intended ultrasound path by scar, skin fold or irregularity, bowel, other bone, surgical clips, or any hard implants. Additional contraindications include tumors in the skull or less than 1 cm from the skin surface and patient inability to tolerate the prolonged stationary position required for treatment.[43]

A notable recent advancement to the fixed-transducer ExAblate 2100 system is the Conformal Bone System, which features an upgraded, flexible ultrasound transducer intended to better conform to the location of the bone metastasis and reduce treatment positioning-related pain. The ExAblate 2100 Conformal Bone System is in a midstage clinical trial.[44]

Evidence is scant, with 3 trials reporting results on 188 patients in 2012.[45-47] These studies reported that no adverse events occurred. One RCT compared MRgFUS with sham treatment for bone metastases pain, and another RCT compared MRgFUS with external beam radiation therapy. MRgFUS was reported to be well tolerated, with transient treatment-related pain the most commonly reported toxicity, and a small study (n = 36) comparing MRgFUS to external beam radiation reported that both patient groups achieved pain relief.[46] The small case series (n = 18) reported a statistically significant improvement in pain, with no adverse events and increased bone density in about one-fourth of patients.[47]

Photo courtesy of InSightec

The Cost Equation

The technology is a major capital investment. The ExAblate 2100 system purchased with a compatible MRI system ranges from $2.0 million to $3.5 million, depending on the system configuration and number of clinical applications (from one to four). Without an MRI system, the system ranges from $750,000 to $1.5 million, depending on configuration and number of clinical applications. Extended-service contracts add about $75,000 or more per year.

Specific cost information for ExAblate therapy for treating pain from bone metastases was not available at time of publication. However, reported per-procedure costs for ExAblate treatment of uterine fibroids were $10,000 to $25,000, depending on procedure complexity. Overall, costs for treating bone metastases will depend on whether ExAblate replaces or is an add-on to other treatments for bone metastases pain. In some cases, it may be an option for patients who are not candidates for external beam radiation therapy or targeted therapy.

The U.S. reimbursement climate is not great at this point, with many major third-party payers (e.g., many Blue Cross/Blue Shield plans) listing the technology as "investigational" and not eligible for reimbursement. Health Canada gave a thumbs-up to the procedure in August 2013. Aetna's MRgFUS policy does not mention the bone metastases indication, although the policy lists several cancer indications as "investigational." Some payers might change policies when reviewing MRgFUS again in light of FDA approval and a recently published RCT. On the other hand, payers may be awaiting more data because of the relatively small amount of available evidence and FDA's requirement for InSightec to conduct two postmarket studies.

The company made small inroads in the coding arena. For pain palliation, Healthcare Common Procedure Coding System Level II C9734 is used for the delivery of one session for a Medicare patient. The C code for this procedure was created in April 2013 and is a temporary code developed by CMS and assigned to an Ambulatory Payment Classification group. The company indicated it is working to gain a code for use with all patients undergoing pain palliation regardless of the type of payer.

Related ECRI Institute Publications

- **Health Technology Forecast:** Magnetic Resonance-guided Focused Ultrasound for Treatment and Palliation of Cancer, December 2013
- **Emerging Technology Evidence Report:** Magnetic Resonance-guided Focused Ultrasound Ablation of Uterine Fibroids, February 2011

7 NanoKnife System: Real or False Hope for Patients with Cancer?

Cancer and hope go hand in hand, especially when a patient is given news of a malignant tumor in a delicate, inoperable location for which surgery, chemotherapy, or radiation are not options. Offering only comfort care may fall short for many patients and their families. One technology that may be diffusing before its time is being promoted by oncology clinics of several dozen health systems[48] for treating delicate, inoperable malignant tumors: NanoKnife® irreversible electroporation system (AngioDynamics, Latham, NY).

The technology involves a major capital investment, has no approved indications for specifically treating cancer (FDA approval is for soft-tissue ablation only), and is not without potentially serious risks to patients. Should you jump on the bandwagon to be an early adopter, or wait for evidence to accumulate and for health insurers to develop coverage policies?

