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Costs. Time. **Hearts.**

**Assisting the heart with low risk of complications has always been the goal.** More than 160,000 intra-aortic balloons (IABs) a year are used globally by clinicians to protect and assist their patients’ heart\(^1\). This makes IAB the most widely accepted mechanical circulatory support device.

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- **In the BCIS-1 long-term mortality data**, elective IAB Pump (IABP) use during high-risk PCI was associated with an observed 34% reduction in long-term, all-cause mortality\(^3\).

**With its low risk of complications, ease-of-use, and cost-effectiveness Maquet’s IAB is a great start to saving a heart.**

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MAY/JUNE 2016

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About the Cover

The Abbott Absorb everolimus-eluting coronary stent is the first bioresorbable scaffold to undergo U.S. Food and Drug Administration (FDA) review. An expert FDA review panel voted in favor of the stent’s approval earlier this year and a final market approval decision is expected later in 2016. See the story on Page 16. Watch a video interview with Gregg Stone, M.D., at ACC.16 explaining ABSORB Trial data showing poor outcomes in small coronary vessels, at http://bit.ly/1qptcgn.

Web-Exclusive Feature

Editor’s Choice of the Most Innovative Trends and Technologies at ACC.16

DAIC Editor Dave Fornell takes a video tour of some of the trends and interesting new technologies from the vendor booths on the expo floor at the 2016 meeting of the American College of Cardiology (ACC).

Watch the video at http://bit.ly/248Lz3b

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Wow!
That Sums up TAVR Data at ACC 2016

There has been a lot of conjecture that transcatheter aortic valve replacement (TAVR) may one day replace open-heart surgical aortic valve replacement (SAVR). However, after attending the American College of Cardiology (ACC) 2016 meeting, it is evident that change will come much sooner than anyone anticipated. “Wow” is really the key summary I can offer regarding the TAVR vs. SAVR data presented at ACC. Three key presentations showed TAVR as equal or superior to surgery.

The Partner 2A trial for the Sapien XT showed the device was equal to surgery in intermediate-risk surgical patients. The improved Sapien 3 device replaced the XT toward the end of the Partner 2 trial. The valve has a fabric skirt that significantly reduces paravalvular leak, which was an issue with the earlier versions of the Sapien. The PARTNER results were separated for the XT and Sapien 3 arms of the study. The data for Sapien 3 show it clearly performed better than surgery in intermediate patients.

U.S. CoreValve pivotal trial results showed TAVR was better than surgery, and the three-year results presented at ACC show a continued positive trend. The lines between TAVR and surgery for all-cause mortality also continue to diverge in favor of TAVR.

Cardiothoracic surgeon Steven Bolling, M.D., University of Michigan, said TAVR is a brand new technology being implanted by new, inexperienced operators. But, within five years of the technology gaining U.S. market approval, it has beaten out the performance of very specialized, experienced surgeons. He noted that new interventional cardiology operators were able to show better patient outcomes with TAVR than his own surgical outcomes, and he has the experience of performing more than 5,000 surgical valve procedures. Bolling said if a test between two competing technologies shows them to be at least equal, the easiest one to use will always be the ultimate winner. He said there is little doubt in his mind that TAVR will become the standard of care in the next few years.

The three main questions standing in the way of full acceptance of TAVR as a new standard of care are: 1. How it performs in low-risk patients; 2. Durability; and 3. Its ability to gain reimbursement. The U.S. Food and Drug Administration (FDA) gave the green light earlier this year for low-risk patient trials for both the CoreValve and Sapien 3. The results of those trials in a couple years will be very highly anticipated. The long-term durability of TAVR valves will also be assessed in these patients over the next decade.

As the cost of TAVR decreases, the current cost-conscious healthcare environment will likely embrace it, especially as this minimally invasive technique increasingly becomes a same-day outpatient procedure.

We welcome your comments on the topics found in Diagnostic and Interventional Cardiology. Please send your thoughts to dfornell@sgcmail.com
FDA Approves World’s Smallest Pacemaker

The U.S. Food and Drug Administration (FDA) cleared the world’s smallest and first transcatheter-deployed pacemaker in April, the Medtronic Micra Transcatheter Pacing System (TPS). The miniaturized pacing technology is cosmetically invisible and small enough to be delivered through a catheter. It is implanted directly into the heart, providing a safe alternative to conventional pacemakers without the complications associated with cardiac lead wires.

"For many years we’ve been hopeful that a transcatheter pacing solution — with a safety and effectiveness profile on par with conventional devices — would become available, and today Micra has achieved this milestone,” said Dwight Reynolds, M.D., regent’s professor and chief of the cardiovascular section at the University of Oklahoma Health Sciences Center, and principal investigator in the Micra TPS Global Clinical Trial. “In the clinical trial, the Micra was successfully implanted in nearly all patients, and met its safety and effectiveness endpoints by wide margins. This gives us great confidence that this miniaturized device will bring patients the most advanced pacing technology, combined with the less-invasive nature of the new technology.”

Comparable in size to a large vitamin, the Micra TPS is attached to the heart with small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device. Unlike traditional pacemakers, the Micra TPS does not require leads or a surgical “pocket” under the skin, so potential sources of complications related to such leads and pocket are eliminated — as are any visible signs of the device. It responds to patients’ activity levels by automatically adjusting therapy.

Micra TPS is approved for both 1.5T and 3T full-body magnetic resonance imaging (MRI) scans.

The Micra incorporates a retrieval feature to enable retrieval when possible; however, the device is designed to be left in the body. For patients who need more than one device, the miniaturized Micra TPS was designed with a unique feature that enables it to be permanently turned off so it can remain in the body and a new device can be implanted without risk of electrical interaction.

News Briefs

- The U.S. Food and Drug Administration (FDA) has received a small number of reports of adverse events believed to be associated with computed tomography (CT) imaging of some implantable and wearable electronic devices. These include insulin pumps, cardiac implantable electronic devices and neurostimulators. The agency’s current understanding is that when a CT scanner directly irradiates the circuitry of certain implantable or wearable electronic medical devices (i.e. when the device is visible in the resulting CT image), it can cause sufficient electronic interference to affect the function and operation of the medical device. The probability that this interference can cause clinically significant adverse events is extremely low. Furthermore, the probability of X-ray electronic interference is lower when the radiation dose and the radiation dose rate are reduced. Interference is completely avoided when the medical device is outside of the primary X-ray beam of the CT scanner.

- Medtronic announced positive clinical data from one of the endpoints in the RevElution Trial for its novel, next-generation drug-filled stent (DFS) at ACC.16 in April. These new data showed rapid vessel healing without inflammation in optical coherence tomography (OCT) data of the complete one-month follow-up patient cohort. The trial has completed enrollment in the 50-patient cohort of the RevElution Trial, which will be used to support CE (Conformité Européenne) mark.

- A new implantable medical device intended to help patients with heart failure by stimulating the vagus nerve did not significantly reduce rates of heart failure-related hospitalization or death.
The more frequently a hospital performs a transcatheter aortic valve replacement (TAVR) the better patients fare, on average, immediately after the procedure, researchers reported at the American College of Cardiology (ACC) 2016 meeting.

TAVR was first approved by the U.S. Food and Drug Administration (FDA) in 2011 to treat patients with severe aortic valve stenosis for whom standard surgical valve replacement is too risky. The valves are now being tested in trials in intermediate- and low-risk patients.

“In a large dataset of over 40,000 cases of TAVR performed in the first four years after the technology was approved by the FDA, we found that outcomes significantly improved first during the early learning phase. In addition, even after hospitals achieved a volume of 100 or so cases, there continued to be improvement in patient outcomes with higher procedure volume,” said John D. Carroll, M.D., professor of medicine and director of interventional cardiology at the University of Colorado Hospital, and lead author of the study.

The findings are important because they shed light for the first time on a key factor involved in determining patient outcomes following treatment with this novel procedure, Carroll said. This will help inform decisions by healthcare professionals, patients and payers about how to ensure the best outcomes for patients treated with this new technology, he said.

“These results support the view that the healthcare system as a whole benefits when hospitals perform procedures in higher volumes, improving outcomes,” Carroll said.

“Although neither drug significantly improved the overall rate of survival to hospital discharge, amiodarone showed a favorable trend in that direction.

Researchers have confirmed that certain heart rhythm medications, when given by paramedics to patients with out-of-hospital cardiac arrest who had failed electrical shock treatment, improved likelihood of patients surviving transport to the hospital. The study was published online in the New England Journal of Medicine and helps answer a longstanding scientific question about the effectiveness of two widely used antiarrhythmic drugs, amiodarone and lidocaine, for treating sudden cardiac arrest. The study followed the patients from hospital admission to hospital discharge. Although neither drug significantly improved survival to hospital discharge, amiodarone showed a favorable trend in that direction.

Delayed or deferred stent implantation in patients showed no clinical benefit in patients experiencing the deadliest form of heart attack, ST-segment elevation myocardial infarction (STEMI), according to research presented at the American College of Cardiology’s 65th Annual Scientific Session (ACC.16). Researchers noted delayed or deferred implantation failed to reduce death from any cause, hospitalization for heart failure, subsequent heart attacks or the need for a repeat procedure to restore blood flow to the heart.
Cardiology Technology Trends at ACC.16

Advances in echo, ECG, hemodynamics and information technology

By Jon Brubaker, MBA, RCVT; Tom Watson, BS, RCVT; and Sabrina Newell MS, RCS

There were several new trends seen in cardiovascular technologies showcased on the expo floor at the 2016 American College of Cardiology (ACC) meeting in April. These insights are from clinical analysts from the evidence-based research and consulting company MD Buyline.

Echocardiography

Various levels of ultrasound machines, including portable equipment, continue to be highlighted on the floor of ACC. Vendors showcased more compact, portable systems with a larger number of software features than previous models. The implementation of speckle tissue tracking (myocardial strain) software seemed to be a focal point for systems, such as Toshiba’s Aplio 500 and the new M9 from Mindray. Vendors vary on the terminology used to describe tissue tracking. Although tissue tracking is not a new technology in cardiac imaging, it is now notably simpler to perform an analysis. Strain imaging can be a useful indicator for myocardial function, ventricular dyssynchrony and cardiotoxicity management.

Vendors Respond to Financial Pressures Hospitals Face

Vendors are responding to the financial constraints healthcare providers face by providing a wider range of equipment that is scalable to meet specific technological, as well as financial, needs. We typically see vendors offer a premium system to meet high-technology applications, such as 3-D/4-D transesophageal echo (TEE), while also offering a significantly lower-priced option to meet the daily needs. For example, GE was showing the premium Vivid E95 along with the high-end model Vivid S70. Philips also highlighted the premium Epiq 7 platform along with the high-end Affinity platform. Facilities are realizing they can customize premium-level technology or avoid it all together.

Major vendors in the ECG market now sell multiple systems that are smaller and less sophisticated versions of the premium system. Basic similarities include the analysis algorithm, storage and communications ability. Needs of a busy, urban hospital are not necessarily the same as those of remote sites. Sites can find significant savings through a wise mix of equipment.

