The brave new world of Healthcare Technology Management
What does tomorrow hold?

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Welcome to your May issue of HealthCare Business News! This month we’re delivering our annual “health technology management” issue — as a result of last year’s acknowledgment that this new title has officially replaced the term “biomed” to describe these essential health care professionals.

We again interviewed a number of professionals in the sector to find out what their pain points are today, as well as the big opportunities they either currently are seeing or anticipate they’ll see in the coming months. As always, their viewpoints proved enlightening and they’re well worth checking out in our piece that starts on page 50.

Another viewpoint I personally found very interesting was that of Richard Kimball Jr. in this month’s Cost Containment Corner (p. 33). Kimball spoke with HCBN about value-based care and made a good and clear case for it. I know the discussion on value-based care is far from over and the challenges to incorporate it are many, but to me at least, it’s clear that it’s really the direction we need to head if we intend to deliver on the real promise of health care and the investments we’ve made as a country in the technology and research.

In reference to investments in research, this month’s IT Matters deviates a little bit from our standard offerings. This month we take a look at some of the upcoming events that should be of great interest to the IT crowd (see p. 34).

Delving further into the issue, we get into some of the modalities that biomeds/htms might interact with regularly. We have industry sector reports on no fewer than five different equipment subsets. Patient monitors (p. 58) may offer the most radical deviation from the standard established with the equipment. Our story takes an expanded look at the wearables market and how that may turn the sector on its head.

Our infusion pumps ISR (p. 78) explores the pros of smart pump integration and the potential drawbacks of having systems connected to EHRs and potentially providing access to hackers. While it wouldn’t offer the wealth of information or numerous records that the recent high-profile medical record hacks scored, it could deliver a new set of problems.

We have reports on testing equipment, ventilators/respirators and defibrillators to round out the rest of the list, with the stories starting on pages 44, 66 and 72 respectively.

So get your annual check-up on those modalities and more. And as always, we welcome your feedback, ideas and questions!

Until next issue!

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Marty Zimmerman, president and chief executive officer of LFC Capital, Inc.

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- Overuse of medical imaging in U.S. for breast, prostate impacted by region
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- Editor’s Choice
The rising rate of hospital shootings: What health care professionals need to know

Posted online March 2, 2015, by Gus Iversen

Most people in the U.S. are painfully aware of the disturbing increase in school shootings over the past several years, but the fatal shooting of a Boston surgeon in January is a sad reminder that hospitals are not exempt from this horrific trend.

Research outlined in a new JAMA article indicates that hospital shootings are becoming increasingly prevalent. These “active shooter incidents” have gone from nine per year from 2000 to 2005, to an average of 16.7 per year from 2006 to 2011.

DOTmed News reached out to Gail Normandin-Carpio, an independent risk management consultant for Omnisure Consulting Group, to explore the strategies a hospital can use to minimize their vulnerability to these threats. Normandin-Carpio is a registered nurse specializing mental health and corrections, and also a former law enforcement officer.

Omnisure experts recommend that all health care facilities have a Disaster Preparedness and Emergency Operation Plan that includes active shooter incidents. They describe five steps that can be taken to limit the likelihood of an incident, and also mitigate the damage if an incident occurs. The steps are: prevention, protection, mitigation, response and recovery.

For prevention, a hospital should bring in a qualified professional to conduct a security risk assessment. Unique considerations must be made for individual facilities, such as whether or not mental and behavioral services are provided, as well as socio-economic factors.

For protection, metal detectors and security cameras are important, but a well-trained staff that doesn’t become complacent trumps other measures.

That well-trained staff will also be able to handle the third step, mitigation, better. If a situation is brewing, employees must be trained to soothe tensions and defuse tempers.

If a situation goes beyond the mitigation level, staff needs to be trained for response. Hospital employees need to act on a three-part plan: run, hide, fight.

Finally, after the incident has passed, health care facilities need a crisis communications plan that includes staff, patients, visitors, law enforcement agencies, and the media.

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MRI explodes at NJ veterinary hospital

Posted online March 9, 2015, by Gus Iversen

A New Jersey veterinary hospital’s MRI exploded on Friday around noon, as three construction workers were disassembling the unit for replacement.

At the time of the explosion there were roughly 60 animals and 100 staff members in the western part of the Oradell Animal Hospital, where the explosion took place. Some of those animals were undergoing operations when it happened.

The explosion caused a portion of the hospital’s roof to collapse. All three construction workers were injured in the blast, one of whom is in critical condition at Hackensack University Medical Center.

According to news reports, the hospital employees staged a fast and efficient evacuation. Some animals were taken to neighborhood stores for temporary shelter while others with more urgent medical needs were taken to other veterinary hospitals. No animals or hospital employees were injured in the explosion, and the following statement was posted to the facility’s Facebook page:

“All of our employees, clients and patients were carefully evacuated out of our building today due to the explosion. Each and every one of our employees worked together during the situation and they all get a great big thank you.”

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Paying more for comparable outcomes in prostate treatment

Posted online March 11, 2015, by Gus Iversen

Researchers at UCLA have released a study that puts hard numbers into the actual cost of a very common prostate condition in men over 50: benign prostatic hyperplasia (BPH). More importantly, their findings suggest that the more expensive treatments have yet to illustrate better clinical outcomes than the more affordable options.

The cost of treatment for BPH at UCLA varied by 400 percent depending on the chosen course of action. For patients in whom therapeutic treatments are no longer effective, there are a range of surgical options ranging from in-office minimally invasive procedures to surgical removal of the majority of the prostate tissue.

The researchers took a cue from a 2013 study conducted at the University of Iowa, which called over 100 hospitals to inquire on the cost of a hip replacement and discovered a wide range in estimates. For the UCLA study, however, an advanced time-driven activity-based costing strategy developed by Harvard Business School health care economists was used to calculate expenses.


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King v. Burwell: Interpreting five words in the ACA

Posted online March 5, 2015, by Gus Iversen

Oral arguments concluded yesterday in a Supreme Court case with the potential to bring the Affordable Care Act to its knees. The case against Burwell, (Sylvia Burwell, effectively representing the ACA as U.S. secretary of Health and Human Services) hinges on five words out of the several hundred page document colloquially known as Obamacare.

Although inconsistent with most of the ACA, there is a passage that specifies health care subsidies are available through an, “exchange established by the state,” which — if taken out of context — may imply that states without their own markets should not receive federal subsidies.

David King, the lead plaintiff, is a Virginian who did not want to pay for health insurance. Without government subsidies, he would have been exempt from mandated coverage. With the aid of subsidies however, the government deemed King’s coverage affordable, meaning he would incur penalties if he refused to enroll.

Louise Sheiner, policy director for the Hutchins Center on Fiscal and Monetary Policy, told DOTmed News that at least 14 states will be unaffected because they set up their own health care marketplaces. The impact would be primarily on at least 19 states: the ones that have not gotten involved with the federal program on a local level.

The ACA also states that federally subsidized insurers cannot charge premiums to people with pre-existing conditions. Without subsidies, ACA coverage in those 19-plus states would only have cost benefits for a minority of high hospital spenders (sick people). The insurers, in turn, could be forced to charge higher premiums to stay in business... and the experiment fails.

The oral arguments found Justice Anthony Kennedy and Chief Justice John Roberts at the center of attention. Regarded as swing votes, Roberts was mostly quiet, while Kennedy questioned whether the plaintiff’s interpretation of the ACA was even constitutional.

If the ACA wins then all states will continue to earn subsidies. A final decision is not expected until June.

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Hormone disrupting chemical exposure costs EU over $200 billion annually

Posted online March 10, 2015, by Gus Iversen

Exposure to endocrine (or hormone)-disrupting chemicals (EDCs) may be costing countries in the European Union 1.23 percent of their gross domestic product. Those staggering numbers were unveiled in studies published in the Endocrine Society’s Journal of Clinical Endocrinology and Metabolism, and are considered conservative.

EDCs, which can be found in everyday items like paper receipts, food can linings, flame retardants and pesticides, interfere with the body’s natural hormones.

The researchers found that pesticides were the single factor contributing to the most health care expenses, while the main condition by a similar landslide was neurological effects. These types of CEOs are focusing on population health management, buying health plans, partnering in joint ventures, etc. Bowen explained that CEOs still have to be “masterful executors” as well as great collaborators.

Bowen believes that this report highlights the need for hospitals to deploy the right strategies, including a strong succession plan to successfully manage leadership changes. “You have to be able to identify successors, give them stretch assignments, [deploy] development plans, create transition plans and communicate how people are doing and evaluate that.”

ACHE conducted a separate report and found that a little over half of hospitals have committed to succession planning.

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CMS unveils the next phase for accountable care organizations

Posted online March 12, 2015, by Gus Iversen

The U.S. government’s vision for a value-based health system is largely built on the idea that consolidating services among care providers can mean better utilization of resources. ACOs reflect that vision.

The Next Generation Model, as it’s being called, will allow qualified ACOs greater flexibility to make riskier decisions with higher reward margins than were available under the Pioneer Model and Shared Savings Program; previously released ACO programs.

CMS issued a statement on March 10th indicating participants in the new model, like in its predecessors, will be evaluated on their ability to deliver better care for individuals, better health for populations, and lower growth in expenditures.

Next Generation Model ACOs will also have additional coverage of telehealth and post-discharge home services, coverage of skilled nursing care without prior hospitalization, and reward payments to beneficiaries for receiving care from ACOs.

Their performances will be evaluated with quality metrics — including patient experience ratings — made publicly available.

This latest ACO model represents another step forward in the interest of setting clear, measurable goals and a timeline to move U.S. health care toward better care, smarter spending, and healthier people.

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Hospital CEO turnover rate remains high: report

Posted online March 10, 2015, by Lauren Dubinsky

The hospital CEO turnover rate in 2014 was 18 percent, which is among the highest annual rates in the last 15 years, according to a new American College of Healthcare Executives (ACHE) report that included 4,501 U.S. hospitals. However, it was a slight decrease from 20 percent last year.

“It’s on the upper end of what it has been historically,” Deborah Bowen, president and CEO of ACHE, told DOTmed News. The turnover rate for the decade before 2013 ranged from 14 percent to 18 percent — in 2012 it was 17 percent and in 2011 and 2010 it was 16 percent.

The rise in turnovers is attributed to the increase in consolidation among health care organizations, demand for executives who can lead in this new multifaceted, ever-changing environment and retirement of leaders from the baby boomer era.

Bowen said that in order for hospital CEOs to be successful in this new health care environment, they need to be both a strong manager and visionary. “All of these paradigm shifts are going to mean CEOs have to be more innovative and more entrepreneurial,” she said.

These types of CEOs are focusing on population health management, buying health plans, partnering in joint ventures, etc. Bowen explained that CEOs still have to be “masterful executors” as well as great collaborators.

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Share this story: dotmed.com/news/25276
Apple unveils new open source framework to revolutionize medical research

Posted online March 10, 2015, by Lauren Dubinsky

Apple announced its open source software framework for medical and health research, ResearchKit, which will be released next month. It will aid physicians and scientists in collecting data from iPhone apps.

"With hundreds of millions of iPhones in use around the world, we saw an opportunity for Apple to have an even greater impact by empowering people to participate in and contribute to medical research," Jeff Williams, senior vice president of operations at Apple, said in a statement.

Apple’s HealthKit is a software framework that was introduced to its iOS 8 mobile operating system to allow health and fitness apps to communicate with each other. When the iPhone app user grants permission, data from the Health app including weight, blood pressure, glucose levels and asthma inhaler use can be accessed.

In order to get information on the user’s gait, motor impairment, fitness, speech and memory, ResearchKit can also request access to the iPhone’s accelerometer, microphone, gyroscope and GPS sensors. A few research institutions have been pioneers in creating apps with ResearchKit for breast cancer, cardiovascular disease, Parkinson’s disease, asthma and diabetes.

UCLA’s Jonsson Comprehensive Cancer Center created the Share the Journey app, which is a research study investigating why some breast cancer survivors recover more quickly than others, why their symptoms fluctuate over time, and ways to improve their status. The app will utilize surveys and the iPhone’s sensor data to monitor fatigue, mood and cognitive changes, sleep disturbances and declining physical activity.

A few of the other apps include the MyHeart Counts app, created by Sanford Medicine to determine the role that physical activity and lifestyle play in cardiovascular health, and the Parkinson mPower app, developed by Sage Bionetworks and the University of Rochester to track the symptoms and record activities of users with Parkinson’s disease.

This makes managing studies easier for researchers, who used to spend a lot of time recruiting study participants. With the app, the participants don’t have to drive to an institution.

Share this story: dotmed.com/news/25283
Alzheimer’s breakthrough: Focused ultrasound restores memory in mice

Using focused therapeutic ultrasound on mice, a team from the Queensland Brain Institute in Australia have come up with a way to open up the brain-barrier and allow waste removal cells to access and eliminate the neurotoxic amyloid plaques responsible for destroying brain synapses and causing cognitive decline in Alzheimer’s patients.

Once treated, their test mice showed improved performance in three memory tasks: a maze, a new object recognition test, and a memory test to avoid certain places.

Clearing the build-up of defective beta-amyloid and tau proteins from a patient’s brain is an important step in treating Alzheimer’s, but the brain-barrier prevents traditional medicine from accessing them. By using focused ultrasound to open up the barrier and allow waste removal - microglilia - cells to get in and clear out the toxic clumps, the researchers have been able to fully restore the memories of 75 percent of their test mice, with zero damage to surrounding tissue.

The research was funded by a $9 million investment by the Australian government in focused ultrasound.

The researchers hope to have human trials underway by 2017.

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Alma unveils Harmony XL Pro, six-in-one aesthetic device

The Harmony XL Pro can be used to treat six major indications: skin remodeling, vascular lesions, pigmented lesions, tone and texture, hair removal, and acne.

The different settings can be used as single treatment modes or in conjunction with one another in the interest of smoother outcomes. They also allow for an expansive range of patient types.

“The versatility of the Harmony platform allows doctors to provide tailored, customized solutions for every age group, while also building long term relationships by meeting their needs as they change over time,” said Dr. Ziv Karni, Alma’s CEO, in a statement.

The system incorporates ClearLift 4D, which allows providers to maintain the desired height for the treatment — be it deep or superficial — depending on the skin type or area of the body being treated. The fractional Q-Switched laser can also be adjusted throughout treatment for optimal outcomes.

It also features the first technology to combine a non-ablative laser with simultaneous contact cooling and vacuum technology to treat acne vulgaris safely and effectively, a trademark of Alma’s called ClearSkin with Cooled ER:Glass 1540 Laser with Vacuum.

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Total artificial heart is successful bridge for kidney-heart transplant cases: report

Two patients with chronic kidney and heart failure were successfully transitioned to combined heart-kidney transplantation through the temporary use of a SynCardia Total Artificial Heart, according to a recent report.

The heart “may be the mechanical circulatory support device most likely to recover patients with marginal renal function and advanced heart failure,” stated the authors of the report, published in the January-February 2015 peer-reviewed journal Transplantation Proceedings.

A woman, 55, received the SynCardia Heart, and after 148 days of support, she received a heart-kidney transplant and was discharged from the hospital 15 days later. A man, 56, received a SynCardia Heart and was transplanted with a donor heart and kidney 123 days later. He was discharged from the hospital two weeks after the transplant.

The Total Artificial Heart can be a life saver for patients with left and right ventricular failure, a SynCardia spokesperson told DOTmed News. If they have biventricular heart failure and good kidney function prior to implant surgery, and if the patient develops kidney failure following surgery, in most cases, the Total Artificial Heart helps reverse the kidney failure which results in normal kidney function.

On the basis of the 10 authors’ experience with the two patients, “we consider (the Total Artificial Heart) a safe and feasible option for bridging carefully selected patients with heart and kidney failure to combined [heart-kidney transplants],” reported the physicians.

With recent FDA approval of the 13.5-pound Freedom Portable Driver, clinically stable SynCardia Total Artificial Heart patients who require kidney dialysis can be discharged from the hospital and receive their dialysis as outpatients.

Since January 2010 more than 550 SynCardia Hearts have been implanted – the youngest patient to receive one was 9 years old; the oldest was 80 years old. The record for the longest length of time that a patient has lived with the artificial heart was nearly four years before receiving a successful donor heart transplant.

Share this story: dotmed.com/news/25281

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Obesity health toll, costs lead WHO to urge dramatic cut in sugar intake

Posted online March 10, 2015, by Thomas Dworetzky

Obesity has a dramatic impact on both systemic and individual health care costs. According to the CDC, the estimated annual medical cost of obesity in the U.S. was $147 billion in 2008 U.S. dollars; the medical costs for people who are obese were $1,429 higher than those of normal weight.

Now a new WHO guideline urges adults and children to cut daily intake of free sugars by roughly half in North America and Western Europe and even more in other areas – to less than 10 percent of total energy intake. A further reduction to below 5 percent, or roughly 25 grams (6 teaspoons) per day would provide additional health benefits.

“We have solid evidence that keeping intake of free sugars to less than 10% of total energy intake reduces the risk of overweight, obesity and tooth decay,” says Dr. Francesco Branca, Director of WHO’s Department of Nutrition for Health and Development. “Making policy changes to support this will be key if countries are to live up to their commitments to reduce the burden of noncommunicable diseases.”

The WHO guideline does not refer to the sugars in fresh fruits and vegetables, and sugars naturally present in milk.

One can of sugar-sweetened soda contains up to 40 grams (around 10 teaspoons) of free sugar, advised the WHO report, published Wednesday. The report finalizes draft advice, first released last year, after a year of consultations.

In Europe, WHO found that adults consume from about 7-8 percent of total energy intake in countries like Hungary and Norway, to 16-17 percent in countries like Spain and the UK. Intake is much higher among children, ranging from about 12 percent in countries like Denmark, Slovenia and Sweden, to nearly 25 percent in Portugal.

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Varian to equip, run two new proton therapy centers in England

Posted online March 11, 2015, by Thomas Dworetzky

Two new national proton therapy centers in England will be equipped with the Varian ProBeam proton therapy system, according to Varian Medical Systems.

It will also operate the London- and Manchester-based three-room centers. They will be located at University College London Hospitals NHS Foundation Trust in London and The Christie NHS Foundation Trust in Manchester.

The contract is for £80 million. The company anticipates signing the deal and booking the equipment portion of the contract this summer, with installation to take place beginning in August 2017.

The centers are scheduled to be open for patient care in 2018.

Share this story: dotmed.com/news/25297
Study: Is angiography's appropriate-use criteria in need of a revision?

Posted online March 12, 2015, by Lauren Dubinsky

It’s time to make changes to the angiography appropriate-use criteria (AUC), according to a new Sunnybrook Health Sciences Centre study published in the Annals of Internal Medicine. It uncovered that just over half of the patients considered appropriate had obstructive coronary artery disease (CAD) and about 31 percent of the patients considered inappropriate, in fact, did suffer from obstructive CAD.

The researchers assessed 48,336 patients from 18 hospitals in Ontario, Canada, with stable ischemic heart disease or angina who underwent an angiogram from October 2008 to September 2011. The physicians used the AUC developed in 2012 and deemed about 58 percent of the patients appropriate, about 11 percent inappropriate and 31 percent uncertain.

Ultimately, 45.5 percent of the patients who underwent angiograms had obstructive CAD. The study stated that this “raises concerns about the ability of the AUC to guide clinical decision-making.”

“Typically we associate ‘appropriateness’ with angiograms revealing obstructive coronary artery disease, with patients going on to receive subsequent revascularization such as a stent or bypass surgery,” Dr. Harindra Wijeysundera, principal investigator and interventional cardiologist with Sunnybrook’s Schulich Heart Centre, said in a statement.

“Typically, we associate ‘appropriateness’ with angiograms revealing obstructive coronary artery disease, with patients going on to receive subsequent revascularization such as a stent or bypass surgery.”

Look of love: MRI study shows romance’s lasting brain changes

Posted online March 16, 2015, by Gus Iversen

Even without actively thinking of their sweetheart, a person in love demonstrates different brain activity than someone who is not in love, according to a new study conducted using resting-state fMRI.

Using flyers and Internet advertisements, the researchers solicited healthy, heterosexual college students from Southwest University in Chongqing, China. After interviewing them, 100 of the students were divided into three groups: people intensely in love, people moderately in love, and people who is not in love, according to a new study conducted using resting-state fMRI.

“With a population of over 85 million people, health care is a major social and economic force for Egypt,” said His Excellency Dr. Adel El Adawy, Minister of Health, in a statement.

“Therefore, enhancing health technology management and governance systems, ensuring performance efficiency and capacity building by nurturing strong local expertise, and maximizing the provision of continuing medical education are key pillars in the Ministry’s focus on health system strengthening to support the attainment of international health indicators in Egypt,” he continued.

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GE partners with Egypt to create Biomed Center of Excellence

Posted online March 16, 2015, by Gus Iversen

GE Healthcare, in cooperation with the World Health Organization (WHO) has signed on to a partnership with Egypt’s Ministry of Health to enhance the country’s health care technology and training resources.

As part of the agreement, a feasibility study for the establishment of a Biomed Center for Excellence will be conducted. A second phase will follow, in which construction will get underway.

Experts approximate 50 percent of medical equipment in developing countries is not functioning optimally. On top of that, 85 percent of hospitals in Africa reported difficulty finding qualified medical engineers. The partnership with GE, and the plans for the Biomed Center of Excellence, are both in the interest of resolving those problems.

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Interoperability may reduce medical errors but there is a lack of interoperable devices: survey

Three in five nurses believe that interoperable medical devices have the potential to dramatically reduce medical errors, according to a new Harris Poll national survey commissioned by the Gary and Mary West Health Institute.

The survey interviewed 526 nurses from January 7 to 16 who work full-time in a non-school setting. Based on the findings, the lack of interoperability is a big problem — half of the nurses reported that they witnessed a medical error because of it.

Many of those medical errors are a result of manual data entry — almost half of the nurses stated that an error is extremely or very likely to happen when data must be manually transcribed from one device to another. In addition, transcribing all of that data is very time-consuming — more than two out of three of the nurses believe that transcribing is very likely to take time away from patients who need attention.

West Health Institute conducted an analysis last March that found that interoperable devices could save the health care system over $30 billion annually. But a recent HIMSS Analytics report that found that 90 percent of hospitals interviewed use six or more kinds of medical devices that can be integrated with EHRs, but only about a third actually integrate the technology.

The problem is that the current EHRs do not have open-standards-based interfaces for all medical devices and the medical devices don’t have open-standards based interfaces yet, Dr. Joseph Smith, chief medical and science officer of West Health Institute, told DOTmed News.

“As a result, those leading hospitals trying to solve this issue and capture and integrate device-based data have largely contracted with third parties to make the bridging hardware and software solutions,” he explained. “The results are awkward one-off solutions being replicated in different hospitals in different ways.”

To solve this, Smith thinks we need a more “holistic, extensible, generalizable solution that will enable a form of medical interoperability.”

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Hackers access 11 million private records in second massive insurance cyberattack of 2015

Posted online March 17, 2015, by Gus Iversen

On the heels of Anthem’s 80 million member data breach last month, Premera Blue Cross announced today a cyberattack that could jeopardize Social Security numbers, bank account numbers, clinical information and addresses of 11 million of its members in the Pacific Northwest.

Premera said that they became aware of a security breach on January 29th — the same day as Anthem — and that hackers initially infiltrated their IT system on May 5th, 2014. The company has been investigating the attack in partnership with the FBI and Mandiant, one of the world’s leading cybersecurity firms.

