ECRI INSTITUTE'S TOP 10 C-SUITE WATCH LIST:

Hospital Technology Issues for 2012

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INTRODUCTION

ECRI Institute experts compiled a Top 10 list of important technologies and technology-related issues that hospital and health system leaders should pay close attention to this year. The list takes into account the convergence of critical economic, patient safety, reimbursement, and regulatory pressures. As in previous years, the effort began with an open call for nominations throughout ECRI Institute. This resulted in a nominated list of more than 30 technologies and related issues. The list was then circulated among key ECRI Institute thought leaders who individually ranked their Top 10 choices. Once all rankings were compiled, the top 5 technologies emerged fairly quickly. A number of technologies competed for rankings 6 through 10, so we convened a ratings consensus panel to reach agreement. During that session, experts in each area commented on why the final Top 10 topics that made the list are especially important now and offered guidance on important considerations for hospital leaders.

Themes emerging on our 2012 list reflect ongoing impacts of healthcare reform initiatives and new technology developments that emphasize patient-centered care, including safety improvement, interconnectedness of technology, personalized medicine catering to individual care needs and preferences, and ever-increasing cost pressures. While the imperative to integrate health information technology with healthcare technology marches on, emerging devices, drugs, and procedures are tailored more than ever to individual patients' medical characteristics. On the surgery side, we see significant developments in cardiac care and bariatric services that signal important infrastructure and staffing model changes as new patient populations enter the healthcare system to receive these new treatments. Decisions need to be made about the makeup of interdisciplinary teams to learn and implement technologies on both the operations and clinical sides. On the cancer side, we see increasing treatment costs of targeted therapies that require testing entire patient populations to identify the subgroups eligible for treatment. The upfront cash outlay for these individualized therapies may affect decisions to adopt when clinicians and patients weigh the evidence on potential benefits and risks.

Careful consideration of all the factors affecting whether and how to adopt these new interventions will be crucial for short- and long-term strategic planning, effective implementation, and optimal safety and effectiveness for patients.

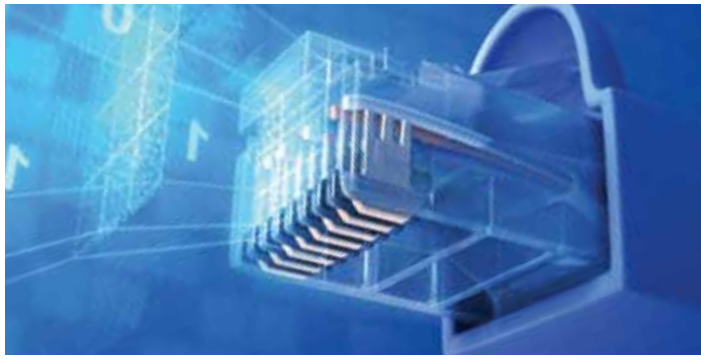
1 Electronic Health Records:

Is your hospital making all the right connections?

What should health systems be doing NOW to ensure they qualify for the reimbursement that will be tied to Meaningful Use?

ACOs, HIEs, PCMHs – the alphabet soup just keeps getting thicker, and additional stages of Meaningful Use must be certified soon if your hospital is to receive the reimbursement guaranteed under the American Recovery and Reinvestment Act of 2009. Myriad efforts are under way in health information technology (IT). Now is the time to tackle the recommended Stage 2 certification criteria for Meaningful Use. Stage 2 continues some of the Stage 1 criteria (e.g., active medication list, problem list) and increases the threshold for other criteria. For example, the threshold for computerized physician order entry doubles from 30% to 60%, and the percentage of vital signs that must be recorded electronically increases by more than half, from 50% to 80% of patients. Other additions include recording the patient's preferred communication method and enabling web-based access to inpatient records. Finalized, approved criteria should be released soon (if not already available).

Stage 2 certification requires hospitals to not only have the necessary IT infrastructure, but also the ability to integrate patient care device data into the electronic health record (EHR) – either directly or through an intermediary system. In what is now often referred to as medical device integration hospitals are challenged with defining which devices are critical priorities and which ones



might be necessary in the future. Vital sign information is a definite now, but what about physiologic monitors and ventilators? Patient scales? Patient-controlled analgesic pumps? Spirometers?

Hospitals must develop a medical device integration plan, which will require clinical engineering (CE) and IT staff to work closely together to coordinate a plan. Typically, no single person in either department has complete understanding of all the needs. CE often doesn't understand IT's project management processes, and IT often doesn't understand CE's critical role. Topping off this cultural challenge is the fact that most hospitals lack access to the necessary information for medical device integration, such as having a complete inventory of medical devices that use the network, their associated IP addresses, and the firmware and software versions in use, to start. Does your hospital have these?

After integrating this information into your hospital's EHR, how

will you share it with other Health Information Exchanges that your organization participates in? The IT challenges, as well as contractual issues (e.g., with your state or regional Health Information Exchange) related to integration seem unending.

Remember, medical device integration and Meaningful Use ultimately aim to improve healthcare and patient safety. Successful deployment should not only ensure reimbursement, but also:

- Enhance patient safety and quality of care
- Facilitate nursing workflow
- Increase physician and nursing satisfaction

A strategic approach with the right medical device intergration connections will get your hospital moving along the optimal path for success.

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2 Minimally Invasive Bariatric Surgery:

Will bariatric services in your facility need to expand to meet the needs of an expanding patient population?

Are you ready for the shifts in care delivery and staffing challenges that new bariatric procedures and devices could bring?

The United States spends $150 billion annually to treat obesity-related illnesses. More than one-third of U.S. adults and almost one-fifth of children and adolescents are obese. Pharmaceutical options have been fraught with controversy, and drug therapy alone can't offer the degree of weight loss that an increasing array of minimally invasive bariatric procedures on the horizon may offer. Hospital executives responsible for strategic planning for services should note that demand for these procedures is expected to surge as patients become aware of them, even if patients have to pay out of pocket. Furthermore, if evidence continues to accumulate showing that patients with a body mass index (BMI) of 30 to 35 with diabetes or who are at risk for diabetes have their diabetes or metabolic syndrome resolve after undergoing one of these new bariatric procedures, payers may eventually see value in covering some of them.

Hospitals offering bariatric services must develop integrated programs to address the increasing number of overweight, obese, morbidly obese, and super obese patient populations who will seek treatment. Hospitals need interdisciplinary bariatric services that include ancillary services such as specialized nursing care, dietary instruction, counseling, ongoing support groups, and exercise training. Such programs also require investment in special equipment, including high-capacity beds, laparoscopic instrumentation for surgery on morbidly and super obese patients, patient lifts, and fluoroscopic imaging tools. Hospitals should plan for care setting shifts (from inpatient surgery to ambulatory surgery and office-based interventions) and staffing model shifts (surgeons to interventionalists and endoscopists). The new procedures will also require hospitals to think about clinician training and the types of clinicians that will be certified to perform each procedure.