Health systems also require integration of their information technology (IT) and ECG systems to allow full access in electronic medical records (EMR). GE introduced Version 9 of its Muse ECG management system at ACC.16, which allows greater connectivity with other vendors’ ECG systems, including newer, wearable Holter monitors and smartphone-based ECG monitors.
Improved Graphic User Interface Technology

Vendors are looking to improve customer interface and software for high-complexity technology in order to provide more efficient workflow processes. They are doing so by introducing new technology that significantly simplifies the data capture and utilization process with a focus on assisting the clinician in key procedural steps. The need to ensure high-quality, complete data capture and reporting is paramount because this will affect reimbursement. Systems are now automatically populating data fields that previously would have needed to be entered manually. The technology also is cross-checking the values to verify they are falling within acceptable ranges and ensure the data points are legitimate.

Hemodynamic monitoring technology vendors showing these improvements include GE Healthcare (Mac-Lab), Philips (Xper Flex Cardio) and Siemens (Sensis Vibe). All three vendors have changed and enhanced their solutions to be less labor intensive and to capture the critical values. This ensures a complete record is captured for accurate diagnosis and complete reimbursement without delays due to missing or incorrect data. We believe this is an important and necessary step because reimbursement is now tied to complete and accurate documentation. Additionally, there is a need to minimize the potential for human error, which can negatively affect the procedure information and the associated reimbursement.

Security Concerns Bring Customizable Options

Vendors in the cardiology market are reacting to market needs for improved protection from security breaches by providing strong security options for equipment, software and management systems. According to vendors, this is driven in part by large IDNs and the government. Current security options offered allow an individual facility or organization to review and choose what degree of security to implement. This is important because strong security may significantly affect workflow and productivity. Allowing for customizations helps providers make a manageable and realistic compromise between security needs and the daily workflow and patient care.

IT Involvement Growing in Clinical Decisions

As the push for integration in healthcare continues to grow, we are seeing IT personnel become more involved in the decision-making process of new and, in some cases, existing technology. Additionally, healthcare provider organizations, which have grown through partnerships, mergers and acquisitions, are looking to begin a process of transitioning these larger systems onto the same or similar vendors for IT software and infrastructure, as well as medical technology.

The need for healthcare providers, from individual physicians to large healthcare systems, to move to an EMR solution also has pulled IT further into the clinical decision making process. This has led to new challenges not only for customers, but also for vendors who are being asked for solutions that work with a range of technology that can vary widely with regard to functionality, consistency and open vs. closed architecture. When vendors with clinical solutions must coordinate and work with large, well-established IT/EMR vendors in their respective markets, the two areas that seem to create particular challenges are integrating/interfacing EMRs with clinical monitoring and/or imaging. At the ACC.16, numerous discussions with multiple clinical vendors touched on challenging experiences trying to work with major IT vendors. It was particularly challenging with EMR vendors that have a sizable market share.

Hospitals need coordination with vendors to achieve the goal of a well-designed, integrated system that allows the hospital to record, capture and use a wide range of disparate data that makes up the complex, clinical picture of medical findings, diagnosis and treatment or therapy solutions. Although IT vendors are adept at capturing and using data, there is a disconnect when it comes to working with the corresponding “experts” on the healthcare side. Multiple vendors described such situations during our discussions at ACC.

The issue is a concern for customers who are being asked to require their medical vendor(s) work with an IT vendor. There can be significant hurdles and roadblocks that both sides must work to remove. Key information and data collected as part of the medical procedure, evaluation, diagnosis or therapy may not be compatible or captured by the EMR. Customers sometimes need to maintain two systems with limited connectivity in order to have a truly complete clinical record that might be achievable in one system with a true sense of cooperation between the medical vendor and the IT vendor.
Analytics: The Next Big Health IT Undertaking

Following EMR implementation and integration of systems, data analytics can help fine-tune business, workflow and outcomes

By Dave Fornell

With all areas of healthcare now migrating to electronic medical record (EMR) platforms, the data they contain can be mined to use increasingly sophisticated analytics software. This includes pulling information to improve department or hospital management, quality assurance to boost outcomes and efficiency, and even the ability to identify patients who are ideal referrals for new clinical programs such as low-dose lung computed tomography (CT) cancer screenings, or candidates for peripheral artery disease revascularization.

Analytics software was one of the top trends seen at the 2016 meeting of the Healthcare Information and Management Systems Society (HIMSS). This article is an overview of analytics presentations from that conference.

With most EMR implementations now complete, providers are shifting resources from the EMR implementation to analytics and population health, said Jonathan Niloff, M.D., vice president and CMO of McKesson’s connected care and analytics division. He said today’s analytical software is much more sophisticated than in the past, where all data points from the EMR and interconnected information technology (IT) systems can now be searched in one location.

Basic analytics data has been available for years but required time-consuming, manual tabulation of data points. Dashboarding features to automatically track specific data have been around for several years to offer overview of key departmental statistics. Over the past year, there has been a wave of new and much more sophisticated analytics software packages released on the market. These are no longer tied to pulling data from one vendor’s IT system, but operate as a third-party software with the ability to pull data from numerous data sources, including not only the EMR but patient reporting systems, picture archiving and communication systems (PACS), cardiology information systems, ADT, medical coding and billing systems, inventory management and lab reports. These systems also offer data beyond traditional software systems, tapping into the raw data of diagnostic modalities and ancillary devices themselves, including CT, digital radiography (DR), angiography and automated contrast injectors. This data can be leveraged to identify trends in usage, contrast dose by procedure or protocol, and radiation doses used.

As interoperability between data and imaging systems has improved, analytical software can now perform more complex data mining, such as reviews of imaging radiation dose levels by patient, by protocol or modality. Outliers in these reports can be clicked on to drill down data to see which machine that exam was performed on, the tech who performed the exam, or look at the specific patient’s EMR data to see if they are extremely obese or if there are other reasons that required a higher X-ray dose. If a particular machine or technologist is suspected of...
having quality issues, the newer analytics systems can pull historical data for a particular machine or technologist to see if there are other outlier exams, which may identify staff that need additional training or older equipment that needs to be replaced.

New analytics software can pull data from operating room or cath lab procedures to track average procedure time and costs by CPT code, types of procedures, disease state, specific physicians or specific implantable devices.

Business uses include better management of inventory, procedural room use, imaging utilization, staff performance, radiation dose management, monitoring factors for patient satisfaction and to help identify bottlenecks in patient discharge, door-to-balloon times, STAT radiology reads, and what contributes to poor or improved patient outcomes. This data has been available for years at many facilities, but it is the new level of analytics software integration that now makes data mining possible for all these things on one screen using one program.

New Analytics Software Integration

Two major analytics software releases in the last year were from GE Healthcare and Siemens. They illustrate the new breed of analytics software being released by numerous vendors today, both large and small. Both vendors created a common, vendor-neutral analytics platform that can operate on both their information systems and those of other vendors. These platforms can be sold separately from other GE or Siemens products as a third-party software system. Both systems sit on top of the EMR, ADT, PACS, cardiovascular information system (CVIS), and other hospital and patient reporting systems. With a big focus now on enterprise IT systems, both vendors say their platforms act as an integration engine for all the -ologies across the healthcare enterprise.

From a cardiology prospective, GE’s system, part of the new GE Cloud product launched at the Radiological Society of North America (RSNA) 2015 annual meeting, can pull up inventory management system data and link disposables and implantable device usage to specific costs, procedures, procedure types, specific physicians, drugs used, expenditures to date and show where specific items are located in departments. The software can also pull data by physician, procedure type, procedure stats based on patients risk scores, length of stay or disease states. Specific outlier patients can easily be identified and data specific to these cases pulled for review.

From a radiology prospective, Siemens Teamplay, launched in 2015, is another example of the simplification of data analytics using a single-point-of-access software. It can be set for any parameters to alert users if that threshold has been reached or exceeded. Siemens said this is particularly useful in X-ray radiation dose monitoring. The software allows side-by-side comparison of a facility’s CT scanner doses with other scanners at the same hospital or healthcare system, comparisons with American College of Radiology (ACR) reference levels or from other Teamplay users.

Data Analytics Implementation Can Be Adversarial

Many healthcare system IT departments run into an “us vs. them” mentality when they first attempted to share analytics with clinicians. There was a perception the data will be used to micromanage departments or discipline staff. There also were questions as to how IT staff were going to pull anything meaningful that could improve clinical workflows or outcomes.

“Credibility is the biggest barrier for us, and that is why transparency is so important,” said Thomas Van Gilder, M.D., JD, MPH, CMO and vice president of informatics and analytics, Transcend Insights, Campbell, Calif. “You need to show this data is specific to patients — not C-suite business analytics. You can connect specific data points to specific patients — that is what will show clinicians how data can help with clinical collaboration to aid care and improve quality. This can also help reduce the ‘us vs. them’ approach to data from payors. You need to work with them on user engagement and make sure you learn what they need, not just try to sell something you developed.”

“You have meetings to make changes and more meetings and changes, that is part of the process. You are designing a new product and it does not matter how I think it should work, it needs to meet the needs of the clinicians using it,” said Thomas Carlough, Pharm.D., manager of analytics for pharmacy and quality, Atlantic Health Systems, Morristown, N.J.
IT staff tasked with helping clinicians improve the quality of their work need to focus on data relevant to their audience. “As a clinician, I need to know my audience when presenting analytics data,” said James Whitfill, M.D., CMO, Scottsdale Health Partners, Phoenix, Ariz. “When I present to orthopedic surgeons about pressure ulcer rates, they don’t care. They want to know about days to discharge or incision infection rates that pertain to their procedures.”

Danyal Ibrahim, M.D., MPH, MHCDS, chief data and analytics officer, St. Francis Hospital, Hartford, Conn., said there are several acceptance stages to data, including denial, anger, the acceptance and then transformation via improvements to change the data. He explained you need to share data freely and show how it was derived. Data is not valid unless the clinicians responsible for it sign off on it to ensure it is correct, he explained. Another tip is including names of clinicians on data, as this makes it more usable and hits closer to home than anonymous statistics.

“If doctors and staff are given easy access to the data, they will view it and work to improve,” said analytics company Health Level CEO Parag Paranjpe. “We found this works better than having someone else monitor the data with the threat of a stick if they do not improve.”

Paranjpe said the ability to quickly review data often reveals issues that the clinicians did not realize were present. However, the information needs to be simple and quick to access and it helps if it is in a graphical format that quickly shows where there are problems.

**Leveraging Analytics to Improve Care**

Coordination of care has become increasingly important at many hospitals. Whitfill said his hospital analyzed records from 10,000 of its patients and found mixed results and areas where they need to improve. However, the analytics also showed the coordination efforts added up to a significant financial savings, based on their own data and Centers for Medicare and Medicaid Services (CMS) data on those same patients.

St. Francis Hospital implemented a heart failure registry of its patients to track their analytics in an effort to cut readmission rates. Ibrahim explained an example of the system: He said they were to see 20 patients who had recent heart failure readmissions and they looked at who made up the care team for these patients. They also looked at patient data to see if they had home healthcare, or if they were sent to a nursing home to see if these might have been factors. Also, were discharge instructions clear or were they followed. If all of the readmission patients were sent to the same nursing home, or if there were missing drug orders at discharge, that can help identify that maybe the post-acute care was the issue, Ibrahim explained.