“The investigation has not determined that any such data has been removed from our system or been used inappropriately,” stated Jeff Roe, president and CEO of Premera, in a video statement to the company’s members.

The data involved dates back to 2002 and pertains to Premera Blue Cross, Premera Blue Cross Blue Shield of Alaska, and their affiliate brands Vivacity and Connexion Insurance Solutions. It may also affect members from other networks who received treatment through those providers while traveling in the Pacific Northwest.

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Etiometry scores FDA approval for its ICU software solution, T3 Monitor

Posted online March 19, 2015, by Lauren Dubinsky

Etiometry, an ICU software development company, announced on Tuesday that it received FDA approval for its T3 Monitor. It’s a software-only solution with a web browser interface that integrates all of the data from patient monitors and other devices.

The company partnered with clinicians from two of the top research hospitals including Boston Children’s Hospital to create this monitor. T3 stands for track, trajectory and trigger — it helps clinicians track the trajectory of patients to trigger appropriate responses.

“The ability to capture, store and analyze the data to develop predictive algorithms for management is really, for us, the holy grail,” Peter Laussen, chief of critical care at The Hospital for Sick Children in Toronto and former chief of the division of cardiovascular intensive care at Boston Children’s Hospital, said in a video.

“It moves us from being prescriptive in our management to being predictive, which is where we want to be.”

The monitor is the foundation for Etiometry’s predictive analytics software called Etiometry Risk Analytics Engine, which is currently being developed. Once it’s completed, it will be able to give clinicians early warnings if a patient is deteriorating.

Share this story: dotmed.com/news/25363
FDA issues final guidance on reusable medical device reprocessing

The U.S. Food and Drug Administration has issued new guidance about the reprocessing of reusable medical devices and to address the recently headline-grabbing problems of the possible spread of infectious agents.

“Despite the recent concerns about multidrug resistant bacteria infections associated with duodenoscopes, patients and health care providers should know that the risk of acquiring an infection from a reprocessed medical device is low” said Dr. William Maisel, deputy director for science and chief scientist at the FDA’s Center for Devices and Radiological Health.

“This guidance is an important step toward further enhancing the safety margin by outlining for manufacturers the steps they should undertake to make their reprocessing instructions effective and clear to the health care community that uses them. Doing so should provide greater assurance to patients that the devices used on them are safe and effective,” he added.

The FDA also announced that the agency’s Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee will hold a public meeting on May 14 and 15, 2015, to discuss recent reports of transmission of infections associated with the use of duodenoscopes at U.S. hospitals.

The final industry guidance, released Thursday, is intended to help device makers in the creation of safer reusable devices and is entitled “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.” The document contains recommendations medical device manufacturers should follow during both pre-market and post-market time frames.

The guidance lists six criteria that need to be addressed in the instructions for use with every reusable device, and also advises manufacturers to think about reprocessing issues during the initial design phase of devices.

Makers of devices are “expected” to do validation testing that shows cleaning, disinfection or sterilization processes will in fact “consistently reduce microbial contamination.”

Manufacturers seeking to bring to market certain reusable devices, such as duodenoscopes, bronchoscopes and endoscopes, are expected to submit to the FDA for review validation data about reprocessing.

BIOTRONIK gets FDA nod for MRI-compatible ProMRI Eluna pacemaker

BIOTRONIK announced today that its ProMRI Eluna pacemaker system received FDA approval. The ProMRI technology built into it enables patients to undergo full-body MRIs with single-chamber and dual-chamber Eluna pacemakers when implanted with Setrox leads.

To develop an MRI-compatible pacemaker, the device itself needs to be made without any ferromagnetic components and the software and firmware that drive the device need to be capable of undergoing an MRI without the magnet field disrupting the computer programs.

In addition, the leads need to be designed to dissipate the energy generated by the MRI. “The leads are really the most important part,” Rex Richmond, vice president of marketing and communication at BIOTRONIK, told DOTmed News.

The magnetic field generated by the MRI creates energy, which is picked up by the leads, and then leads can transmit the energy back to the can or the heart in the form of heat. “Either one of those things is bad so the most important thing in an MRI system is that the leads be able to dissipate that energy of the MRI effectively,” said Richmond.

BIOTRONIK gets FDA nod for MRI-compatible ProMRI Eluna pacemaker

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**Overuse of medical imaging in U.S. for breast, prostate impacted by region**

Posted online March 18, 2015, by Gus Iversen

By looking at medical records from across 84 hospital referral regions (HRRs), researchers found that men with low-risk prostate cancer and women with low-risk breast cancer received unnecessary imaging in over 40 percent of the cases sampled.

The study looked at 9,219 men and 30,298 women treated between 2004 and 2007, and found for men with low-risk prostate cancer, imaging was overused in 44.4 percent of the cases. For women, overuse happened in 42 percent of the cases.

For men with low-risk prostate cancer, frequency of imaging was not associated with race, year of diagnosis, median household income, or marital status.

However, rates for women with low-risk breast cancer were associated with race (black women imaged most), year of diagnosis, median income (most frequent imaging for median income $50,000-$63,000 annually), and marital status (married women imaged most).

The researchers based their findings on the use of CT and bone scans for prostate cancer, and CT, MR, and PET scans for breast cancer. The studies they examined took place in the years prior to the Choose-Wisely Initiative, which set forth recommendations to limit the overuse of medical imaging.

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**IBM Watson investment in EMR provider Modernizing Medicine caps company’s $20 million Series D funding**

Posted online March 18, 2015, by Gus Iversen

An investment which capped the $20 million in Series D funding for Modernizing Medicine, a specialty-specific and ICD-10 compliant EMR provider, represents the latest effort from IBM through its $100 million fund to seed Watson innovations.

Modernizing Medicine is used by over 5,000 health care providers in the U.S., among them are roughly 30 percent of all dermatologists — a segment in which the company ranked first in a Black Book Market Research reports.

Modernizing Medicine is expected to use the funding in part to enhance and expand schEMA, a mobile app which will be accessed through the company's primary EMR and leverage Watson's cognitive capabilities in the interest of better, faster treatment at the point of care.

The app will field medical questions asked in natural language, analyze massive amounts of published and peer-reviewed medical data, then return meaningful clinical information to the treating physician within seconds.

In the interest of transforming and optimizing health care, IBM has other Watson collaborations underway with leading hospitals and research organizations. Among them are Memorial Sloan Kettering Cancer Center, University of Texas MD Anderson Cancer Center, Cleveland Clinic, Mayo Clinic and New York Genome Center.

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GE partners with Sunnybrook and MaRS Innovation for ultrasound chemotherapy monitoring technology

Posted online March 13, 2015, by Lauren Dubinsky

Sunnybrook Health Sciences Centre and MaRS Innovation announced yesterday a partnership with GE Healthcare to develop the chemotherapy monitoring technology, WaveCheck, as a clinical tool. A clinical study investigating the technology is currently underway at MD Anderson Cancer Center in Texas.

WaveCheck uses ultrasound technology and takes only a week to evaluate how a breast cancer tumor responds to chemotherapy. If red shows up on the ultrasound scan then the treatment isn’t working but yellow means it is working.

The technology was invented by Dr. Gregory Czarnota, chief of radiation oncology at Sunnybrook’s Odette Cancer Centre and Michael C. Kolios, professor and associate dean of research graduate studies at Ryerson University’s Faculty of Science.

The conventional way of monitoring chemotherapy is by physical exams, MRI scan, or CT scans, but that can take four to six months to yield an answer. Getting that answer within a week has the potential to significantly alleviate patient anxiety.

This new partnership will bring together GE’s extensive ultrasound technology and market expertise and Sunnybrook’s experience in oncology research and cancer care through the Odette Cancer Centre.

“To reach people worldwide with breast cancer who stand to benefit from this technology, we need a global partner who also values and prioritizes investment in tomorrow’s health care,” Dr. Michael Julius, vice-president of research at Sunnybrook, said in a statement.

In fall 2013, WaveCheck got support from more than 500 people around the world and raised $53,390 on an Indiegogo campaign led by MaRS Innovation. It was also awarded a major grant from the Ontario Institute for Cancer Research in April 2014.

In May 2014, the funds were used to open a second test site for the technology at MD Anderson Cancer Center. The study at the center involving 20 Canadian and 20 American women with locally-advanced breast cancer will help Sunnybrook determine if WaveCheck generates the same results when used at other cancer centers.

Share this story: dotmed.com/news/25323

GE Global Research and VA develop handheld multi-sensing probe to detect pressure ulcers

Posted online March 23, 2015, by Lauren Dubinsky

Scientists at GE Global Research, the research and development division of GE, have developed a new hand-held probe to detect and prevent pressure ulcers. It was born out of a joint project with the U.S. Department of Veterans Affairs (VA) Center for Innovation.

The probe combines multiple sensing and analytic capabilities including thermal profiling, motion analysis, 3-D object reconstruction, image classification/segmentation and vapor detection. It helps detect the earliest signs of an ulcer and also provides objective and comprehensive information on the ulcer’s progression.

The probe has a thermal sensor to measure the temperature profile inside and around the ulcer, an RGB sensor to quantitatively analyze tissue composition, a 3-D sensor to capture the ulcer’s 3-D genomic shape, a chemical sensor to detect vapors released from the ulcer, a hyper-spectral sensor to quantify oxygenated hemoglobin and its ratio, and a situational awareness sensor to continuously monitor the patient’s movement.

The probe is currently being investigated at the Augusta VA Medical Center. In the Center’s Spinal Cord Injury Unit, 18 patients have already consented to participating in the study.

Share this story: dotmed.com/news/25379
Hospital 5 star rating system set to roll out in April: CMS

Posted online March 13, 2015, by John W. Mitchell

The Center for Medicare & Medicaid Services (CMS) is ratcheting up accountability for hospitals with the rollout of a consumer overall 5 star single rating system in April.

CMS spokesperson Alper Ozinal told DOTmed News there is good reason to emphasize hospital scores through a single star rating in addition to category-by-category ratings.

“HCAHPS scores have been found to be positively related to other quality indicators, including process of care, outcomes, safety and readmissions.” He added that HCAHPS scores have been improving in hospitals since introduced in 2006.

“This is a big change,” said Katie Owens, Vice President of Baptist Leadership Group Practice at HealthStream, a company that both surveys nearly 1.7 million patients a year about their hospital experience and coaches hospitals on how to improve scores by creating patient-centered service. “With consumers now so active on social media the use of 5 star ratings on such sites as Yelp, Trip Advisor and Consumer Report, it seems CMS is looking to follow suit to simplify things in the eyes of the consumer,” she told DOTmed News.

The American Hospital Association (AHA), which represents nearly 5,000 hospitals and health care systems, has concerns about this new single star rating system, officially titled HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Star Ratings.

“The current hospital compare site [which was developed with help from American hospitals] was not designed for single star system rating from multiple scores for patient experience,” Akin Demehin, Senior Associate Director for Policy at the AHA explained to DOTmed News.

“Hospitals are committed to sharing quality data but we’re concerned the single star rating (for patient satisfaction) will not be particularly useful to consumers in making health care decisions. We think it might be more understandable for single star ratings planned in the future for clinical outcomes, such as heart attack.”

Owens, with HealthStream, noted that improving patient satisfaction requires a systemic effort to create a patient-centered culture.

AMA-RAND study: Doctors need ‘support and guidance’ on new pay models

Posted online March 19, 2015, by Lauren Dubinsky

Physician practices are embracing the new payment models but are realizing they need assistance in handling the growing amount of data and finding ways to respond to the many different programs and quality metrics from payors, according to a new RAND Corporation and American Medical Association (AMA) study.

The researchers studied 34 physician practices around the world to get an idea of the impact the new payment models are having on them. The payment models examined were episode-based and bundled payments, shared savings, pay-for-performance, capitation, retainer-based practices, accountable care organizations and medical home.

They found that the practices are having challenges with reorganizing their operations with the models’ objectives because of lack of needed data and the fact that different models conflict with each other. The researchers recommend that payors find ways to harmonize aspects of the payment models including performance measures since practices deal with many payors with different performance measures tied to incentives.

Physician leaders reported being optimistic about the new models, but physicians who aren’t in leadership roles have concerns over new documentation requirements. They were on board with new patient registries that detail patients with particular health conditions to enhance care but were uncertain about other documentation requirements in which the connection to improved care is less clear.

The study also found that the operational details of the models are very important because they can make or break the practice’s efforts to improve their processes. Information systems are used to evaluate practice patterns but when information on quality performance feedback and drug prices is missing or incorrect then it’s hard for them to use the data analysis to actually improve care and cut costs.

The study recommends that payors should think about investing in the capability of the practices to manage the information.

The study describes instances in which a physician received a bonus check for satisfying an incentive but didn’t know what they did to receive that bonus and how to satisfy that incentive again in the future.
Linking cancer risk from low-dose radiation to genetics in Lawrence Berkeley lab mouse study

Posted online March 12, 2015, by Gus Iversen

Lawrence Berkeley National Laboratory research may shed new light on the mystery of how individuals will react to low-dose radiation exposure. While high doses are well understood to be harmful to humans, there is increasing evidence that the effect of low-dose radiation is more complex, sometimes yielding both beneficial and detrimental outcomes.

By removing the epithelial cells from the mammary glands of a genetically diverse population of lab mice, exposing them to low-dose radiation, then implanting genetically identical epithelial cells, researchers were able to see how genes and local cells — not the tumor itself — affect tumor growth.

In the research, low-dose radiation is defined as roughly the dose received from ten full-body CT scans, or 100 millisieverts. After 18 months of monitoring the mice, researchers at the U.S. Department of Energy lab found that low-dose radiation hadn’t changed the risk of cancer in most of them. A small minority of mice was actually protected from cancer development by low-dose radiation, while another small minority become more susceptible.

In susceptible mice, the scientists identified 13 regions in their genomes that contribute to an individual’s sensitivity to low-dose radiation.

“If we can identify similar genetic loci in people, and if we could find biomarkers for these gene-environment interactions, then perhaps we could develop a simple blood test that identifies people who are at high risk of cancer from low-dose radiation,” said Jian-Hua Mao, lead researcher and Berkeley Lab’s Life Sciences Division member.

The researchers hope their study will lead to genetic screening tests to help identify who would be better served by non-radiation therapies and imaging methods.

The research appeared in the journal Scientific Reports.

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Lung ultrasound beats chest X-ray for pediatric pneumonia: Mounting evidence

Posted online March 25, 2015, by Gus Iversen

Research from the Icahn School of Medicine at Mount Sinai, entitled Feasibility and Safety of Substituting Lung Ultrasound for Chest X-Ray When Diagnosing Pneumonia in Children looked at 191 patients ranging from newborns to 21-year-olds, who arrived at their facility with symptoms of pneumonia requiring imaging for diagnosis.

The patients were divided into two groups. An investigational group of 103 received lung ultrasound right off the bat. If uncertainty remained, a chest X-ray could be done. The other 88 were the control arm, in which all patients had a chest X-ray followed by a lung ultrasound.

Only 63 of the 103 patients in the investigational group wound up needing follow-up X-ray imaging, resulting in a 40 percent reduction. In addition, no pneumonia cases were missed, and no adverse effects were reported from the sonograms.

“The reduction in chest X-ray utilization in the investigational arm resulted in a cost reduction of $9,620 overall. Median ED length of stay was decreased by 26 minutes for subjects in the investigational arm compared to the control arm by intent to treat analysis,” wrote the researchers in their study abstract.

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‘Instagram for doctors’ lets physicians share
diagnostic images and insights on social media

For doctors at Cincinnati Children’s Hospital Medical Center, image sharing on social media is for more than posting filtered selfies or pictures of their dinner. Under the user name CincyKidsRad, the hospital has joined Figure 1, an app that brings medical professionals together around diagnostic images.

This ‘Instagram for doctors’ — as it’s become known — is paving new inroads for radiologists and other physicians to learn from one another and test their own ability to interpret images.

At Cincinnati Children’s they are no strangers to social media. The hospital is active on most major platforms, so when Figure 1 asked them to give their service a try, it was a logical fit.

“We had posted a case, it had to do with a child swallowing a coin, the case and discussion involved how would you differentiate between swallowing a coin or button battery. Based on discussion, a friend was able to tell in the patient care setting which one had occurred,” said Saad Ranginwala, a radiology resident at the University of Cincinnati.

Towbin and Ranginwala said it’s great when something like that happens, but relying on contributors and content on Figure 1 to inform real world medical decisions is precarious, at best.

“We are not trying to solicit opinions, we are trying to be a source of educational content,” said Towbin, who likens the app’s usefulness to that of a textbook.

Google and Johnson & Johnson
to collaborate on surgical robots

Ethicon, a medical device company owned by Johnson & Johnson, has entered a strategic collaboration with Google in the interest of building better minimally invasive surgical robots.

By combining their intellectual property and expertise, the two companies hope to find new ways to benefit surgeons, patients, and health care systems. Part of the approach will weigh in imaging and data analytics.

The financial terms of the agreement have not been disclosed.

“For more than 60 years, Ethicon has developed products and technologies that have transformed the way surgery is done,” said Gary Pruden, worldwide chairman, Global Surgery Group, Johnson & Johnson, in a statement.

“This collaboration with Google is another important step in our commitment to advancing surgical care, and together, we aim to put the best science, technology and surgical know-how in the hands of medical teams around the world."

Like offerings from other minimally invasive surgical robot manufacturers, the equipment that comes from this partnership will aim to give surgeons greater control, access and accuracy during the procedure. For patients, less trauma and scarring will be associated with recovery.

The companies expect to close the transaction during the second quarter of 2015.

Olympus unveils new FDA-endorsed reprocessing instructions for duodenoscopes

An outbreak of antibiotic resistant “superbug” bacterial infections in patients undergoing procedures with duodenoscopes and other endoscopes has recently stirred some controversy.

The complex design of these minimally invasive surgical tools means residual body fluids and organic debris can sometimes remain in microscopic crevices after cleaning.

Duodenoscopes are used to treat diseases of the liver, bile duct, and pancreas. For Olympus, evidence indicated that even when following the reprocessing — or sterilization — guidelines they provided for a duodenoscope, infections could happen.

Higher level disinfection data was submitted by Olympus in February and the FDA has endorsed new cleaning protocols as consistent, robust, and reliable. Yesterday, Olympus sent letters to customers using the TJF-Q180V duodenoscopes which outline the new instructions. An update to user manuals is forthcoming.

The new validated protocol divides the cleaning process into three steps: pre-cleaning, manual cleaning, and manual high-level disinfection. The manual cleaning step requires a new brush, (called MAJ-1888) that will be shipped to users of the duodenoscope by May 8th, but changes to pre-cleaning and manual high-level disinfection can be implemented right away.

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New cardiology offerings unveiled at ACC 2015

Posted online March 16, 2015, by Lauren Dubinsky

The 64th annual American College of Cardiology conference is just wrapping up today in San Diego, California.

The three-day conference highlighted almost a dozen clinical learning pathways. In addition, many companies announced FDA clearance of their new devices.

On Friday, Boston Scientific announced FDA approval of its WATCHMAN Left Atrial Appendage Closure Device, which it claims is the first alternative to long-term warfarin therapy for stroke risk reduction in patients with non-valvular atrial fibrillation.

The approval came as a result of the WATCHMAN clinical program, which consisted of numerous studies involving 2,400 patients and almost 6,000 patient-years of follow-up. The program proved that the device can be implanted safely, reduces the risk of stroke for eligible patients and can replace warfarin therapy for most of them.

Edwards Lifesciences Corporation released the results of the five-year PARTNER Trial investigating its SAPIEN transcatheter aortic valve on Sunday. It found that SAPIEN has the same outcomes as traditional open-heart surgery.

Toshiba Medical Systems, Inc. announced on Friday that its new Infinix 4D CT received FDA clearance with its Aquilion PRIME CT system configuration. According to a release, this new combination of CT and interventional lab technology gives physicians tools to optimize their time and improve the experience for the patient.

Siemens Healthcare announced that it scored FDA clearance two weeks ago for its new PURE platform for its Artis zee, Artis Q and Artis Q.zen angiography systems. The platform offers the 3D Wizard feature that automatically selects parameters including the amount and injection rate of contrast fluid, X-ray delay to generate a 3-D image, and the syngo 2D/3D Fusion feature that fuses CT, MRI and PET by using just two fluoroscopic images for live image guidance.

Philips Healthcare launched its IntelliSpace Cardiovascular workspace on Sunday, which provides physicians with a holistic view of their patient’s care continuum across the whole cardiovascular service line. It consolidates all of that information so that the whole care team can view it on one workspace.

House passes SGR repeal with overwhelming majority

Posted online March 26, 2015, by Gus Iversen

H.R. 2, the Medicare Access and CHIP Reauthorization Act, aims to eliminate the annual threat of cuts to Medicare providers and secure a five-year period of increased annual payments of point-five percent. After that, Medicare doctors would receive bonuses and penalties based on performance ratings; a big step for value-based health care.

Since 2003, Congress has spent nearly $170 billion on short-term patches, or ‘doc fixes’ to avoid unsustainable cuts imposed by the flawed sustainable growth rate (SGR) formula which was established in 1997 as part of the Balanced Budget Act.

Despite added costs estimated at over $140 billion by the Congressional Budget Office, House Democrats and Republicans have come together behind a bipartisan effort led by Speaker John A. Boehner and the House Democratic leader, Nancy Pelosi.

Despite the overwhelming majority vote, not everybody is thrilled about the legislation. Some members of the house are leery about aspects of the bill which they fear could restrict the use of Medicare funds for abortion services.

Others are concerned it puts too many cost pressures on beneficiaries, who may see higher premiums and would no longer be able to purchase supplemental policies to cover Medicare deductibles.

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CT angiography, nuclear stress test may be equally reliable with stable chest pain: study

Posted online March 17, 2015, by John W. Mitchell

Treatment options used to diagnose the five million patients annually who suffer chest pain should be reconsidered, according to study results presented by the Duke Clinical Research Institute at the 64th American College of Cardiology’s Scientific Session currently underway in San Diego. The study was also posted on line March 17 on The New England Journal of Medicine website.

Lead author Dr. Pamela Douglas, a researcher and physician at Duke, internationally known for her scientific work in non-invasive imaging, exercise physiology and disease in women, led a federally funded study of 10,003 patients to compare the effectiveness of conventional stress tests to a technique called CT angiography (CTA), which enables noninvasive visualization of the arteries leading to the heart.

According to Dr. Douglas, there was a “low event rate” among the patients in the study regardless of the diagnostic treatment they received, which means very few patients had death or heart attack or hospitalization in the study. While CTA did not improve these outcomes that were the primary objective of the study, it did appear to better predict the need for advanced catheterization procedures and was associated with less radiation than nuclear stress testing.

While the costs of the initial tests varied, the overall costs of the two strategies were similar, a factor to consider as doctors and hospitals move away from fee-for-service medicine under the Affordable Care Act. Dr. Douglas says the research indicates that CT scanning should not replace stress testing, but should be considered a reasonable alternative.

In the study, half of the patients were given the CT scan while the attending physicians made the decision which stress test to use in the other half of patients. Of the physicians caring for patients in the functional testing group, only 10 percent chose the relatively low tech and inexpensive treadmill stress test. Two thirds of the patients received a nuclear medicine stress test while the remaining patients received an echocardiogram, also a non-radiation option.

Physicians aren’t being flooded with new or sick patients under health care reform: report

Posted online March 25, 2015, by Lauren Dubinsky

A year after the Affordable Care Act was put into effect physicians have not seen a stark rise in new or sick patients, according to a new athenahealth, Inc. report, funded by the Robert Wood Johnson Foundation. Athenahealth claims that this is the first-of-its-kind report to investigate the effect health care reform had on physicians after one year.