WHAT TO DO

- ECRI Institute believes this technology has diffused prematurely—well before sufficient clinical evidence has been able to accumulate to define its role in treating solid cancer tumors.
- Given the potential procedure risks to patients, equipment cost, and unavailability of health insurer reimbursement, use of NanoKnife for oncologic applications should be confined to ongoing FDA-approved investigational device exemption trials or other controlled trials comparing the treatment to other options.
- Health systems that are already using the system for oncologic applications should consider participating in well-designed, controlled clinical trials to enable accumulation of evidence.

Does NanoKnife Have Promise?

Its promise is the potential to treat tumors in delicate locations and avert some problems encountered with other ablation techniques. Available standard ablation methods include RF energy, cryotherapy, and microwaves, which all rely on temperature to destroy tumors by heating or cooling tissue. The problem is that these methods can also cause collateral damage to adjacent tissues and associated adverse events during and after treatment. The inability to precisely control the affected zones during thermal ablation renders some tumors close to fragile structures (e.g., critical blood vessels) ineligible for treatment. Also, thermal ablation methods may be subject to heat-sink effects in which blood flow through large blood vessels adjacent to tumors prevents adequate heating and cooling of perivascular tumors. This can lead to inadequate tumor ablation and possible vessel damage. Thus, a novel nonthermal ablation method that could precisely target a tumor in a fragile location could reduce these unwanted effects.[49,50]

Irreversible electroporation (IRE)—technology the NanoKnife employs—has been proposed as a solution in these cases. The technology uses a nonthermal ablation technique that exposes target tissue to precisely aimed, rapid series of short-duration, high-voltage electrical pulses.[48] The pulses purportedly disrupt cellular membranes leading to cell death in the treatment zone. Unlike thermal ablation, IRE purportedly does not cause heat-sink effects and can leave intact the acellular portion of tissues, such as blood vessels, ducts, and nerves, potentially allowing ablation of tumors next to these structures without harming them.[48,51]

An interventional radiologist or surgeon performs IRE procedures using a percutaneous, laparoscopic, or open surgical approach.[51] The procedure is not without risks: neuromuscular stimulation by the electric field produced during IRE treatment can cause uncontrolled movement and pain; therefore, IRE requires the patient to be placed under general anesthesia and muscle blockade.[48] Also, to reduce the risk of inducing cardiac arrhythmias that can be caused by the electric field, an electrocardiogram synchronization device coupled to the IRE system is intended to precisely time the energy pulse to occur during (or just before) the ventricular refractory period.[48,52] A single ablation purportedly takes only a minute, and IRE electrodes can be repositioned to allow for multiple ablations.[53] An entire IRE procedure, including setup time and postprocedure imaging, takes an estimated two to three hours. The procedure can be performed as an outpatient procedure or sometimes might require an overnight stay.

Out of the Gate before Its Time?

AngioDynamics is the sole company that produces an IRE system and has reported that more than 1,000 patients have undergone IRE treatment worldwide.[54] Several dozen cancer centers in the United States have acquired IRE systems and advertise their use for treating various cancers.[48] FDA cleared the NanoKnife through the 510(k) process based on equivalence to the predicate device, the Oncobionic System. This system was cleared in 2006 for "surgical ablation of soft tissue" and subsequently acquired by AngioDynamics.[55]

On January 21, 2011, FDA issued a Warning Letter to AngioDynamics requiring the company to stop using terms such as "treatment" or "therapy" "for a particular disease or condition" in its NanoKnife product literature. FDA advised AngioDynamics to follow instructions for a premarket approval application process to demonstrate efficacy and be able to promote the technology for a specific approved indication. In the absence of such an approval, FDA required AngioDynamics to immediately cease marketing NanoKnife for unapproved uses, including treating specific cancers in various organs. Healthcare facilities are using NanoKnife to treat cancer with little objective clinical outcomes data that show that use of NanoKnife provides effective cancer treatment.