“In many ways, the cardiologist becomes the heart failure patient’s primary care physician, so we developed a report to look at vitals to help them monitor these patients,” he said. This includes in-patient and out-patient records for labs, ejection fractions, weight records, etc. He said these basic vitals can help track a patient’s condition and potentially alert the cardiologist to a worsening condition so they can intervene and avoid a readmission. The data also showed a disconnect between medical coders and the physicians, so they now have staff assigned to better coordinate better and ensure correct medical coding.

Sometimes it is helpful to think outside the box with analytics to find new information that was not previously available to improve care. One example of this is at Atlantic Health Systems, when clinicians found they could track hospital meals consumed for diabetic patients so they had a better understanding of these patients’ diet, Carlough said. He said another way analytics helped improve diabetic care was when they found one outlier patient who had consistently poor outcomes. When it was brought to the attention of the nursing staff, they explained that patient insisted on injecting the insulin themselves, but the data showed the patient was not administering it properly.

**Population Health**

Beyond departmental analytics, software can be leveraged to pull stats from across a healthcare system, or across a regional health information exchange. These data can help identify patient populations that are targets for new programs, such as low-dose lung CT screening for lung cancer, patients with diabetic foot ulcers or other symptoms who may benefit from a critical limb ischemia revascularization program, or to preemptively identify and screen patients at high risk for developing heart failure before developing acute symptoms, or CT cardiac calcium scoring screenings of patients who are not sure if they should go on statin therapy.
At McKesson, we believe that the best path to the future of better health is a streamlined one. And your journey requires innovative solutions with open architecture. McKesson Cardiology™ offers a comprehensive solution designed to help make your transition to value-based care as seamless as possible. With improved reliability, flexibility and scalability, you can help maximize your IT investment, optimize performance and coordinate care across your entire enterprise according to your specific organizational needs. Because when you have the right tools for the job, there's virtually no limit to how high you can climb. **FOCUS AHEAD FOR BETTER HEALTH.**
The continuation of positive clinical trial data for transcatheter aortic valve repair (TAVR), showing it is equal to or better than surgical aortic valve replacement (SAVR), was the key news from the American College of Cardiology (ACC) 2016 meeting in April. The continued positive news also made many experts at ACC begin to question the long-term future of SAVR.

TAVR is currently approved for symptomatic aortic stenosis (AS) in high-risk surgical patients and inoperable patients, as well as for failed bioprosthetic aortic valve replacement (AVR) as an alternative to conventional SAVR. Volumes have increased significantly since its U.S. Food and Drug Administration (FDA) approval, and TAVR now represents as much as 30 percent of the AVR market. This percentage is expected to grow rapidly if the devices are approved for intermediate-risk surgical patients.

**Key Late-breaking Trials at ACC.16**

There were three key late-breaking TAVR trials presented at ACC. The biggest news was the result of the randomized PARTNER 2 trial of TAVR vs. SAVR in moderate-risk patients. TAVR showed similar rates of death and disabling strokes after two years compared to open-heart surgery. This study was broken into two parts because the Edwards Lifesciences Sapien XT valve was replaced part way through the trial after the approval of the improved Sapien 3 valve. The results for the Sapien XT portion of the trial (PARTNER 2A) were favorable for TAVR with no difference in stroke and death at two years follow-up overall. It showed superior results for TAVR in the group treated using the femoral access route. Femoral access is the preferred access in 90 percent of patients. Additionally TAVR had lower rates of major bleeding, renal failure and atrial fibrillation, and had shorter length of stay compared to SAVR.

The Sapien 3 portion of the PARTNER II trial showed the newer version of the device, which includes a skirt to reduce paravalvular leak, out-performed SAVR. *(Editor’s note: For more information, a video interview with Chandan Devireddy, M.D., at ACC.16 explaining the drop in TAVR stroke rates, is available at [http://bit.ly/1ShAm5V.](http://bit.ly/1ShAm5V.)*

These results echoed the earlier results from the Medtronic TAVR trial presented at ACC.
CoreValve pivotal trial, which showed TAVR was superior to surgery. Three-year data from that trial presented at ACC.16 showed the divide between TAVR and SAVR continues to diverge in favor of TAVR. (Editor’s note: For more information, watch a video interview with Michael Reardon, M.D., co-principal investigator for the CoreValve trial, at http://bit.ly/1Jt9Sep.)

Two significant concerns for TAVR remain, including the perceived higher incidence where patients require a permanent pacemaker and residual paravalvular leak, which has been associated with higher mortality. In PARTNER 2, pacemaker requirements were not different from SAVR at two years. Additionally the rate of moderate to severe aortic insufficiency (AI), or aortic regurgitation, was only 3.7 percent. Mild AI, which was more common, was not associated with adverse outcomes. These results are reassuring for TAVR.

It is highly likely that TAVR indications for lower risk patients will be approved by the FDA and reimbursed by CMS in the coming years. While there has already been creep in the commercial market into the higher end of moderate risk, this will greatly open access of TAVR to a greater number of patients. Essentially all but the lowest risk patients may now be treated with TAVR and the overall market for TAVR may exceed 50 percent. Additionally the PARTNER 3 (Edwards Sapien 3) and CoreValve Low Risk (Medtronic Evolute R) trials are now enrolling patients to begin evaluating TAVR vs. SAVR in low-risk patients. Within the next five years TAVR may exceed 70 percent of the overall AVR market.

A Paradigm Shift Technology

This is disruptive technology and market forces may change how and where heart surgery is delivered in the United States. Coronary artery bypass graft (CABG) volumes have declined in the U.S. as a result of improved coronary stent technology and changes in appropriate use guidelines for revascularization. Thus far, TAVR has primarily served an unmet need for poor surgical candidates and SAVR volumes have remained stable. However, moving forward, conventional AVR volumes are poised to decline. CABG and SAVR represent the bulk of cardiac surgical volumes at most centers. Smaller and moderate sized programs at more regional hospitals may see overall surgical volumes decline to the point that they are no longer viable. The multidisciplinary nature of TAVR also may not be feasible at many smaller programs.

Additionally with the uncoupling of percutaneous coronary interventions (PCI) in cath labs from surgical backup throughout the United States, the economics of maintaining a surgical program in smaller centers may not make sense and programs may close. Just as coronary PCI has defused from large centers, we may see cardiac surgery in general consolidating in higher volume programs. Given the clear volume outcomes relationship with TAVR, this may be good for public health. While it is hard to predict the future of this consolidation, it is a possible, if not probable, scenario driven to a large degree by the rise of TAVR. (Editor’s note: Watch a video interview with John Carroll, M.D., regarding his ACC.16 presentation on TAVR outcomes related to procedural volume at http://bit.ly/215g8P0)

Editor’s note: Michael J. Rinaldi, M.D., FACC, FSCAI, is the director of clinical research at Sanger Heart and Vascular Institute and a professor of medicine, Carolinas Healthcare System, Charlotte, N.C. He is an expert in TAVR, and has authored several studies that examine its applicability.
Bioresorbable stents have been one of the hottest new cardiovascular technologies discussed at cardiology meetings over the past several years, and the first device is now pending final U.S. Food and Drug Administration (FDA) review. In March, an independent panel of experts convened by the FDA voted 9 to 0, with one abstention, that the benefits of Abbott’s Absorb fully bioresorbable drug-eluting coronary stent outweigh the risks. A final decision on market approval is likely to come later in 2016.

Absorb is a first-of-its-kind, fully bioresorbable stent for the treatment of coronary artery disease. While most stents are made of metal, the Absorb is made of dissolvable polylactic acid (PLA) plastic. It dissolves completely after two to three years, once it has done its job of keeping a clogged artery open and promoting healing of the artery. By contrast, metal stents are permanent implants that restrict vessel motion by caging the artery for the life of the patient.

While these are all seen as positive features of the technology, no clinical evidence exists showing that it makes any difference in real-world outcomes, said Daniel Simon, M.D., division chief, cardiovascular medicine, UH Case Medical Center, president of the UH Case Medical Center, and a co-investigator in the Absorb trials. He said the FDA panel took a sort of limited, non-inferiority approach to the device in regard to target lesion failure, but he said there are many questions that remain about bioresorbable stents that will need to be answered before they become a workhorse device, replacing metallic drug-eluting stents (DES).

“The question we should be asking is what the clinical performance of the device is and how will it be used by physicians in clinical practice,” Simon said. “No one knows what the clinical benefit of a bioresorbable stent is. They do return the vessel to a normal state of vasomotion without caging the vessel, but there is no clinical data yet showing this actually helps patients’ long-term outcomes.”

This clinical question, combined with the device’s delivery issues and its high cost, have restricted its use in Europe. “In Europe, the Absorb is a niche device and it is not being used as a workhorse stent,” he said, explaining it is likely the stent will find similar limited, niche use in the United States once approved.

An FDA panel recommended approval of the Abbott Absorb bioresorbable stent earlier this year. The FDA is expected to make a final decision on market approval later in 2016.
A Paradigm Shift or Hype?

Many cardiology experts see bioresorbable scaffolds as the next step in the evolution of stent technology. Many believe they may offer a change in the standard of care, replacing metallic DES. However, there are barriers to this happening.

“We are very hopeful this technology will help improve long-term outcomes compared to metallic drug-eluting stents, that’s why these were developed,” explained Gregg W. Stone, M.D., FACC, FSCAI, director, cardiovascular research and education, Center for Interventional Vascular Therapy, Columbia University Medical Center, New York-Presbyterian Hospital and the chairman of the Absorb clinical trial program. “Having a fixed metal frame in the artery really limits the long-term outcomes and serves as an ongoing nidus for inflammation, for strut fracture, vessel straightening, compliance mismatch and tissue growth inside the stents. You can get rid of all of that with a scaffold that disappears, but it may take five years, maybe even longer before we see the different event rates. In multiple randomized clinical trials, the Absorb bioresorbable vascular scaffold has demonstrated comparable outcomes to the leading permanent metallic stent. As a first-in-kind device with novel properties, including complete dissolution and natural restoration of vessel function, this is a remarkable achievement.”

While Simon agrees the device is a major step forward in stent technology, he said the technology needs to overcome several issues. To start, the device costs more than a metallic stent and it is more difficult to navigate and deploy because its struts are thicker than the current metallic DES. He said it also requires more imaging than metallic stents, adding procedure time and exposing the patient to more X-ray dose. Accurate vessel sizing is also more critical than metallic stents, because overexpansion causes stent fractures much more easily. More lesion preparation is usually required with the Absorb and procedures usually require more disposables than metallic stenting. The bioresorbable devices also require more dual-antiplatelet therapy and for a longer period of time due to higher stent thrombosis rates, Simon explained.

“We know this will not be a workhorse stent — just look at its usage in Europe,” Simon said. “But, it is a stepping-stone technology. Interventional cardiology is a field that is filled with technological innovation. Everybody wants to get their hands on the Absorb stent and use it, but they will run into issues such as it not being easy to deliver and find it has high rates of thrombosis. I’m all for technological innovation and this is a step forward, but we need more clinical data to validate the technology.”