The long-standing gold standard, open Roux-en-Y gastric bypass surgery, which irreversibly makes the stomach smaller and allows food to bypass part of the small intestine, has been supplanted at many centers by laparoscopic Roux-en-Y gastric bypass. This approach is associated with a two- to three-day hospital stay, but an alternative is still desired. The laparoscopic adjustable gastric band remains a popular alternative because it involves a reversible outpatient procedure. However, evidence still shows that Roux-en-Y gastric bypass is the more effective permanent weight loss procedure, though it has significant risks. While adjustable bands

have been on the market for 10 years (e.g., Lap-Band Adjustable Gastric Banding System, Allergan, Inc., Irvine, CA, USA, since June 2001; Realize Band, Ethicon Endosurgery, Cincinnati, OH, USA, since September 2007) for patients with a BMI of 40 or higher, or 35 with at least one comorbidity, indications for Lap-Band expanded in February 2011 to include individuals with a BMI of 30 to 34 with an existing obesity-related comorbidity.

Bariatric surgeons may be looking with interest at laparoscopic sleeve gastrectomy, which alters the stomach but not the intestines. Unlike Roux-en-Y gastric bypass, which is both malabsorptive and restrictive, laparoscopic sleeve gastrectomy is merely restrictive. This procedure started as the first step of a two-step procedure, and then surgeons observed that some patients achieved sufficient weight loss with the first step to make the second, more invasive step unnecessary. Thus, laparoscopic sleeve gastrectomy has gained traction. While this procedure does not shift existing bariatric services, it may not help your bottom line because many payers do not reimburse for it because the quality of available evidence on efficacy thus far is low.

One of the newer procedures, gastric plication, also referred to as gastric imbrications or laparoscopic greater curvature plication, does not involve removal of stomach tissue. Rather, the stomach is folded and sewn, which is theoretically reversible. Its diffusion is currently limited, in part because most payers don't cover it because of lack of sufficient evidence of its efficacy. The procedure has great appeal to patients because of early reports of extensive weight loss achieved, and patient inquiries can be expected to increase. The procedure was developed outside the United States and is now under investigation at the Cleveland Clinic (Cleveland, OH, USA) as part of a larger clinical trial. A Gastric Plication Resource Center website promotes the procedure and collects information. As of July 2011, about 400 procedures have been reported with relatively short-term (3-year) results. Some surgeons are also combining the procedure with lap banding. Some U.S. bariatric surgeons have expressed concern that accounts of substantial weight loss in a short time span using this procedure compared to other weight loss surgeries may drive patient demand before sufficient evidence is available to support safety and efficacy. Hospitals should exercise caution to avoid premature adoption outside the context of a clinical trial because of possible

New devices under development that are implanted endoscopically through the mouth could change the type of clinician providing bariatric services and shift care from an inpatient setting to an ambulatory surgery setting.

risks to patients, which could in turn place hospitals at risk if patient outcomes are negative.

New devices under development that are implanted endoscopically through the mouth could change the type of clinician providing bariatric services and shift care from an inpatient setting to an ambulatory surgery setting. The EndoBarrier Gastrointestinal Liner (GI Dynamics, Lexington, MA, USA) is an impermeable sleeve that allows partially digested food leaving the stomach to move through the gastrointestinal tract without allowing nutrients to be absorbed through the intestinal walls. Its purported benefit is to mimic the effects of bypass surgery, though it has not yet demonstrated the ability to achieve the weight loss that Roux-en-Y gastric bypass achieves. With the patient under general anesthesia, the surgeon uses fluoroscopic guidance to insert a catheter through the esophagus into the stomach, then into the small intestine. In the ongoing international late-phase trial, most patients were discharged the same day they underwent the procedure.

The intragastric balloon, also inserted through the mouth, has received the CE (Conformite Europeene) mark in Europe and remains in U.S. clinical trials. Filled with either air or a saline solution, a balloon is inserted into the gastric cavity to reduce the stomach's ability to hold food. These balloons must be removed six months after implantation or serious adverse effects can occur. Most patients regain weight after removal unless they have adopted lifestyle changes or a procedure is performed to achieve more permanent results. For insurers to consider coverage, the balloon would likely need to be positioned as a step-up procedure that enables morbidly or super obese patients who want to become eligible for Roux-en-Y gastric bypass to lose enough weight to become candidates for Roux-en-Y gastric bypass.

Another device in development is the implanted intra-abdominal vagus nerve blocking system (Maestro System, EnteroMedics, St. Paul, MN, USA). It uses high-frequency, low-energy electrical pulses to block vagus nerve signals in the abdominal region, purportedly inhibiting gastric motility and increasing satiety. The surgeon programs the device to intermittently send electrical impulses through the implanted electrodes to block vagus nerve signals. In September 2011, investigators reported 18-month data stating that sustained results were observed: mean reductions of glucose to near normal levels (as reflected by changes in HbA1c [hemoglobin A1c]), excess weight loss of almost 25%, and lower blood pressure in patients with hypertension. The Maestro rechargeable VBLOC system received the CE mark in March 2011 for distribution in Europe.

3 Digital Breast Tomosynthesis:

Is leapfrogging from film to 3-D breast tomosynthesis the right decision?

Is your hospital using digital mammography technology? If not, should you move to it now or go directly to 3-D digital breast tomosynthesis? Hold on; it's not as straight forward as you might think.

Mammography technologies and screening always garner wide attention and can be controversial. Among the controversies are low reimbursement, high capital equipment acquisition and maintenance costs for digital systems, data storage needs, disagreement about risks and benefits of screening by age group, and trade-offs between how to reduce false positives without increasing false negatives. Adoption of full-field digital mammography since it became commercially available in the United States in 2000 has been slow because of these controversies. As of July 2011, 22% of mammography facilities still operated film-based mammography.

Enter the new twist on full-field digital mammography—three-dimensional (3-D) digital breast tomosynthesis. The potential is improved diagnostic accuracy, but with a price—literally and figuratively. It requires higher capital outlay with higher operational costs, and its clinical benefit is far from clear at this point. And the biggest misconception for those using film mammography may be that 3-D breast tomosynthesis supplants full-field digital mammography—it does not. Rather, it is additive to full-field digital mammography. Thus, no "leapfrogging" from film to 3-D tomosynthesis is possible—you need both full-field digital mammography and the 3-D tomosynthesis technology to implement 3-D breast tomosynthesis.