The researchers used near real-time data from athenahealth’s cloud-based network that includes over 62,000 health care providers and 62 million patients. The report investigated the impact that health care reform had on patient volume, insurance coverage and payor mix.

It found that primary care providers experienced a slight increase in new patient visits however it wasn’t significantly higher than the rate in 2013. In fact, health care reform has lessened the proportion of uninsured patients receiving care in physician offices particularly in Medicaid expansion states.

“Amongst other findings, and counter to what many predicted, we haven’t seen a swell of new and sicker patients materialize in primary care or across specialty settings,” Josh Gray, vice president, athenaResearch, said in a statement.

Studies have yet to demonstrate HIEs improve speed, quality, safety and cost: paper

Posted online March 26, 2015, by Lauren Dubinsky

Despite the plethora of studies that highlight the benefits of health information exchanges (HIEs), a new Indiana-Purdue University research paper uncovered that there actually isn’t much evidence that HIE improves speed, quality, safety and the cost of patient care. The paper was published in the journal Health Affairs.

The researchers analyzed 27 HIE benefit studies. They found that there was “no strong documented evidence in the studies that health care benefits are directly attributed to the use of HIE.”

“There is a dearth of rigorous studies that link HIE adoption to clear benefits,” according to the paper. “Moreover, the scant high-quality evidence that does exist was conducted in disparate settings and evaluated different outcomes."

Additionally, the studies that aimed to identify casual relationships, mostly only found benefits when it came to health care cost measures. Two out of six of those studies, which were conducted in a single clinic affiliated with an Indiana hospital and a health care system in Israel, found that the decline in health care costs were due to a decrease in diagnostic and imaging tests.
Europe had 360,000 cases of tuberculosis in 2013: study

Posted online March 18, 2015, by Lauren Dubinsky

In 2013, 1,000 people per day and about 360,000 people in total in Europe contracted tuberculosis (TB), according to a new study published yesterday by the European Centre for Disease Prevention and Control (ECDC) and the WHO Regional Office for Europe.

Compared to 2012, it’s a 6 percent drop in cases but the rates of multidrug-resistant (MDR) TB are still very high in the 18 “high-priority” countries, which are responsible for a majority of the 38,000 TB-related deaths in 2013.

According to Zsuzsanna Jakab, WHO regional director for Europe, Europe is the most affected area in the world by MDR-TB. “This calls for a considerable scaling up of access to safe, rational and efficient new TB drugs, as well as innovations on rapid diagnosis and care centered on the needs of patients,” she said in a statement.

The good news is that the rate of TB has been declining over the past decade but at the current rate of 6 percent, it will take the European Union (EU) and the European Economic Area (EEA) until the next century to finally be rid of TB.

Marc Sprenger, the director of ECDC, stressed that since the rate of decline in TB cases is not the same across every EU country, there is a need for “tailored intervention, which targets each country’s settings.”

The countries with high instances of TB are reporting higher rates of reinfection and most of the countries with low instances are made up of foreign patients and the rates are steady or slowly declining.

Jakab and Sprenger both agree that there needs to be more efficient use of the current tools and interventions as well as new and more effective ones to complement the current ones. Going forward, the WHO Regional Office for Europe and ECDC will focus on the high-priority countries and also the countries with fewer new cases of TB.

FDA issues separate MRI recalls to GE and Siemens

Posted online March 26, 2015, by Gus Iversen

On March 20th, the FDA posted two separate Class 2 recalls, one concerning 9,369 GE MRI systems and another concerning 132 Siemens MAGNETOM MRI systems.

The GE notice cites the manufacturer reason for recall as follows, “GE Healthcare has become aware of a potential safety issue involving MRI systems due to software versions not being maintained properly at some sites.”

GE sent an “Urgent Medical Device Correction” letter dated March 9, 2015, to all affected customers, (6,432 of whom are outside of the U.S.). The letter described the safety issue, safety instructions, affected product details, product correction and contact information.

For GE, this is the second recall of the year.

FDA notice for Siemens MRI systems cites the manufacturer reason for recall as, “The gradient output supervision was permanently turned off on the MAGNETOM system, meaning that gradient outputs could exceed IEC60601-2-33 limits and peripheral nerve stimulation could occur.”

A Customer Safety Advisory Notice, dated March 6, 2015, was sent to end users to inform them of the potential issue and what measures were being taken to mitigate possible risks, according to the FDA.

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U.S. health care system could save $8 billion annually with more electronic business transactions

Posted online March 18, 2015, by Lauren Dubinsky

If the U.S. health system performed a few routine business transactions electronically instead of manually it could save $8 billion annually, according to the new 2014 CAQH Index. Those transactions include claim submission, eligibility and benefit verification, prior authorization, claim status inquiries, claim payment and remittance advice transactions.

This second annual CAQH Index monitored the progress from manual phone, fax or email transactions to HIPAA electronic administrative transactions between health care providers and health plans. It used data from participating health plans from 112 million enrollees, which is almost 45 percent of the privately insured population in the U.S.

The analysis found that the adoption rates for fully electronic transactions automated for both health care providers and health plans only rose a little, but the volume of those transactions increased to double-digit rates for eligibility and benefit verifications, claim status inquiries, and claim payments.

But the rates vary considerably — 92 percent electronically transact claim submissions, but only 7 percent electronically transact prior authorization. Additionally, about half of the claim payments and remittance advice transactions are still done manually.

The significant potential cost savings are a result of both the bigger volume of transactions and the difference in cost between electronic and manual transactions. Each manual transaction can cost a health plan about $2, and a health care provider over $5, but each electronic transaction can cost health plans as little as 5 to 10 cents and providers $1.60.

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Nanotechnology-based medical device market expected to grow $3.5 billion from 2014 to 2019: report

Posted online March 24, 2015, by Lauren Dubinsky

The global nanotechnology-based medical device market is expected to reach $8.5 billion by 2019, growing at a compound annual growth rate of 11 to 12 percent, according to a new MarketsandMarkets report. In 2014, the market was worth $5 billion.

The market consists of biochips, implantable materials, medical textiles, wound dressing and active implantable devices. It’s segmented into therapeutic applications, diagnostic applications and research applications.

The growing elderly population, rise in R&D spending and international research collaborations are fueling the market. But the hefty price tags of nanotechnology-based medical devices and the long time it requires to receive regulatory approval is inhibiting growth to a certain degree.

North America is leading the global market, but Europe is close behind. Both regions can attribute their success to highly developed health care systems, a plethora of nanotechnology-based medical device manufacturers and a few nanotechnology development government programs.

The Asia-Pacific region is gaining traction and has earned its place as the fastest-growing segment in the overall global market. The rising elderly population, growth in international research collaborations, increase in R&D spending and the growing health care industry is propelling this part of the market.

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Most ER physicians order unnecessary imaging tests: study

**Posted online March 26, 2015, by Lauren Dubinsky**

Most emergency room physicians order unnecessary MRI and CT tests in order to err on the side of caution, according to a new study published in the journal *Academic Emergency Medicine*.

Dr. Hemal Kanzaria, lead author of the study and emergency physician at the University of California, Los Angeles (UCLA) and his fellow researchers surveyed 435 emergency room physicians — 68 percent were board-certified and about half resided in academic emergency departments.

They found that 85 percent of them think that too many diagnostic exams are ordered in their EDs, and 97 percent reported that at least some of the advanced imaging exams they order are medically unnecessary. The main reason they order unnecessary tests is because they are afraid of missing a low-probability diagnosis and getting hit with a lawsuit.

In order to curb this problem, 79 percent of the physicians believe there needs to be malpractice reform, 70 percent cited more patient involvement through education, 56 percent said shared decision-making, 55 percent want feedback on test-ordering metrics and 50 percent believe better educating physicians on diagnostic testing is the answer.

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PET/CT cardiac imaging offers new level of diagnostic outcome: study

A new generation of PET/CT cardiac imaging scanners offers patients significantly improved diagnostic outcomes with lower radiation doses than the more common SPECT technology, especially in female, obese and patients with comorbid liver and gastro conditions, according to researchers at Intermountain Medical Center Heart Institute in Salt Lake City.

“The PET/CT was correct 88 percent of the time as opposed just 30 percent of the time in the standard SPECT imaging in identifying a blocked artery. This is nearly as good as the current gold standard of coronary angiogram, which is an invasive procedure done in a cardiac cath lab where the patient must undergo anesthesia,” Dr. Kent Meredith, the lead author of the study, told DOTmed News.

Some 5 million patients with stable chest pain present in hospital emergency rooms a year, as well as many others in doctor’s offices. There are several diagnostic protocols available, including treadmill stress tests, echocardiograms, nuclear medicine stress tests and advanced technology scanning such as the SPECT (Single-Proton Emission Computed Tomography) and now PET/CT (Computed Tomography - Positron Emission Tomography - Computed Tomography).

The study was conducted by comparing the results of a 2,483 SPECT and 2,178 PET/CT scans conducted at Intermountain Heart Institute and screening for patients who had both a scan and a heart catheter procedure.

According to Meredith, patients receiving PET/CT have a reduced exposure to radiation by a factor of 10. He said this is an important benefit as patients exposed to higher levels of diagnostic radiation over a lifetime are at a higher risk of cancer. SPECT patients also receive a false negative about six percent of the time, while there were no false negatives noted using the PET/CT during the study period.

“The reduction in false positives prevents patients from undergoing unnecessary invasive procedures in the cath lab. This is safer for the patient and reduces health care costs. We also saw a reduction in false negatives for patients, so both of these situations are highly desirable for patients,” said Meredith.

Insights into cerebral malaria from GE MRI in Africa may lead to fewer fatalities

The malaria parasite ends the lives of roughly 1,300 children every day — and most of them are in Africa, where roughly 15 to 25 percent of cases are fatal.

Although malaria can be killed with drugs, finding ways to treat the effects of the disease has troubled physicians because the pathogenetic processes by which it operates are unknown.

By using an MRI provided by GE Healthcare, a team from Michigan State University led by Dr. Terrie Taylor, were able to gain previously unknown insights into how malaria operates in children at the Queen Elizabeth Hospital in Blantyre, Malawi.

In their work, the researchers confirmed a long-held hypothesis that cerebral malaria is sometimes fatal because it triggers massive swelling in the brain. Traditional autopsy could never confirm this suspicion because any pressure on the brain would be relieved in the process of opening the skull.

Since 2008, the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, has funded the MRI scans of hundreds of African children by Taylor and her team. Going forward, the goals will be to better understand the swelling and develop ways to relieve it.

Royal Philips and Mount Sinai team up to create a digital image repository for tissue samples

Royal Philips and Mount Sinai Health System in New York today announced a collaboration to create a digital image repository comprising patient tissue samples and data analytics.

The repository will be used to uncover new tissue-based tests, advance clinical research and improve cancer care.

“The digitization of pathology gives us the unprecedented opportunity to access vast amounts of unlocked data from tumor tissue and view it within the context of other images, results and clinical information,” Perry van Rijssingen, general manager of the Philips Digital Pathology Solutions, told DOTmed News.

Mount Sinai has seven hospital campuses that care for 170,000 inpatients and 2.6 million outpatients every year. All of the campuses have compiled hundreds of thousands of tissue samples in glass tissue slides over time, which will be used to create the repository.

“We hope that in the future, the physician will be able to make a better informed decision using predictive analytics to help personalize patient care,” he said. “A repository of patient cases with similar tissue pattern characteristics, linked to known patient outcomes, could help him, hopefully, in the future to select the best treatment option for a particular patient.”

Royal Philips and Mount Sinai have already announced an expanded digital pathology collaboration.
Upcoming Events

NESPRS 2015 Annual Meeting
Location: Water's Edge Resort & Spa
Westbrook, CT
Dates: June 5 – 7
Years in Existence: 56
Who should attend: Professionals in the plastic surgery and reconstructive fields
Average attendance: +4,500
Who should attend: Medical associations, medical professionals, manufacturers, importers, distributors, wholesalers, retailers, general hospital suppliers and distributors of supplies

SOE 2015
Location: Austria Center Vienna
Vienna, Austria
Dates: June 6 – 9
Average attendance: +4,000
Who should attend: Professionals in the ophthalmology fields including technicians and assistants

ExpoMED 2015
Location: World Trade Center Mexico City
Mexico City, Mexico
Dates: June 10 – 12
Years in Existence: 2

ESPNIC 2015
Location: Lithuanian Exhibition and Congress Centre LITEXPO
Vilnius, Lithuania
Dates: June 10 – 13
Years in Existence: 26
Who should attend: Doctors and nurses in the field of pediatric and neonatal intensive care fields

IAMSE 2015 Annual Meeting
Location: Paradise Point Resort & Spa
San Diego, CA
Dates: June 13 – 16
Years in Existence: 19

CAS 2015 Annual Meeting
Location: Shaw Centre
Ottawa, Ontario, Canada
Dates: June 19 – 22
Years in Existence: 71
Average attendance: 1,000+
Who should attend: Anesthesiologists and assistants

ESHRE 2015 Annual Meeting
Location: International Lisbon Fair
Lisbon, Portugal
Dates: June 14 – 17
Years in Existence: 31
Who should attend: Professionals in the human reproduction and embryology fields

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UMC New Orleans, LCMC Health

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Five Top Product Lines – Level I trauma care; women’s health (OB/GYN); cancer care; orthopedics (including pediatric and research orthopedics); and neurology sciences.
Annual Clinic Visits – 486,694
Number of beds in new University Medical Center facility: 446

1. Architect rendering of University Medical Center New Orleans at night, set to open Summer 2015.
2. This is a bird’s eye view of the construction project.
3. University Medical Center as seen in November 2014 near the end of construction.
4. A worker inspects one of the exam rooms in the UMC Emergency Department. The scroll pattern on the walls, similar to wrought ironwork in New Orleans’ iconic French Quarter, is repeated in patient rooms throughout the hospital.
5. The Emergency Department, located in the UMC Diagnostic & Treatment Building, includes 56 exam/treatment rooms, five trauma rooms, nine rapid treatment rooms and a radiology area.
6. The reception area in Inpatient Tower 2 highlights the colorful, modern design features in University Medical Center New Orleans.
7. The five-level UMC Ambulatory Care Building contains more than 214,700 square feet of space for clinics and services. Campus is 1.3 million square feet, including three, six-level Inpatient Towers, a five-level Diagnostic & Treatment Building and a five-level Ambulatory Care Building.
HealthCare Business News interviewed Greg Ferin, CEO of LCMC Health about New Orleans health care post-Katrina and the latest shifts toward population management. LCMC Health is made up of Children’s Hospital New Orleans, Touro, New Orleans East Hospital, Interim LSU Hospital and University Medical Center New Orleans (UMC New Orleans).

HBCN: How did your career path lead you to become a hospital CEO?

GF: I’ve been in New Orleans for 16 years, working in various positions, including at Children’s Hospital, where I transitioned from finance to operations. I became the CEO of LCMC 10 months ago.

HBCN: Tell me what makes LCMC Health unique.

GF: We have grown quickly because we had to. Hurricane Katrina significantly changed the hospital landscape in New Orleans. Charity Hospital, the safety net hospital for the city, was destroyed and University Hospital closed due to damage, which later reopened as Interim LSU Hospital. The State is replacing these facilities with the new University Hospital that I’ve already mentioned, and an agreement with New Orleans East Hospital, a new facility that opened in 2014 to also replace a hospital destroyed in Katrina. And we’ve recently signed an agreement to manage West Jefferson medical Center, which I believe will go into effect this summer. The sheer size of our patient settings and amenities we offer differentiates us. Patients want and expect quality and safety on demand. We also work with physicians across a wide range of practice models, from employed doctors in our academic centers to the medical staff in our community hospitals that have a strong tradition of the private practice model. This includes working with some physicians in stand-alone surgery and imaging center agreements.

HBCN: What should people know about LCMC Health?

GF: We are the only private, nonprofit, full-service children’s specialty hospital in the state. We operate the largest birthing hospital in the state at Touro, which makes 3,349 deliveries a year. With the intensive care units in our facilities, we are the referral center for the most critically ill patients in the state. We do not turn anyone away. We are also a significant player in both Louisiana State University’s and Tulane’s medical training programs, as well as research trials, such as in oncology. With our mix of services, we take care of our population from birth to end of life, which includes the nursing home facilities provided at Touro. We have an experienced leadership team here at the system who are charged with helping each of the hospitals in our system to succeed in delivering the best in modern patient care.

HBCN: What are the biggest challenges at LCMC Health?

GF: I think the single biggest shift is toward population management (keeping patients healthy). This is a big change. I see this affecting demand for inpatient services, with a leveling off and even declining. The new payment model (ACA) will focus on cost containment as services shift from inpatient to the outpatient. We have to focus to reduce care variation by managing outcomes. We have a challenging environment, all being driven by a move away from fee-for-service. Information technology is the single biggest component of every decision I make now. All the devices in a hospital – from patient monitors to infusion pumps must have connectivity to the electronic health care record. This is a cost component that didn’t exist until recent years. But we’re still putting the latest medical technology and design into the new hospital to create efficiencies and patient safety. For example, there will be MRI in the operating room, so rather than move a patient out of the OR for imaging to check placement before the surgery is complete, we’ll do it right in the OR.
The case for value-based care

By Sean Ruck

HealthCare Business News recently spoke with Richard Kimball Jr. about the move to value-based care. Kimball is a health care technology professional with a background in investment banking, venture capital and public policy. He is also a Fellow in Stanford’s Distinguished Careers Institute and is behind the health care technology start up HEXL.com.

With the ACA finally in place (at least until the next election) the push for value-based care has gained momentum. Meanwhile fee-per-service, while lucrative for some facilities, seems to be a dirty phrase in the public mind. Although it’s getting more ink as of late, the value-based care reimbursement plan isn’t new. “It’s been around for a long time in various pockets around the country, particularly in Southern California with Heritage and HealthCare Partners. The delegated capitated model has been around for about 25 years,” he says.

According to Kimball, those facilities and a handful of others started along the road as far back as the mid ‘80s, likely with diagnostic-related groups taking the first steps in that direction. “That was started when Medicare started paying hospitals for a full procedure rather than its separate components. From there, we went to bundled payments which handled a broader range of procedures and components,” Kimball says.

The shift to value-based reimbursement is being accelerated by the creation of the Accountable Care Organizations. Hospitals and physicians are beginning to get experience in value-oriented paradigm.

The problem with ACOs, says Kimball, is that while hospitals and physicians do share in the improvements to patient care, it’s only a small improvement and doesn’t justify the reengineering of the care delivery infrastructure. “The ACOs are only getting 0 to 2 percent savings below fee-per-service, where Heritage and HealthCare Partners may be attaining 20 to 30 percent below fee-for-service costs,” Kimball says.

Even hitting the 2 percent savings below fee-per-service may be unattainable for many facilities unless they can restructure and retrain clinicians in the new paradigm. Complicating the matter further is the fact that some hospitals are turning a healthy profit right now, so they’ll be reluctant to move into a new structure, especially when it has the potential to hurt the facilities that are doing the best by moving to value-based care. “It’s a very tricky timing matter. Fee-for-service is reasonably profitable. If a hospital moves too quickly, they’ll get financially hurt, because they won’t be able to downsize quickly enough,” says Kimball. “So one way to do this is to take groups that aren’t profitable to begin with, for example, the Medicare or Medicaid population and reduce their utilization rates, but continue with commercial on a fee-for-service basis and try to maximize volumes, i.e. the opposite that providers what to do in a capitated environment.”

It’s easier said than done though. From what he’s seen, Kimball doesn’t believe that medical schools are shifting gears to help the health care professionals of tomorrow develop the proper mindset to make the change that’s needed. “They’re all being trained about how to fix sick people. There’s very little discussion about preventive medicine. In some ways, it’s culturally conflicting for doctors in hospitals, because they’re designed to be manufacturing plants to treat disease rather than prevent. There’s been quite a separation from the medical world to the public health world.”

Conversely, most medical professionals have the knowledge to make the value-based care shift, at least in theory. “It’s telling that 65 percent of Americans die in an institutional setting – hospital, nursing home or hospice, yet only 7 percent of doctors do,” says Kimball.

If done right, while it may be painful at least at the start, with downsizing likely necessary, hospitals that survive and react intelligently could experience significant growth to their bottom line. “Right now, hospitals average a 56 percent bed occupancy rate. If volumes come down by 20 to 30 percent we would have an even greater oversupply of hospital beds than we do now. And the health care industry is supply driven. Over-supply will drive more demand.”

Kimball cautions that there is a potential negative that requires monitoring. “There’s a real risk here of the provider group denying care to some patient groups in order to maintain profitability. There’s a risk that some may cut corners to deliver profits and ultimately end up with worse outcomes.”

We’re currently at a tipping point Kimball says. “I think we have better data than we’ve had in the past and a better ability to understand it. I think that the ACA has put out the concept of value-based reimbursement that people have rallied around. I think it’s a start and in the next few years we’ll see innovations at Medicare for new reimbursement models. I think patients are going to demand something different and transparency in the market place will help that. Because we’re already doing this in pockets around the country, we know there’s value in this move to value-based reimbursement. I think it will take 10 or 20 years to change the system. I think it will take entrepreneurs to shake up the system. Hospitals will not do it all on their own.

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A banner year for health IT education

By Sean Ruck

Health IT has many major challenges ahead. From integrating PACS to perform above and beyond its originally intended level, to dealing with employee-owned devices being utilized in the workplace, to the looming ICD-10 deadline that can’t be kicked down the road forever, health IT professionals have their plates full. Fortunately, for every problem, professionals are finding answers and the professionals within the health IT community are increasingly open to sharing those answers with their peers.

One of the more popular ways to exchange information is to attend conferences. With spring finally here, the show and conference season is starting to pick up. HealthCare Business News spoke with Dr. David Hirschorn, one of the leading voices in health informatics, about some of the big events taking place over the next few months. The first, ACR 2015, takes place in National Harbor, Maryland. The show, taking place from May 17 and runs through May 21.

ACR has presented an annual meeting for nearly half a century. According to Hirschorn, this year marks the first year that there will be a “knowledge pathway” or educational track, dedicated to informatics and innovation. Hirschorn, who co-chaired the group that developed the educational tracks for informatics, is excited about the offerings.

Attendees will have the chance to learn more about the potential impact mobile apps will have on radiology and will also learn about FDA regulations that continue to shape the future of those mobile apps. Another offering deals with social media and how it can be used to advance medical imaging efforts. Other educational track offerings include a section on optimizing electronic health records to improve patient care; image sharing and data management; clinical decision support; sections on dose reduction/control; teleradiology; and personalized medicine.

On the final day of the conference, the informatics and innovation educational track wraps with a topic that Hirschorn has been delving into quite extensively — clinical test result management. According to Hirschorn, clinical test result management requires non-routine communication between the radiologist and physician of record for the patient — such as in-person meetings and phone calls.

Just a week later, the IT offerings get ramped up from one learning path to the whole focus of the conference when the Society for Imaging Informatics in Medicine presents its annual meeting at the Gaylord National Resort & Convention Center in National Harbor, Maryland. The show, taking place from May 28 through the 30, is carrying the theme, “Creating the Image Enabled Enterprise.”

Immediately following the opening presentation, a town hall-style discussion will take place where attendees will learn more about the future of PACS during the presentation, “Surviving (and Thriving) in a World Without PACS.”