Poor Performance in Small Vessels

Stone said the first generation device does have limits, particularly in small vessels of 2.5 mm or smaller, where it had higher rates of in-stent thrombosis in the pivotal Absorb III trial. That trial showed safety and efficacy non-inferiority for the Absorb compared to the Xience V stent. But, data analysis found a sub-group of patients with vessels smaller than 2.5 mm that were stented where there was a cause for concern. Stone presented this sub-group analysis at the 2016 American College of Cardiology (ACC) meeting in April.

“There were some slight trends toward worse adverse event outcomes with the Absorb scaffold,” Stone said. “We saw non-significant trends in scaffold thrombosis and increased target vessel myocardial infarction. So, we did a detailed analysis of these events to see where they might be coming from. One of the big differences between devices and metallic drug eluting stents is that they are thicker, so we suspected that in smaller vessels the struts would occupy more space, which could lead to blood turbulence and increased platelet deposition. It turned out about 19 percent of patients had this device used in vessels smaller than 2.5 mm, the smallest size the Absorb was intended for. And, sure enough, those where the vessels where the scaffold thrombosis and target lesion MI events tended to cluster,
whereas the other 80 percent of patients who had the right sized vessels for Absorb, the outcome rates were very similar between Xience and Absorb."

This data was shown to the FDA panel in March and will likely play a role in labeling restrictions on the use of the stent in small vessels. “We recommended to the FDA that there is a need for rigorous training so we can help physicians avoid treating these very small vessels,” Stone explained. He said the Absorb labeling will likely have some sort of warning about using the stent in small vessels and that some sort of quantitative imaging should be used to properly size the vessels.

**Delivery Issues**

The Absorb has 157 micron strut thickness, which is comparable to the first generation Cypher DES from more than a decade ago. Like the Cypher, Simon said Absorb’s larger profile causes delivery issues in smaller, tortuous vessels, adding time to procedures. “The most important thing is delivery of the stents — operators want shorter procedures,” Simon said.

A reduction in the stent strut thickness to profiles closer to current generation metallic stents should make the stent easier to use and deliver, Simon said. However, longer stent sizes are needed and there are still questions of how to build a bioresorbable stent that does not require additional lesion prep, he explained.

Stone said a new, thinner Absorb stent of less than 100 microns will enter trials later this year, which he said will be much closer to the 91 micron thickness of a Xience stent.

**Potential Advantages**

Despite the faults of this first generation technology, Simon said the future for these devices might be very bright if it can show superior outcomes data over today’s metallic DES. Simon said there are possible advantages, such as the return of vasomotion, enabling future coronary artery bypass graft (CABG) surgery because no permanent hardware is left behind. Data also suggests these devices might reduce the incidence of angina.

Simon said the stent may be ideal for mid-left anterior descending (LAD) coronaries that are typically the site for CABG bypass grafts. The current use of metallic stents prohibits future CABG options.

However, it will be the long-term target lesion revascularization rates that will be a key indicator of the future of the device. Trials will have to be run to gather data in all these areas to justify the higher cost and drawbacks of the current device, Simon explained.

“This is science and you have to show not only equivalence, you have to show your device has clinical advantages,” he said. “In science, disappearing is not enough, you need to show clear clinical evidence that it is better than what you are currently using.”

**Future of Bioresorbable Stents**

To address some of the unanswered questions regarding bioresorbable stents, the Absorb IV Trial will begin recruiting patients in 2016. This large, randomized trial will include 5,000 patients and is powered to show late superiority of Absorb compared to Xience. Stone said the earliest results might be presented in 2020. He also said another trial is gearing up to test the Absorb in ST-elevated myocardial infarction (STEMI) patients, which he said might be a sweet spot niche for bioresorbable stents.

“If those trials are positive, then I think bioresorbable technology will ultimately be used in the majority of patients,” Stone said.

**Competing Technologies**

Other stent technologies in development will compete with bioresorbable devices. These include new metal stents that eliminate the need for polymers to carry the anti-proliferative drug coatings. Simon said Medtronic’s drug-filled metallic stent that elutes the drug through microscopic holes, BioSensors BioFreedom, is a polymer-free DES, and Boston Scientific’s Synergy stent uses a bioresorbable polymer on a metallic stent. Simon noted all three of these stents are designed as workhorse devices. He also noted Synergy already sees much wider use in Europe than the Absorb, because it offers many of the benefits of both metallic and drug-eluting stents. **DAIC**
Clinical Application of FFR-CT

Early clinical users are seeing declines in cath lab admission rates and are changing the way they diagnose obstructive coronary artery disease

By Jeff Zagoudis

Fractional flow reserve-computed tomography (FFR-CT) is still in the early stages of clinical implementation in the United States, but it is already changing clinical practice as a non-invasive alternative to diagnosing patients with chest pain. Approved by the U.S. Food and Drug Administration (FDA) in November 2014, the technology provides both anatomical and functional assessment of the coronary arteries, a task no other method has accomplished to date.

DAIC spoke with three users of the HeartFlow FFR-CT technology, each in various stages of clinical practice:

• James Min, M.D., professor of radiology and medicine and director of the Dalio Institute of Cardiovascular Medicine, Weill Cornell, New York-Presbyterian Hospital, has been using the technology since April 2015;
• Geoffrey Rose, M.D., FACC, FASE, cardiologist at the Sanger Heart & Vascular Institute-Charlotte (N.C.), Carolinas Healthcare System, began using FFR-CT in late 2015; and
• Bjarne Norgaard, M.D., Ph.D., Aarhus University Hospital, Denmark, has the most experience with FFR-CT, having used it in clinical practice for two years and in a research capacity for three years prior.

Each practitioner’s experience has been unique, but all three are seeing the benefits of this groundbreaking technology.

Current Practices

At present, there are a variety of methods available to identify suspected coronary artery disease, each offering advantages and disadvantages in terms of sensitivity and specificity. Regardless of the method used, the majority of patients end up in the cardiac cath lab for invasive angiogram and potentially a catheter based FFR measurement.

Recent data suggest, however, that many of these patients are being sent to the cath lab unnecessarily. A three-year retrospective study published in the June 2014 American Heart Journal found that nearly 60 percent of 661,063 patients referred for elective angiography had non-obstructive coronary artery disease (CAD) — nearly two-thirds of these patients sent to the cath lab did not have a clinically significant coronary disease.[1] “We’re sending two out of three patients to get an invasive, expensive procedure for no reason,” Min told DAIC.

CT angiography has provided a non-invasive option for assessing the coronary arteries by visually confirming the presence of stenosis. This is still not a perfect test, according to Rose. “The Achilles’ heel of CT angiography has been when we have intermediate lesions, we don’t know what to do with them,” said Rose. “The sensitivity is terrific, but the specificity is not very good.”

For the first time, clinicians are able to see anatomical and functional information of the coronary tree in a single scan, allowing greater diagnostic certainty for patients with chest pain.
Clinical Trial Benchmarks

Performance benchmarks for FFR-CT have been established through a few major clinical trials, most prominently the PLATFORM trial out of Europe. Ninety-day results, presented at the European Society of Cardiology (ESC) and Transcatheter Cardiovascular Therapeutics (TCT) meetings last year, revealed the need for invasive coronary angiography was eliminated in 61 percent of patients. FFR-CT also had a significant impact on economic and quality-of-life (QOL) outcomes. Mean costs were 32 percent lower for FFR-CT patients in the noninvasive testing stratum, compared to those who underwent coronary angiography. A sensitivity analysis found costs were still lower for the FFR-CT group even when the cost weight of the technology was set to seven times that of CT angiography.

The rate of reduction for cath lab admissions remained the same in the one-year results, presented at the 2016 American College of Cardiology (ACC) annual scientific sessions in April. Furthermore, none of that group had experienced an adverse clinical event after one year. On the economic side, FFR-CT evaluation resulted in a 33 percent cost savings to the healthcare system compared to patients who received standard care.

The impact of FFR-CT on treatment decisions was further corroborated in the FFR-CT RIPCORD Study, presented at the EuroPCR 2015 conference last May. Three experienced cardiologists reviewed coronary CT angiography images of 200 patients with stable chest pain and agreed on one of three treatment options: optimal medical therapy, percutaneous coronary intervention (PCI) or coronary bypass surgery. The physicians were then shown the FFR-CT analysis for each patient and asked to make a second treatment decision. In total, reviewing the HeartFlow data resulted in a change in treatment plan for 36 percent of patients. Also of note, in 18 percent of the cases initially decided for PCI, one or more of the target lesions was changed following FFR-CT analysis.

Patient Selection

One of the biggest clinical questions about FFR-CT is which patients are best suited for evaluation. The technology seems to have found a niche in assessing CAD in patients with intermediate lesions, particularly those where multiple lesions are present. In these cases, the technology can help determine if any of the lesions are severely limiting blood flow and/or which lesion(s) are the most significant. “If you’re doing a CT angiogram and there’s clearly high-level, multi-vessel disease, there’s very little incremental information we’re going to gain by using FFR-CT,” Rose said. The same is true for the other end of the scale, as smaller lesions are unlikely to have a significant impact on blood flow. All three users define intermediate lesions as those with blood flow capacity limited to 40 to 70 percent.

At Sanger Heart & Vascular Institute, all patients whose CT angiograms reveal intermediate lesions are qualified for FFR-CT analysis. The difficulty, Rose told DAIC — and one that is faced by hospitals across the United States — is that CT is rarely a first-line diagnostic test for chest pain patients since the sensitivity and specificity are lower compared to nuclear myocardial perfusion imaging (MPI) and other modalities. This second-line status also means that CT angiograms are often not covered by insurance providers.

The situation is different for Norgaard in Denmark, where CT is a first-line diagnostic test conducted for all patients presenting with chest pain. Like with other users, Aarhus University Hospital requests FFR-CT analysis for patients with one or more stenoses of 40-70 percent. Norgaard estimated this comes out to 15-20 percent of patients.

At Weill Cornell/New York-Presbyterian, Min said the primary venue for FFR-CT is in the emergency department and all CT scans are sent to HeartFlow for FFR assessment.

Benefits of FFR-CT

Early clinical reports indicate FFR-CT has indeed helped reduce the number of patients referred for unnecessary catheterization procedures. Many of the institutions using the technology are still gathering hard data, but Rose and Norgaard have both noticed changes in their respective practices. Rose estimated that 30 percent of patients submitted for FFR-CT analysis have been sent on to the cath lab, a significant reduction for Sanger Heart & Vascular Institute.

While hard data may be lacking, anecdotal evidence reinforces the benefits of FFR-CT. Rose recalled performing a HeartFlow analysis on a very obese woman who had come into the office with chest pain. Nuclear stress test results were normal, however the patient continued to show symptoms. Sending her to the cath lab carried additional risk due to her obesity, so the team performed a CT scan — at less than 3 mSv of radiation dose — and identified significant obstructive coronary disease, which was confirmed...
“In addition to streamlining care and preventing people from having to undergo two tests, it gives a higher sense of diagnostic certainty, which is difficult to quantify but is good for the diagnostician and the patient.”