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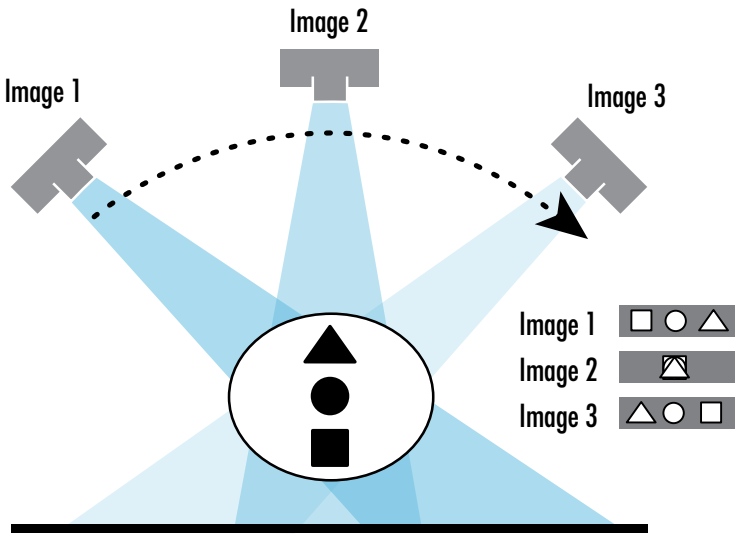
In standard full-field digital mammography or film-based mammography images, overlapping tissues partially shadow subtle details. Digital breast tomosynthesis reduces the effect of overlapping tissue by synthesizing and displaying a thin section of the breast. Images of the entire breast are viewed by scrolling through a stack of thin sections. The clarity of detail in each section appears quite dramatic because the "fog" from overlapping tissue is virtually eliminated.

Hologic's Selenia Dimensions 3D (Bedford, MA, USA) is the first full-field digital mammography unit in the United States with digital breast tomosynthesis capability. It received U.S. Food and Drug Administration (FDA) approval on the basis that the technology will supplement, not supplant, two-dimensional (2-D) full-field digital mammography. In other words, both digital breast tomosynthesis and 2-D full-field digital mammography have to be conducted as one combined exam. Facilities currently pay about

$400,000 to $450,000 for a new Hologic Selenia Dimensions 3D system. All other mammography technology manufacturers are also working on their own systems, and approval of competing systems is expected in the next year or two.

Initial data suggest that the technology improves radiologists' performance in distinguishing cancer from noncancer cases and that it reduces patient recalls for additional imaging. In some manufacturer-sponsored trials, the radiologists' reading performance reportedly increased 7%, and reduction in patient recalls has been reported to be about 30% to 40%. However, data are not yet available from multicenter trials of routine use in clinical practice. As a result, additional reimbursement is not available for digital breast tomosynthesis.



With digital breast tomosynthesis, a full-field digital mammography unit obtains 15 to 20 images in a sweeping arc or scan over 15 degrees. Up to about 50 to 60 thin (1 to 2 mm) sections of the breast are then synthesized or reconstructed from one such scan. Because one sweep supplements another standard 2-D full-field digital mammography view, the patient radiation dose is approximately doubled because the full-field digital mammography is still required. The potential increase in cumulative radiation to the patient becomes important because women are expected to have periodic screening exams over 30 to 35 years. At present, manufacturers of digital breast tomosynthesis are attempting to limit dose from digital breast tomosynthesis and 2-D full-field digital mammography (as combination) to within the maximum FDA-imposed limit for just 2-D mammography, where risk-benefit profiles have been modeled and deemed acceptable.

Proper reading of digital breast tomosynthesis requires experience and training. Reading the images also takes additional (unreimbursed) time. FDA mandates a minimum of eight hours of training for each staff member routinely involved in mammography (radiologist, technologist, and medical physicist), and some believe that this is just a starting point for becoming skilled at interpreting the image sets. Of particular concern are

microcalcification lesions, which, some assert, breast tomosynthesis cannot easily distinguish. Clinical trials suggest that performance on lesions with calcifications, in particular, is improved if the radiologist has both experience and training with digital breast tomosynthesis.

Full-field digital mammography images are large and can place storage and cost burdens on a hospital's picture archiving and communication system. Digital breast tomosynthesis exacerbates this burden because it adds another 50 to 60 images or more per view per patient. At present, Hologic addresses this by compressing the stored digital breast tomosynthesis images. Standards for image storage and exchange (such as DICOM [Digital Imaging and Communications in Medicine]) and for workflow management have not yet been finalized for digital breast tomosynthesis.

Digital breast tomosynthesis is still very new and probably suitable only for sites at the leading edge of technology use and that have considerable capital and operational resources. Even some early adopters are taking a "wait and see" stance to determine whether the clinical utility provides a benefit that is worth the investment. The challenges are significant at present and include lack of competing technologies from other vendors, lack of image exchange and workflow management standards, high capital costs, lack of reimbursement, and the potential need to stratify patients who can benefit from digital breast tomosynthesis (e.g., when a site buys a single digital breast tomosynthesis unit as a replacement of one of several mammography units at the facility).

4 New CT Radiation Reduction Technologies:

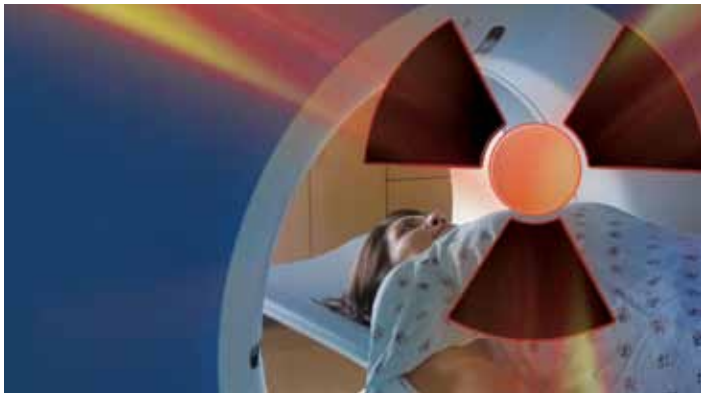
Are you doing enough to slice the dose and the risk?

Has your hospital reduced the risk of unnecessary radiation exposure for patients? Are you measuring the radiation dose delivered to patients during computed tomography (CT) scans? Does reducing risk mean you have to buy new CT systems?

CT radiation dose superseded slice number as the dominant CT-related topic two years ago, and it shows no signs of abating. In a way, the issue has evolved as another twist on personalized, patient-centered care. Gone is one-size-fits-all CT technology with no dose control, replaced by technology designed to optimize CT scanning parameters to individual patients and protect against excessive radiation exposure. The high interest in improved dose-reduction technologies has not peaked yet.

Precision engineering coupled with advanced computer controls have enabled CT scanners to eliminate x-ray dose that makes no contribution to the final image. The overall dose reduction from these steps is relatively small, but important, especially for pediatric and adolescent patients frequently seen in emergency departments. Unfortunately, these changes are available on only the most advanced platforms and cannot be retrofitted to existing systems. While these developments are important, the acceptance of "iterative reconstruction" has garnered the most interest.