In June 2013, FDA granted an Investigational Device Exemption to AngioDynamics to conduct a clinical trial of NanoKnife for treating focal prostate cancer. Clinical trials are also under way in Europe for treating liver and pancreatic cancers.[56] No RCTs of IRE for treating solid tumors have been reported, but data from multiple case studies have been published recently on several dozen patients with liver or pancreatic cancers.[57-60] Some of these studies reported successful ablation in some patients, and some reported being able to down-stage cancer to the point at which patients could undergo an operation. The studies reported IRE-related adverse events, including three blood vessel thromboses, two duodenal leaks, and one instance each of abdominal pain/pancreatitis, cardiac arrhythmia, spontaneous pneumothorax, and subcutaneous hematoma.[57-60] One study reported 1 patient death at 90-day follow-up.[60]

The Cost Equation

Potential adopters must consider technology costs and infrastructure/staffing costs. The system has been offered as a rental, rental with option to purchase at the end of the rental term, and for purchase through a payment plan. ECRI Institute proprietary databases on equipment and disposables costs identified the U.S. national average prices for the NanoKnife generator as $200,530, the single-use 15 cm NanoKnife electrode probe as $1,888, and the single-use 25 cm NanoKnife electrode probe as $1,984. The cost of a service and maintenance agreement for the generator ranges from $30,000 to $85,000, depending on the warranty length.

IRE procedures may be performed in an interventional radiology suite or an operating room (OR) and have been performed as an outpatient procedure, though more often as an inpatient procedure. Similar to other ablation techniques, an interventional radiologist or a surgeon can perform IRE. An anesthesiologist familiar with cardiac synchronization must be present during the procedure.

The need for anesthesia services outside an OR setting can be a significant resource issue for some hospitals. The NanoKnife system requires frequent maintenance and quality checks of the equipment. Various imaging technologies (i.e., computed tomography [CT],

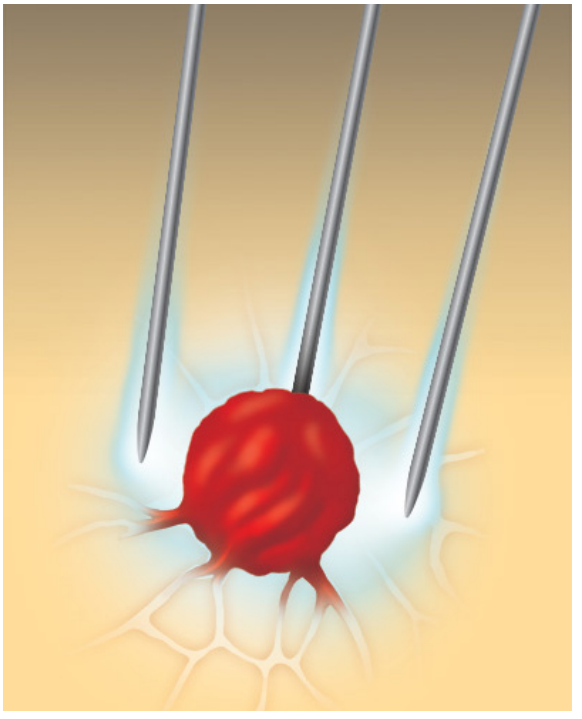

Photo courtesy of ECRI Institute

ultrasonography, magnetic resonance, positron emission tomography) are used for preoperative imaging, guidance to insert IRE electrodes, and follow-up evaluation of the treated area. The IRE procedure time of two to three hours represents a substantial resource requirement, in excess of that required for other thermal ablation procedures. Longer procedure times can affect patient throughput. For example, microwave ablation algorithms, which are rapidly supplanting RF ablation, are typically only 6 to 10 minutes, bringing the total procedure time to less than 1 hour.