While Dennison’s talks will help to set the mood for the show, in all, there are more than 60 educational offerings and events to choose from during the show, meaning IT professionals should find topics of interest no matter what they’re looking to learn about.

Another event to mark on your calendar (or in your smartphone) is the NYC Medical Imaging Informatics Symposium happening in New York in September. Hirschorn has put together the symposium for the last five years and already has a number of well-respected presenters lined up, the likes of which included Dr. Eliot Siegel and Dr. Keith Dreyer. Hirschorn has worked with other luminaries in the field to present the latest in imaging informatics, helping to keep participants educated and able to handle the fast-moving changes in health IT today.

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Dr. David Hirschorn

senter Donald K. Dennison, of the consulting firm Don K. Dennison Solutions, Inc., will likely give attendees quite a lot to consider when he gives his talk, “The Next Imaging Evolution: A World Without PACS (as we know it).”

During his presentation, Dennison will explore how some of the components of the picture archiving and the communications components that make up PACS are starting to be picked up by other applications, with for example, EMR systems taking some of those roles over. With those changes to the actual systems also comes a change to some of the long-standing processes within the hospital, with radiologists no longer the gatekeepers of all the related information. Attendees will learn why the change is occurring and how to best prepare for the future.

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**Pacemaker System with Full-Body ProMRI Technology**

BIOTRONIK recently announced that the FDA has approved its ProMRI Eluna pacemaker system. BIOTRONIK ProMRI technology allows patients to undergo full-body magnetic resonance imaging (MRI) scans with both single-chamber (SR-T) and dual-chamber (DR-T) Eluna pacemakers when implanted with Setrox pacing leads.

**Precision system for highly proficient revision knee surgeons**

DJO Global, Inc., a global provider of medical device solutions for musculoskeletal health, vascular health and pain management, is launching the new Exprt Precision System for highly proficient revision knee surgeons.

The Exprt System redefines total knee revision arthroplasty, providing advanced technology to experienced revision surgeons that leads to greater value and efficiency in the operating suite. Exprt’s streamlined, compact design reduces turn times, minimizes waste, and has proven implant design technology - all for 40 to 70 percent of the cost of comparable knee revision systems. A simple, comprehensive 2-tray system replaces the traditional 8-tray setup used during complex, total knee revisions, dramatically reducing prep time, eliminating unnecessary surgical steps, and allowing the precision skills of revision surgeons to truly hit the mark.
Laser to address aesthetic concerns of patients
Alma Lasers, a global innovator of laser, light-based, radiofrequency and ultrasound solutions for the aesthetic and surgical markets announced the addition of the Harmony XL Pro platform to its product portfolio.

The Harmony XL Pro platform consists of multiple modules offering powerful solutions for 6 major indications: Skin Remodeling, Vascular Lesions, Pigmented Lesions, Tone and Texture, Hair Removal and Acne. Each may be treated using a single technology or a combination of technologies and treatment approaches to achieve outstanding clinical results. The modules are designed to work independently or together as a single cohesive, harmonious system.

All-in-one interventional lab and CT solution
Expanding the industry’s first seamless integration between interventional labs and CT technology, Toshiba America Medical Systems Inc.’s all-new Infinix 4DCT has received FDA clearance with the Aquilion PRIME CT system configuration.

Toshiba’s Infinix 4DCT is an all-in-one interventional lab and CT solution to deliver real-time CT images during procedures instead of CT-like images. The system significantly improves workflow with its SURE Guidance technology, which allows for automatic transition between modalities. In addition, it is capable of saving significant time by allowing clinicians to perform CT and interventional procedures within the same room and verify treatment success following procedures.

New breast CT system
Koning Corporation, announced that the FDA has approved their Koning Breast CT (KBCT) system and KBCT-guided biopsy bracket.

KBCT is the first ever commercially available, 3D breast CT scanner designed specifically to image the entire breast with a single scan without compression of the breast tissue. The system acquires hundreds of images in ten seconds producing ‘true’ 3D images allowing a fast procedure with excellent patient comfort. Optional accessories for KBCT include a biopsy bracket to enable KBCT-guided breast biopsies of suspicious lesions, and a collimator which is used to limit the x-ray beam to the area of interest. The biopsy bracket provides 3D targeting at comparable or lower radiation exposure compared to stereotactic guided biopsy.
Q&A with
Mary Logan
president and CEO of AAMI

By Sean Ruck

HealthCare Business News caught up with Mary Logan for our annual check-in to learn the latest happenings at the Association for the Advancement of Medical Instrumentation.

HCBN: Last year, you talked about taking on responsibility for a standards committee dealing with anesthesia and respiratory technology. Are there any updates surrounding that effort?

ML: Ramping up standards work takes time, but there are definitely updates. First, though I want to say that the most important benefit of AAMI taking over this work has been the increased opportunity to collaborate with the American Association of Anesthesiologists. It’s a great group to work with because they’re often very technologically oriented. So they have fantastic insight into technology even beyond just the anesthetic and respiratory-related technology.

Regarding the updates, we think there will be more than 10 standards this year adopted as American National standards. Next year, we’ll be hosting an international meeting for an international standards committee with 29 countries participating and 23 more observing. So that’s an exciting thing for AAMI to lead and prepare for.

HCBN: It’s been nearly a year since AAMI University was launched. How is that coming along?

ML: Since the site launched on May 31, we’ve had over 7,000 individuals create personalized dashboards that can be used to manage and track their personal certification information. We’ve launched four online programs for the industry as well: effective communications, pillars of leadership, training in a regulated environment; and documents and records management. AAMI University’s system offers instant access to training certificates and webinars and we continue to add more and more content.

We launched the university with the content we already had for our industry training courses and then turned them into online materials. As we develop more training modules, it gives us the opportunity to increase the library. The exams have also moved online which saves attendees travel dollars.

HCBN: Are there any big changes or new items being introduced into the university?

ML: Courses that we’re going to launch are mostly industry courses, but some will be of interest to hospitals. There’s a course on crisis management and another on internal auditing in a regulatory environment and yet another on demystifying ethylene oxide calculations.

We’re also partnering with Virginia Tech to offer a course on international standards for electrical safety. It’s our first experience partnering with a university offering four-year degrees.

HCBN: What have been AAMI’s three biggest news items since HCBN spoke with you last year?

ML: I would say the top three of my proudest accomplishments would have to be the launch of AAMI University, the development of a new strategic plan finished at the end of the year, and last year, the future forum led to some really big projects in the HTM area. The biggest among them were the publication of the HTM Levels Guide, and the career planning handbook and leadership development guide.

The HTM levels guide is a resource to help HTM departments. It includes a check-list of key characteristics defining each of the levels of professionalism. It’s to help each department grow in their professionalism and leadership. The career planning handbook is really a resource for individuals. It was developed to help individuals chart their career paths for professional growth. It offers guidance on things like how to interact with your boss in order to self-promote and a companion piece is also available that helps people grow the ability to manage staff.

In general, one of the hallmarks of AAMI in the past five years that has been different than in earlier years, is the that we’ve really taken on big technology issues and tackled each of them. Infusion systems, for example, have been a priority for AAMI going back to 2010 and each year we’ve added more to that discussion. Alarm management is another. And another big thing has been wireless – health care organizations complain a lot about wireless issues. We started a task force to develop a really detailed FAQ. It is a huge list of questions and answers. We also took on a big issue in addressing humidity levels in the OR and convened with over 20 health care organizations to address the problem – almost every organization, including the AHA, co-authored and co-signed a document that will help organizations to address that issue.
We’ve also just published a compendium of medical device integration and informatics.

**HCBN:** What tops the “wish list” of your members at this time?

**ML:** One of the things that keeps coming up is not new, but it keeps rising to the top every time we do a Top 10 challenge list. It’s the supportability of medical devices. Manufacturers and HTM professionals see that support in a different way. HTM professionals feel they’re being denied access to information like manuals for instance. Meanwhile, manufacturers are worried about the quality of parts when they’re not being sourced directly from them. We are planning to have an event on supportability. It’s a high priority on two staffer’s work lists so stay tuned for that.

Another thing that is controversial in the field is standardization of the profession. The HTM field doesn’t have any practice standards. One of the hallmarks of a real profession is having practice standards. Inside of health care, all the professionals have practice standards. Yet even those that are now well-established were very controversial when they were first introduced. AAMI has some in the pipeline and it will be a long term effort. Not everyone in the field understands why standards are needed, but they’re important because if they don’t exist, regulators will develop their own set of standards. We’ve already seen that with CMS coming up with standards for preventive maintenance. If we had standards strongly in place, I don’t think we would have seen that problem come up.

**HCBN:** What do you anticipate will be the biggest challenge or challenges facing the association in the coming year?

**ML:** What keeps me up at night now is how industry consolidation will impact AAMI as a professional association. In terms of the profession, what worries me the most from an AAMI perspective is trying to figure out what effect the convergence of medical devices with IT will have on the HTM profession. In 10 years I think the important part of the medical device will be the data inside and not the mechanical thing itself. So in light of that, what will be the role of the HTM professional? I think the future has to be a willingness to learn the IT functions and be willing to serve in a role where one foot is in IT and the other in HTM.

What I’m also concerned about is that the pressure to reduce the cost of health care will push more health care out of hospitals and into homes. I don’t believe that state or federal regulators understand or have figured out that landscape.

**HCBN:** What do you believe will be AAMI’s most crucial role in helping health care in the future?

**ML:** I think it’s the same critical role that we’ve always had with a slightly different emphasis. That is, to help with patient safety and risk management issues related to the full life cycle of technology. That takes on a completely different meaning when we’re talking about home health and health IT, where you don’t have the same historical or current level of understanding about the level of risk that standalone medical device management has had.

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AAMI’s 2015 Annual Conference & Expo

AAMI 2015 is the premier industry event for BMETs, clinical engineers, and other healthcare technology management (HTM) professionals, and clinicians. Join us in Denver for four days full of learning opportunities, networking, and to see the latest innovations, upgrades, and advances in healthcare technology!

This year’s conference will hold some big changes for those who have attended past conferences. Among those changes is a revamped schedule that will be consistent from day to day, so no guessing when the next sessions will start. Also for those of you looking for more opportunities to visit the Expo Hall, we’ve listened! The hall will be open during lunch time each day with more than 200 medical equipment manufacturers, including many of the world’s leading companies.

Here is a snapshot of the keynote sessions for AAMI 2015 that promise to educate, inspire, and motivate. They include:

- **Why the Healthcare Industry Needs to Work Together on Cybersecurity: A Hacker’s Perspective**
  
  Hear from Billy Rios, Founder of Laconicly LLC as he describes what an attack against a health care organization looks like from a hacker’s perspective. He will outline the current cybersecurity requirements, as well as key areas for improving cybersecurity within the health care industry.

- **The Changing Landscape of Patient Safety**
  
  Dr. Tejal Gandhi, President and Chief Executive Officer of the National Patient Safety Foundation and the NPSF Lucian Leape Institute will share new directions in patient safety that are critical to ensure that hospitals, health systems, and providers in the ambulatory care arena are providing the safest care. Based on extensive experience in patient safety research and operations, she will describe these new areas—such as patient engagement, safety across the care continuum, and health information technology—and potential strategies to make progress to move forward the safety agenda to prevent harm to patients.

- **The Joint Commission Update**
  
  George Mills, MBA, FASHE, CEM, CHFM of The Joint Commission will share the latest information on Joint Commission activities, future plans for the organization, and how activities and plans will impact your facility. You will learn how best to prepare for a Joint Commission inspection survey. Don’t miss this direct access to The Joint Commission—and bring your questions for a follow-up Q&A breakout session.

"AAMI 2015 is simply the best place for technology-oriented health care professionals to get cutting-edge training on pressing technology challenges. We continue to update the event to make sure it is progressive, and conference attendees consistently report that they learn new ideas, tools and solutions they can implement immediately. It’s the best way to stay on top of best practices and to prepare for an accreditation survey. This conference epitomizes the AAMI tagline: Advancing Safety in Healthcare Technology."

– Mary Logan, JD, CAE, President & CEO, AAMI

“We are excited about the totally revamped schedule that allows for a variety of session formats focusing on the most pressing topics facing the HTM community. In addition, there is more time carved into the schedule to allow attendees to visit the expo hall which includes an expanded AAMI/HIMSS Interoperability Showcase, an interactive AAMI booth, Biomedical Society Row, and a record number of exhibits. There are a lot of new features to both the conference and expo that HTM professionals will not want to miss!”

– Deborah Reuter, SVP, Education

“The opportunity for learning abounds at AAMI 2015! Speakers are committed to ensuring their presentations provide attendees first-hand experience and opportunities for engagement throughout the educational sessions. We are also offering a new track on cross-department collaboration and examples of ways to build relationships with IT, nursing, C-suite, and other hospital departments. ”

– Tirza Lofgreen, Director of Education and oversees the annual conference programming
AAMI Exhibitors 2015

Advanced Ultrasound Electronics — Booth 241
AUE is a leader in ultrasound equipment refurbishing and parts. New or refurbished parts, systems, transducers, and peripherals are tested and backed by cutting-edge technology. AUE’s tech support and service will exceed your expectations. Please visit us at AAMI 2015.

Ampronix — Booth 635
Ampronix is a renowned authorized reseller of the medical industry’s top brands, as well as a world class manufacturer of innovative technology. This year Ampronix will be highlighting an LCD monitor retrofit for the OEC 9800 mobile C-arm. The monitors come mounted on an articulating arm for increased versatility and the do-it-yourself installation can be performed in approximately an hour.

Ampronix will also have for demonstration: SCANMAXX (analog to digital video signal converters), MODALIXX (universal LCD replacement for CRT monitors), and MEDVIX (high quality and affordable surgical monitors).


Bayer HealthCare Radiology Division — Booth 301
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Cadex Electronics Inc — Booth 829
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DOTmed — Booth 131
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Dunlee — Booth 108
The Dunlee team is excited to see you at AAMI! Stop by booth #108 to hear about the products, services, and resources we have available to you. In addition to our replacement tubes, we will be showcasing our Technical Resources, like the Dunlee App and Technical Webinars.

Medical Equipment Dynamics — Booth 130
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oneSource Document Management Services — Booth 919
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Pacific Medical — Booth 611 & 547
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Richardson Healthcare — Booth 813
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Siemens Healthcare — Booth 805
Siemens Healthcare is one of the largest suppliers of technology and equipment to the health care industry and a leader in medical imaging and laboratory diagnostics. We provide a comprehensive portfolio of consulting, training, and services available tailored to customers’ needs. For us, service means more than fixing what breaks. It means providing you with the education, tools, and support you need to work smarter. As your partner, we will help you succeed in your day-to-day work so you can get the results you deserve. In fact, we provide you with the same high level of training we give our engineers.

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**TransAmerican Medical Imaging — Booth 500**

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**USOC Medical — Booth 529**

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**Varian Medical Systems — Imaging Components — Aftermarket Products — Booth 927**

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In “The City on the Edge of Forever” a Star Trek episode that aired in 1967, Mr. Spock complained that he was unable to gain access to the data in his tricorder, lamenting that he could, if only he were able to tie his device in with the ship’s computers, a remarkably prescient vision of the present-day dilemma of interconnectivity.

What Healthcare Technology Management professional hasn’t felt exactly the same way, like futuristic breakthroughs in testing equipment were “on the edge of forever,” when faced with a challenge in the field?

While the technology has advanced, test equipment still has a long way to go, says Purna Prasad, director of clinical technology and biomedical engineering at Stanford University Medical Center, in the heart of California’s Silicon Valley.

“It has not evolved with the speed of technological advancements,” Prasad says, “and that is where biomedical engineers are facing a problem.”

Prasad says that ideally test equipment would be application-based and operating in a mobile environment, so technicians can just use their own smartphone, tablet or laptop, without having to carry around three or four pieces of equipment every time they go out.

Even better, says Prasad, biomedical test equipment would automatically connect with the computerized maintenance management systems, requiring the intervention of technicians only when safety characteristics are violated.

For now that is just “beam me up” thinking, and for it to happen, says Prasad, “manufacturers will have to think outside the box.”

The present state of the test-equipment landscape has manufacturers trying to address the challenge that many biomedical engineering departments are stretched thin. “People at facilities now are trying to do more with less,” says Michael Bayliss, global sales manager for Datrend Systems.

Beyond that, the push to integrate data throughout the health care delivery system means that manufacturers must develop devices that communicate with electronic health records systems, while ensuring that equipment is safe to use on the patients and meets the functional specifications of the manufacturer.

One device that illustrates the focus on greater productivity and app-like ease of use is the vPad-IN, an infant incubator and infant radiant warmer testing system that Datrend recently introduced. It uses the same Android tablet technology that comes with Datrend’s electrical safety analyzers, and which Bayliss says allows technicians to multi-task during the testing, which can be a time-consuming process.

“The minute you open up an incubator, you have to wait for it to re-stabilize,” Bayliss says. “Running an automated test wirelessly

By Lisa Chamoff

Testing equipment: Still a challenge, but getting easier
avoids having to re-start. Because you’re using a tablet, you can also use it for internet access and email.”

Safety issues and ensuring recommended service are also trends that are emerging, pushed in part by CMS requiring that imaging equipment, lasers, and new equipment without a long enough history to establish an adequate risk-based assessment for maintenance would have to follow OEM guidelines for preventative maintenance.

For example, CareFusion offers biomedical engineers software that communicates with their medical devices, says Gregory Alkire, vice president of sales and marketing for Pronk Technologies.

“When you went to test their device you had to have a very specific simulation,” Alkire says. “We created a custom setting to meet that need.”

While there is a move in the biomedical testing industry toward automation and the creation of electronic test records, this has gone much more slowly than the mainstream shift to EMRs for patient records, since HTM departments get to choose whether they use paper or electronic records, Alkire says.

“Ten years ago, you’d think that everyone was going to be headed to electronic test records,” Alkire says. “My sense is that it’s moving very slowly in terms of the biomedical departments, in part because there are not ideal solutions for it. It can take more time using automation with records than documenting results on paper. There’s much slower adoption than you’ve seen on the health care side.”

Despite the slower pace, however, companies are providing solutions to increase productivity, minimize human error, and improve data traceability for regulatory compliance. In March, Fluke Biomedical launched improvements to Ansur, its test automation software platform.

The update includes the addition of an electronic signature, a feature that allows users to create their own signature to sign test reports electronically. This new feature is compliant with the FDA requirement, 21 CFR Part 11. The Ansur 3.0 update also includes customizable authorization levels, allowing organizations to set different user access levels, particularly if they want to reduce the ability to alter a procedure, and customizable test fields.

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Industry Sector Report: Test Equipment

The idea is to cut the total test time while maintaining the integrity of the data, says Shirin Khanna, senior marketing manager for Fluke Biomedical.

“Testing is meaningless if you can’t show you did it, and did it as required,” Khanna says. “The beauty of Ansur is that it caters to organizations looking to reduce total test time, perform the tests quickly and document the data easily as well as organizations that prefer collecting comprehensive information to monitor trend and risk.”

Automation in X-ray testing
The same focus on automation and workflow extends to X-ray test equipment. Aside from recently adding a Survey sensor for X-ray leakage and scatter radiation to its RaySafe X2 X-ray measurement system, which was introduced in November 2012 and updated a year later with the RaySafe X2 Prestige, the company is looking to make the software on the base unit more useful while on the job. Generally, technicians use the base, which operates on an Android platform, and then transfer data to their computers, says Göran Zelander, senior product manager for diagnostic X-ray at Unfors RaySafe, which was acquired last year by Fluke Biomedical.

“We are incorporating features in the X2 base unit software to minimize the need to connect a PC while performing measurements,” Zelander explains.

RaySafe has added features at the request of users, including the ability to add notes to a measurement and to access old measurements.

“When you perform measurements with the RaySafe X2, you can scroll through exposures captured during that session, and earlier sessions,” Zelander explains. “Previously, when a user would change a sensor or shut off the RaySafe X2, the earlier measurements would no longer be viewable on the base unit. We learned this wasn’t optimal for our customers, so we made improvements to the software to enable users to access stored measurements.”

The base unit also shows the entire waveform and the company added a zoom function, providing a simpler way to see what happened at a specific time of a long exposure.

“Ease of use means productivity gains, and that’s what it’s all about,” says Zelander.

A technical boost to data connectivity was unveiled by Radcal at RSNA 2014 and recently at the ECR 2015. It’s Accu-Gold Nugget, which the company states is the first Wi-Fi device for data transmission after each X-ray exposure by any non-invasive diagnostic x-ray meter. Patrick Pyers, vice president of sales, marketing and business development for Radcal, says the traditionally-used Bluetooth is not reliable, especially when it comes to radiological testing. The Bluetooth signal can easily be dropped because of a lead wall or other instrument interferences. Wi-Fi is less prone to interference, Pyers says, and is a strong and secure connection to the measurement device.

‘Ease of use means productivity gains, and that’s what it’s all about,’ says Zelander.
“With a five-minute exposure, as the Accu-Gold Plus is capable of measuring, it provides a lot of data points so you need a stable connection,” Pyers says.

Using Wi-Fi also opens the device up to various operating systems, according to Pyers. At last year’s RSNA, the company did a demonstration where they connected the device to Google Glass to show the new technology’s futuristic capabilities.

One changing aspect of the X-ray testing sector is the rise of digital mammography, which uses different beam qualities. At the same time RaySafe launched the software release, it also expended to measure kVp also on tungsten rhodium, which is a common beam quality in digital mammography.

“Every time manufacturers add a beam quality, we have to verify our system,” Zelander says. “For that, we are closely collaborating with mammography manufacturers to make sure that our solutions always cover the beam qualities of the different digital mammography machines.”

**Portable and rugged**

As with all electronics, smaller is better, but can also be more fragile, and prone to breakage. So the trend toward more portable also creates the need for greater ruggedness.

One of the latest offerings from Datrend looks like the kind of tablet one would take on a camping trip. The vPad-ES Rugged includes the company’s electrical safety analyzer, housed in a waterproof, lockable, protective case that is designed for field engineers on the road, who work in harsh environments and travel long distances, Bayliss says. The tablet can be taken out of the case and used remotely with Bluetooth.

“It just makes it a little bit easier to carry around,” Bayliss says. “We looked at doing a specialized case and just thought this was a better solution.”

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Industry Sector Report: Test Equipment

DOTmed asked the leading test equipment manufacturers to submit up to three of their products to be featured in this Guide. To learn more about these products and rate them, please visit the Equipment Guide in DOTmed’s Virtual Trade Show, or go to: www.dotmed.com/test

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ATS provides ultrasound phantoms for routine performance monitoring, training, in-process production testing of imaging systems and transducers. Custom designed phantoms are available. Multipurpose phantoms exceed ACRTechnical standard.

BC Group / ESU-2400H
The ESU-2400H offers a deeper buffer depth that allows for advanced waveform analysis including multiple pulsed output modes. Also provides a more stable measurement for complex waveforms such as coag spray. This unit provides future-proofing against new generators that are currently being developed. Existing ESU-2400’s can be upgraded at the factory.

BC Group / NIBP-1040BE Kit
The NIBP-1040BE is a battery operated (rechargeable) simulator, leaving you wanting very little when it comes to simulated parameters. It provides NIBP, IBP, ECG, ECG Performance Waveforms, Arrhythmias, Temperature (YSI 400 & 700), Static pressure and optional, SPO2, Fetal Maternal and Cardiac Output.

BC Group / ULT-2000 series
TEE testing is soon be mandated. Get ahead of the problem and protect your patients and your valuable Ultrasound Transducers. The ULT-2000 series analyzers give a printout, qualitative and quantitative results. They can also detect bite holes and provide real-time metering. Our new “Soft Touch” adapters prevent damage to your delicate transducers.