Iterative reconstruction seemingly achieves the impossible—reducing dose without reducing image quality, or perhaps even improving it. At one time, imaging scientists believed that reducing



noise while improving image quality was akin to an alchemist synthesizing gold from base metals. Filtering out the noise in an image is not rocket science, but standard techniques used are known to smooth out images and remove fine details. However, CT uses multiple projections of the same anatomy and uses the fact that noise is random and changing while the anatomy is fixed to take an iterative approach that enables imaging physicists to distinguish true anatomy from random noise. In fact, similar techniques have been used in nuclear medicine for some time. CT technology users had not adopted the iterative approach because it is time-consuming and requires considerable computing power to make it clinically practical. But the radiation-dose issue made CT imaging experts reconsider its use.

All CT manufacturers now offer a type of iterative reconstruction. While differences in implementation exist, ECRI Institute clinical engineers determined through independent testing completed in

2011 that the overall effectiveness of the techniques is similar. The main issues are additional costs, availability, and the effect on image-processing time. The cost issue bears consideration largely because of the additional computing hardware required. For that reason, iterative processing was introduced on premium CT platforms, where it is now a standard feature. The technology is even becoming available on lower-cost CT systems (i.e., 64 slices and below). However, manufacturers have reported delays obtaining FDA 510(k) clearance for the technology as FDA is paying increasing attention to the labeled dose reduction claims. As a result, iterative reconstruction is available outside the United States on more CT scanner platforms than within the United States, particularly for 16- to 64-slice machines. When looking at iterative reconstruction options, hospitals should consider the acceptability of image processing times, since less costly versions compromise on the computing hardware. For owners of scanners that lack the option of iterative reconstruction, a third-party alternative is available that can be used on any existing CT scanner.

While the CT scanner technology is important, dose monitoring and measuring are critical to achieving lower radiation doses. After all, one cannot control something that isn't being measured. How little we actually know about the dose patients receive from CT scans can be surprising. Assessing the amount of radiation dose delivered during a CT scan is not trivial, and collecting the data can be time-consuming. To facilitate dose monitoring, a number of software options are becoming available today, both from CT manufacturers and third parties. Previous efforts at dose surveys have proved effective at identifying optimal dose levels and helping users achieve them. ECRI Institute believes that these tools are just as important as CT scanner technology and will be vital for optimizing CT dose.

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5 Transcatheter Heart Valve Implants:

Is your hospital prepared for a surge in demand for hybrid ORs?

Will you have the infrastructure and staff models in place to treat patients seeking new transcatheter solutions for cardiac valve problems?

New transcatheter approaches to solve tough cardiac valve problems herald a new era of minimally invasive cardiac surgery using catheters under radiographic/fluoroscopic image guidance. New patient populations never before eligible for treatment may come knocking at your door. Will you have the hybrid OR or hybrid cath lab you need to open that door? Patients previously treated with open heart valve surgery may have a minimally invasive option. For hospital executives involved in strategic planning for cardiovascular services, now is the time to plan for the infrastructure and staffing models that you'll need to successfully and safely adopt these new technologies.

In late 2010, the Melody Transcatheter Pulmonary Valve (Medtronic, Minneapolis, MN, USA) received approval under FDA's Humanitarian Device Exemption process. Availability of this device may enable patients with a congenital pulmonary valve insufficiency to reduce the number of open heart surgeries needed over a lifetime to fix the defective valve. Thus, the Melody valve could shift some care for these patients from the surgical suite to the hybrid OR suite and alter the staffing model for treatment.

On June 27, 2011, an FDA advisory panel recommended that the Sapien transcatheter aortic heart valve (Edwards Lifesciences Corp., Irvine, CA, USA) receive marketing approval, and FDA approved the valve on November 2, 2011, for use in patients with severe stenosis who are not candidates for open heart surgery. The manufacturer has been poised for aggressive marketing, according to market analysts, by having in place clinical specialists, sales staff, and reimbursement advisors. The company also had contracted with case proctors and had set up training centers at the time of FDA approval. Facilities that participated in the clinical trials (i.e., PARTNER I and II) are not required to take training to perform the procedure. These facilities were expected to be able to perform the procedure as soon as they received device shipments because, according to market analysts, the facilities had pre-identified eligible patients within their practices who could be eligible for the procedure. The company asserted that the first 250 clinical sites for performing the procedure had already been vetted within the company at the time of approval. Centers going through the training process will be required to accomplish the following: fundamentals courses, prescreening about five patients locally to present at training, and intensive, whole-team training. Edwards stated intentions of being very involved with centers to ensure high success rates. Training times will require a full heart team of eight, according to the company. The U.S. Centers for Medicare &

The hybrid cath lab model may be the ultimate destination for many of these procedures due to its lower cost.

Medicaid Services (CMS) announced September 28, 2011, that it "received a formal national coverage determination (NCD) request from the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC). Within the US, [transcatheter aortic valve replacement] TAVR has historically been performed only by physician investigators in centers of excellence within clinical trials, not by other practitioners or in facilities with limited experience with TAVR. This limited experience in the US raises the question of generalizability of the existing evidence base to more 'real world' settings." The process to reach a final, implementable national coverage determination takes 9 to 12 months from the date that the review began, meaning a decision can be expected between June and September 2012. Until then, coverage determinations will be left to local carriers.

Medtronic also has its own aortic heart valve (CoreValve) in development. Aortic valve stenosis affects many elderly patients (65 years of age or older), and previously most of the affected patients had no treatment option and had to accept a greatly reduced quality of life. Thus, this new minimally invasive option, when approved, could bring a new patient population into the healthcare system for treatment. This will increase demand for and utilization of hybrid ORs.

The MitraClip system (Evalve, Inc., Menlo Park, CA, USA) uses metal clips to repair mitral valve regurgitation and is already on the market in Europe but continues in phase III trials under FDA's investigational device exemption status. This is another procedure that may drive patients from the cardiac surgery suite to the minimally invasive hybrid OR. It may also introduce a subgroup of patients who previously had no options to the healthcare system for treatment.

What do hospitals need to plan for to support these new transcatheter procedures? Should it be a hybrid OR that is a cardiovascular OR that contains a single or biplane cardiac catheterization imaging system? Or should it be a hybrid cardiac cath lab designed to be an OR? The answer lies in the acuity and complement of the procedures to be performed and the lead specialists (e.g., invasive cardiology, cardiothoracic surgeons) needed for each of these procedures. The hybrid cath lab model may be the ultimate destination for many of these procedures due to its lower cost. Also, patient volumes for transcatheter valve procedures may be relatively low from the onset, which may favor a hybrid cath lab, which could be used for routine cath lab procedures. However, this migration may occur only after procedures mature and proficiencies improve. The hybrid OR provides the opportunity for simultaneous hybrid procedures such as open surgery in conjunction with transcatheter procedures. Hospitals will need to synchronize their hybrid OR/lab decisions based on their longer-term cardiovascular strategic plans.

6 Robotic-assisted Surgery:

Are costly robot wars coming to your operating room?

Is a challenger to the da Vinci robotic surgical system on the horizon? Will competition bring down the high capital costs of robotic surgery?