Searches of 11 representative, private, third-party payers that publish their coverage policies online (i.e., Aetna, Anthem, Blue Cross/Blue Shield Alabama, Blue Cross/Blue Shield Massachusetts, CIGNA, HealthPartners, Humana, Medica, Regence, Wellmark, United Healthcare) identified 2 payers (i.e., Aetna Anthem) with policies that denied coverage for use of IRE to ablate tissue. Other payers have no policies addressing use of NanoKnife. However, the device is used even with lack of payer coverage, as patients in need of hope may choose to pay out of pocket.

Related ECRI Institute Publication

- **Emerging Technology Evidence Report**: Irreversible Electroporation (NanoKnife System) for Treating Malignant Solid Primary Tumors and Metastases to the Liver, July 2013

8 Real-time MRI Adaptive Radiation Therapy: A Ray of Hope or Hype?

Radiation therapy is big business—part of cancer treatment for about half of all patients with cancer in the United States, according to U.S. National Cancer Institute estimates. While various forms of radiation therapy have been standard treatment for many cancer types for decades, precisely targeting the tumor and delivering the prescribed dose have been the main challenges. One of the latest developments is the integration of MR images (rather than CT images) that are obtained coincidentally during the radiation treatment, which then allows "on-the-fly" changes to target size and dose. This "MR-adaptive radiation therapy" technique theoretically holds promise.

What do you need to know to plan long-term to offer the best in image-guided radiation therapy (IGRT) services that produce optimal patient outcomes? Should you invest in the newest, multimillion-dollar real-time IGRT technology or adopt a wait-and-see approach?

What's the Next Big Thing in IGRT?

Today's IGRT typically uses a linear accelerator with an attached CT imaging system to accurately position and verify the patient and tumor target positions before initiating treatment. One disadvantage of CT-based IGRT is CT's poor contrast resolution for soft-tissue malignancies, such as brain, breast, kidney, liver, lung, and pancreatic tumors. On the other hand, MRI provides excellent soft-tissue contrast but cannot be attached to a linear accelerator because each would disrupt the other's operations significantly from the interaction of RF systems, magnetism, and x-ray radioactive sources. Thus, the challenge for a long time has been how to combine MRI with a linear accelerator for real-time MR-guided imaging.

Now that option is here. ViewRay™ (ViewRay, Inc., Cleveland, OH), the first MRI-guided radiation therapy system for the U.S. market, was FDA cleared in May 2012.

The system's design is intended to avoid the incompatibility problem by using cobalt-60 radiation sources rather than a conventional linear accelerator. Cobalt-60 is a radiation source that uses gamma rays instead of x-rays used in conventional linear accelerators, and it does not require accelerating and bending electric and magnetic fields, as does a linear accelerator. Thus, it avoids magnetic interference with an MRI system. The ViewRay system uses three cobalt-60 sources in a rotating gantry to deliver radiation therapy. The other important component is the low-field-strength MRI system—a split-coil 0.35 T system. The cobalt-60 sources rotate in a gantry that

WHAT TO DO

- ViewRay is a relatively new development as the first "real-time" MRI-guided radiation therapy system. With cost estimates of $8 million plus $0.5 million per year in maintenance, ECRI Institute cautions health systems to curb enthusiasm for now. Hospital capital planning and technology assessment committees of facilities that are not participating in clinical trials should wait for clinical results from ViewRay before making such a major investment.
- Consider also other developments in adaptive radiation therapy, such as MRI simulation, though this approach is not without its challenges. This approach uses 3 tesla (T) MRI instead of CT for radiation therapy planning, with potential benefits to patients that include reducing exposure from ionizing CT radiation. Some centers (i.e., those with high volume and/or pediatric cases) are using this approach to also avert fusion errors that can occur when trying to fuse MR and CT data. Several trials are also ongoing to compare CT and MRI simulation techniques. Patient-motion errors during MRI have to be minimized, which requires immobilizing the patient by using an immobilization device that can be accommodated in the MRI machine. This can be accomplished through flexible coils or open-bore designs. Also, flat-top exam tables must replace the concave tables typically used for MRI when doing the radiation treatment planning to best ensure accurate setup for the patient during treatment.
- Adaptive fluorodeoxyglucose positron emission tomography imaging is also in clinical trials for radiation treatment planning and delivery.

sits within the split-coil of the MRI magnet. The low-field magnet minimally disrupts the cobalt-60 treatment fields. The MRI system has been designed to acquire and display patient images every 250 milliseconds during treatment. This means the MR images themselves can be used to "gate" the treatment. The MR images display actual treatment volumes, which obviates the need to use motion surrogates such as chest-wall motion tracking to gate treatments.