Cadex / C7400ER
Healthcare depends heavily on batteries, so much so that battery management needs strengthening. This is not yet happening and AAMI rates battery management as one of the top 10 challenges. A U.S. FDA survey says that up to 50% of issues in hospitals are battery related. The Cadex C7400 ER keeps all batteries within a capacity of 80–100%. Knowing the performance improves reliability, reduces cost and assists in troubleshooting as fewer devices need repair.

Cadex / C8000 Battery Test System
The C8000 stands in a class by itself by offering a large test range at an affordable price. You can monitor the cells in a battery pack, test SMBus functions, capture load signatures and use the simulated loads to verify battery runtime. Turn the C8000 into a control center by connecting an external load bank and environmental chamber.

Cadex / 5100 Battery Tester
The Cadex 5100 is an easy-to-use battery tester for personal patient monitors and communications devices in hospitals and care homes. Simply slide the battery into a custom adapter and press TEST, CHARGE or CYCLE. You receive a clear battery assessment with a dependable replacement guide. The CS100 improves system reliability and saves money as each battery can be used fully.

CIRS / Multi-Purpose Multi-Tissue Ultrasound Phantom
The CIRS Model 904/GSE Multi-Purpose Multi-Tissue Ultrasound Phantom provides a reliable tool for quality assurance and control checks on any ultrasound system. The phantom contains features that enable fundamental testing procedures to assess sonographic and elastographic imaging performance.

CIRS / Radiography/Fluoroscopy QA Phantom
The CIRS Model 903 Radiography/ Fluoroscopy QA Phantom is a solid QA assessment tool for x-ray image quality programs including CRDR systems. The phantom enables evaluation of minimum detectable contrast, low contrast resolution, optical density, high contrast resolution, dose, iodine contrast visibility and linearity, as well as digital subtraction effectiveness under various conditions.

CIRS / Tissue-Equivalent Phantom for Mammography
The CIRS Model 011A is a breast tissue-equivalent mammography QA tool designed to monitor image quality and dose, while testing the performance of advanced mammographic systems. It has a specified adipose and glandular composition and features a range of embedded image quality targets, including simulated calcifications and fibrous calcifications in ducts and tumor masses.

Datrend / vPad-ES
The vPad-ES is Datrend’s innovative new Electrical Safety Analyzer. It employs an Android-based tablet PC as the user interface. It provides a touchscreen with large, bold fonts for ease of viewing, icon-based test functions, and wireless communication with PCs and printers. Upgrades can be accomplished by adding apps as needed.

Datrend / vPad-IN
The ONLY incubator analyzer to test to IEC 60601-2-19 and 2-21, vPad-IN is built on the tablet-based Vision Pad platform for greater flexibility and scalability. Changes to tests can be made without disturbing the heat environment. Measures all parameters automatically following user-defined protocols. Simultaneous measurements of humidity, airflow, sound, and 6 different temperatures. Results can be merged with safety test data and imported into commonly-used CMMS Systems.

Datrend / FMS-3
The FMS-3 Fetal/Maternal Simulator sets a new standard of value in simulators for fetal monitors. FMS-3 provides enhanced simulation capabilities, more simulation channels, additional functionality, and full 5-lead Maternal ECG simulation. Its unique features include three (3) channels of ultrasound simulation for detection and monitoring of “Triplets.”

Electronic Control Concepts / Model 820 kVp / mA Meter
The Model 820 kVp / mA Meter measures X-ray Voltage (kVp & kV), tube current (mA & mAs), dose and dose rate (mR & μGy), exposure time, and the number of pulses. Data is displayed on a 7” tablet and can be saved and exported to a spreadsheet. A graph of either kVp, dose, or mA can be viewed for each exposure.

Electronic Control Concepts / UXI Meter
The UXI Meter measures peak and effective X-ray Voltage (kVp & kW), tube current (mA & mAs), dose and dose rate (mR & μGy), exposure time, and the number of pulses. Data is displayed on a 7” tablet and can be saved and exported to a spreadsheet. A graph of either kVp, dose, or mA can be viewed for each exposure.

Electronic Control Concepts / Model 890 Dose Meter / Exposure Time Meter
The Model 890 Dose Meter / Exposure Time Meter measures X-ray dose and dose rate. The Model 890 is a new solid state instrument used to assess the performance of radiation generators and determine the effective dose or X-ray radiation delivered by the X-ray under specific test conditions.

Fluke / IDA-5 Infusion Device Analyzer
Ensure infusion pumps are tested accurately and quickly with the IDA-5 infusion Device Analyzer. The IDA-5 is based on sophisticated measurement technology trusted by biomedical professionals around the world for over 20 years. The IDA-5 is a full-featured device with built-in automation that measures instantaneous flow, average flow, occlusion pressure and dual flow based on IEC60601-2-24.

Fluke / ESA609 Electrical Safety Analyzer
The ESA609 Electrical Safety Analyzer is a rugged, portable and easy-to-use analyzer designed for general electrical safety testing. Engineered for on-the-go technicians, the ESA609 requires no training to use and has a rubberized case that allows it to sustain the rigor of transportation, and helps prevent damage if accidentally dropped. Additionally, its functional strap and leatherweight design make it one of the most portable electrical safety analyzers in its class.
RaySafe / RaySafe ThinX

Need an easy to use, first call device for your biomedical department? No menus, no buttons, just expose! The RaySafe ThinX RAD is a fast, accurate, basic multi-parameter instrument for simultaneous measurement of dose, dose rate, kVp, HVL, exposure time and pulses. All parameters are conveniently displayed in the large LCD.

Rigel Medical / UNI-SIM Vital Signs Simulator

The UNI-SIM incorporates 6 vital signs into one hand-held simulator. Battery-operated, the UNI-SIM can simulate NIBP, SpO2, ECG wave forms, temperature, respiration and invasive blood pressure simultaneously. It reduces the time taken to test the correct performance of a wide range of medical devices and equipment used in hospitals, operating theatres and other facilities.

Rigel Medical / Rigel 288 Electrical Safety Analyzer

The 288 is a hand-held, battery operated medical electrical safety analyzer that combines the features of an automatic/manual tester with a data logging/asset management facility. Control is through a menu driven GUI. A large data memory and Bluetooth facility make this an effective mobile unit, with a memory for up to 10,000 devices.

TSI / Certifier FA Plus

Portable, high-performance flow analyzers for ventilator testing. Measures and displays up to 18 parameters of ventilator performance with excellent precision and high accuracy.

TSI / Gas Flowmeters

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When one of the leaders interviewed for this article was asked about emerging Healthcare Technology Management trends, their response was: “It depends on what you mean by Healthcare Technology Management.”

This insightful statement is the overriding theme of DOTmed’s annual look at the health care technology management sector. The average “break-fix” operation at any hospital now has health care economics, informatics and strategic planning staking out territory in the HTM agenda.

The realization that the performance metrics expected under the Affordable Care Act, such as population health management (getting paid more to keep people healthy rather than when they become ill) and value-based purchasing (hospital and physician pay for performance) are only possible through meaningful information sharing. This has attracted the attention of the hospital C-Suite which is now dedicating large budgets to create electronic health record (EHR) systems needed to succeed.
Almost every very medical device in a hospital now has a computer chip and software. Every clinician who lays hands on a patient needs to have, in real time, what the device knows. It is clear that hospital leadership has elevated HTM to an unprecedented level of strategic importance in the scheme of things, which is reflected in the work our experts do every day to get devices communicating across electronic health records. A recent study indicates that for nurses, device interconnectivity across the electronic medical record cannot happen fast enough. Results of a Harris Poll-sponsored released in March by the West Health Institute revealed that half of a sample base of nurses report that they have seen a medical error caused by a lack of coordination among medical devices.

It’s no wonder the demand for experts to improve the performance of medical devices remains strong. The Bureau of Labor Statistics expects a 20 percent increase in hiring over the next three years. The nine experts/leaders interviewed for the 2015 HTM Trends review are:

• **Keith Chapman**, Director of Clinical Engineering, Virginia Commonwealth University Health Systems

• **Chuck Demanche**, MBA, CRA a career hospital HTM professional and imaging director. He currently works through Soyring Consulting.

• **Izabella Gieras**, Director, Clinical Technology at Huntington Hospital, Pasadena, CA – Past President, American College of Clinical Engineering (ACCE)

• **Patrick Harning**, Assistant Vice President, Clinical Engineering, Catholic Healthcare Initiatives, Denver, CO

• **Jennifer Jackson**, Director of Clinical Engineering & Device Integration, Cedars-Sinai Medical Center, Los Angeles, CA – Past President ACCE

• **James Keller**, MS Vice President Health Technology Evaluation and Safety, - ECRI Institute, Plymouth Meeting, PA – Past President of the ACCE.

• **Purna Prasad**, Ph.D, C.C.E. Director of Clinical Technology & Biomedical Engineering, Stanford Health Care

• **Skip Smith**, Vice President, Physical Asset Services - Catholic Health Initiatives, Denver, CO

• **Paolo Zambito**, Senior Vice President Strategy and Business Development, LCMC Health, New Orleans, LA. (Also a former hospital CEO & COO)

**HCBN - What emerging HTM trends are on the very edge of the radar right now?**

Jennifer Jackson, Cedars-Sinai – No doubt, device integration. In the last year my department worked to link 1,500 IV pumps with the electronic medical record. We’re an 851-bed hospital and on a weekly basis generate up to 13,000 medication orders. Whatever we can do to help our nurses eliminate transcription errors through

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integration is a good project. Through beta testing trial and error we’re evaluating new opportunities for additional device integration and adopting new technology.

**Purna Prasad, Stanford Health Care** – There are some very exciting developments. For example, technology has moved out of the hospital into the home with patients using wearable devices and tethered devices such as infusion pumps and monitors. These patients now come to the biomed department to get batteries charged and the equipment calibrated, so we’re now caring for more patients in an outpatient setting. These are new demands that require a very enhanced set of skills for our profession.

**Paolo Zambito, LCMC Health** – LCMC Health is a young organization. We started as Children’s Hospital and through acquisition, and management agreements we have expanded rapidly to a five-hospital system. This includes two community hospitals, and two Louisiana safety net/teaching hospitals, one of which is a replacement hospital being built by the state to replace Charity Hospital destroyed in Hurricane Katrina. We have a lot of data flowing across the electronic medical record that are not all linked yet because our health system has grown so quickly. We just hired our system Chief Information Officer. So going forward, we’re looking at the bigger strategic issues of the best way to get all of our disparate devices to communicate, to turn stand-alone facilities into a system. At LCMC, we want to make sure that as we make decisions about equipment and vendors, we are doing something meaningful with the data at the bedside that translates to improved patient outcomes.

**Izabella Gieras, Huntington Hospital** – This year one of the projects we’ll be working on is to meet the deliverable standard of the National Patient Safety Goal to reduce alarms. Hospitals must have protocols and education in place to reduce medical device non-actionable false alarms by 2016. Non-actionable false alarms contribute to caregiver fatigue and threaten patient safety. Patients don’t like it either.

**Chuck Demanche, Soyring Consulting** – The biggest change I see emerging is how can biomed contribute to cost reduction under the new reality of the Affordable Care Act. Biomed has traditionally been an expense department but now administrators are asking these managers to contribute with work optimization in clinical departments through integration. This is the reality, given thinning margins as hospitals and doctors make the transition from fee-for-service to outcomes and wellness. Another big emerging issue is that a lot of medical devices under the care of the Biomed Department are becoming wireless. So security of protected patient information is something all hospitals must figure out.

**HCBN - What trends in capital spending in HTM are you noting?**

**Technology moved out of the hospital into the home, with patients using wearable devices and tethered devices such as infusion pumps and monitors,’ says Purna Prasad, Stanford Health Care.**

**Jim Keller, ECRI** – Four trends are worth noting this year. Interest in disinfection systems is nearly double. Ebola, general infection control, and the cost of acquired infections are key factors. Because more and more clinicians want to view imaging and patient data in the OR, we’re seeing an increased number in purchases of OR integration systems. There is a significant uptick in purchases of the St. Jude’s CardioMEM Heart Failure Monitoring System. This is partly due to the manufacturer’s claims that the system helps reduce hospital readmissions. This is related to an overall trend we expect to see over the next few years with the big growth growth we expect in home monitoring systems. And we have seen increased interest from hospitals for 128 slice and higher CT scanner technology.

**Keith Chapman, VCU Health Systems** – We’re taking a hard look at the addition of any new equipment and asking the question, “What Value does it bring to our operation and patient care?” We’re not going to buy new equipment just because a company wants to sell it to us. For example, is the resolution of a new 64-slice CT needed or is the resolution of the existing 16-slice CT meeting the patients’ need? We’re looking at extending the life of existing equipment and we have committees across many departments that review capital equipment purchases.

**Skip Smith, CHI** – We have three university hospitals in the CHI system, so we have a real demand for new technology. We have to balance this against the reality that capital spending is very surgical right now. We visit our hospitals every three years to set priorities for new equipment. All this is done working in tandem with the hospital administrator. To reduce costs, we’re also increasing training to develop in-house expertise to service equipment, rather than relying on OEM (Original Equipment Manufacturer).

**Jennifer Jackson, Cedars-Sinai** – As I said, we’re interested in equipment that will integrate well across the EHR (Electronic Health Record). But we’re also just the right size with enough specialties to be able to have an opportunity to test new technology, such as some of the advanced imaging being created in CT. So this creates new demand for biomed services. Something we think has potential is using information from across the EHR to make computer-assisted predictive decisions about health risks, such as cardiac events.

**HCBN – How will HTM help hospitals and physicians achieve the goals set in the Affordable Care Act, such as value-based purchasing (VBP)?**

**Jim Keller, ECRI** - It’s always been the role of clinical engineering to help the hospital management to make good decisions about whether to buy a particular technology, so that hasn’t changed under ACA. But I do see more and more hospitals forming interdisciplinary VBP committees. Clinical engineering has an important role in these committees. These teams take a more evidence-based approach to decision making than perhaps has been done in the past – it’s not
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so much about what a particular doctor might want to purchase, for example. There is also a lot more emphasis on patient safety (a key focus of the ACA). So more review of the recall history or other safety matters for devices being considered for purchase will be an important part of the VBP process.

‘Our focus is on the patient experience and outcomes, so one of the things we’re looking at is how do we increase information access for patients?’ says Paolo Zambito, LCMC Health.

Paolo Zambito, LCMC Health – Our focus is on the patient experience and outcomes, so one of the things we’re looking at is how do we increase information access for patients? Because we have so many specialists and subspecialists, how do we make it easy for patients to make decisions about the doctor they need to see, down to making an appointment? Then, once they have been referred, what is the best way to send information flow back to referring physicians so the best decisions are made for the patients? For us it’s achieving a rhythm, and rigor is paramount in following our strategic plan to achieve value in all our systems, including biomed. For instance, one of our strategies is to continue to restore primary care in our service area that took a hit after Katrina. Primary care is key in achieving the goals under the ACA and it needs a good functioning HER as well as integration with an HIE. Clinical engineering has a key role in creating that functionality. It is a biomed issue, but it’s really the same issue for every department – there can’t be silos to meet the challenges that lay ahead.

Patrick Harning, CHI – Everyone has to be on the same page about what is available on the EHR, which helps clinicians do their work efficiently. I think redundancy of information is important to make sure the info is always available to them in the event we have to shut any system down. The clinicians in the tech-heavy departments, such as in the OR and cath labs, are also counting on biomed to be savvy with smart new technology – including handheld devices - as a tool to help improve their workflow.

HCBN – What is the state of the relationship between HTM managers and clinical managers?

Purna Presad, Stanford Health Care – Three years ago Stanford adopted LEAN as an enterprise-wide methodology to optimize work flow. Every day from 7:30 to 9:30 all calendars are blocked off so that the hospital leadership can make rounds in the hospital. On every unit, a biomed representative makes rounds with the manager to make sure that equipment is operating properly. In nursing units, ORs and cath labs, biomed prepares the equipment for use at the beginning of every shift change to make sure it is functional. This whole system approach has created a really good working floor not just between biomed and the clinicians on the floor, but all the ancillary departments, because it is the standard that our leadership models and expects.

Izabella Gieras, Huntington Hospital – For the first time, those of us in health technology (HTM) are launching hospital-wide initiatives in order to achieve the device integration and information sharing that the bedside caregivers need and want. At the same time any change is stressful, so it’s part of our job now to help calm anxiety on the floors by being available to educate and consult as we go through a device conversion. But once the caregivers get used to the workflow improvement the devices bring by communicating with the EHR, we get called pretty quickly if they have to go back to the old way of manually charting because something is not working right. So this has changed the relationship for the better – biomed staff are much more visible and appreciated on the floors.

Jennifer Jackson, Cedars-Sinai – We all have the same job – to help the patient. It can be easy to get distracted from this point so we have to have confidence working together to pick the right strategy. Clinical managers want us to help optimize their workflow and we’re in a good position to support and help them. The first question is always: Is technology the answer to a problem? Because sometimes it isn’t. But the relationship has evolved where we can more easily have those kinds of discussions.

‘The first question is always: Is technology the answer to a problem? Because sometimes it isn’t,’ says Jennifer Jackson, Cedars-Sinai.

Chuck Demanche, Soyring Consulting – Biomed has worked more to get the clinical managers involved. This helps the clinicians avoid that deer-in-the-headlights look when a Joint Commission (JC) inspector asks a clinician about their equipment. Evolving standards under the JC have created the expectation that clinical managers know about the equipment they use. So I think there’s more understanding when biomed shows up to perform PM (preventative maintenance) on a device – it’s not viewed as an inconvenience.

Paolo Zambito, LCMC Health – From my perspective the relationship is good. I started my career as a nurse – I got my training at Charity Hospital, which we are rebuilding as University Medical Center. Of all my degrees, my nursing degree is the one that helps me the most, as it gives me insight into what the clinical staff needs and how processes should be integrated with biomed, and we see how much has changed over the years and how the clinical engineering aspect of care has to be well integrated. Integration is so important, as there are many patient touch points in our system, from the clinic setting to the hospital and everything in between, including our focus on research and clinical trials.
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Keith Chapman, VCU Health Systems – Biomed has moved past its longtime role of a break-fix ancillary service. We serve much more in a consultant role now. A clinician will call us and ask if we can get a device to measure something they need and it’s our job to listen and come up with a solution that allows us to change the parameters on the machine through the software, to better serve the staff on the floor and improve patient care.

HCBN – What do patients need to know about HTM? Izabella Gieras, Huntington Hospital – It would be good if patients knew the basics. But we are often in patient rooms when a device is not working properly and the biomed tech often talks to patients. A lot of patients ask questions about the devices being used as part of their care. They want to know why an alarm is going off, for example. Part of the orientation we do with our staff is how to talk to patients and their caregivers.

Jennifer Jackson, Cedars-Sinai – My family and friends certainly have no idea what I do in the hospital. The doctors and nurses are the face of who and what a patient sees. In that regard we’re like other ancillary departments in the hospital who are there to take care of patients. Our job is to keep the technology maintained and operating perfectly so patients don’t notice it - like a car. You notice if your car isn’t working right.

Chuck Demanche, Soyring Consulting – The bottom line is it’s our job to make sure that patients realize the great benefit of medical devices and systems, and make sure no patient gets hurt from these devices.

Skip Smith, CHI – If I were talking to my mom, I’d tell her that we want to contribute to a good patient outcome. Our sweet spot in biomed is a good result without delay or harm. The biomed field actually evolved from the work of Ralph Nader in the 1960s, when he uncovered widespread problems with electrical safety in many devices, so we have a long tradition of making things safe, as well as effective.

‘If I were talking to my mom, I’d tell her that we want to contribute to a good patient outcome. Our sweet spot in biomed is a good result without delay or harm,’ says Skip Smith, CHI.
Digital health: Consumers, outcomes lead the way

By Bipin Thomas

Digital health means something very different today than it did just a few years ago. “Digital Health” used to describe the technologies that providers and payers used to organize passive information about their patients and members. Today it’s the health care consumer who’s driving that technology. In the new health economy, digital health has turned the old business-to-consumer model into a consumer-to-business one.

What’s responsible for this shift? Two things: the outcome economy and consumer behavior. Trends towards greater visibility and more intelligible data in both realms have created a feedback loop. First, new technology makes consumers more informed, which raises their expectations for access and participation in decision-making. Second, that technology also allows consumers to transmit more accurate information to their health care team, including their physician and insurance company. The result? More accurate information about their patients enables doctors to make specific recommendations about long-term sustainable health changes.

The Outcome Economy

Until recently, the outcome economy had grown slowly because of the difficulty in accurately and continuously understanding what consumers want. But new technologies have helped illuminate those preferences.

Increasingly intelligent hardware platforms, also known as the “Internet of Things” (IoT), are the backbone of the outcome economy. Devices of all kinds can now send data automatically via embedded hardware and sensors to a health care organization. That organization can use those data to generate real-time insights into how consumers are using their products, services, and recommendations.

Organizations can also learn which metrics their patients use to define what “being healthy” means to them. Many consumers will want to lose weight, for instance, others may have specific signs related to family history they want to monitor. In effect, these metrics enable digital health businesses to identify, measure, and aim for their patients’ desired outcomes.

Consider the example of the remote patient monitoring platform. With this technology, health care organizations are focusing on improving patient outcomes using consumer-friendly medical devices, wearables, and sensors at the patient’s home. These intelligent devices capture real-time data for care management, engage patients with timely care interventions, and deliver relevant patient education materials.

With this kind of technology-enabled consumer-centric approach, digital health can help patients stay healthier by adhering to their personalized care pathway. The subsequent improvements in their health can also significantly reduce readmissions and demonstrate cost savings over traditional methods of care.

Consumer Behavior

In the new model of digital health, everyone from medical device manufacturers to pharmaceutical companies must adapt. Providers and payers especially will have to transform themselves to become more retail-oriented, and quickly learn consumer behavior.

For instance, insurance companies might tailor policies to specific patient health conditions. Similarly, they might offer incentives such as premium reductions for their members to undergo wellness training or to practice a healthier lifestyle.

Providers will need to use data to make their existing relationships more beneficial for consumers. For instance, physicians will need to coordinate even more closely with pharmacies to keep consumers more compliant with drug regimens. Perhaps using real-time communications and data.

Home health care is one area where the technology and data sharing between consumers and businesses is poised to make a big impact. As financial incentives have changed, organizations that keep patients out of hospital are being rewarded. It follows that the technology associated with home health care will continue to increase in sophistication and utility.

The new incentives are not so much around cutting expenditures but rather about coaching the consumer on how to achieve his or her best outcome.

Empowered consumers, rapid innovation, and increased competition from non-traditional players are the hallmarks of today’s health care ecosystem. Existing stakeholders have to adjust accordingly. For example, both health plans and health systems have to add retail health expertise to their skill set. They will also need to harness analytics to understand and improve the consumer experience.

One of the most important things to remember is that you don’t have to be born digital to thrive in the new health economy. With leaders spurring their organizations to evolve, even the most traditional organization can evolve into a true digital health company.

About the author: Bipin Thomas is a global thought-leader on consumer-centric health care transformation. Thomas is the chairman of ICURO, a consumer-centric digital care outcomes research and management organization, and is a former senior executive at Accenture and UST Global.

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Industry Sector Report: Patient Monitors

The patient monitoring market is exploding, with wearable technologies ranging from activity trackers like Fitbit and the Apple Watch, to patches that monitor ECG, skin temperature, and heart and respiratory rate. But the question is which ones are actually useful for physicians.