— James Min, M.D.

through invasive FFR. “The correlation was perfect, she was stented and she’s doing great,” Rose said.

Norgaard spoke of a recent patient who was experiencing chest pain over the course of several months. The patient, whose brother had died at a very early age of cardiovascular disease, had several angiograms performed and underwent two catheterizations, all of which came back normal. Eventually, a CT scan revealed no stenoses but did reveal severe CAD. Further FFR-CT analysis found very low values in the left anterior descending artery, which was confirmed through invasive FFR. The patient ended up having coronary bypass surgery and made a full recovery. Cases like this illustrate what Norgaard says is FFR-CT’s primary role: that of gatekeeper to the cath lab.

Beyond just keeping patients out of the cath lab, though, the technology can be used as a decision-making tool before performing revascularization. Aarhus University Hospital has seen a major shift in its approach to diagnostic testing: Norgaard noted that prior to implementing FFR-CT, the hospital did 300-350 myocardial perfusion scans per year; in 2015, it performed 300 FFR-CT scans and only 30 MPI scans. “We have totally replaced myocardial perfusion imaging,” he told DAIC.

Rose also spoke of a young man (<30 years old) with a family history of significant coronary disease who presented with chest pain. A CT angiogram revealed high-grade plaque in the left anterior descending artery approaching 50 percent but the FFR-CT scan was normal. As a result, the healthcare team was able to work with the patient on preventive measures and lifestyle changes.

“I think it has streamlined it more than anything,” Min said of the impact on cardiac care. “In addition to streamlining care and preventing people from having to undergo two tests, it gives a higher sense of diagnostic certainty, which is difficult to quantify but is good for the diagnostician and the patient.”

Limitations of FFR-CT

While the technology has shown promise, it is by no means the perfect diagnostic test. Under the current model of FFR-CT analysis, where data has to be sent to HeartFlow for FFR calculation and sent back to the hospital, turnaround times are a concern, particularly for emergency department cases. Campbell Rogers, M.D., chief medical officer at HeartFlow, told DAIC that HeartFlow hears this concern frequently from providers and that the company has been asked about licensing out the technology so calculations can be done in-house.

“Our technicians and operators use our tools in an incredibly controlled environment, much like the manufacturing of a medical device, and that’s where the precision reproducibility comes from,” Rogers said. He added that giving the software to hospitals would put the onus on the physician, who likely has not had the same training as a HeartFlow operator, to perform the calculations, which could impact the accuracy, speed and reproducibility.

The other limitation of the technology is that the FFR calculations can only be as precise as the CT images allow, and Norgaard noted that false-positives are still a risk, “but we have had conclusive results in more than 95 percent of cases,” he said.

Norgaard said it took about a year of clinical use to convince his cardiology department that the technology was worth the investment. DAIC

References:
Healthcare organizations, clinicians and medical equipment manufacturers have long focused on the management and reduction of radiation dose. With the increased availability of and reliance on high-dose imaging modalities for rapid and comprehensive diagnosis and treatment, the need for better radiation dose management has only increased. Addressing this issue will require an organized and coordinated effort from many within the medical industry, regulatory agencies and professional associations, medical professionals and the patients themselves. The involvement of these four main pillars is essential for creating meaningful, sustainable advances in this field.

Industry
Medical system manufacturers associated with ionizing radiation equipment must continue to improve their technology and reduce or minimize the amount of radiation exposure required to produce high-quality images. Many vendors have already incorporated coordinated dose reporting and dose management capabilities into their systems. Some companies have begun to introduce new systems that blend software management capabilities with new hardware and imaging chain capabilities to offer decreasing levels of radiation exposure without compromising image quality. A number of medical imaging and cardiology vendors have active dose management and dose reduction programs in place within their systems.

Regulatory Agencies and Professional Associations
Regulatory agencies have the responsibility to establish clear and meaningful standards that set the industry’s guidelines for not only equipment manufacturers, but also healthcare professionals’ use of ionizing radiation. It is challenging to compile this tremendous amount of information related to patients, operators and organizations. However, it is essential to do so in order to benchmark exposure data and utilization trends against established guidelines and national standards.

Several organizations, namely the American College of Cardiology (ACC), American College of Radiology (ACR), American Association of Physicists in Medicine (AAPM) and National Council on Radiation Protection and Measurements (NCRP), have collaborated to create reference guidelines for acceptable radiation dose based on both collected data and evolving trends. Although some institutions are taking advantage of these resources, it will be up to each organization to be proactive in maximizing the tools available.

Aside from the U.S. Food and Drug Administration’s (FDA) 2010 “Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging” and the availability of online resources from the FDA, there are currently no set national guidelines related to the documentation of radiation dose. Because of this, hospitals must follow current state
mandates. In California and Connecticut, imaging professionals have already been tasked with documenting the dose from all computed tomography (CT) studies. Texas has taken this mandate a step further by requiring not only CT dose data, but also fluoroscopy exams, as well.

The ACR has also built the National Radiology Data Registry (NRDR), which serves to collect, manage and benchmark dose information, as well as other related exam data, in the absence of a national standard for radiation dose. Additionally, in an aggressive effort toward optimizing patient dose across the industry in the United States, the Medical Imaging and Technology Alliance (MITA) developed the MITA Smart Dose CT initiative, XR 29, which became a law in 2014. This rule mandates that beginning in 2016, CT units must adhere to the MITA standard in order for organizations to receive premium Medicare reimbursement levels.

Medical Professionals

Although much of the responsibility falls on equipment manufacturers to create tools for managing and reducing dose, there is also some responsibility on behalf of the medical professionals using the technology. Currently, there is a substantial disparity in how medical imaging and cardiology exams are ordered according to pathologies, patient histories and physician preference. When a patient’s treatment plan involves the decision of when or whether to use ionizing radiation, it is important for clinicians to understand when to consider employing alternative imaging modalities. The physician community needs to discuss these lower-dose or no-dose options when clinically appropriate.

Making great strides toward this goal, the ACR and ACC, in parallel efforts, have established criteria programs that provide the referring physician community with evidence-based guidelines to consider when deciding whether to employ ionizing radiation as a part of diagnosing or treating a patient. Programs like these are especially important in pediatric imaging because most of the known dose values and trends correspond to adult but not to pediatric levels. In order to actively reduce the levels of radiation dose within pediatric imaging exams, we need to continue building upon existing data present in the ACR’s Dose Index Registry (DIR).

This will help to supplement the current efforts, which include modifying exam protocols, making technical changes to medical imaging equipment, and implementation and following through on dose awareness and reduction campaigns. Movements such as Image Gently, Image Wisely and Step Lightly have done a great job at highlighting the concern of pediatric dose. They have also facilitated more educational opportunities for imaging professionals to minimize dose and maintain image quality when possible.

Once the decision has been made to incorporate ionizing radiation into the treatment or diagnosis path, both the equipment end users and radiologists have the responsibility to help manage radiation dose. This begins with the operator being qualified, well trained and held accountable for use of the equipment. Within the market, there is a large disparity in imaging exam protocols among physicians and technologists. Comprehensive training on the equipment and exam protocols is needed to optimize dose and image quality simultaneously.

Many times, radiologists actively collaborate with referring physicians in the selection of medical imaging procedures, recommendations for follow-up imaging, exam protocols and the number of images needed for various procedures. This is especially true when using live fluoroscopy, which correlates to higher dose levels. Because of this, it’s vital that radiologists of all subspecialties have complete buy-in for an organization’s dose management program and continue to educate hospital staff and referring physicians.

It is also incumbent on the hospital to ensure the equipment is well-maintained through service and preventive maintenance. In addition, an organization’s radiation safety program must remain a priority, with dedicated staff responsible for overseeing the implementation and continued adherence to the plan.

Another area of concern is the effort in reducing repeat exams. It’s paramount to establish seamless access to prior and related studies. We must also take strides to overcome the current challenges in IT system interoperability that exist when a patient’s historical portfolio of images and reports needs to be available to all clinicians involved in patient care.

Comparison Chart Compiled by Diagnostic and Interventional Cardiology

Scranton Gillette Communications assumes no responsibility or liability for any errors or omissions in this chart.
## Radiation Dose Monitoring