A four-armed surgical robot under development by Titan Medical, Inc. (Ontario, Canada) may be poised to compete "arm-to-arm" with the da Vinci Si surgical robot (Intuitive Surgical, Inc., Sunnyvale, CA, USA) in the next few years. The Amadeus Composer is described as "smaller and sleeker" than the da Vinci with four "snakelike" external arms to facilitate improved dexterity inside the body. Titan Medical indicates that the system will address one of the main complaints surgeons have voiced about the da Vinci—lack of haptic feedback (i.e., tactile feedback when cutting or suturing tissue). Titan is reportedly incorporating a patented haptic force feedback technology, and the system will operate via an Internet protocol to permit remote physician control from long distances if required. Like the da Vinci, the Amadeus system is being designed to provide robotic assistance for a wide range of surgical procedures. The company also hopes to leverage the smaller size of its physician control console and tableside cart to provide more flexibility and maneuverability, especially in older ORs where space is at a premium. A prototype of the Amadeus surgical robot is expected to be ready to test on animals in 2012; human trials are slated for 2013. The company states that a final production model should be ready to start the FDA regulatory process by 2014. Estimated pricing for the Amadeus surgical robot has not been announced, but Titan indicates that it intends to compete aggressively to make a dent in Intuitive Surgical's market share.

At last count, nearly 1,500 of the almost 2,000 da Vinci surgical robots deployed worldwide are in U.S. hospitals. As of mid-2011, more than 300,000 robot-assisted procedures had been performed using the da Vinci system, and each year this number rises by about 30%. Prostatectomy and hysterectomy remain the leading procedures performed. The latest FDA-approved da Vinci application is transoral robotic surgery for head and neck cancer. Its potential benefit lies in sparing the patient from radical ear-to-ear incisions across the neck and the subsequent scarring. With more than 5,500 hospitals in the United States, there seems

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to be room for more market penetration, and the features of the Amadeus system may be attractive to many facilities that have not yet adopted robotic surgery for general and oncologic surgical procedures.

Despite a lack of definitive evidence for the superiority of robot-assisted surgery compared to traditional laparoscopic surgery for many applications, steady growth in both the types and numbers of robotic procedures continues. In the midst of this growth, questions remain about clinician learning curves, what the ideal training program is, how many procedures are needed to maintain proficiency, and what criteria hospitals should use to credential surgeons using these systems. The issues of OR scheduling bottlenecks and patient throughput also persist with much variation in reported operative times for the same procedure. Although experts believe that operative times and complication rates decrease as surgeons and their OR teams gain experience, the high cost and lack of additional reimbursement associated with use of surgical robots continue to make this technology financially challenging. Proponents of robotic surgery state that the benefits this technology offers, including improved visualization, precision, and dexterity for the surgeon, make these systems well worth the added cost incurred to implement and maintain them (last estimated at about $3.5 million over a five-year period for the da Vinci system). While this may be true, the real unanswered questions are how much value they add and, more importantly, how and when will they definitively improve patient care and long-term outcomes?

Whether implementing a robotic surgery program or acquiring the latest CT or magnetic resonance imaging (MRI) system, new healthcare technology almost always costs more, at least initially, and validation rarely comes until enough time, training, and experience are available to answer at least some of the key clinical questions. Even after clinical validation and acceptance are achieved, cost continues to limit the diffusion of many new technologies. As the only FDA-approved multipurpose surgical robot on the market, the da Vinci Si has virtually no competition at present. As a result, the da Vinci system's $1.75 million to $2.25 million list price is rarely discounted, keeping it out of reach for many small and medium-sized hospitals. A challenger may be arriving soon.

7 New Cardiac Stent Developments:

Are new devices on the horizon signaling a personalized treatment trend for coronary artery disease?

Will a new class of coronary stents and balloons be on your supply shelves soon? Will they replace existing options or just add to your inventory headaches?

Even with the recent market withdrawal by Johnson & Johnson (New Brunswick, NJ, USA) of its Cypher stent because of lackluster sales, much is happening with cardiac stent developments for coronary artery disease. The next generation is expected to herald devices that include antibody coatings, bioabsorbable stents, stents designed especially to treat bifurcated lesions (Y-shaped lesions affecting two arteries), and drug-eluting balloons. The need for a more personalized approach is apparent from a number of signals, including high rates of off-label use of existing stents, high complication rates from treating bifurcated lesions with current stents, and higher-than-desired reocclusion and reintervention rates.

The next generation is expected to herald devices that include antibody coatings, bioabsorbable stents, stents designed especially to treat bifurcated lesions, and drug-eluting balloons.

While the waters of controversy have receded since November 2006, when long-term clot risk concerns were raised in a meta-analysis presented by researchers at the European Society of Cardiology in Barcelona, Spain, questions related to stent use remain. A large number of cardiac interventionalists have opined that the most appropriate clinical use for drug-eluting stents is actually off-label (i.e., for multivessel disease and/or patients with comorbid conditions) because those patients are sicker and have more to lose with recurrent stenosis and revascularization. Indeed, in a recent paper published in the *Archives of Internal Medicine* (2011 April 25[Epub ahead of print]), Peter W. Groeneveld, M.D., M.S., and colleagues noted that 60% of drug-eluting stent usage in the Medicare population is off-label to treat patients with more complex disease and comorbidities. FDA-approved labeling for drug-eluting stents includes use in discrete, previously untreated blockages in patients' native coronary arteries.

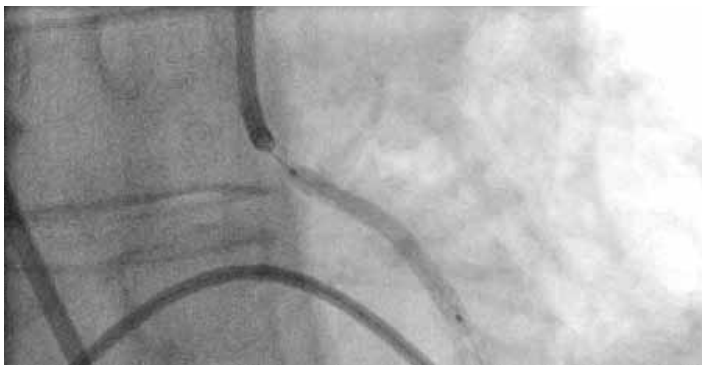
New stent developments appeal to cardiac interventionalists, who want to see stents that get completely covered with endothelial cells rapidly, which is the promise of antibody-coated stents in development. These physicians also look forward to the day when stents can scaffold the vessel to enable it to stay in place until the vessel remodels, and then the stent scaffold disappears. One antibody-coated stent, the Genous Bio-engineered R stent (OrbusNeich, Hong Kong), received the CE mark for use in Europe in 2005, and the first bioabsorbable stent, Absorb Bioresorbable Vascular Scaffold (Abbott Laboratories, Inc., Abbott Park, IL, USA), received the CE mark in January 2011. But these stents remain in mid- to late-phase development for the U.S. market. The

Achilles heel of the bioabsorbable stent, some believe, is radial strength. The problem is figuring out how to carry a drug-eluting substance that is relatively short-lived so that after six months, for example, both the drug and the scaffold are largely eliminated, leaving an open artery that grows its own endothelium.