The patient wears the device around their neck, on their wrist or attached to their skin and it continuously monitors their vitals in real time so their physician can stay informed on the status of their health. But the problem is that physicians are being hit with a tidal wave of information and a drastic change in workflow is needed for them to stay afloat.

Since the wearable industry is still in its infancy, problems like these are still being ironed out. Companies are working on solutions to get physicians the most important information they need at the time they need it.

But even with this influx of sleek, new wearables, there’s still a need for the larger, more comprehensive monitors commonly used in the intensive care units. However, that could change within the next few years.

Wave of wearables

The global wearable medical device market is expected to grow by 21.3 percent and generate $41.3 billion in revenue by 2020, according to a recent IndustryARC report.

Many companies, both OEMs and start-ups, are interested in breaking into this market but not all of them are sticking around.

The one way to separate a consumer wearable from a medical diagnostic wearable device is whether it has approval from the FDA. Vital Connect’s HealthPatch MD scored approval last April and partnered with the telemedicine company, LifeWatch, in November to roll the patch out to hospitals.

It weighs less than 10 grams, is less than a quarter inch thick and is worn on the patient’s skin to continuously measure ECG, heart rate, heart rate variability, respiratory rate, skin temperature, posture and steps.

The patch itself is disposable but the sensor chip inside of it is reusable. It can communicate with a smart phone and the data can be sent into the cloud where it can be stored and sent to a physician’s smart phone or a nursing station.

Another company making a splash is Sotera Wireless with its ViSi Mobile System, which received FDA approval in October 2013. It weighs just over four ounces and straps onto a patient’s wrist in the ICU or on the general medical-surgical floor to...
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Industry Sector Report: Patient Monitors

continuously measure ECG, heart rate, respiration, skin temperature and noninvasive blood pressure.

All of the information is sent to a central nursing station and a mobile device, and is also automatically entered into the patient’s EMR.

Philips Healthcare has a range of cableless, wearable sensors on the market including the Philips Mobile CL noninvasive blood pressure cuffs, SpO2 sensors and respiration accessories. When they are used in conjunction with the Philips Cableless Measurement pods, they gather vital sign data as the patient moves throughout the hospital.

“Monitoring is becoming more available and more ubiquitous,” says Dr. Joseph Frassica, vice president and chief medical informatics officer and chief technology officer of Philips Healthcare. “We realize that moving monitors that are geared to and calibrated for the very sick patient in the ICU to lower-acuity settings is probably not the best strategy for health care systems because those monitors that provide enough vigilance for a very sick patient can create quite a bit of noise in a low-acuity setting.”

The cableless sensors are part of Philips IntelliVue Guardian Solutions, which utilizes the information from the sensors to generate acuity scoring so that nurses and physicians can be alerted when a patient is deteriorating.

“Guardian automates that acuity scoring so that it happens in real time as the measurements are taken,” says Frassica. “It can potentially activate rapid response teams where they’re needed in a much more efficient way.”

A mix of excitement and skepticism

When it comes to these technologies, physicians have mixed emotions. They’re excited because they see the potential but also skeptical because of the fear that it may interfere with the doctor-patient relationship.

Dr. Steven Steinhubl, director of digital medicine at Scripps Health, has encountered a few physicians in the field who express hostility toward the outpatient wearables. “The hostility isn’t directed toward the technology itself,” he says. “There is the idea that this technology is going to take away the doctor-patient relationship even more.”

They think the patient isn’t going to come into the office to discuss their health because they can now remotely send them the wearable information. But Steinhubl tries to explain to them that when well incorporated, these technologies can actually improve that relationship because patients still need 45 minute office visit with an expert diagnostican and educator who can understand and synthesize all of the complicated wearable data.

Physicians are also concerned about the exorbitant amount of information the wearables produce. “Now they can have this ongoing, constant record over a period of time to learn a lot more about what’s going on with that patient versus just a snapshot when they come into the see them,” says Eric Selvik, vice president of marketing at Vital Connect. “But they are also a little bit wary because it’s a lot of data and they can be a little oversaturated.”

That oversaturation can be detrimental to hospitals. “It’s so much information and the problem that has occurred in the industry is that most people opened up all of that data to the care professionals so they’re seeing every blood pressure reading five times a day from a patient and it’s screwing up their workflow,” says Sean Slovenski, CEO of Intel-GE Care Innovations, a joint venture between Intel Corporation and GE that conducts research on these wearable devices to advise health care organizations.

To solve that, Vital Connect is working with physicians to understand what information they need, so they can create algorithms in order to provide them with only that information. Care Innovations already has its own software and analytics platform for that called Health Harmony, which was launched in November.

The platform figures out what pieces of information the physicians need to prompt them to interact with their patients. Instead of giving them 12 vital readings a day on a patient who just left the hospital with congestive heart failure, they aim to only give them one reading when the vitals fluctuate in an unusual way.

The platform includes a patient portal so the patient can collect and share information on their vitals, a view for the clinician into the portal so they know when to intervene and a view for the family care giver who delivers about half of the care in the home.

Cost is also a concern for physicians since hospitals and practices don’t have as much money to spend in this new health care environment. CMS is currently not providing reimbursement for these technologies, but industry experts believe that hospitals will see a return on investment through avoiding readmissions and satisfying incentives.

It’s a given that if a hospital can continuously monitor a patient both in their general wards and at home, they will be able to spot a problem before it becomes costly. “To put a thousand dollars of equipment into someone’s home, who could cost you several hundred thousand dollars if they get readmitted, is cheap,” says Slovenski.

In addition, earlier this year CMS set monthly reimbursement for managing two...
chronic conditions in individuals. Steinhubl thinks that's an area where wearables can be used as part of the solution.

**What about the traditional monitors?**

The traditional patient monitors might not be as sleek and attractive as the new wearable technology, but they’ve still come a long way in the past few years.

One of the most notable advancements in recent years is that many of the patient monitors can be integrated with the EMR now. “That's huge because it saves nursing time,” says Brandi Crow, clinical analyst at MD Buyline. “You don’t have to double-document everything.”

When she was working as a nurse in an ICU about ten years ago, she would have to document full blood pressure, heart rate, and cardiac output every 15 minutes, and sometimes even every five minutes, and then enter all of it into the EMR.

“That’s a lot of time for data entry, but now with device integration, it can be integrated with the nurse call system, the IV pumps, the ventilators and everything can then be documented in the EMR,” she says. “It has to be validated by whoever is documenting, but it goes in there and you’re not having to double-enter and waste a lot of time.”

Welch Allyn released its new Welch Allyn Connex Spot Monitor (CSM) on March 30, which can wirelessly transmit information into the EMR both in a hospital and office setting. “Many customers today have our products out there that aren’t connected to their EMR, and this product is designed with connectivity in mind to bridge the gap for that,” says Garrison Gomez, senior director of integrated solutions and diagnostic cardiology at Welch Allyn.

Gomez claims that this is the only patient monitor on the market that goes across both the hospital and office setting. They have done interoperability testing with EMR partners ahead of its launch and Cerner and Epic are now integrated with the monitor.

The next big trend coming down the pike is having it so patient monitors can communicate with other devices. “If you could get the data from these different devices and they could talk to each other, you could utilize the data to help provide better care in real time,” says Jeff Moffatt, senior marketing manager for monitoring and IT systems at Draeger.

End Tidal CO2 monitoring is now becoming a requirement in the med-surg area because of the realization that postoperative pain management patients need to be monitored carefully in order to prevent an overdose.

If a patient-controlled analgesia pump (PCA) and an End Tidal CO2 monitor could communicate with each other, the monitor could alert the PCA pump if the patient’s respiratory status is being suppressed and automatically lock the patient out, preventing them from administering any more dosages.

Draeger is one of the leaders in this area with the introduction of its Smart Device Connect (SDC), which is an open protocol. SDC is not intended to be proprietary—the idea is for medical device manufacturers to adopt these open standards so a range of different devices can communicate.
The idea of having these closed and open loop functionalities have really taken interoperability to the ultimate level,” says Moffatt. “But at its basic level, the SDC is going to allow devices to talk to each other so you can do things like share alarm data and vital sign information and have more interoperable remote control.”

In with the new and out with the old?

Even with all of the wearables coming to the market, there’s still a need right now for the traditional monitors. Critically ill patients in the ICU require the comprehensive and thorough monitoring only they can provide.

“Heavy duty equipment like that can monitor to a level of accuracy that something held in your hand or placed around your neck or stuck in your watch can’t quite get to at this point in time,” says Slovenski.

However, in the next five to 10 years, that could change if the technology improves. “Technology only gets better, faster, cheaper and more accurate over time,” says Slovenski.

Almost all of the experts DOTmed spoke with agree that wearables will replace Holter monitors in the near future. In fact, Steinhubl believes that Holter monitors should be replaced right now.

He conducted a study at Scripps almost a year ago that compared a wearable patch and a Holter monitor and found that the patch was much more convenient — it diagnosed 60 percent of clinically significant dysrhythmias and had a lower overall cost.

In general wards, nurses will usually make rounds every six to eight hours to measure patients’ vital signs, but Steinhubl believes that hospitals would benefit from continuous monitoring. “When someone is in the hospital it seems almost ludicrous that you’re not monitoring them 24 hours a day, seven days a week,” he says.

When it comes to hospitals’ goals, nothing is more basic than saving lives and they can achieve that with these wearables that track vitals continuously. As the health care industry moves into an increasingly value-based landscape, saving lives also yields many financial benefits for hospitals.

“It’s only a matter of time that any monitoring equipment in the hospital and anywhere else will eventually be replaced by something much smaller, just as accurate and much less expensive, that the person can have on them anywhere they are,” says Slovenski.

But when that happens is anyone’s guess. “It could be next year — someone could have a major breakthrough — or it could be in 20 years but it’s coming and it will happen for sure,” says Slovenski.

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# DOTmed Registered Patient Monitors Sales & Service Companies

For convenient links to these companies, go to www.dotmed.com and enter [DM 25509]. Names in boldface are Premium Listings.

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Industry Sector Report: Patient Monitors

CJPS / VitalPoint® HOME
VitalPoint® HOME provides remote monitoring of chronically-ill patients and helps reduce hospital readmissions. Easily send the patient instructions and reminders to take their medication or vital signs. All the data is gathered in HIPAA-compliant servers and viewed using any Windows® computer or tablet with the RDC software. The device can monitor: Blood pressure, Blood oxygen saturation, Pulse rate, Weight, Glucose, Prothrombin time and ratios, Temperature, Fluid status, and Electrocardiogram data.

CJPS / VitalPoint® PRO
VitalPoint® PRO is a full-featured bedside unit that helps monitor a patient’s vital signs using a multitude of non-invasive sensors. Our compact, easy-to-use unit is designed for clinical settings where sub-acute patient care is provided by health care professionals. The device is able to monitor arrhythmia, measure blood pressure, blood oxygen saturation, pulse rate, respiration rate, heart rate, and temperature, and provide electrocardiogram data, and displays any three of seven waveforms.

CJPS / NOMAD™
NOMAD™ is a remote bedside monitoring system consisting of multiple VitalPoint® PRO vital signs monitors that can be watched and controlled remotely via any Windows-based computer, or tablet with the NTS software. The system can be networked via any Intranet, or wirelessly. Providing real time remote monitoring of patients from anywhere, at any time. No dedicated server is needed and there is no installation needed.

Covidien / Nellcor™ Bedside Respiratory Monitoring System, PM1000N/PM1000N-RR
The Nellcor™ bedside respiratory patient monitoring system incorporates the latest Nellcor™ digital signal processing technology for accurate, reliable readings and its intuitive, easy-to-read, graphical user interface and color touchscreen provide you with easy access to the critical information you need. The system provides continuous SpO2, pulse rate and respiration rate monitoring, Nellcor™ SatSeconds alarm management, so you can confidently detect respiratory complications early and intervene quickly.

Covidien / BIS™ Brain Monitoring System
Directly monitors a patient’s level of consciousness. By providing insight into the direct and patient-specific effects of anesthesia on the brain, the BIS™ brain monitoring system helps clinicians determine and administer the precise amount of drug to meet the needs of each individual patient, leading to increased patient anesthesia satisfaction.

Covidien / Capnostream® 20p Bedside Capnography Monitor
The Capnostream® 20p patient monitor is built on a legacy of proven performance. For nearly two decades, clinicians have relied on Microstream® technology for an accurate, continuous view of ventilation adequacy on intubated and non-intubated patients, from neonate to adult. The new Capnostream 20p monitor, with the Apnea-Sat Alert feature, alerts caregivers to repetitive patterns of apneas and oxygen desaturation, revealing a more complete picture of a patient’s respiratory status.

Criticare Systems / VitalCare Vital Signs Monitor
The nGenuity™ patient monitor is ideal for continuous monitoring applications, including surgical centers and post-operative monitoring. The nGenuity monitor is an easy-to-use system with intuitive user interface featuring a large, bright, color LCD display. All units include heart rate, ECG, ComfortCuff® NIBP, SpO2 and temperature monitoring with optional CO2, ST/Arythmia analysis and printer.

Criticare Systems / nGenuity Patient Monitor
For IV sedation or anesthetic sedation monitoring, Criticare’s nGenuity™ patient monitor provides straightforward operation with user configurable display, enabling clinicians to quickly access results. The nCompass offers optional interfacing with Criticare’s Pet® IQ anesthetic gas analyzer enabling identification and quantification of anesthetic gases, including halogenated agents. The nCompass comes standard with heart rate, ECG with ST/Arythmia analysis, ComfortCuff® NIBP, SpO2 and temperature monitoring. Optional features include CO2, IBP and printer.

Dräger / Infinity® Acute Care Patient Monitoring System
This system is a breakthrough in streamlined workflow, ease of use, continuous surveillance, and data access. The handheld M540 transport monitor stays with the patient throughout the entire care pathway – with no change of cables or leads. The 15” or 17” touchscreen medical cockpit brings comprehensive data to the bedside to support clinical decision making.

GE Healthcare / CARESCAPE Monitor B450
The CARESCAPE™ Monitor B450 is an important component of the CARESCAPE monitoring platform. It is a lightweight bedside monitor that is robust enough to meet changing patient acuity and care area needs as well as capable of maintaining all bedside monitoring functions during intra-hospital transport.

GE Healthcare / CARESCAPE Central Station
The CARESCAPE TM Central Station is a clinician-centric workstation designed to help increase workflow productivity and may improve the quality of patient care. Integration with other medical devices and systems provides access to historical data as the patient moves within a care area, or between care areas, allowing clinicians to perform in-depth analyses at a central location. By collecting comprehensive patient data, providing convenient access for review and simplifying case reporting, the CARESCAPE Central Station offers exceptional clinical decision support.

Masimo / EMMA™ (Emergency Mainstream Analyzer)
EMMA is a compact, portable, lightweight mainstream capnograph that requires virtually no warm-up time with full accuracy in 15 seconds. The continuous capnograph allows for confirmation and continuous monitoring of endotracheal tube placement, enables clinicians to assess the depth and effectiveness of compressions, and allows clinicians to recognize return of spontaneous circulation (ROSC).1 Its primary use is short-term monitoring of end-tidal CO2 and respiration rate in adults, pediatric, and infant patients.

1 “Monitoring respiratory rate and end-tidal carbon dioxide in the positive-pressure ventilated patient represents the greatest opportunity to avoid harm and improve clinical outcomes in all of resuscitation.” Daniel Davis, MD Professor of Clinical Emergency Medicine Director, Center for Resuscitation Science UCSD Emergency Medicine San Diego, CA
Masimo / SedLine® brain function monitoring

SedLine® brain function monitoring advances neuromonitoring technologies to improve the care of patients under anesthesia or sedation. The core product is a state-of-the-art EEG-based brain function monitor. Utilizing 4 channels of information, the SedLine monitor measures the effects of anesthesia and sedation by monitoring both sides of the brain’s electrical activity to enable more individualized titration and improve the care of patients under anesthesia or sedation.

Masimo / Patient SafetyNet™ Remote Monitoring and Clinician Notification System

Combining Masimo rainbow SET® Pulse CO-Oximetry™ and rainbow®Acoustic Monitoring with wireless clinician notifications via pager or smartphone, Masimo Patient SafetyNet provides an unmatched level of safety for up to 80 patients on four floors—facilitating early clinical response to preempt sentinel events and avoid unnecessary ICU transfers.

Mindray / The all new Passport 12

• 12" high resolution touchscreen display
• Up to 8 waveforms
• Standard features include: 3, 5, or 12-lead* ECG, 2 IBP, SpO2, NIBP, respiration, temperature, integrated recorder
• Choice of Masimo SET® SpO2 or Nellcor® OxiMax® SpO2

The Passport 12 Patient monitor is an inspired result of ingenuity and efficiency offering a modular approach to the traditional configured multi-parameter monitor. Flexible for virtually any clinical environment, the Passport 12 offers a compact, yet powerful OR, PreOp, PACU monitoring solution that delivers enhanced capability and more optional features — adding flexibility according to your clinical requirements.

Mindray / DPM6/7

3/5-lead ECG, Non-invasive blood pressure, SpO2, Pulse rate, Respiration, Dual-channel invasive blood pressure & temperature, Integrated recorder. DPM6™ and DPM7™ offer a broad range of patient monitoring capabilities in a robust, modular design. With features such as ETCO2, 5-agent multi-gas analysis with auto-ID, extensive data storage and independent display support (DPM7 only),

The high resolution, touchscreen displays provide the exceptional visibility and usability needed when monitoring patients in the anesthesia environment.

Mindray / V Series

Integrated touchpad and sizeable display, integrated module bay. Modern user interface eliminates common difficulties, VPS Module, data follows the patient. Powerful VAccess enables remote patient data. Modular design is fully scalable each care unit, integrated wireless capability. The V Series V21 and V12 patient monitoring system has the flexibility and adaptability for clinicians’ changing environments and provides the users with an advanced device anywhere in their facilities. The system also provides immediate connectivity through its thread safe VAccess application, bringing the user in touch with patient data streams, such as electronic medical records, at a single location, without compromising the monitoring of patients.

Mortara / Surveyor S19 Patient Monitor

Mortara presents the innovative Surveyor™ S19 patient monitor featuring 3, 5 and 12-lead ECG, NIBP, SpO2, CO2, IBP and CO. The configurable S19 monitor includes a 19-inch touchscreen, displays up to 8 waveforms, and provides a 12-lead diagnostic quality ECG format. The thin and sleek design of this monitor makes it ideal for wall mounting, during which it occupies minimal space in crowded treatment areas.

Mortara / Surveyor S12 Patient Monitor

Mortara presents the flexible Surveyor™ S12 patient monitor featuring 3, 5 and 12-lead ECG, NIBP, SpO2, CO2, IBP and CO. The configurable S12 monitor offers a 12-inch touchscreen, displays up to 8 waveforms, and provides a 12-lead diagnostic quality ECG format. Its extensive battery runtime and integrated handle are what make the Surveyor S12 an excellent choice when portable monitoring is required.

Sotera Wireless / ViSi Mobile System

The ViSi Mobile® System is able to continuously measure and display all vital signs (ECG, HR/PR, SpO2, Blood Pressure (cuff-based and also cuffless on a beat-to-beat basis), RESP, Skin Temp) with monitoring accuracy and resolution typically found in ICUs. ViSi Mobile is a comprehensive system, designed to enhance patient safety by allowing early detection of patient deterioration and connecting clinicians with their patients anywhere, any time.

Space labs / XPREZZON® Patient Monitor

XPREZZON® delivers innovative technology and design. Space labs DNA allows XPREZZON to become an additional workstation via an embedded CITRIX client. Utilizing a bar code scanner and DNA, clinicians can admit a patient or input information into the eMAR through the monitor. Highly visible alarm lights illuminate front and back. XPREZZON intuitively dims its display in low ambient light. The sleek, framework glass screen makes cleaning easier and aids in infection control.

Space labs / XCS Xprezz Mobile App For iPad

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Welch Allyn / Vital Signs Monitor 300 Series

This is a full-featured patient monitor that provides automated vital signs before, during and after medical procedures. Featuring separate modes for neonatal, pediatric and adult patients, the monitor also incorporates Welch Allyn’s revolutionary SureTempPlus electronic thermometry capabilities for quick, accurate temperatures. Features simple, pushbutton menu operation.

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Industry Sector Report: Ventilators

Ventilators get more automated, specialized

By Lisa Chamoff

In the decades since ventilators first made their appearance in the ICU, they’ve evolved from machines that ran on manually calculated settings dialed in by respiratory therapists to high-tech devices that utilize software to manage ventilator function and get the right mix of pressure flow and volumes for each patient.

But the challenges of lung injury, infection, and weaning remain.

In recent years, strides have been made to address these issues, including manufacturers returning to creating neonatal-specific platforms in addition to infant-to-adult models. Both have been improved with features designed to better outcomes and enhance patient safety, connect to electronic records systems and make the devices easier to use.

Prioritizing patient safety
Enhancing patient safety is the goal with all mechanical ventilators, including adult devices, with features such as prioritized alarm messages, troubleshooting guides embedded in the user interface, and customizable data displays, says Edwin Coombs, director of marketing for intensive care and neonatal care with Draeger Medical.

Automated weaning software is also now common, such as the Smartcare/PS in Draeger’s V500 ventilator, and others, including Hamilton Medical’s Adaptive Support Ventilation, Covidien’s Proportional Assist Ventilation and Maquet’s Neurally Adjusted Ventilatory Assist. This technology can assess a patient’s readiness to wean from mechanical ventilation and alter the level of support according to the assessment of physiologic parameters. “The result is a reduction in weaning time and length of admission in the ICU, which can translate
into a significant cost reduction and greater customer satisfaction,"
Coombs says.

Another trend is improving workflow design through mechanical ventilation. For example, Draeger ventilators have the capacity to deliver invasive ventilation, non-invasive ventilation, which other manufacturers offer, as well as oxygen therapy, so caregivers can use one device, decreasing the amount of disposable circuits and avoiding clutter at the bedside, which Coombs says improves efficiency and reduces cost of care.

Despite the strides made, however, especially with the advent of complex algorithms in the latest ventilators on the market, expert knowledge is still crucial to successful outcomes, says Dr. Aliaksei Pustavoitau, medical director of respiratory care services at The Johns Hopkins Hospital in Baltimore, who is now testing four of the newest models from leading ventilator manufacturers, including Covidien, Draeger, GE, and Hamilton Medical, “to see if they do what they claim,” Pustavoitau says. His institution is looking to replace its aging ventilators in the next five years.

He feels that the biggest change he has seen from older machines to the latest ones is that “the computer and processing power has become different,” Pustavoitau says. “That’s where the greatest range of possibilities lie.”

**Shift to two types of ventilators**

Infant-to-adult ventilators are attractive because they offer one user interface for staff to become familiar with, and also make maintenance easier, says Kathey Leibold, an analyst with MD Buyline.

But one-size machines definitely do not fit all. A machine must deliver volume and pressure specifically for the micro-preemie, and must also compensate for leaks, since the endotracheal tubes used on the infants don’t have cuffs, in an effort to prevent damage to the airway. Monitoring, alarms, and settings must also be designed for the smallest of patients. Respiratory therapists have found that even machines with neonatal or infant software aren’t always the best choice, Leibold says.

“You really need a dedicated ventilator that is designed specifically and only for those really tiny patients,” Leibold says. “A tiny preemie is not the same as an adult.”

Staff in neonatal units have also historically preferred to keep their machines inside the NICU, to avoid potentially spreading infection to some of the most vulnerable patients.