### COMPARISON CHART

<table>
<thead>
<tr>
<th>Company name</th>
<th>Agfa HealthCare</th>
<th>Bayer Healthcare</th>
<th>GE Healthcare</th>
<th>Imalogix</th>
<th>Medic Vision Imaging Solutions</th>
<th>Novarad</th>
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<tbody>
<tr>
<td>Product name</td>
<td>DoseMonitor Platform</td>
<td>Radmetrics Enterprise Platform</td>
<td>DoseWatch</td>
<td>DoseWatch Explore</td>
<td>Imalogix</td>
<td>SafeCT</td>
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<tr>
<td>FDA cleared year</td>
<td>2012</td>
<td>2013</td>
<td>2015</td>
<td>2014</td>
<td>Yes</td>
<td>2010</td>
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<tr>
<td>CE mark approval year</td>
<td>2013</td>
<td>2013</td>
<td>2012</td>
<td>2015</td>
<td>2014</td>
<td>N/A</td>
</tr>
<tr>
<td>Briefly explain what the software monitors, reports and visualizes</td>
<td>Automated monitoring of dose data collected, reporting and analysis solution</td>
<td>The Radmetrics Enterprise Platform by Bayer is a solution for integrated radiation dose management and contrast analytics; providing actionable insights to help meet compliance needs, increase quality, and improve workflow; the solution integrates seamlessly with radiology workflow and hospital IT infrastructure; the software tracks patient radiation exposure and provides it in several different manners; it incorporates protocol management and has a customizable dashboard</td>
<td>Enterprise-wide dose management solution that captures, tracks, alerts and reports on patient radiation and contrast dose; analytics assist in quality control and dose optimization; data is automatically collected directly from imaging devices or PACS, supporting multiple vendors in CT, IR, nuclear medicine, mammography, rad and fluoroscopy; DoseWatch displays detailed information on the patient (e.g., name, age, BMI, effective dose), the exam (e.g., protocol, acquisition parameters), radiation dose (series, study and cumulative metrics), and contrast injection (agent, concentration, injected volume, etc.); provides on-demand and scheduled PDF reports, customizable</td>
<td>DoseWatch Explore is an introductory dose management solution compatible with select GE CT devices; this easily accessible cloud-deployed Web application provides detailed exam-level dose and protocol information, analytics and reporting; no IT integration needed, making this offer an ideal first step for healthcare organizations interested in managing dose data and practices</td>
<td>Innovative cloud-based platform for performance management and dose monitoring solution; we take the complexity out of the process to achieve compliance; there is virtually no IT involvement — we automate the process to map your protocols and provide advanced analytics that go beyond dose monitoring; in a concise dashboard you can compare dose trends, identify outliers and trends, and performance across your enterprise with ease. Imalogix is simple, powerful, smart, sophisticated</td>
<td>Full compliance with XR-29 Dose Check and Dose Report functions</td>
</tr>
<tr>
<td>At what level is dose monitored and analyzed</td>
<td>Patient, study, modality and facility</td>
<td>Patient, modality, study, series level, organ, enterprise site, equipment, staff, protocol, specialty</td>
<td>Patient, series, study, cumulative dose metrics w/ support for multi-site/department configurations; in multi-site organs with multiple patient IDs across records</td>
<td>Study and series-level dose and protocol details for connected GE CTs; excludes patient ID info</td>
<td>Acquisition, study, location ID, manufacturer, size, age, sex, protocol, time, tech, physician</td>
<td>Patient</td>
</tr>
<tr>
<td>What modalities can be monitored</td>
<td>CT, XA, DR and MG</td>
<td>CT, CT/FET, PET, angiography, interventional/cardiovascular/fluoroscopy, CR/OR, MS, NUC, MDM, utilization for all NR/US</td>
<td>CT, contrast injection details, nuclear medicine, interventional/cardiovascular, mammography, radiography, surgical/mobility c-arms, fluoroscopy</td>
<td>GE Healthcare CT systems</td>
<td>CT, fluoros (cardiovascular, IR, XA and PET), molecular imaging, mammography, CR/DX</td>
<td>CT</td>
</tr>
<tr>
<td>System supports diagnostic reference levels (DRLs) set locally</td>
<td>Yes</td>
<td>Customizable per ct, exam, level DRLs, based on local DRLs, registries, regulatory bodies</td>
<td>Yes, ACR, national and custom DRLs; selection on exam level DRLs, based on local DRLs, registries, regulatory bodies</td>
<td>Manual upper threshold entry only</td>
<td>DRLs are set by age, sex and size and evaluated at acquisition, exam and patient cumulative dose</td>
<td>Yes</td>
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<tr>
<td>Does software offer pediatric DRLs</td>
<td>Yes</td>
<td>Offers DRLs filtered to patient age, gender, weight, height, BMI and/or type</td>
<td>Yes, ACR, national, and custom DRLs are supported; segment by age, weight, height, study and series type</td>
<td>No, patient specific information is not captured</td>
<td>DRLs are set by age, sex and size and evaluated at acquisition, exam and patient cumulative dose</td>
<td>Yes</td>
</tr>
<tr>
<td>How does the software help providers comply with Joint Commission requirements</td>
<td>Yes</td>
<td>Web-based radiation management system, assists with DRLs; do not analyze, benchmarks, and reporting</td>
<td>Yes, documents radiation dose index on every exam produced; captures exam specific dose index and summarizes by series or anatomic region; documents dose in a retrievable format; displays performed and scheduled studies; documents incidents where dose indices exceeded defined ranges</td>
<td>Tracks and records exam, dosimetric information, overexposures and protocol parameters for each exam for every CT connected</td>
<td>Imalogix provides protocol review, threshold, DRLs, alerts and documented follow up</td>
<td>Full compliance with JointCommission requirements for all CT scanners</td>
</tr>
<tr>
<td>Does software help meet dose recording requirements set by the state of California, Texas or other U.S. states</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No, collection/reporting of radiation dose indices (RDIs) required by Calif., Texas. Joint Commission is automated identification of outliers, statistical analysis, ac parameters and quality metrics provided to support protocol review, EMR/RIS/dictation integration is available</td>
<td>Displays ac parameters for radiation dose indices (RDIs) for GE CT; data is aggregated, analyzed, and summarized within the application to provide insights about practice-level dose performance</td>
<td>Yes, we provide a comprehensive library with alerts to meet state requirements and workflows as well as the ability to analyze, annotate and export results to the appropriate reporting systems</td>
</tr>
<tr>
<td>If you are an OEM, what vendors offer your solution</td>
<td>N/A</td>
<td>MICoxon, Siemens, Philips, Toshiba, Landauer, CMS Imaging</td>
<td>GE Healthcare is the sole owner of DoseWatch; GEHC sells the product directly via internal sales channels</td>
<td>GE is sole owner of DoseWatch Explore, sells product directly</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>What differentiates your software from competitors</td>
<td>Feature set, ease of use, straightforward implementation</td>
<td>Vendor neutral, multi-modality SW for radiation dose mgmt, contrast analytics, protocol mgmt; dashboards drill down; Monte Carlo-based dosimetry and phantom dosimetry for organ specific dose values</td>
<td>One solution integrating radiation and contrast dose management across all radiation emitting devices; offering flexible connectivity/data access options, e.g. DCM Upload, MPPS, FDRS, PACS retrieve, OCR and proprietary, mammography, rad and fluorosupport; auto capture for nuc med; vendor neutral contrast injection tracking for class-4 inj integrated with CT, in multi-site organs with multiple patient IDs, cumulative dose and patient dose history monitored across patient records; incidence map in CV-IR, patient iso-center tool, mA modulation quality tool, plus, ALARA/Image Gently/Wisely education</td>
<td>Cloud-deployed Web application, without any IT integration required and no required hardware; automatically retrieves, tracks and reports radiation dose for GE CT devices</td>
<td>We are a cloud solution; our installation times are best in class; automatically maps protocols, tracks injections, optional physics support; exceptional, elegant and intuitive interface</td>
<td>Supports all scanners, equal to OEM solutions, at a fraction of the price; better performances than all 3rd-party products; enterprisese solution: single system serves the entire organization</td>
</tr>
<tr>
<td>CT dosimetric information recorded</td>
<td>CTDiVol, DLP, SSDE, effective and organ dose</td>
<td>CTDiVol, DLP, SSD, CRP, mammography, exam, acqu., organ dose</td>
<td>CTDiVol, DLP, SSD, effective and cumulative dose, target region</td>
<td>Series number, CTDiVol, DLP, ref pt, effective, cumulative, target region dose</td>
<td>CTDiVol, DLP, SSD, effective dose, cumulative dose, target region dose</td>
<td>CTDiVol, DLP, SSD, effective and organ dose</td>
</tr>
<tr>
<td>Angiography dosimetric information</td>
<td>Air kerma, DAP fluoro time, peak skin dose</td>
<td>DAP ref at air kerma, fluoro time, PSD, # exposures</td>
<td>Air kerma, DAP cine/fluoro time, number of exposures</td>
<td>DAP fluoro time, air kerma</td>
<td>N/S</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Additional submitted information appears on our website at www.DIcardiology.com.
It is a vendor-agnostic and multi-modality Web-based solution that collects, measures, analyzes, and reports patient and staff radiation exposure, assisting healthcare providers to take control of quality of care, efficiency, patient and staff safety. Portal has a powerful analytics engine that allows for easy analysis of important dose metrics such as CTDIvol, SSD, DLP, DAP, air kerma and occupational dose in the OR.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>DoseWise Portal</td>
<td>DoseMonitor</td>
<td>Picom365</td>
<td>DoseTrack</td>
<td>syngo Workflow Dose Management, powered by Radimetrics Exposure</td>
<td>DoseWise Portal DoseMonitor Picom365 Sectra DoseTrack syngo Workflow Dose Management, powered by Radimetrics Exposure</td>
<td>Dose Tracking System</td>
</tr>
<tr>
<td>N/A, Class 1 device</td>
<td>2012</td>
<td>2000</td>
<td>2013</td>
<td>Yes, 2013</td>
<td>N/A</td>
<td>Yes, 2014</td>
</tr>
<tr>
<td>2016</td>
<td>2013</td>
<td>Pending</td>
<td>2013</td>
<td>N/S</td>
<td>N/A</td>
<td>Yes, 2014</td>
</tr>
</tbody>
</table>

Patient dose monitored directly from modalities to capture all exposure events. All dose-related DICOM info captured, MPPS, static dose pages

All X-ray modalities can be monitored including CT, fluoroscopy, DR and mammography

Supports patient safety and regulatory reporting including: cumulative dose tracking scorecard – presents meaningful use of a patient’s cumulative dose; dosimetry worksheet – provides immediate feedback on the radiation dose delivered during examination; protocol management tools – supports multiple scanners; interleaves protocols on diagrams, tracks revisions to protocols, and customizes style sheets; reporting – flexible dashboards to access data

Displays dose multi-DEM, multimodality sliced by scanner; protocol; operator provides box view with easy outlier identification

DTS provides a virtual patient dose map with real-time tracking of estimated peak and accumulated skin dose during an intervention; procedure, color-coded and easy to read 3-D spatial visualization of radiation exposure to the patient and clear indication of radiation distribution; real time feedback enables the clinician to make procedural adjustments and thus limit exposure in any area for prolonged periods; estimation of peak skin dose available on cardiovascular/neurovascular procedures

- **Patient dose monitored directly from modalities to capture all exposure events. All dose-related DICOM info captured, MPPS, static dose pages**
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**Comparison Chart Compiled by Diagnostic and Interventional Cardiology**

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**May/June 2016**

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**25**
Reducing Cardiac Ultrasound Exam Times

Enhanced image quality, automation and smart device-based functionality are helping technologists acquire the information they need in less time.

By Jeff Zagoudis

Healthcare institutions are trying to drive productivity by increasing patient throughput while still maintaining a high quality of care. The goal is usually to reduce imaging exam times to increase the number of patients seen each day. The biggest challenge may come from ultrasound, which has the highest degree of operator variability and reproducibility issues. The last few years, however, vendors in the space have introduced several new technologies and features to help achieve these time-savings.

Enhanced Image Quality, Acquisition

Any imaging modality is only as good as the image quality it can provide, and ultrasound manufacturers have been working to expand capabilities in this area. Three-dimensional and even 4-D ultrasound have been on the market for several years but are only now starting to increase traction in the marketplace, as providers realize it can greatly reduce operator variability in acquisition and interpretation.

That has always been the goal of 3-D echocardiography, according to Federico Asch, M.D., associate director of the echocardiography core lab at Medstar Health Research Institute, Hyattsville, Md., and assistant professor of medicine (cardiology) at Georgetown University. “But it’s always been a theory; in practice we were not able to do that. But we’re getting there.”

One recent example of this is GE Healthcare’s new flagship ultrasound system, the Vivid E95, launched in the middle of 2015. The system offers 3-D and 4-D imaging, powered by GE’s cSound technology that captures and processes much larger amounts of image data than previous-generation systems — roughly a DVD’s worth of information per second. The algorithm also automatically removes image artifacts such as tissue coming in and out of plane.

Siemens’ newest premium ultrasound system, the Acuson SC2000 Prime, performs real-time 3-D/4-D echo with live color flow Doppler overlaid on the image using a single-beat acquisition. The system also offers transesophageal echo (TEE) functionality, a technique seeing rapid growth in the face of dozens of new complex transcatheter structural heart devices released in the last few years.

The rise of 3-D and 4-D echo is not a signal, however, of the demise of 2-D ultrasound. Toshiba’s Aplio Platinum Series CV (cardiovascular) ultrasound systems, including the Aplio 300 Platinum CV and Aplio 500 Platinum CV, enhance image quality through a series of new features. Two-dimensional wall motion tracking, plus spectral and color Doppler, deliver high detail and resolution throughout the entire field-of-view, resulting in accurate and easy-to-use 2-D strain resolution.

Automated Data Quantification

Perhaps the most significant way that ultrasound exam times are being reduced is through automation of various processes, including data quantification.