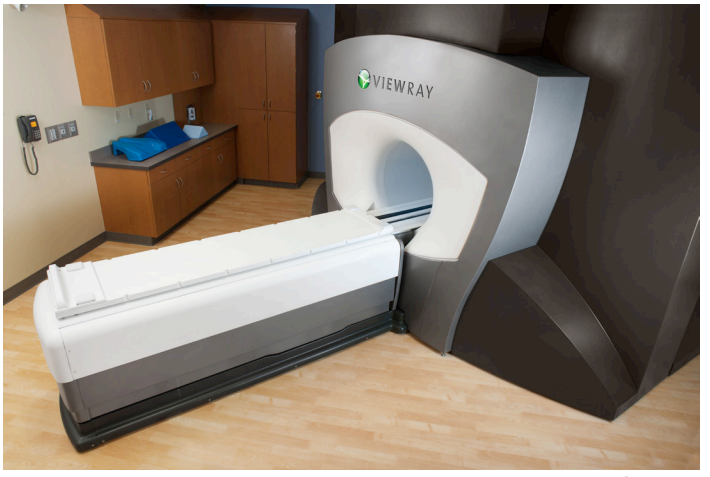

Photo courtesy of ViewRay

The system has a dedicated system for initial treatment planning using externally acquired images. This treatment planning system can be used to replan and reoptimize treatment using images from the ViewRay MRI system while the patient is on the treatment table. This "adaptive radiation therapy" is a very powerful concept. As treatment progresses, the treatment volume and surrounding tissue change. The system is intended to image these changes and reoptimize a plan when patients arrive for their next treatment fractions. ViewRay claims that a typical treatment can be replanned within two minutes.

FDA did not require ViewRay to conduct and submit clinical trial information on actual patients treated, and no objective clinical evidence on real patients is yet available to demonstrate ViewRay's impact on patient outcomes and whether it improves outcomes relative to standard radiation planning and treatment modalities now in common use.

Three ViewRay installations were expected to be operational at the end of 2013: Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine (St. Louis, MO); University of California, Los Angeles (UCLA) Health System and Jonsson Comprehensive Cancer Center; and University of Wisconsin Carbone Cancer Center (Madison).

The Cost Equation

The system's estimated initial capital costs are expected to exceed $8 million, with annual service costs expected to top $500,000. These costs do not include site renovations or the expected cobalt-60 source replacement costs (every five years). Additional reimbursement is not available at this time, so capital costs must be absorbed.

Related ECRI Institute Publication

- **Product Brief:** ViewRay System (ViewRay, Inc.) for Real-time Magnetic Resonance Image-guided Radiation Therapy, November 2013

9 Inside Out: Will Intelligent Pills Magically Improve Medication Adherence and Prevent Readmissions?

As hospitals seek to reduce ED visits and readmissions, patient adherence to prescribed chronic medication regimens crops up as a recurring topic. According to the World Health Organization, the average medication adherence rate among patients with chronic diseases in developed nations is only 50%. Proteus Digital Health Feedback System (Proteus Digital Health, Inc., Redwood City, CA) is a new technology that uses a sensor integrated into solid oral medications to track ingestion and feed information to the patient, caregivers, and prescribing clinicians. The developer calls it "digital medicine."

Should your pharmacy and therapeutics committee plan to use oral digital medicines for patients discharged with chronic disease medication regimens, especially if it shows promise to reduce readmission rates? Read on to learn the ins and outs of this technology's promise.