There are a number of exciting options now on the market, as a number of makers now have neonatal-only machines.

Draeger introduced the Babylog VN500, a neonatal/pediatric-specific ventilator, in 2010. It offered “easy-to-read data and graphics, alarm messages, and parameter screens,” says Coombs, adding that these “were paramount features for the neonatology group.”

Data management was also a key issue for hospital IT departments, and with the VN500, a comprehensive set of patient values, alarms, settings, and waveforms can be exported to a variety of information systems and physiologic monitors.

One plus was its interface. The VN500 has much in common with Draeger’s infant-to-adult V500 ventilator, including a similar user interface and hardware components, though there are some differences. The VN500 has infant-specific features, including an optional control for leakage compensation, while the V500 has specific adult applications, such as automated weaning protocol. There may be additional changes to the neonatal machine to allow it to be even more specifically tailored for the youngest patients. “As technology and market clearance for infant-specific features of the VN500 move forward over time, there will be more differentiation between the two models,” Coombs says.

Another developing trend in neonatal ventilation is the use of volume guarantee ventilation, Coombs says. Studies have shown that infants who receive volume ventilation versus conventional pressure ventilation tend to have less variation in CO2 values, potentially less intraventricular hemorrhage, and a lower incidence of bronchopulmonary dysplasia and other lung-related injuries. “To be successful in using this mode of ventilation, proper monitoring of tidal volumes and airway leakage is essential,” Coombs says.

Covidien staked its claim in the neonatal ventilation market with its Puritan Bennett 980 ventilator, including a neonatal platform, in the U.S. in 2014. The neonatal ventilator comes with infant-specific
applications such as Leak Sync software, which automatically detects and compensates for fluctuating leak sizes, as well as presets that track the most relevant parameters in a particular instance. There is also the ability to use non-invasive synchronized intermittent mandatory ventilation, which may help reduce the need to use invasive approaches to ventilation with endotracheal tubes, says Gary Milne, director of clinical marketing for respiratory solutions with Covidien.

The Puritan Bennett 980 ventilator is another machine aimed at the youngest patient. It has safety features that include a 1 percent resolution change in an automated increase in oxygen, which automatically turns off so the neonate is not exposed to elevated levels beyond need, Milne says. Volume-based delivery, which needs to be accurate on small babies, is within 10 percent of what is set within one standard deviation and can deliver down to 2-milliliter tidal volumes. In pressure-based approaches, the milligrams per kilogram can now be monitored both on inspired and expired volumes, which allows for assessment of lung protective volumes in pressure-based modes.

Hamilton Medical showed its T1 full-featured transport ventilator and its C1 ventilator, which will offer neonatal applications, at last year’s American Association for Respiratory Care Congress. Maquet promoted its Servo-U neonatal-through-adult ventilator and the Servo-N, a dedicated infant platform at the same meeting. The companies’ machines are currently pending FDA clearance, according to Leibold, who wrote about the conference for MD Buyline.

GE Healthcare has added some unique features to its CARESCAPE R860 ventilator, a neonatal-to-adult model that is pending FDA clearance and is available in Europe only as of today. One such feature, called Metabolics, measures inhaled and exhaled gases, which the physician can use to assess a patient’s nutritional status, says Paul Hunsicker, clinical manager for GE Healthcare Life Care Solutions.

“No one tells you to carbo load before surgery,” Hunsicker says. “Fifty percent of patients have some form of severe to moderate malnutrition. Metabolics allows us to measure caloric requirements of patients so they can be fed appropriately. This can address issues with weaning and healing in some patients.”

The device also has a mode of ventilation called Spontaneous Breathing Trial, designed to help caregivers assess when patients are ready to come off mechanical ventilation and breathe on their own, to avoid the complications and costs that come with prolonged ventilation.

The CARESCAPE R860 also has a touchscreen user interface designed to simplify the navigation process using technology that’s similar to what users are familiar with seeing in phones and tablets. The company has also developed features that may help reduce ventilator induced lung injury through the ability to measure functional residual capacity.

“We’re trying to help people better understand the impact of the settings on the patient,” Hunsicker says. “When we think of patients in ICU, all these tools help mitigate or at least allow clinicians a way to reduce these issues and provide appropriate care.”

Dr. William Dinan, director of pulmonary medicine and medical director of respiratory therapy at the Henry J. Carter...
Specialty Hospital, a long-term acute care hospital in Upper Manhattan that specializes in patients who have trouble coming off of ventilators, says one manufacturer’s weaning mode has never been proven superior to another. Even these days, Dinan says, the respiratory therapist’s and the doctor’s knowledge of weaning, and knowing what caused the respiratory failure to begin with, have the biggest impact.

“When you add the bells and whistles of the high-tech stuff, the software, it doesn’t end up making a difference with respect to one high-end ventilator to the next one,” Dinan says.

‘All the difference in the world’

While ventilators have become more sensitive and more accurate, some are better than others for specific patients and clinical situations, says Robert DiBlasi, a respiratory therapist and neonatal pediatric specialist at Seattle Children’s Research Institute.

“What little difference there is, is all the difference in the world, and you need to take performance into consideration for all patients that you treat,” DiBlasi says. For example, they vary in detecting leaks and some are more sensitive to trigger, or the way a patient initiates a breath. New data is guiding the decision to ventilate with volume and to choose a ventilator that’s highly accurate in choosing these volumes, DiBlasi says.

The team at Seattle Children’s Research Institute evaluates performance in the laboratory and has provided ventilator manufacturers with input on how they can potentially improve their products.

“Overall, clinicians should never assume one mechanical ventilator is better than the other,” DiBlasi says. “Our research has shown that there are disparities in performance and safety. Although most of these ventilators undergo similar testing for 510(k) clearance, they don’t take into account all patient populations that could be potentially supported by this.”

DiBlasi advises facilities, when purchasing ventilators, to make sure the company provides good technical support and that it is willing to work with clinicians or end users on performance.

“Try to select a company you know is willing to work with you,” DiBlasi says. “It’s not simply a point of sale. It’s more, how am I going to develop an ongoing relationship?”

Making a connection

Connectivity is important for all medical devices, and can impact ventilator purchase decisions. Pustavoitau, of Johns Hopkins, says one of the most important questions to ask a vendor is how the ventilator integrates into hospital IT systems, and about the device’s ability to communicate with the facility’s current monitoring systems.

Ventilator manufacturers have been working with hospitals that purchase their products to make sure they interface with EMRs, says Leibold of MD Buyline. Covidien, for example, has an EMR interface solution called the Vital Sync Virtual Patient Monitoring Platform, while CareFusion offers Knowledge Portal, which connects ventilators to hospital IT systems.

“Like everything in a hospital, it has to be connected and it has to be connected seamlessly,” Leibold says. “Between two ventilators, one that works best with their information system is one they choose.”

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ventilation. The Newport™ HT70 Plus portable ventilator combines ruggedness, ease of use and clinical proficiency with exceptional mobility for patients from 5kg to adult. All models of the Newport HT70 ventilator family can be used for home care, transport, hospital, long-term care and emergency preparedness, as well as for invasive or noninvasive ventilation.

Draeger / Evita® Infinity® V500

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Draeger / Babylog® V5000

Providing a comprehensive array of invasive and non-invasive ventilator support the as well as simple oxygen therapy, the V5000 is a complete solution for your neonatal and pediatric needs. Our customizable user interface streamlines workflow. Advanced technology identifies the changing clinical requirements of the infant to maintain consistent ventilation.

GE Healthcare / CARESCAPE R860 Critical Care Ventilator

GE Healthcare’s newest ventilator features built-in advanced lung protection tools and a touch-screen user interface. It was designed with a variety of clinicians and users in mind. It monitors and displays patient respiratory history and trends on the screen. It also has lung protection tools, including the InView software suite for measuring lung volume and Functional Residual Capacity, as well as SpiroDynamics. The ventilator also includes nutrition information right on the touch screen. 510(k) pending at the U.S. FDA and not available for sale in the U.S.

GE Healthcare / CARESCAPE R860 NICU Ventilator

With the CARESCAPE R860, validated to treat the most vulnerable patients, special color-coding distinguishes this NICU option from other ventilators in a fleet. Specialized ventilation modes are included that help transition neonatal patients off of mechanical ventilation. Modes like Volume Support help support spontaneous breathing and NPPAP, which stimulates the baby to breathe and can help prevent intubation. By precisely tailoring ventilation to serve the sensitive needs of neonates, diagnostic therapy capabilities can be expanded. 510(k) pending at the U.S. FDA and not available for sale in the U.S.

Hamilton Medical / MR1

The MR1 MRI ventilator guarantees uncompromised continuous ventilation care from the ICU to the MRI scanner and back. The integrated high-performance turbine enables the HAMILTON-MR1 to be completely independent from compressed air. This reduces weight and saves space during intrahospital transport. The HAMILTON-MR1 includes Hamilton Medical’s standardized Ventilation Cockpit user interface and the unique intelligent ventilation mode, Adaptive Support Ventilation (ASV®).

Hamilton Medical / C3

The HAMILTON-C3 mechanical ventilator is a compact high-end ventilation solution for all patient groups. The HAMILTON-C3 features a 12.1-in high-resolution display that shows all relevant patient data at a glance. The C3’s compact design and independence from external power and air supplies allow for maximum mobility throughout the hospital. The integrated high-performance turbine guarantees optimal performance even with noninvasive ventilation. The C3 provides an extensive monitoring package with a 72-hour trend function.

MAQUET / SERVO Ventilators

MAQUET SERVO ventilators are known worldwide for performance, reliability, and adaptability. Neonatal to adult, the SERVO-I can be used for transport, Heliox treatments, and conditionally in the MRI environment. The platform offers all conventional modes of ventilation, capnography, and the revolutionary NAVA® technology (Neurally Adjusted Ventilatory Assist). NAVA allows the patient and ventilator to work in synchronous harmony. NAVA provides monitoring of diaphragmatic activity during all modes of ventilation allowing the clinician to evaluate dysynchrony and interpret effects of treatment. NAVA can also be used in non-invasive ventilation (NIV NAVA®), which provides assist levels capable of matching the patient’s neural demands regardless of leakage or user interface.

ZOLL / Eagle II® Ventilator

The ZOLL L731 Eagle II™ Ventilator is used in the management of patients ≥5 kg with acute or chronic respiratory failure. It can be used inside the hospital, during transport, and in MRI suites. The Eagle II is a full-featured, portable critical care ventilator designed to be durable and lightweight with a 10-hour battery, and multiple modes of ventilation including non-invasive ventilation.

ZOLL / EMV® Ventilator

The ZOLL 731 EMV® Ventilator is used in the management of patients ≥5 kg with acute or chronic respiratory failure. It can be used outside the hospital, during transport, and in aeromedicine. The EMV® is a rugged, full-featured portable critical care ventilator designed to be durable and lightweight with a 10-hour battery, multiple modes of ventilation, and altitude compensation from -2,000 to 25,000 feet.

ZOLL / AEV® Ventilator

The ZOLL 731 AEV® Ventilator is used in the management of patients ≥5 kg with acute or chronic respiratory failure. It can be used outside of the hospital during transport. The AEV® is a rugged, full-featured portable critical care ventilator designed to be durable and lightweight with a 10 hour battery, and multiple modes of ventilation including non-invasive ventilation.
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Defibrillators and the uphill battle against cardiac arrest

By Gus Iversen

It can happen out of nowhere – over dinner, during a basketball game, or at home reading the paper – and when it does, a few short minutes can mean the difference between life and death.

The mortality rate associated with cardiac arrest can look frighteningly out of place in today’s advanced health care landscape. According to the American Heart Association, less than ten percent of the 359,400 cardiac arrest victims stricken outside of a hospital setting in 2013 survived. The survival numbers for cardiac arrest within hospital walls are better, but still lower than 50 percent.

Defibrillation is useful against ventricular fibrillation, a culprit for cardiac arrest, and physicians depend on advanced life support (ALS) systems to monitor a number of patient vitals while also administering shocks when needed. For patients at high risk for ventricular fibrillation, defibrillators can be surgically implanted to give them permanent protection against cardiac arrest.

But cardiac arrest’s unpredictability is a big part of what makes it such a deadly problem. It typically happens outside of medical facilities, and on people who don’t expect it. It’s a health care battle that is largely fought outside of hospitals. Automated external defibrillators (AEDs) and cardiopulmonary resuscitation (CPR) are frontline defenses—and every minute without them cuts drastically into the victim’s chance for survival.
Counting on regular people to save lives

Over the last several years, AED manufacturers have waged a successful campaign to integrate their systems into everyday locations like restaurants, gymnasiums, schools, health clubs, casinos, and on board fire trucks. As such, AEDs must be intuitive enough for someone with no medical experience to operate them while under the pressure of a medical crisis.

Debra Ford, director of marketing at Defibtech, a company that manufactures AEDs, says they are manufacturing a full-color interactive display system that—along with audible instructions—shows the rescuer what to do with step-by-step video footage.

There are many cases where abnormal heart rhythms cannot be shocked and, according to Elijah White, VP of marketing at Zoll Medical, a manufacturer of AED and ALS solutions, CPR is the one thing that virtually all cardiac arrest patients need. He says the general public associates AEDs with shocking people, but they also can provide crucial support in administering CPR.

“...and they will be expected to deliver chest compression, so our system tells them if they are going fast enough or deep enough.”

An estimate from the FDA states that roughly 2 million of those AED systems are currently out in the market. Many of them spend years buried in closets gathering dust; like most fire extinguishers, they happily pass the time unneeded. Unfortunately, that can lead to operability problems.

After years of planning, a change in regulations

The FDA estimates that 72,000 reports associated with AED failures were submitted, (although not validated) between January 2005 and September 2014. Over that same period, 111 manufacturer recalls on defibrillators were implemented.

Previously subject to 510(k) approval, AEDs and ALS devices with automatic mode functionality have officially been up-classed to premarket approval (PMA) processes. After a long period of speculation and planning, the change in policy took place this year.

Regulation changes apply to any device that has an advisory algorithm to decide if a heart rhythm is shockable or not. White says that means all AEDs — and the majority of ALS devices — will need to submit newly required paperwork to keep their devices FDA compliant. Strictly manual defibrillators and internal defibrillators however, are not subjected to the change.

“We’ve been talking to the FDA about this for many years so it’s not a surprise to the industry,” says White, who regards the change in policy as a good thing.

Defibtech’s Ford agrees that the new regulations are good for the industry and does not anticipate them interfering with their business or their customers.

Despite the number of recalls and failures reported, White says AEDs are very straightforward designs and generally reliable devices, “It’s not like a car with a lot of moving parts.”

Most defibrillators have two or three key failure points—which can be replaced—and an overall average usability cycle of eight or nine years, which can be made even longer by diligently keeping up with recommended self-testing, says White.

“Installing the battery pack so self-tests can be performed, checking the active status indicator and listening for audible cues so action can be taken if necessary,” are ways Ford says one can ensure the systems are in working order.

“Other recommendations include storing the AED under specific environmental conditions, and should the AED be dropped, mishandled, or otherwise compromised, a manual self-test can be initiated to assess its condition,” she says.

An inside job

While AEDs can be found all over, and ALS devices can be found in crash carts, hospitals, and some ambulances, there is another kind of defibrillator that can be installed inside the human body. Transvenous implantable cardioverter defibrillators (ICDs) utilize a transvenous wire lead which stretches from a pulse generator beneath the shoulder and down into the heart to automatically detect any cardiac arrhythmias and deliver a life-saving shock when necessary.

Patients with an underlying cardiovascular condition that puts them at risk of cardiac arrest may be candidates for these internal systems, which deliver shock in a timely fashion and offer survival rates upwards of 98 or 99 percent. However, transvenous defibrillators are not without their drawbacks.

Dr. Kenneth Stein, chief medical officer for Rhythm Management at Boston Scientific, says the human heart beats approximately 100,000 times per day. Over the course of many years, that puts a strain on these wires. That means even the best transvenous defibrillators have a failure rate around one percent after seven to ten years.

If an infection develops and the transvenous ICD has to be removed, a laser must be used to melt the scar tissue and free up the wire. That presents another potential problem. “As these wires are present in the body for extended periods of time, years typically, anchoring fibrosis develops,” says Dr. Daniel Cantillon, cardiologist at Cleveland Clinic, “which means scar tissue is developing in the veins that hold the wire closely to the blood vessel and the heart itself.”

A new approach to internal defibrillators was pioneered by Cameron Health, a company Boston Scientific invested in and later purchased. With subcutaneous ICDs the lead does not have to run through blood

Over the last several years, AED manufacturers have waged a successful campaign to integrate their systems into everyday locations like restaurants, gymnasiums, schools, health clubs, casinos, and on board fire trucks.
Industry Sector Report: Defibrillators

vessels but instead utilizes a pulse generator and electrode beneath the skin.

S-ICD does not have those kinds of removal complications. Instead, they provide a way to avoid navigating blood vessels with the lead by using a shocking coil that is planted and tunneled through the soft tissues of the body from the space just under the left arm—the axilla region—up, just to the left of the breast bone.

These systems are still in their first generation but Stein says developers are looking for ways to implement some of the more advanced features of transvenous ICDs into S-ICDs. That means better battery longevity, smaller size, and remote monitoring capabilities.

“Remote monitoring technology is a really important and useful feature as you look to the long-term,” says Stein, who says his company’s transvenous ICD systems already feature EHR integration.

Even with those added features, there is a drawback to S-ICD systems that could make a transvenous system better for certain patients. “A traditional ICD can serve as both an ICD and a pacemaker,” says Cantillon, “so for patients who need both, the traditional version is more appropriate.”

Data and maintenance
Defibrillators are linking up with hospital IT in the interest of yielding better insight into patient care as well as quality assurance and monitor readiness information.

“The biomed in a given hospital could be responsible for keeping 200-300 crash cart defibrillators ready at all times,” says White. “That sometimes involves walking around the hospital checking, which we think is unsustainable so we’re pushing to automate that process.”

By connecting the devices to the network, a Healthcare Technology Management specialist could look and see that perhaps two of the several hundred defibrillators did not do their scheduled self-check, so he could go and check on those instead of checking all of them.

Getting that defibrillator data integrated into the EMR is also a priority. Zoll is starting to package its data regarding the treatment someone received for cardiac arrest in an HL7 format so that it can integrate into the record. Giving the cardiologist access to that data—namely, the initial first rhythm at the time of presenting—can have a significant impact on the course of treatment.

Tomorrow’s defibrillators
CPR trained individuals can register through an app called PulsePoint to tell them when a cardiac arrest has been reported in close proximity. The app also identifies the location of the nearest defibrillator. According to White, technology like that will continue to catch on
until there will become a universal standard for reporting the location of an AED.

He also expects tomorrow’s AEDs to preserve that crucial first rhythm data and allows it to be rolled up into the patient’s EMR and accessible by the advising physician. Although some EMS services today will send interns out to retrieve the AED and record that data, White says it is not a common practice.

“What we really want to do at Zoll is advance chest compression technology to the point where rescuers do not need to stop chest compression,” says White. Using today’s defibrillators you have to stop chest compression in order for the device to accurately analyze rhythm.

Boston Scientific’s Stein points out that there are still more cardiac arrests among people who do not have an indication for a defibrillator than there are for those who do have an indication for a defibrillator. He says, “Advancing research on who should get these devices is still critically important.”

“Disparities in access to defibrillators from country to country, and even in the U.S., based on gender and race are very concerning,” says Stein, who adds individually programming these systems for the needs of the patient and extending battery life in the interest of reducing future surgeries, among other issues that challenge defibrillators.

The low survival rates for cardiac arrest – and the fact that they have not shown significant signs of improving – can render a sense of futility. But that doesn’t mean there aren’t reasons for being optimistic. White says a patient in Arizona is three times more likely to survive cardiac arrest. There are also hospitals throughout the world that pride themselves on uncommonly high success rates. Knowing those kinds of success rates are achievable justify the continued drive to innovate.

“Technology is one piece of the puzzle but it’s a cultural thing too, and the good news is that we know we can do better,” says White.

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DOTmed asked the leading defibrillator manufacturers to submit up to three of their current products to be featured in this Guide. To learn more about these products and rate and review them, and see other models not shown, please visit the Equipment Guide in DOTmed's Virtual Trade Show, or go to: www.dotmed.com/defb

Cardiac Science / Powerheart AEDs
Powerheart AEDs are reliable, easy-to-use, and technologically advanced life-saving devices.
• The Powerheart AED calculates electrical impedance for each patient and customizes the energy level delivered.
• Patented Rescue Ready daily, weekly, and monthly self-tests ensure anytime functionality.
• Powerheart AEDs are rugged and durable with a 7-year device warranty.

Defibtech / Lifeline PRO
The Lifeline PRO provides full manual control over shock energy and delivery when operated in manual mode. When in use an ECG appears on the color video display, and the rescuer can select the energy level and decide when to initiate charge and shock. The Lifeline PRO can also be operated in semi-automatic or AED mode. In this mode the AED determines if a shock is required based upon reading the victims arrhythmia.

Defibtech / Lifeline ECG
The Lifeline ECG can display either an ECG or video instructions for the rescuer. In video mode, or semi-automatic AED mode, the AED provides video and audio step-by-step CPR coaching and guidance on where to place the defibrillating pads, and when to begin CPR. For example, when the VIEW’s audio says, “Place pads on patient’s chest,” the video shows exactly where to place the pads.

Defibtech / Lifeline AUTO
Differing from the original Lifeline semi-automatic AED, the Lifeline AUTO AED does not require the rescuer to push a shock button. It shocks automatically when it senses a shockable rhythm. The Lifeline AUTO AED’s advanced arrhythmia detection technology reduces the apprehension of concerned people who want to help, but may be hesitant to provide assistance.

HeartSine / samaritan PAD 350P
The HeartSine samaritan® PAD 350P was designed especially for use in public areas by providing a sophisticated defibrillator for adult or pediatric use, inside a lightweight and easy-to-operate system. Its advanced technology is balanced against the demands of real world use. The SAM 350P uses HeartSine’s practical Pad-Pak™, which incorporates the battery and electrodes in a single-use cartridge – meaning only one expiration date to monitor and one item to replace after use.

Physio-Control / LUCAS Chest Compression System
The LUCAS Chest Compression System is designed to help improve outcomes of Sudden Cardiac Arrest victims and improve operations for medical responders. Performing at least 100 compressions per minute, LUCAS can be deployed quickly with minimal interruption to patient care.

Physio-Control / LIFEPAK 15 Monitor Defibrillator
The LIFEPAK 15 monitor/defibrillator can adapt to evolving protocols and new guidelines. The 15 provides the widest range of energy dosing up to 360 joules, CPR metronome for guiding chest compressions, and the broadest selection of monitoring options available, including 12 Lead ECG, non-invasive blood pressure, invasive pressure, continuous temperature, EtCO2, carbon monoxide, SpO2, and methemoglobin. The 15 also includes Bluetooth capability.

ZOLL / R Series Code-Ready Monitor/ Defibrillators
ZOLL’s resuscitation platform is designed to promote consistent, high-quality CPR and high-current defibrillation for adults and pediatrics. The technologies included in our R Series® Monitor/Defibrillators include Real CPR Help® to provide real-time feedback on compression quality, See-Thru CPR® to reduce pause time by filtering the CPR artifact, and ETCO2 to signal the earliest changes in patient condition. ZOLL offers its customers more than just a way to deliver a shock. We offer tools to help improve CPR quality, which improves outcomes.