Siemens’ eSie Valves advanced analysis of the mitral valve, showing a 3-D reconstruction of the heart from echo along with color flow Doppler showing a jet of mitral regurgitation. The software is designed for full assessment of the mitral and other valves in 3-D for more accurate quantification and planning for either transcatheter or surgical interventions.
The 2015 American Society of Echocardiography (ASE) annual meeting saw the debut of HeartModel A.I., an advanced algorithm from Philips Healthcare delivering what the company calls Anatomically Intelligent Ultrasound (AIUS). First deployed on the Epiq 7 ultrasound system, HeartModel A.I. provides advanced quantification, automated 3-D views and robust reproducibility for cardiac ultrasound exams. The algorithm is built on a digital database of anatomical structural models, which are used to gather left ventricular and left atrial dimensions and volumes. These models automatically adapt to variability in patient anatomy, which the software has learned to do based on machine learning review of thousands of previously recorded echo exams.

Philips claims the technology is able to gather cardiac volume information three to six times faster than 2-D ultrasound systems. This allows physicians to more quickly and accurately assess disease states, determine treatment and guide related therapies.

Siemens offers similar functionality through its eSie Valves software package, introduced on the Acuson SC2000 Prime in 2014. As the name suggests, this semi-automated advanced analysis program captures valve measurements during cardiac procedures. Where other systems may take several minutes to provide this information, eSie Valves returns aortic and mitral valve measurements in seconds.

While impressive, these early forays into artificial intelligence cannot yet offer automatic quantification of the entire heart. Asch highlighted the right ventricle as one example, but he believes the capability will one day be available.

**Touchscreen and Tablet Systems**

As tablets and smartphones become everyday devices for a large majority of the population, many imaging system manufacturers are shifting their user interfaces to mirror mobile device functionality. In the ultrasound market, this has led to several new systems that are touch-screen operated, tablet-based or both. Users can now tap, pinch, drag and swipe their way through an examination.

“That’s an approach to the market for non-sonographers,” said Jon Brubaker, MBA, RCVT, ultrasound market analyst for MD Buyline. “This is something they’re familiar with. It comes with a touchscreen so they can easily get the images and don’t have to spend a lot of time getting the end product they need.”

Mindray adopted tablet technology for ultrasound last year with the release of the TE7 system. Though still cart-based, the TE7 completely eliminates the traditional ultrasound keyboard, even offering one-touch image optimization. Cardiovascular-specific functions on the system include continuous wave (CW) Doppler and a TEE transducer.

Carestream Health entered the ultrasound market at the 2014 Radiological Society of North America (RSNA) annual meeting with the introduction of the Touch Prime and Touch Prime XE premium systems. In this case, the touchscreen offers an appearance and layout similar to traditional keyboards with the flexibility of a soft user interface with full smart-touch functionality. Etched marks on the glass screen help users quickly locate primary buttons without having to look away from the screen.

Many of these systems with mobile device functionality are targeted for use at the point of care, where conditions may be different in every scenario. For these cases, a number of these technologies were on display at RSNA 2015, including:

- The iViz handheld ultrasound system from Fujifilm Sonosite, cleared by the U.S. Food and Drug Administration (FDA) just before the show. The high-resolution, 7-inch display touch-screen offers a wide dynamic range and vibrant color flow images, with multiple imaging modes and exams available with the tap of a finger. In what the company calls an industry-first, the iViz offers full bi-directional connectivity with the electronic medical record (EMR), meaning users can both send reports and receive patient demographics; the latter functionality eliminates manual entry of patient information for a significant time savings.

- The Lumify app-based ultrasound system from Philips Healthcare received FDA approval in July 2015. Rather than operate from a dedicated handheld system, Lumify turns any compatible Android smart device into a display screen simply by plugging in the USB transducer. The transducer handles all of the image acquisition and processing and is controlled through the downloadable cloud-based Lumify app. The app is free to download, but the transducer is rented on a monthly subscription basis.
Federal Requirements for Imaging Clinical Decision Support

Although delayed, the groundwork for CDS requirements has been created and new implementation deadlines are being set for 2017

By Dave Fornell

Healthcare providers will need to start preparing for the next big healthcare information technology (IT) implementation — clinical decision support (CDS) software. Under congressional legislation based on a compromise between numerous medical societies to accept required CDS documentation for Medicare reimbursements, large scheduled cuts in reimbursements were suspended in the 2014 Protecting Access to Medicare Act (PAMA). A deadline was originally set for providers to begin required use of CDS starting in 2017, but it is likely this will be pushed back to 2018 or later.

The new Centers for Medicare and Medicaid Services (CMS) CDS requirements were the focus of a session at the Radiological Society of North America (RSNA) 2015 meeting in December. Joseph Hutter, M.D., lieutenant commander in the U.S. Public Health Service who is with the CMS Center for Clinical Standards and Quality, defined the major components of the planned requirement. This includes the need for appropriate use criteria (AUC) to be developed by provider-led entities (PLE) such as medical societies. Providers will need to implement a CMS-qualified CDS system. These systems will need to provide documentation on the Medicare claims. The systems also will require prior authorizations reserved for consistent claims outliers in the future.

The PAMA included a timeline for CDS software development and implementation. It originally required the first sets of AUC to be specified by November 2015, but this has now been moved to June 30, 2016, Hutter said. These rules are supposed to be designated by PLEs, and the first round of applications to become a PLE started Jan. 1, 2016. PAMA also required the initial list of CDS mechanisms to be approved and available by April 2016, but this has now been moved to the more realistic time frame of June 30, 2017, he explained.

However, Hutter said picture archiving and communication system (PACS) vendors told CMS it would take at least 12 to 18 months for them to program and deploy CDS solutions in their annual software updates. That timeline is based on when they received the final parameters for what AUC rules need to be included in such software.

Additionally, healthcare IT departments faced a major implementation of ICD-10 codes in 2015, with the codes going

An example of a dropdown menu for chest pain and the possible reasons to order an exam from the QPID clinical decision support software. Choosing specific selections then leads to a list of possible imaging exams and rates them based American Collge of Radiology (ACR) appropriate use criteria.
live nationwide Oct. 1 last year. The government realized it would be difficult for most health systems to immediately implement or budget for CDS software based on the original deadline. This is especially true since PACS vendors have not even created CDS software for providers to evaluate.

Hutter said this would logically delay when physicians will be required to report AUC consultations on claim forms, which was originally set for Jan. 1, 2017. He said the new deadline for implementation has not yet been set and will likely depend on when AUC and rules for CDS software can be fully outlined. Based on the PACS vendor timelines to implement any new software, it is unlikely CDS will become a requirement until at least the summer of 2018.

**Goal of Changing Physician Behavior**

Once the CDS requirement is implemented, documentation will need to include the national provider identification, identify the CDS systems used and whether the CDS was consulted, said Curtis Langlotz, M.D., Ph.D., medical informatics director for radiology, Stanford Healthcare, Calif. He said based on the original implementation date of Jan. 1, 2017, two years of this data would be collected as of Jan. 1, 2020. At that time, CMS would create a list of the 5 percent of outlier physicians. “There is no requirement that the physician needs to follow the CDS advice, but it needs to be available,” Langlotz said. But, if they consistently do not follow AUC, that is when it will become a problem.

He said these outlier physicians who continually disregard AUC recommendations listed in their CDS would be required to get pre-authorization for their orders after 2020. However, this deadline will now likely be moved back along with the rest of the CDS timeline.

“The goal is to change ordering behavior,” Langlotz said, explaining CDS guidance and the threat of lower reimbursement will help providers make more economical decisions based on evidence-based medicine. He said the need for CDS in imaging and other tests is similar to the need for pharmaceutical computerized physician order entry (CPOE) systems that have been around for a decade. Pharma CPOE systems are now widely implemented in healthcare to eliminate the major patient safety concerns due to potential drug interactions, inappropriate or dangerous doses, wrong drugs, and to catch redundant or inappropriate drug prescriptions. CMS hopes similar CPOE for diagnostic tests and imaging will have a similar impact to reduce the number of inappropriate or high-cost tests when less expensive and more appropriate options are available based on AUC.

**Defining CDS for CMS**

CDS may be a burdensome regulatory exercise unless CMS puts in place rules and implementation processes, said Keith White, M.D., medical director of imaging services, Intermountain Health, Utah. This includes the need for local engagement with clinicians, which might include multidisciplinary team input on rules that are created. White said there needs to be a focus on evidence-based medicine, and one issue is that a lot of AUC is based on expert opinion, not clinical data. CDS also needs to offer a seamless workflow, otherwise clinicians will work around it. These CDS systems also should have a way to provide feedback so the system can be improved.

“We need to get clarity on what AUC will need to be included on these systems,” White explained. This will drive the creation guidelines for specific conditions instead of attempting to boil the ocean. He said CMS should periodically specify general clinical conditions for which ordering physicians need to consult CDS. These might include creation of pathways for specific conditions such as pulmonary embolism or chest pain.

White said a primary group helping CMS determine what should be in guidance documents for CDS requirements is the High Value Healthcare Collaborative (HVHC). This consortium of 17 healthcare systems and The Dartmouth Institute for Health Policy and Clinical Practice is working to improve healthcare value by defining quality and outcomes over costs across time, in a sustainable manner, while serving as a model for national healthcare reform. The group has had meetings to hash out some of the details for CDS requirements and is passing these recommendations onto CMS.

“The recommendations from PAMA and the HVHC will be baked into the final CMS rules,” Hutter said.

He said CMS wants the rules to be based on grassroot efforts from hospitals and the medical societies, not dictated by the government. “You are part of it and you can change it, but you need to speak up,” Hutter said. “We will get some things wrong and we will need to fix them, but we need feedback from the providers. There is no secret sauce or black box to make
everything work perfectly. If there is another protocol out there we are not aware of, let us know about it.”

One question raised about the establishment of PLEs is that CMS needs to make sure competing technologies supported by various societies do not create rules that establish one as the preferred imaging modality over another. An example of this might be the use of computed tomography (CT) over magnetic resonance imaging (MRI), or use of MRI over nuclear imaging. However, the flipside of that argument is that providers should not use AUC rules that are written to favor what resources they have available if they do not have a nuclear imaging program or access to MRI at their facility.

“Transparency is very important,” Hutter said, addressing these concerns. He said there is a need for a transparent process for how the evidence-based rules are created and agreed on. If an MRI is indicated by AUC, then a patient needs to be told by the facility where they can get access to an MRI. However, if MRI is indicated by AUC but is only available during daytime hours and imaging is needed immediately, then a CT might be the next best option depending on the situation, he explained.

The Evolution of Cost Controls Leading to Clinical Decision Support

The federal requirement for CDS software came from an evolution in federal efforts to reduce rapidly rising healthcare costs, explained Keith Dreyer, D.O., Ph.D., FACR, FSIm, vice chairman of radiology at Massachusetts General Hospital and associate professor of radiology at the Harvard Medical School, Boston. He spoke at the RSNA 2015 meeting. In 2005, Congress passed the Deficit Reduction Act (DRA), which was designed to cut rapidly rising imaging costs in Medicare. To do this, the DRA established the sustainable growth rate (SGR) formula, which began yearly cuts in reimbursements across radiology.