Stent manufacturers are also pursuing low-profile, very thin, and flexible stents intended to minimize stent thickness using newer alloys that enable these stents to maintain sufficient radial support of the artery. The intent is to enable physicians to deploy them to places they previously could not reach with less irritation of the artery.

Another innovation is pursuit of stents intended to enable better treatment of bifurcated lesions. These difficult-to-treat lesions are associated with high complication rates when two stents are used—one in each affected vessel branch. Developers are trying to solve the problem with new designs for these lesion types. An example of one such stent in development is the Tryton Side Branch Stent (Durham, NC, USA), a bare-metal stent intended to treat a range of bifurcated lesions and intended for use with a conventional drug-eluting stent in the main vessel. Tryton takes a slightly different approach from other developers, in that it focuses on the side-branch lesion rather than the main vessel lesion.

Drug-eluting balloons under development combine a conventional noncoated balloon catheter with an antiproliferative agent to reduce scar tissue growth in a vessel after percutaneous transluminal coronary angioplasty. Unlike drug-eluting stents, which deliver antiproliferative drugs within several weeks to months, drug-eluting balloons are designed to deliver the drug dose within several minutes during percutaneous transluminal coronary angioplasty. Most drug-eluting balloons currently in clinical use or in development are coated with paclitaxel, now in wide use with current drug-eluting stents. The Moxy paclitaxel-eluting angioplasty balloon (Lutonix, Inc., Minneapolis, MN, USA) currently under development would likely be used either in place of conventional noncoated angioplasty balloons alone or in place of noncoated balloons and as an adjunct to bare-metal stenting. Some interventionalists think that a drug-eluting balloon might be useful in a vessel with lots of areas of disease and in which other stents are going to be deployed or if a drug-eluting stent cannot be deployed.



8 Ultrahigh-field-strength MRI Systems:

What's the big attraction?

Are higher resolution and more detailed images worth the extra $1 million cost of ultra-high-field strength (3T) MRI?

MRI is highly valued for its ability to provide high-resolution images of soft tissue without using ionizing radiation like conventional x-ray, CT, or fluoroscopy. MRI uses a powerful magnetic field and pulsed radiofrequencies (RFs) to create images. The relative strength of the magnetic field is measured in teslas (T). The most common magnetic field strength used today for diagnostic MRI is 1.5T (i.e., high-field strength). In the past few years, new MRI systems have emerged that use a 3T field-strength magnet, also called ultra-high-field strength. These 3T systems offer better image resolution but cost about $1 million more than standard 1.5T systems. MRIs with even higher strength (7T and higher) are being used for some medical research applications at a few institutions. In daily clinical practice, however, MRI field strength is limited to 3T, and reimbursement is usually the same regardless of field strength. So what difference does higher field strength make in patient outcomes?

Also important to note is that the increased performance of 3T MRI can be used to either increase image quality or decrease study time—not both.

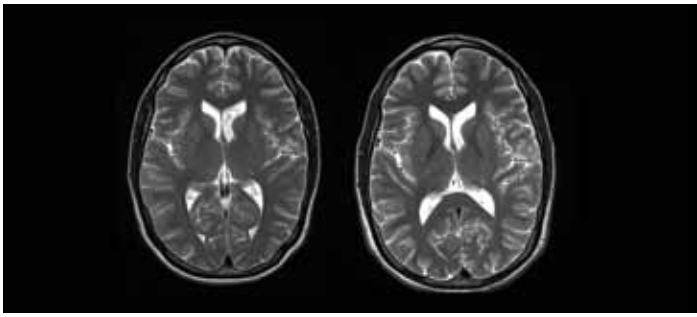
Signals emitted by protons in patient tissue are used to create an MR image. Because the emitted signal is tiny, the number of signal-emitting protons needs to be maximized. As the strength of the applied magnetic field increases, the number of protons available for imaging also increases. Theoretically, if the magnetic field strength doubles, the signal-to-noise ratio also doubles and image quality should improve. Yet, other factors affect the final image quality. The physical interactions that control image quality and artifacts are complex. Some of these interactions improve the visibility of pathology and anatomy, while others detract from it. In particular, an effect that has received a lot of attention with ultra-high-field MRI is called the "dielectric effect" (i.e., increased image artifact related to inhomogeneity of the RF field). It was the major reason for the poor body-imaging results that early 3T system researchers reported. Today, all manufacturers have developed methods to minimize or eliminate dielectric artifacts so that 3T can now be used for routine body imaging.

Also important to note is that the increased performance of 3T MRI can be used to either increase image quality or decrease study time—not both. If used to decrease study time, a 3T system can make it possible to improve workflow efficiencies for some routine MRI exams. More complex studies that require the highest-quality images, however, will take longer. Also, 3T MRI systems are more susceptible to certain artifacts, which require training and experience to control. Added patient safety concerns

are also associated with this technology, including patient heating and incompatibility with some types of implants. (Although early studies indicate that many implants pose no additional danger in 3T environments, most implants have not been tested yet.)

Over the past 10 years, many studies have compared 3T MRI with lower-field-strength systems. Most of these studies reported improved image quality for 3T systems (although the image quality has not improved doubly over that achieved with 1.5T). Thus, more lesions can be detected with increased confidence. But the clinical value of these advances is difficult to gauge, since most comparative studies are not designed to evaluate whether patient-oriented outcomes improved as a result of decision making based on a 3T versus a 1.5T MRI exam. Given the inconclusive evidence, 3T MRI research has moved to exploring what new clinically useful information can be obtained with 3T systems, with a particular focus on neurologic applications, such as functional MRI, diffusion-weighted MRI, and spectroscopy. For other applications, little evidence suggests that 3T is necessary or that it improves patient outcomes over 1.5T.

Although 3T allows improved image quality, users must be aware of its potential drawbacks. Importantly, any facility wishing to implement a 3T system must understand that adjusting imaging protocols will require considerable ongoing radiologist involvement. Radiologists must be readily accessible



and committed to the project. Since the benefits of 3T MRI for neurosurgical applications are well established, facilities that serve neurosurgery programs should seriously consider acquiring a 3T system. Purchasing an expensive (average $2.4 million) 3T system for routine MRI applications, however, is still difficult to justify—at least until additional research demonstrates added clinical utility.

9 Personalized Medicine for Cancer Care:

Is your oncology service ready for the costly implications?

What will new $100,000+ personalized therapies mean for hospital oncology services? Can you afford the upfront cost outlay? Will reimbursement be sufficient?