ZOLL / X Series Monitor/ Defibrillator
The ZOLL X Series® Monitor/ Defibrillator is ideal for transporting critically ill patients. It is lightweight with extensive monitoring capabilities. Weighing less than 12 pounds (6 kilograms), the X Series is compact without compromise in capability, performance, and display size. This monitor/defibrillator combines the clinically superior therapeutic capabilities of ZOLL defibrillation, pacing, and CPR assistance with advanced monitoring parameters. The X Series has every advanced monitoring and communication capability required for critical care transport.

ZOLL / AutoPulse Resuscitation System
The ZOLL AutoPulse® Resuscitation System provides consistent, high-quality CPR to victims of sudden cardiac arrest. Easy to use and battery operated, its load-distributing LifeBand® squeezes the patient’s entire chest to improve blood flow to the heart and brain. The only device of its kind, AutoPulse automatically sizes to the patient, and has shown improved survival in numerous clinical trials.
MedPAC's annual March report to Congress:
Still pushing for site-neutral payments

By Jill Rathbun

In its March 2015 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) reiterated its recommendation from its 2014 report that Congress should direct the Secretary of Health and Human Services to reduce or eliminate differences in payment rates between outpatient departments and physician offices for selected ambulatory services.

Unfortunately, some of these ambulatory services that were identified by MedPAC in its 2014 report were diagnostic imaging services.

At least MedPAC does specifically state that the putting this principle in place of paying the same rate for the same service across settings into practice can be complex.

The policy, officially known as Site Neutral Payments, requires that the definitions of the services and the characteristics of the beneficiaries across the setting be sufficiently similar. For imaging services in particular, this is even more difficult given that changes that are similar. For imaging services in particular, this is even more difficult given that changes that are similar.

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The policy, officially known as Site Neutral Payments, requires that the definitions of the services and the characteristics of the beneficiaries across the setting be sufficiently similar. For imaging services in particular, this is even more difficult given that changes that are similar.

Then there is the concept of unit pricing and MedPAC’s belief that the unit prices by type of facility can be the same. However, these payment systems are not derived from the same data sources or from the same philosophy.

The physician payment system is a system that is budget-neutral with the payments having to “fit” into the available amount of money. This means that the data used to calculate payments can be reduced several times as part of the calculation of relative value units (RVUs). It is a relative system. It is neither a cost-based nor a charge-based system.

Beyond that, for imaging services paid under the physician fee schedule, Congress and/or the administration has specifically, either through legislation or regulation, reduced payment 13 times in the last nine years to physicians when performing imaging services in their offices.

It is hard to tell what office-based payments for imaging services would have been in 2015 if they had been left untouched as many other services in the physician fee schedule have been. Would there have even been a site of service difference in payments between hospital outpatient departments and physician offices?

Another element that MedPAC states is necessary to put the site-neutral payments principle in place is the similar characteristics regarding the Medicare beneficiary that is being treated.

Emergency rooms at trauma centers, for the purposes of billing Medicare, are considered hospital outpatient departments, unless the patient is admitted to the hospital as an inpatient and then the cost of all the services provided in the ER get rolled into the DRG payment for the admission.

In many instances, patients getting care and who are in need of diagnostic imaging services in an emergency room or trauma center could have a higher level of acuity than a patient that is seen in physician offices for a previously scheduled diagnostic imaging study.

Even MedPAC, in constructing the list of services that would be compared, had an elimination criterion for services in which the volume performed in an emergency room department was too high to make it comparable to services provided in a physician office.

There would also need to be considerations for facilities in rural areas and for facilities which, due to financial instabilities, had no other choice but to form some type of alliance to be able to keep the doors open to provide for access to care in their community.

While, on their face, comparing payments between various sites of services looks to be a relatively easy apple-to-apple comparison, it is much more complicated and possibly even impossible due to all the nuances of the various systems.

And it could be distracting at a time where everyone is trying to develop alternative payment models that are more about performance and value than unit prices.

About the author: Jill Rathbun is managing partner at Galileo Consulting Group, in Arlington, VA. She will be commenting for DOTmed HealthCare Business News magazine on such vital issues for all health care professionals as the implications of the President’s FY 2016 budget, the new make-up of Congress, possible Medicare payment proposals from the Centers for Medicare and Medicaid Services, reports from the Medicare Payment Advisory and more.

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Best known for his roles in movies like Footloose and The Rookie, Dennis Quaid took the stage at the 2009 HIMSS annual meeting to play an altogether different kind of role: advocate for hospital patient safety. Two years earlier, when Quaid’s twin daughters were only ten days old, they were accidentally given one thousand times the prescribed amount of heparin, a blood thinning medication administered through an infusion pump.

The mistake was caught in time for the overdose to be counteracted with other medication, but the situation remains a high profile example of how serious an infusion pump accident can be. If the wrong button is pressed, or the wrong medication is dispensed, the results can be deadly.

To err is human, and in most professional settings, the impact of an error is relatively minor; reputations may be tarnished, money may be lost. The life-and-death burden that health care professionals deal with every day is part of why they deserve recognition for the exceptional work they do. It is also why automating medication administration through infusion pumps is emerging as a big area for process improvement, patient safety, and risk reduction among forward-thinking chief nursing officers (CNOs).

“A survey asked 4,900 CNOs, ‘If you could only integrate one medical device with EHR this year, what would it be?’,” says Jeff McGeath, VP of patient care device integration at Iatric Systems, a company that specializes in integrating health systems. “Of the respondents, 44 percent said smart pumps.”

Verifying ‘the five rights’ faster
In the old days, infusion pumps were little more than mechanical levers connecting medicine to a line which ran into the patient’s vein. While those basic systems can still be found in hospitals today, they are steadily being displaced by smart pumps; infusion pumps with software running on them.

McGeath says most smart pumps follow a basic model: Clinicians at the bedside scan the patient’s wristband so the system knows who the patient is, then scan the medication so they know the drug. An automatic verification takes place – does this patient have an order for this drug at this concentration? A third scan of the pump itself creates a record of which specific piece of equipment was used for the transmission.

All told, that satisfies the five rights of medication administration: right patient, right drug, right dose, right route, and right time. Based on those three scans, a smart pump will either accept or deny the infusion.

“You’ve got much more of a visual user interface on the pump where you can key in certain parameters and settings; you can
integrate with your drug library and pharmacists can approve and manage the formulay,” says McGeath.

Jaime LaMontagne, VP of global product management for Infusion Therapies at Smiths Medical, a major manufacturer of infusion pumps, has witnessed the progress taking place with smart pumps. She says the move to wireless technology enabling smart pumps to integrate with several other systems across the hospital, has made a huge difference.

Network connectivity not only expedites care, but also allows programmed guardrails to ensure patient safety. “Smart infusion systems are now equipped with medication error-prevention software that alerts users or interrupts the infusion process when a pump is programmed outside of preconfigured limits,” says LaMontagne.

But that does not mean smart pumps are foolproof. If a hospital is using agency nurses or a mix of pumps within the organization, different pump interfaces can create usability problems. For instance, one may have a lot of up and down arrow buttons on the front while another might have all buttons on the bottom right-hand corner. McGeath describes an informal study he participated in at Connectathon a couple of years ago. “I was there with three different pump manufacturers and we showed that manually programming a pump – the average between the vendors – took 27 button clicks on the face of the smart pump.” That means 27 opportunities to hit the wrong button.

“Research tells us that incorrect programming is the root cause of the majority of adverse medical events that occur in connection with infusion pumps,” says Julie Sawyer Montgomery, VP of global marketing and sales for Hospira Medical Devices, a leader among infusion pump manufacturers.

To safely leverage the power of smart pumps, software needs to be established that integrates with the medical record, adheres to best practice protocols, and closes the loop on self-checking and automation. As of fall 2014, McGeath says only nine hospitals in North America were fully integrating their pumps with the EHR – progress has been slow but momentum is building.

**Closing the loop**

Clinicians can use the touch pad on the pump to select what drug they are administering, and if they go outside those guardrails (“fat fingering,” or a mistake) then the pump will automatically reject the command.

But guardrails don’t matter if the pump is filled with the wrong medication to begin with. That’s why the industry is coming together around the need to integrate smart pumps with the EHR and close the loop entirely.

In February, Smiths Medical launched an interoperable version of their PharmGuard Infusion Management software to achieve that goal. With it, their Medfusion 4000 pumps can communicate with the EHR through IHE PCD (Integrating the Healthcare Enterprise Patient Care Domain) profiles.

“IHE PCD profiles aim to improve patient safety and clinical ef-
Industry Sector Report: Infusion Pumps

The expanding home care market
As health care continues to emphasize cost effectiveness, many long term patients are being moved out of traditional hospitals to home care or alternate-site treatment facilities. This shift has resulted in a growing demand for cost effective infusion pumps that are worth the investment for facilities operating on a smaller scale.

LaMontagne says the CADD Solis VIP (Variable Infusion Profile), a multi-therapy infusion platform from Smiths Medical, is meeting that need with versatility. The system – which includes a smart infusion pump, medication safety software, and dedicated cassette reservoirs or disposables – has five delivery mode options which can be programmed for a variety of different protocols, and has an interface designed to be intuitive.

Montgomery says that providing care in non-traditional settings creates new obstacles, “Ensuring compliance can be challenging and wireless technology is often not hospital quality.” EHR integration is one way to maintain quality assurance remotely, but security measures are vital.

Cyber security concerns
Cyber security is a big issue for all connected medical systems and devices – not just smart pumps. Knowing how to safely lock down these systems is of paramount concern. If a hacker gained access to smart pump formularies and decided to tamper with them, for example, they could inflict massive harm on all the patients being served by that integrated system.

Essentia Health, a major hospital network in the Midwest, conducted a full network evaluation in 2012 and publicly disclosed the extent to which IT experts were capable of hacking into their systems. Among many other things, the hired hackers were able to access infusion pumps and tamper with the dosage settings via web administration interfaces which were intended to allow nurses to remotely change dosages from their workstations.

Essentia shed light on just how vulnerable health care networks can be. There is no reason to assume similar evaluations at other networks or hospitals would yield any better outcomes, so there is a lot of work to be done in protecting medical data and networks.

The National Cybersecurity Center of Excellence (NCCoE) and the National Institute of Standards and Technology (NIST) are two agencies working together to mitigate those kinds of dangers. The FDA has recognized the problem too and puts the responsibility on vendors to ensure the security of their systems.

System integration predictions
McGeath believes integrated smart pumps are at a tipping point. “It’s no longer just insiders talking about it. I’m the technical committee co-chair for IT, so I work with the manufacturers and software vendors, so although we’ve been expecting this for a long time we’re now seeing outside interest too.”

Over the next two or three years, he expects the number of hospitals with integrated smart pumps to skyrocket. Managing the cyber security risks associated with integrating – not just pumps, but all health care technology – is an objective that must evolve alongside the increased connectivity.

“When hospitals have a conversation about medical device integration, it won’t be ‘Oh, they’re talking about heart rates and blood pressure, and glucose and SBO2 readings,’ No – when they say medical device integration it will mean smart pumps. That’s the next new territory for medical device integration,” says McGeath.

Smiths Medical’s LaMontagne says connectivity and integration of devices across the hospital and other treatment areas will continue into the next ten years. “Smart pumps will not only send data to the EHR but they will start to exchange data with other devices in the patient care area, such as monitoring and alarm management,” she says.

“Future infusion pumps will be able to monitor patient vital signs and adjust dosages,” says Hospira’s Montgomery, adding that allergic reactions from drug interactions could also be reduced through this technology.

In the end, integration is less about the health record than it is about the subjects of those records. As Montgomery puts it, “These new pumps will be more connected to the patient than ever before, thus keeping them safer than ever before.”

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## DOTmed Registered Infusion Pumps Sales & Service Companies

For convenient links to these companies, go to www.dotmed.com and enter [DM 25512]. Names in boldface are Premium Listings.

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Baxter / SIGMA Spectrum
Baxter’s SIGMA Spectrum Infusion System was designed to help reduce errors when programming an IV infusion. It automatically defaults to the drug safety library at the initial start-up of the system and provides a safeguard specific to titration programming. It also offers wireless connectivity capability to integrate pump infusion data into a hospital’s EMR system. Baxter standard IV administration sets are used with the SIGMA Spectrum, thereby helping to minimize touch contamination.

CareFusion / Alaris® System
The Alaris® System is the most comprehensive IV medication safety system on the market. Built on a modular platform, the Alaris System with Guardrails® Suite MX software provides safety beyond dose error reduction. It is the only smart pump that can protect every infusion, intermittents and all infusion modalities, including large volume pump, PCA and syringe. In addition, Alaris EMR interoperability delivers true electronic medical record interoperability by offering seamless two-way connectivity between the Alaris System and leading HIT systems.

Hospira / LifeCare PCA Infusion System
The first and only PCA pump with integrated bar code identification, Hospira’s LifeCare PCA™ has the flexibility to use Hospira bar coded pre-filled drug vials or pharmacy-generated bar codes for custom-filled vials. This combination virtually eliminates potential for drug and concentration errors at the bedside, and helps make LifeCare PCA™ a market leader that supports your patient satisfaction and safety goals.

Hospira / Plum360 Infusion System
Hospira’s Plum 360™ infusion system with Hospira MedNet™ safety software helps enable clinical excellence with:
- Air management that doesn’t require disconnecting from the patient
- A secondary line that connects directly to the cassette
- Infusion programming that automatically defaults to the drug library
- Proven EMR integration, ready when you are.

Hospira / SapphirePlus Infusion System
The SapphirePlus™ Infusion System’s compact and lightweight design reduces complexity at the bedside and enables easily transporting between care areas. With Hospira MedNet Safety Software and low flow continuity the SapphirePlus™ Infusion System is the perfect fit for all critical and acute care environments. The unique large, color touch screen is easy to read and provides intuitive programming, presenting only relevant keystroke options to reduce user errors.

Numia Medical / MicroFuse Dual Rate Infuser
The MicroFuse Dual Rate Infuser is designed to empty a syringe over 20-40 minutes depending on syringe size. It features single-handed syringe loading and push button controls that require no programming. The Dual Rate’s user-friendliness combined with its compatibility to generic syringes and microbore sets make it ideal for use with critical, non-rate drugs.

Numia Medical / MicroFuse Extended Rate Infuser
The MicroFuse Extended Rate features infusion times from normal 20-40 minutes to slow rates of 12-24 hours, push button controls that require no programming and single-handed loading. The Extended Rate’s ease of use and compatibility to generic syringes and microbore sets makes it a superb choice for a wide variety of specialty application extended infusions.

Numia Medical / MicroFuse Rapid Rate Syringe Infuser
The MicroFuse Rapid Rate Syringe Infuser is designed with rates of 1-6 minutes or 2-8.4 minutes, simple push button controls that require no programming and single-handed syringe loading. The Rapid Rate’s user-friendliness combined with its compatibility to generic syringes and microbore sets make it the ideal choice for specialty applications requiring rapid, accurate infusing.

Smiths Medical / Medfusion® 4000 Wireless Pump
The Medfusion®4000 Wireless Syringe Infusion Pump with PharmGuard® Infusion Management Software offers the most clinically acceptable syringe pump while advancing the ability to collect CQI data, push protocol libraries and deploy firmware updates. The Medfusion®4000 pump is for those who require a high accuracy of medication delivery with small volume infusion while being user friendly and intuitive.

Smiths Medical / Medfusion® 3500 Pump
The Medfusion®3500 Syringe Infusion Pump with PharmGuard® Infusion Management Software is the clinically preferred syringe pump for those who require a high accuracy of medication delivery with precise, small volume infusions in a high acuity care area while being easy to use. With the largest installed base of syringe pumps in the U.S., the Medfusion®3500 syringe pump is the #1 syringe pump choice for the top pediatric and general hospitals.

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Helping infants breathe easier

Mary Ellen Avery’s research into the Respiratory Distress Syndrome (RDS) is considered to be one of the most significant advances in neonatal care.

Neonatal RDS affects infants whose lungs have not yet fully developed. When Avery began her work, about 15,000 babies succumbed to the syndrome on an annual basis. It’s now estimated that her pioneering research has helped save more than 800,000 lives.

Avery was born on May 6, 1927 in Camden, New Jersey. Her family lived next to a pediatrician named Dr. Emily Bacon, who inspired Avery to pursue a medical career at an early age. It was Dr. Bacon who took Avery to see her first premature baby.

In 1948, Avery graduated at the top of her class from Wheaton College with a chemistry degree and enrolled in medical school at Johns Hopkins University School of Medicine. Upon graduating in 1952, Dr. Avery was diagnosed with tuberculosis, a condition that fueled her interest in the function of the lungs.

After a long recovery and a trip abroad, Dr. Avery returned to Johns Hopkins to complete her internship and residency. She then moved on to Harvard Medical School, where she had a research fellowship in pediatrics. It was here that she discovered the cause of RDS. When comparing the lungs of infants who died of the syndrome with those of healthy animals, she noticed that the babies were missing a white substance, which she hypothesized played a critical role.

While reading through the available literature on the subject, Dr. Avery came upon an article by Dr. John Clements, who was studying the consequences of toxic gas inhalation for the U.S. Army. He had come across the substance in his research. While on vacation, Dr. Avery got into her car and drove to Maryland to meet with Dr. Clements. “And what was a baby doctor doing going to visit somebody who was studying war gas defenses?” she later wrote, “Well, I was the somebody that said, ‘I’ve got to meet this man.’”

Dr. Clements proved to be instrumental in helping Dr. Avery figure out the essence of the white substance. It turned out to be surfactant, a mixture of fat and proteins in the lungs that enables people to breathe. Babies carried to full-term almost always develop surfactants before they are born, whereas premature babies don’t. “There was one moment of insight, and that was it,” she wrote of the meeting.

Her findings served as the foundation for an influential 1959 paper published in the American Journal of Diseases and Children. A Japanese pediatrician then used the paper to identify a treatment for RDS — he developed a synthetic surfactant from the lungs of cows. Dr. Avery was thrilled about the new intervention.

Dr. Avery went on to become an assistant professor of pediatrics at Johns Hopkins University, where she was also put in charge of newborn nurseries. She then served as chair of the department of pediatrics at McGill University in Canada, and in 1974, she returned to the U.S. to join the faculty of Harvard Medical School.

Dr. Avery was the first woman to serve as physician-in-chief at Boston’s Children’s Hospital and the first woman to serve as president of the Society for Pediatric Research. She was also the first pediatrician to head the American Association for the Advancement of Science. In 1991, President George Bush presented Dr. Avery with the National Medal of Science for her contributions to understanding and treating RDS.

She passed away on December 4, 2011, at age 84. No matter what position she held throughout her distinguished career, Dr. Avery always had a deep love for science. “I am so saturated and pleased to share it with anybody who will listen,” she once said.

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We address the likelihood that centralized nuclear centers will return to hospitals in light of the recent torrent of hospital mega-mergers, and look at the current state of the market.

**New Equipment Guide**
See the latest molecular imaging equipment from the leading manufacturers; modalities include PET/CT, PET/MR, SPECT, SPECT/CT and Gamma Cameras.

**Features:**

**Radiopharmaceuticals**
Experts weigh in on the Molybdenum-99 shortage: What are the production alternatives, who will it impact, how will it change imaging practices? We also discuss the effect of reimbursement on radiotracer innovation and adoption of the costly procedures and examine the latest in imaging dementia, treatment responses to FDG and hypoxia imaging tracers.

**SNMMI Pre-event annual meeting coverage**
We report on the Society of Nuclear Medicine and Molecular Imaging's quality standards initiative, as well as provide in-depth coverage of its Centers of Excellence, including:
- The launch of The Therapy Center for Excellence
- The Pet Center of Excellence
- The Center for Molecular Imaging Innovation and Translation, featuring its new leader

Plus: Clinical practices for PET/CT

**Imaging Children**
When are PET/CT scans appropriate? What are the best choices for diagnostic imaging for the common ailments of childhood, like stomach aches and bangs on the head? And what are the best ways for an institution to monitor and educate patients and staff about using various imaging modalities appropriately on children? What are the benefits and drawbacks of each?

**Interviews and Spotlights**
- SNMMI Q&A with Dr. Hossein Jadvar, president-elect of SNMMI for 2015
- ASNC Leadership Q&A with Dr. David G. Wolinsky

**Hospital Spotlight**
Virginia Commonwealth University Health System, Interview with John Duval, CEO

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**COMING IN JULY – WOMEN’S HEALTH ISSUE**

**Industry Sector Reports:**
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- Imaging Center Management
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**COMING IN AUGUST – PARTS & SERVICE ISSUE**

**Industry Sector Report:**
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**HealthCareBusiness news** | MAY 2015 | 87
Leading Age is a not-for-profit trade organization serving 6,000 members who represent organizations across the spectrum of aging services. Leading Age works with most states in the country as well as 30 international partners to develop two-year outcome and 10-year impact goals to advance aging services. Organization members touch four million people every day - most elderly - in a personal way. Larry Minnix, D.Min, has been President and CEO of Leading Age since 2001 and has been an advocate for aging services for more than 40 years. He joined HCBN for a discussion about the impact of baby boomers on future services. Born between 1946, the end of World War II and 1964, U.S. baby boomers number 76 million. The last of the baby boomers will turn 65 in 2029.

**HBCN:** Is the demand for services by baby boomers as unprecedented as many demographers and social scientists have put forth?

Absolutely. Baby boomers are reshaping aging and health services. It’s no longer about selling whatever solution you have to sell, but is much more about what the baby boomer wants to buy. They want value and most of all they want to stay in their homes for as long as possible. Boomers also want to act and feel as young as possible, to have a good quality of life.

**HBCN:** What strategies do Leading Age members have to provide services to the baby boomers?

There are four emerging strategies. The first is insurance products to allow baby boomers to remain in their homes. Under these plans, a concierge service helps people pick and choose the services they want, such as home visits a few times week, all under the senior housing community’s brand. Then, if needed, they become residents in the agency’s community in the future as their physical condition changes. A second strategy is to develop affordable housing to serve elderly people of modest means with all the services needed to keep them living independently and out of the nursing home or hospital. Third is to get seniors enrolled in Medicare health plans that offer acute and post-acute health care services in coordination with their housing support system. And fourth, develop freestanding service and care networks to meet the total needs of the elderly. This means looking at what an older person wants and needs in relationship to their community and family. Are they getting enough to eat and do they have transportation to see the doctor? These, for example, are both important factors in keeping older people healthy.

**HBCN:** More and more of your members who have focused on housing for the elderly are now incorporating health service into their operations. What explains this trend?

Under the new model of the Affordable Care Act (Value-based Purchasing and Population Health Management) housing agencies want the same thing as hospitals and doctors - to keep older adults healthy, out of the hospital, and living at home as long as possible. Leading Age members now proactively design everything from primary care clinics to population health management into their operations to make residents happier and save state programs money on health care costs. It’s common now for state health agencies to help fund senior housing communities with programs to control such chronic conditions as diabetes and falls in order to reduce visits to the ER. This results in fewer hospital admissions, which makes boomers happier and helps control health care costs.

**HBCN:** What advice do you have for hospitals and doctors about baby boomers?

Fall out of love with the way you do things now and fall in love with change. Get to know the housing and public health groups in your market, they can help meet your goals of population health management. The huge fly in the ointment is going to be dementia and Alzheimer’s. It is the most dreaded of conditions and right now affects half of all elders over the age of 85. The way things stand right now, without treatment, every person, family, housing agency and hospital must have an Alzheimer’s plan as the baby boomers move through the system. Think of baby boomers as customers and remember that customers eventually get what they want in the marketplace.

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