WHAT TO DO

- Discuss the technology with your clinical groups, and gain clinician buy-in for its use for the population targets in your area.
- Plan adoption strategies that include developing criteria for identifying patients you will want to target for intelligent pill prescribing.
- Plan how and which clinical staff will monitor the data received, and develop protocols for action steps expected for various scenarios.
- Plan education strategies for patients, their at-home caregivers, and families to gain buy-in, and develop responses to resistance that may occur because of "Big Brother is watching" perceptions.
- Meet with information technology and biomedical engineering departments in your health system to discuss implementation and monitoring of the software and data repositories.

Proteus System

The Proteus Digital Health Feedback System is a networked medication adherence—monitoring system intended to aggregate data pertaining to patient medication use (and other metrics). The system provides tools that patients and healthcare providers can use to track and optimize adherence to prescribed medication dosages. The system comprises three main components: the ingestible sensor embedded in the medication, a personal monitor, and a mobile phone or web-based communication platform.

The medication-embedded ingestible sensor is a 1 mm^2 microfabricated chip sensor that a drug manufacturer can embed into any oral medication the patient swallows. When the patient swallows the sensor-embedded pill, the pill releases a chip that is activated by stomach fluids that in turn power the sensor. The sensor then transmits digital information about the drug taken, its dose, and time of ingestion. The system captures this information through a wearable personal battery-powered monitor consisting of an adhesive foam patch (measuring 5 × 11 × 1 cm). After about seven minutes of activation, the sensor becomes inactive and is subsequently excreted through fecal elimination. The patch can measure heart rate, respiration, activity, body position, and monitor-wearing adherence. The monitor transmits this information (via Bluetooth telemetry) to a computing device. The monitor is designed to be worn for seven days.[61,62] The third component is a mobile phone or web-based communication platform that is used by the patient, clinician, or other caregivers to view the data, which is sent securely to either the mobile phone or a web-based platform.[62]

FDA regulates the system components separately. In March 2010, the manufacturer received 510(k) clearance to market the personal monitor portion (then called the Raisin Personal Monitor). In July 2012, FDA granted a de novo 510(k) clearance for the Proteus Ingestible Event Marker. The company received CE (Conformité Européenne) mark approval to market the complete system, including the ingestible sensor and personal physiologic monitor, in August 2010.

Investigators from a clinical trial of 111 subjects who ingested 7,144 markers reported that "the system's positive detection accuracy and negative detection accuracy in detecting ingested markers were 97.1% and 97.7%, respectively.

It differentiated 100% of multiple drugs and doses taken simultaneously by type and by dose. Medication adherence was >85%. The most common adverse effect was mild skin rash from the monitor's electrodes. No definitive marker-related adverse effects were reported."[62] More trials are planned. In May 2013, Proteus Digital Health announced that the company, Oracle, had invested in the technology to enable clinical trials as Proteus works to create "digital medicines." The company is collaborating with numerous pharmaceutical manufacturers to produce digital medicines. Although the separate components (drug and sensor) have both been approved, each digital medicine will likely require FDA regulatory approval.

Courtesy of Istock

The Cost Equation

Costs for the Proteus Digital Health Feedback System and the Helius subscription-based monitoring service have not been widely reported yet. According to the company, the cost will depend on the context in which the system is used. Data are lacking at this time on the technology's potential cost-effectiveness in improving patient adherence to medical therapy or reducing disease complications or hospital readmission as a result of improved adherence to therapy.

Related ECRI Institute Publication

- **Health Technology Forecast:** Intelligent Pills (Proteus Digital Health Feedback System) to Monitor Patient Medication Adherence, June 2013

10 Big Data: Does It Signify Big Decisions?

Big data analytics have been used to improve baseball team performance, giving smaller-market Major League Baseball teams the ability to find and hire players—at a bargain price—who were previously undervalued and often overlooked by larger-market teams. By studying statistics of undervalued players, such as on-base percentage, runs batted in, and even stolen bases, recruiters analytically evaluated and quantified each player's potential. Is this a model that healthcare can employ successfully to fix the system, improve access, lower costs, and improve patient outcomes? Just maybe.