Cancer care has always been costly, but the rate of increase heralded by recent approvals of new drugs and biotechnologies represents an unprecedented trend as major pharmaceutical companies, such as Roche Diagnostics (Indianapolis, IN, USA), announced plans this year to focus the majority of their development over the next decade on personalized therapies. Paradigm shifts are occurring, owing to the mapping of the human genome more than a decade ago. These changes are purportedly taking chemotherapy and biotherapy out of the "blunt instrument" category into the "targeted, personalized therapy" category. The result is many new and high-cost pharmaceuticals and biotechnologies with per-patient price tags of $100,000 and up. And none of them are replacements for existing interventions—they are all add-ons to existing therapy regimens.

Many in the oncology community are excited about these kinds of therapies because they offer new treatment options for advanced cancers for which no effective therapeutic options have been available. In the past 3 to 15 months, 5 new targeted cancer therapies for treatment-refractory, advanced cancers (melanoma, Hodgkin's lymphoma, lung cancer, and prostate cancer) were approved, including the first personalized therapeutic cancer vaccine.

Patients are looking to hospital oncology departments to see whether these new personalized treatments are being offered. Yet, the average observed survival improvements associated with these therapies, while encouraging, are relatively modest—measured in two to six months. Also, the therapies have potentially serious or even life-threatening side effects that will require discussion between the physician and patient to weigh potential benefits and harms. For example, a new treatment for metastatic melanoma (Yervoy) was approved with a black box warning (required by FDA) regarding possible development of fatal immune-mediated adverse reactions due to T-cell activation and proliferation, which can involve any organ system.

These paradigm shifts also signal the following:

- Potentially more outlay of capital by oncology centers on a per-patient basis to cover upfront costs for preparation of personalized vaccines

- Additional genetic testing of patients to determine eligibility (e.g., genetic mutations) for some of the therapies
- More time spent by clinicians with patients to explain results and options
- Potential serious or even life-threatening side effects that require close clinical monitoring of patients
- Potential for further mutation of cancer cells resulting in patients with treatment-refractory disease after only several months

The much-touted Provenge personalized cancer vaccine for treatment of symptomatic metastatic, castration-resistant prostate cancer was the first cancer vaccine to reach market, and more personalized vaccines are in mid- to late-phase development by various biotechnology companies. However, Provenge has not become the blockbuster expected in the 18 months since its FDA approval. Initially, speculation over the slow diffusion and utilization centered on the required upfront cash outlay (the therapy costs an estimated $97,000 per patient for the full course of treatment over several weeks) and lag time to reimbursement. The developer, Dendreon Corporation (Seattle, WA, USA), ended a contract in October 2011 with the company that possessed the technology used to process patient cells to produce the personalized vaccine and laid off 500 employees. Following that action, new questions emerged about the conflicting evidence used to support the vaccine approval. These events could make some skeptical about other therapeutic cancer vaccines now in development.

These changes are purportedly taking chemotherapy and biotherapy out of the "blunt instrument" category into the "targeted, personalized therapy" category.

Another personalized approach contrasts with the cancer vaccine approach; it uses immunotherapy to attempt to modulate a patient's existing immune responses. Several pathways leading to immune tolerance of tumor cells have been identified, and the recently approved monoclonal antibody ipilimumab (Yervoy, Bristol-Myers Squibb, New York, NY, USA) for treatment of metastatic melanoma is intended to inhibit one of these pathways to mount a T-cell antitumor immune response. The estimated cost for a full course of treatment is $120,000.

Still other approaches are reserved for patients whose tumors harbor specific genetic changes that are targeted by the therapies and are therefore likely to respond. However, the response can be relatively short-lived as tumor cells change and develop resistance. Two newly approved therapies in this category are crizotinib (Xalkori, Pfizer, Inc., New York, NY, USA) and vemurafenib

(Zelboraf, developed by the Genentech unit of F. Hoffmann-La Roche, Ltd., Basel, Switzerland). Crizotinib is an anaplastic lymphoma kinase (ALK) inhibitor for non-small cell lung cancer (NSCLC). Vemurafenib is a B-RAF inhibitor for metastatic melanoma.

Xalkori is expected to be suitable for only about 4% to 7% of patients with NSCLC who harbor ALK. However, identifying eligible patients means that every patient with NSCLC will need to be tested for the presence of ALK. Zelboraf is expected to be used in a higher proportion of patients and will compete with Yervoy. Zelboraf targets the most commonly observed B-RAF mutation in patients with metastatic melanoma, V600E. The proportion of the patient population with metastatic melanoma who have this mutation ranges from about 40% to 70%. In the near future, B-RAF status will be common knowledge for all patients with melanoma because of the focus on this pathway. The potential of B-RAF inhibitors is limited, however, by the fact that the vast majority of patients will eventually develop resistance to the therapy. However, these inhibitors are expected to remain a central focus of melanoma treatment and clinical study in coming years. The estimated cost of these drugs is nearly $10,000 per patient per month, with several months or more of therapy anticipated for a full treatment course.

Another targeted therapy that may soon reach market is ruxolitinib, known as a Janus kinase (JAK) inhibitor (codevelopers Incyte Corp., Wilmington, DE, USA, and Novartis AG, Basel, Switzerland). The drug acts as an inhibitor of JAK1 and JAK2. It is under study for treatment of myelofibrosis, a relatively uncommon disease with no effective treatment. JAK signaling is involved in the regulation of blood cell production and proliferation, and JAK2 signaling, in particular, has been implicated in driving the pathology of myelofibrosis. Activating mutations in JAK2 have been identified in about 60% of myelofibrosis cases; however, ruxolitinib is not intended solely for use in JAK2 mutation-positive cases possibly because JAK2 signaling may still be important even in JAK2 mutation-negative cases. FDA is expected to render a decision by late 2011.

A first-in-class targeted drug approved in late 2011 is brentuximab vedotin (Adcetris, Seattle Genetics, Seattle, WA, USA) for Hodgkin's lymphoma and anaplastic large-cell lymphoma, two less common cancers. Adcetris is known as an antibody-drug conjugate (ADC). ADCs have been described as "guided missiles against cancer cells." A dozen companies are developing at least 15 ADCs for various cancers. ADCs employ a monoclonal antibody linked to a cancer drug. The antibody targets a specific tumor cell antigen and, because the drug is linked to the antibody, once the antibody binds to the target antigen, the drug is delivered to the tumor cell to exert its anticancer effects. Adcetris' estimated cost per patient is expected to be $95,000 to $100,000.

10 Proton Beam Radiation Therapy:

Should it be part of your strategic plan or will carbon ions supplant protons?

What about proton therapy? Should your hospital be thinking about it? When?

*Ph*oton beam radiation is the most common type of external beam radiation therapy used to treat cancer today, and many methods have been developed to increase dose, target tumors more precisely, and reduce collateral tissue damage. Nonetheless, *pr*oton beam radiation therapy continues to hold major interest for the oncology community, hospitals, and patients. Since clinical research began 70 years ago, the promise of protons is their theoretical ability to deliver high-dose radiation precisely targeted to the tumor with little collateral damage occurring along the route of the proton beam as it travels to the tumor. Thus, the technology holds potential to reduce acute and long-term side effects of radiation therapy. But over the past 30 years, little about this technology has changed, and some radiation physicists assert that unless proton radiation therapy technology advances to use multiple beams converging on the tumor target, rather than just a single beam, improved patient outcomes over other current radiation oncology techniques are not likely. Reducing acute and long-term side effects is especially important when treating tumors located around or near critical structures such as the brain, eye, spinal cord, ureter, or nerve bundles and when treating children because of their vulnerability to radiation side effects, including stunted growth and secondary cancers.