In 2008, Dreyer said the Medicare Improvements for Patients and Providers Act (MIPPA) required providers of high-ticket CT, MRI and nuclear imaging services to become accredited through the American College of Radiology (ACR), Joint Commission or other designated bodies.

In 2010, Congress passed the Patient Protection and Affordable Care Act (ACA), which set criteria for healthcare reforms that are largely driven by IT implementations needed to avoid CMS reimbursement cuts. Dreyer said this has led to an explosion in electronic health record (EHR) adoption in the past few years. The proliferation of EHRs now allows for the implementation of CDS software based on AUC. Between 2011 and 2012 the ACR Select AUC CDS integration was started to check the appropriateness of imaging exams for various patient presentations and conditions.

In 2014, Dreyer said Congress adopted an AUC requirement in the SGR patch that was part of the PAMA. This act prevented a 24 percent reimbursement reduction originally schedule through the DRA. He explained the AUC requirement was accepted as a way to help cut imaging costs because of its overwhelming support by numerous medical societies.

Dreyer said Massachusetts General Hospital has been an early adopter of CDS for imaging and has seen a noticeable decline in high-cost exams after implementation of its CDS program.

Video Examples of CDS Software

See examples of clinical decision support (CDS) software on the show floor of the Healthcare Information and Management Systems Society (HIMSS) 2016 meeting in March. Ascendian Healthcare Consulting also discusses the state of CDS software and its purpose with DAIC Editor Dave Fornell.

Enter this link to view the video: http://bit.ly/1pLeUeo
A typical hospital has data problems...

As soon as a cardiac patient engages with your institution, you begin compiling information on him. Unfortunately, unconnected, difficult-to-access data can lead to serious problems.

60% of hospital data is unstructured

18% of errors come from inadequate information

1. Patients or Paperwork? The Regulatory Burden Facing America’s Hospitals, PricewaterhouseCoopers and American Hospital Association.
2. Unstructured data a common hurdle to achieving guidelines, Health Management Technology, June 2012.

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data once and report efficiently and effectively

CONNECT

disparate information and take control of your data

EQUIP

physicians with critical data, where and when they need it, to deliver optimal care

LUMEDX HealthView

data integration · analytics · imaging & reporting · cloud-based or client-server

learn more: www.lumedx.com · let’s talk: 800.966.0669

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Booth 337
GE Healthcare released its new Muse ECG management platform, MUSE v9, at the American College of Cardiology (ACC) 2016 meeting. New IT capabilities allow better access to all ECG waveforms and related data from multiple vendors, devices and test types. From resting ECG to stress to new devices like Holter monitor patches and wearables, cardiologists can now review all test types of ECGs consolidated under a single patient record. It has also opened its doors to multiple communication protocols and now uses HL7 or DICOM to access orders and send test results to the hospital EMRs and archival systems.

GE Healthcare | www.gehealthcare.com

**Kardia Band for Apple Watch Delivers Medical-grade ECG Anywhere**

AliveCor introduced the first medical-grade ECG band for the Apple Watch, Kardia Band (pending FDA 510(k) clearance, expected availability late spring) along with a new app for smartphones. The Kardia Band for Apple Watch and new Kardia app allow people to discretely capture a single-lead ECG by touching an integrated sensor that communicates with the Watch app. It offers atrial fibrillation (AF) detection.

AliveCor | www.alivecor.com

**FDA Approves Abiomed Impella for Cardiogenic Shock Post-heart Attack or Surgery**

The U.S. Food and Drug Administration (FDA) has cleared Abiomed’s pre-market approval (PMA) for its Impella heart pumps to provide treatment of ongoing cardiogenic shock. In this setting, the pumps — which include the Impella 2.5, Impella CP, Impella 5.0 and Impella LD — stabilize the patient’s hemodynamics, unload the left ventricle, perfuse the end organs and allow for recovery of the native heart.

Abiomed | www.abiomed.com

**FDA Clears Corindus CorPath Robotic System for Peripheral Interventions**

The FDA has cleared the Corindus Vascular Robotics CorPath System for use in peripheral vascular interventions. This is the third clearance for the CorPath, including the initial clearance for percutaneous coronary intervention (PCI), which was followed by a clearance for radial PCI. This 510(k) clearance was based on results of the RAPID (Robotic-assisted Peripheral Intervention for Peripheral Artery Disease) Study.

Corindus | www.corindus.com

**Koven Technology Introduces Smartdop XT Vascular Testing System**

The Smartdop XT by Koven is a fully automated vascular testing system that enables rapid, multiple-level bilateral studies in minutes. It features single-button automated operation and easy-to-use, Windows-based operating software which easily integrates into an existing electronic health record (EHR) or picture archiving and communication system (PACS).

The Smartdop XT quickly and easily performs ankle-brachial indexes (ABI), toe-brachial indexes (TBIs), segmental pressures, venous reflux and post-exercise arterial studies. It also features a custom test screen to expand testing capabilities.

Koven Technology | www.koven.com
CMS Releases Interactive Mapping Medicare Disparities Tool

The Centers for Medicare & Medicaid Services Office of Minority Health (CMS OMH) released a new interactive map to increase understanding of geographic disparities in chronic disease among Medicare beneficiaries. The Mapping Medicare Disparities (MMD) Tool identifies disparities in health outcomes, utilization, and spending by race, ethnicity and geographic location. It includes a dynamic interface with data on the prevalence of 18 chronic conditions, end stage renal disease or a disability; Medicare spending, hospital and emergency department (ED) utilization, preventable hospitalizations, readmissions and mortality rates. It offers the ability to sort by state or county of residence, sex, age, dual-eligibility for Medicare and Medicaid, and race and ethnicity.

CMS | www.cms.gov

Siemens Launches New Version of Sensis Hemodynamic System

Siemens launched a revamped version of its Sensis hemodynamic system at ACC.16. Sensis is the company’s solution for procedural recording and documentation in interventional cardiology and electrophysiology. Sensis Vibe offers a reimagined hemodynamic system that meets the rising demand for proficient data management and streamlines documentation and reporting in the interventional environment. With intuitive operation and simplified data entry as well as seamless integration with Siemens’ Artis family of angiography systems, the Sensis Vibe can help facilities document the course of a cath lab procedure for follow-up care and administrative processes.

New features include FlashDoc, the system’s redesigned approach to procedure data documentation; the QuickAdd component searches the system database for matching entries as soon as the user begins typing; and the CaseLog component enables the physician to follow the entire course of a procedure at a glance.

Siemens | www.usa.siemens.com/healthcare

St. Jude Medical Begins U.S. Launch of MultiPoint Pacing Technology

St. Jude Medical Inc. announced the U.S. launch and first U.S. implants of the Quadra Assura MP cardiac resynchronization therapy defibrillator (CRT-D) with MultiPoint Pacing. Previously FDA approved, MultiPoint Pacing technology is a new approach designed for CRT patients who are not responsive to other pacing options. A small group of patients do not respond optimally to CRT therapy and these non-responders cannot be identified at the time of implant. MultiPoint Pacing offers a new tool for individualized therapy.

St. Jude Medical | www.sjm.com

Digisonics Introduces New CVIS Enhancements

Digisonics showcased new functionality for its cardiovascular information system (CVIS) solutions at ACC.16. This included enhancements to streamline cardiovascular workflows, particularly for adult and pediatric cath labs and integration with hemodynamics systems to create workflow efficiency by autopopulating demographics, hemodynamic measurements, medications and other data directly into clinical reports. An interactive display tablet with drawing pen provides an easy way to label and reference coronary anatomy. A complete library of Mullins congenital heart and peripheral vascular procedure-based diagrams can be edited to display in the cardiovascular reports.

Digisonics | www.digisonics.com

ScImage Releases Miniature Security Appliance for Picom365 Cloud PACS

ScImage launched PicomSentry, a preconfigured appliance that enables users to utilize ScImage's Picom365 Enterprise PACS with plug-and-play convenience, at ACC.16. Once connected to the customer’s internal network, it can be remotely configured by ScImage’s technical implementation team and replaces traditional server or gateway hardware. Enabling the secure acquisition and transfer of DICOM and non-DICOM objects, patient studies, reports and HL7 messaging can be securely transferred to and from Picom365 Cloud PACS and the local site using PicomSentry. It offers efficient interoperability for telecardiology reading capabilities, PicomSentry supports all diagnostic disciplines including echo, ECG, vascular, radiology and others.

ScImage | www.scimage.com

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Routine mammography may also be a useful tool to identify women at risk for heart disease, according to a study presented at the American College of Cardiology’s (ACC) 2016 annual meeting. This could potentially allow for earlier intervention.

Data from this study show for the first time a link between the amount of calcium in the arteries of the breast — readily visible on digital mammography — and the level of calcium buildup in the coronary arteries. Coronary arterial calcification (CAC) is considered a very early sign of cardiovascular disease. Importantly, the presence of breast arterial calcification also appears to be an equivalent or stronger risk factor for CAC than other well-established cardiovascular risk factors such as high cholesterol, high blood pressure and diabetes. Earlier research showed a link between breast arterial calcification and atherosclerotic disease — even heart attack, stroke and other cardiovascular disease events. But researchers said these data provide a more direct relationship between the extent of calcified plaque in the mammary and coronary arteries, and a comparison to standard risk evaluation.

“Many women, especially young women, don’t know the health of their coronary arteries. Based on our data, if a mammogram shows breast arterial calcifications it can be a red flag — an ‘aha’ moment — that there is a strong possibility she also has plaque in her coronary arteries,” said Harvey Hecht, M.D., professor at the Icahn School of Medicine and director of cardiovascular imaging at Mount Sinai St. Luke’s hospital, lead study author.

About 70 percent of the women who had evidence of breast arterial calcification on mammograms were also found to have CAC as shown on a non-contrast computed tomography (CT) scan of the chest. For women under 60 years of age with CAC, half also had breast arterial calcification — an important finding as very few would be thinking about or considered for early signs of heart disease. There were even fewer false positives among younger patients. Researchers said if a younger woman had breast arterial calcification, there was an 83 percent chance of CAC.

Notably, breast arterial calcification also appeared to be as strong a predictor for cardiovascular risk as standard risk scores such as the Framingham Risk Score, which underestimates women’s risk, and the 2013 Cholesterol Guidelines Pooled Cohort Equations, which tends to overestimate risk, Hecht said. When researchers added 33 asymptomatic women with established coronary artery disease, breast arterial calcification was more powerful than both risk assessment formulas, which suggests the presence of subclinical atherosclerosis may be a more important indicator of heart disease than other risk factors.

“This information is available on every mammogram, with no additional cost or radiation exposure, and our research suggests breast arterial calcification is as good as the standard risk factor-based estimate for predicting risk,” Hecht said. “Using this information would allow at-risk women to be referred for standard CAC scoring and to be able to start focusing on prevention — perhaps even taking a statin when it can make the most difference.”

Calcified arteries seen in mammograms may be a new tool to assess cardiovascular risk in women, especially in younger women.
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