With digitization of data through electronic health record (EHR) implementation and increasing creation of patient outcomes registries by payers and product manufacturers, big data opens the door to a new approach to making decisions in healthcare. One way in which healthcare is beginning to use big data from EHRs is to develop and use computer algorithms to analyze those data.[63] Because most of EHR data are unstructured, these data were once considered unusable. Now with tools such as natural-language processing, pattern recognition, and machine learning, EHR-based data are being used to aid understanding of real-world effectiveness of healthcare operations. This has allowed healthcare executives to better leverage their information to "improve care, control costs, and ready their organizations for the advent of outcomes-based reimbursement."[64]

Big data may help healthcare facilities improve effectiveness and efficiency in a few areas. With regard to patient care, big data provide the opportunity for facilities to generate new information in hopes of improving both systems of care and patient outcomes. For example, by analyzing EHR data, facilities can use tools to alert providers and patients of potentially harmful events, such as medication side effects, allergic reactions, and even the development of an infection. This has the immediate potential to reduce hospital admission and readmission rates.

Big data also has the potential to achieve operational efficiencies. Supply chain and value analysis initiatives have focused on reducing costs of providing care by better managing inventory sitting on shelves and standardizing products used through evaluation of big clinical data to ascertain which produce the better patient outcomes. By using big data analytics on benchmarking prices paid for products, facilities can also determine good prices in their market for products and services. Along with inventory management, big data also can enable facilities to automate processes. For example, by being able to see the products used during procedures, administrators can better understand total cost and usage of products. This can help improve demand planning and eventually reduce inventory costs.

While analysis of big data help supply chain and value analysis, it can also help healthcare facilities optimize patient flow for services. By tracking and analyzing data to see where patient flow is heaviest or where it appears to be disrupted, hospital leaders can pinpoint and correct system inefficiencies and prioritize adjustments that may be needed. The ability to analyze patient flow on a real-time basis to highlight the delays going on in a hospital will allow decision makers to appropriately reallocate resources. This technique could help save time and money in areas such as the ED and OR.

If big data has so much potential, why is its use taking so long in healthcare?

Courtesy of Istock

Overall, gathering and cleaning data to make them usable is still in its infancy at most facilities. Health systems may need assistance in these endeavors from organizations more experienced at collecting, aggregating, cleaning, and analyzing big data, such as ECRI Institute does through its various pricing, adverse event management, and clinical data analytic tools. Administrators are beginning to grasp the idea that data analytics can reduce costs and improve patient care.

Another reason for slow adoption is the fragmentation of data in multiple places. Each clinical site, from an outpatient lab to a hospital to a nursing home, has an individual repository of data. With data residing in individual silos, data sharing can be a seemingly insurmountable challenge, but survival requires strategic planning for big data aggregation and analysis.[65]

Healthcare big data is very much in its infancy. It is a powerful tool that holds tremendous potential to solve some of the most critical issues in the United States and elsewhere. Only a handful of the largest healthcare systems in the United States have embarked on implementing the necessary technology and personnel required to optimize analytics. Most community hospitals will most likely have to partner with other organizations, such as an Accountable Care Organization, to successfully take advantage of analytics.

Related ECRI Institute Publications

- **Health Technology Trends**:
  - Special Issue: What does big data look like in healthcare? December 2013
  - Big oncology data: ASCO rolls out real-time learning decision-support system, June 2013
  - Oncology projects demonstrate vision of learning health system, June 2013
  - Healthcare data: The big picture, June 2011
- **Health Technology Forecast News Brief**: Alzheimer's disease meets "big data," July 2013
- **ECRI Institute's 20th Annual Conference on the Use of Evidence in Policy**
  - Data BIG and small: What healthcare decision makers are using now (Recordings): https://www.ecri.org/Conferences/Pages/Annual_Conference_2013_Agenda.aspx

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