But proton therapy is expensive. Only large, custom-built particle accelerators (cyclotrons or synchrotrons) can produce proton

beams. A single cyclotron can fill a large room, weigh up to 240 tons, and cost $100 million or more. The average construction time for a proton treatment center is two to three years, and after construction is completed, system validation can take another year. Building a proton center with five or six patient vaults costs upwards of $200 million. Once the center is in operation, expenses for staffing, ongoing equipment services, and maintenance can cost an additional $20 to $25 million per year. Synchrotrons, which are smaller, lighter, and less expensive than cyclotrons, have also become available recently to support the long-awaited "low-cost" single proton treatment room model. But a single-room proton center can still cost more than $20 million to build. If a facility goes this route, the cost to add additional treatment rooms in the future may also be higher than a more traditional proton center design that utilizes a single cyclotron to serve multiple treatment rooms. On a per-patient treatment basis, proton therapy is currently estimated to be three times more expensive then state-of-the-art photon therapy. Yet, the clinical efficacy of protons versus photons has not been established at this time.

That said, for centers offering proton therapy, the CMS final 2012 Hospital Outpatient Prospective Payment System (HOPPS) rules included a nearly 15% payment increase for proton therapy compared to 2011. Level I proton therapy (Ambulatory Payment Classification [APC] 0664) includes most prostate treatments; the payment rate in 2012 will be about $1,184 (up from $1,032). Level II (intermediate or complex proton treatments [APC 0667]) payment will be about $1,549 (up from $1,350). The 2012 rule applies only to hospital-based proton therapy centers (i.e., Loma Linda University, Loma Linda, CA; Massachusetts General Hospital, Boston, MA; University of Pennsylvania, Philadelphia, PA). Local Medicare carriers negotiate rates with the six freestanding proton centers, which are expected to generally follow suit from the HOPPS rule.

Complicating the proton therapy picture is increasing interest in another type of radiation therapy—carbon ion therapy and the purported advantages it may offer over protons and photons. The properties of heavy ion beams (e.g., carbon ion) may allow improved administration of radiation therapy compared to photon or proton beam radiation. Like proton beams, particles in carbon ion beams lose the majority of their energy immediately before they deposit the energy at a tumor target. This phenomenon, known as the Bragg peak, potentially allows planning for targeting the radiation dose to a specific tissue depth and sparing of adjacent tissue. Compared to protons, the path of heavier carbon ions is less influenced by passage through overlying tissue and, therefore, the peak of ionizing radiation is tighter, potentially allowing more precise targeting and delivery. In addition, heavier particles such as carbon ions have a more severe impact on atoms within target cells, which produce more intense cellular damage and can potentially increase the biologic effectiveness of carbon ion beams relative to proton or photon beams. In particular, the relative biologic effectiveness of carbon ions purportedly increases with tissue depth, coinciding with the Bragg peak. Lastly, collisions between carbon ions and atomic nuclei produce positrons through nuclear fragmentation. The generated positrons can be imaged using positron emission tomography, potentially allowing visualization of the delivered dose distribution.

Developers include Ion Beam Applications S.A. (Brussels, Belgium) in a joint venture with SAPHYN (SAnté et PHYsique Nucléaire, or Nuclear Health and Physics, a semipublic company, Caen, France) and financial partners, and Siemens, AG (Munich, Germany).

Carbon ion centers, like proton centers, cost about $200 million to build. Two carbon ion beam facilities are currently operating—one in Japan for 10 years and one that went online in 2009 at University Hospital Heidelberg, Germany. Another is planned to open in Germany in 2012: NRoCK, the North European Radio-oncological Center Kiel, Schleswig-Holstein. In the United States, Colorado State University announced in 2010 a partnership with the Japanese facility to perform carbon ion therapy research. Collaborations among several hospitals in Michigan and separately among several hospitals in Ohio to explore developing carbon ion centers were announced in 2008, though progress on further development is unclear at this time.

In 2008, the U.S. Institute of Medicine designated proton therapy

as a top priority for comparative-effectiveness research, and still no appropriately designed randomized controlled trials (RCTs) are under way to directly compare proton to photon treatment in terms of patient survival, side effects, and quality of life. With regard to carbon ion therapy, 10 trials are ongoing or planned currently. Some of these trials are RCTs that will compare carbon ions to protons. Although large RCTs comparing proton therapy to photon radiation would be ideal in determining proton therapy's safety and effectiveness, these trials are unlikely in the United States due to ethical concerns about denying what some clinicians consider a potentially more effective treatment for certain patients. So promise and hope win out over evidence. Ongoing trials provide little in the way of direct comparisons that might help assess proton therapy effectiveness. ECRI Institute has reviewed the clinical data on proton therapy many times over the last 15 years, only to reach the same conclusion: no data are available that can address the primary key questions of comparative effectiveness. With carbon ion therapy's genesis at centers in Europe and Japan, perhaps the evidence development will take a different track to enable U.S. hospitals to better determine whether to pursue protons or carbon ion center development.

Despite the high costs, technical complexity, and lack of comparative-effectiveness evidence on protons, advocates for proton therapy remain enthusiastic. However, skeptics at some cancer centers of excellence are holding out to see what develops with carbon ions.

To date, about 70,000 people worldwide have received proton therapy. At least 33 proton therapy facilities are currently in operation worldwide, including centers in Canada, China, England, France, Germany, Italy, Japan, Korea, Russia, South Africa, Sweden, and Switzerland. More than 20 new proton centers are currently under construction or in the planning stages worldwide. In the United States, 9 centers currently offer proton therapy, and by 2013 the number is expected to rise to 15. Because of the limited number of centers currently available, proton therapy is usually reserved for patients with a specific need for precise tumor targeting. The types of patients for whom it is recommended include adults with tumors adjacent to vital structures and some children with certain types of tumors requiring precise targeting. About 15% of all cancer cases are now considered potentially appropriate for proton therapy, including malignancies in the abdomen, central nervous system, eye, lung, and prostate, and some noncancerous conditions such as arteriovenous malformations of the brain. Proton therapy is not considered appropriate for nonsolid tumors and tumors likely to metastasize. The reimbursement picture for proton radiation therapy is still unclear. Though many insurers currently provide some coverage for some clinical indications, reimbursement is spotty and at the discretion of local carriers. Time will tell whether the promise of proton therapy is realized. Until then, facilities planning to adopt this technology should carefully consider the high cost, limited evidence, and uncertain reimbursement climate before making a decision.

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