

IT needs to be crucial part of healthcare to usher in innovation

By OMAR FORD

Medical Device Daily Staff Writer

ATLANTA – Swirling lights, multiple screens with various news outlets reporting on the future of healthcare in the country, and loud acoustics helped kick off the **Health Information and Management Systems Society** (HIMSS; Chicago) annual conference or HIMSS 10 as it has been dubbed by organizers and participants held here at the Georgia World Congress Center.

The key take away the opening video montage that displayed past comments of President Bush and President Obama on healthcare was that change was just on the horizon. It was a theme that was echoed throughout the day in multiple sessions.

But early yesterday morning, Barry Chaiken, MD, a chairman of HIMSS, kicked off the need for change mantra and wasted very little time spelling out the problems and
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Ultrasonic thrombolysis tech studied for hemorrhagic stroke

By LYNN YOFFEE

Medical Device Daily Staff Writer

Among the emerging stroke treatment trends presented last week at the **American Stroke Association's** (Dallas) International Stroke Conference in San Antonio, Texas, was a relatively new approach for hemorrhagic stroke which combines clot-busting drugs with ultrasound waves to drain bleeding in the brain.

Up to 40% of people who experience a hemorrhagic stroke die within a month. Survivors are often left severely disabled.

David Newell, co-executive director, **Swedish Neuroscience Institute** (SNI; Seattle) presented a small study known as SLEUTH (Safety of Lysis with Ultrasound in the Treatment of Intracerebral [ICH] and Intraventricular Hemorrhage [IVH]) in which tissue plasminogen activator (rt-PA) was delivered through an ultrasound microcatheter
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Washington roundup

Imaging radiation issue seen as addressed by accreditation

By MARK McCARTY

Medical Device Daily Washington Editor

The medical imaging radiation dilemma has taken center stage in the nation's capital in recent days, thanks in part to coverage by the mainstream media, but a hearing of the health subcommittee of the House Energy and Commerce Committee suggests that radiation technologists and other practitioners are the primary point of interest for policymakers and academicians.

Industry may find itself with a requirement to spend more time with customers to keep users abreast of the details of imaging equipment, although the **Medical Imaging & Technology Association** (MITA; Arlington) had unveiled last Thursday an initiative by its members to update CT software to provide a variety of features
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JH researchers develop new scanning tool for melanoma

A Medical Device Daily Staff Report

Johns Hopkins (Baltimore) researchers have developed a noninvasive infrared scanning system to help doctors determine whether pigmented skin growths are benign moles or melanoma, a lethal form of cancer.

The prototype system works by looking for tiny temperature differences between healthy tissue and a growing tumor, according to the Johns Hopkins. The researchers have begun a pilot study of 50 patients at Johns Hopkins to help determine how specific and sensitive the device is in evaluating melanomas and precancerous lesions, Johns Hopkins noted.

The researchers noted that further patient testing and refinement of the technology are needed, but if the system works as envisioned, it could help doctors address a serious health problem. According to the **National Cancer**
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Don't miss today's MDD Extra: Cardiology



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*Report from Europe***PPD opens new contract research facility in Ireland****A Medical Device Daily Staff Report**

PPD (Wilmington, North Carolina) reported that it has officially opened its contract research facility in Athlone, Ireland, which includes an 18,000-square-foot analytical testing laboratory and clinical supplies business. The company said the facility expands the company's global scientific expertise, laboratory capacity and supplies network to meet growing client demand in Europe, Middle East and Africa for these services.

PPD will offer fully integrated product and analytical development services, including method development; validation; stability, release and quality control testing; and global clinical supplies services, including secondary packing, labeling and storage. The facility will also provide regulatory services, product licensing and marketed product support, including qualified person services for all drug dosage forms, with particular emphasis on inhalation and biopharmaceutical products.

The cGMP analytical testing laboratory conducts testing for clinical programs and marketed products spanning all phases of drug development and builds upon more than 20 years of PPD laboratory expertise. It joins the company's scientific and therapeutic experience with state-of-the-art facilities and instrumentation to deliver comprehensive, best-in-class laboratory services.

Expanding our laboratory operations into Europe enables us to continue to deliver on our strong history of providing quality work and customer service to our growing client base in this region," said Magdalena Mejillano, vice president of laboratory services, PPD. "The Irish government, through IDA Ireland, has provided us strong support, and we continue to benefit from Ireland's highly skilled work force and business-friendly climate. We are

**Coming Wednesday
in *MDD Perspectives*****Political chasm over reform effort remains
both deep and wide**

A fair number of Americans gathered in front of their TV sets last week, but not to watch Canada vs. the U.S. in Olympic gold-medal hockey clashes. Rather, they had their eyes glued – some for hours on end – to the so-called Healthcare Summit. What they saw was partisan politics in action, or, more precisely, in inaction. Read about it in tomorrow's edition of *MDD Perspectives*, an op-ed e-zine that provides fresh commentary and opinions on issues that you can't find anywhere else. And best of all, it's free. If you don't already subscribe to this complimentary e-zine, go to medicaldevicedaily.com to sign up.

pleased to join Athlone's strong, growing pharmaceutical and biopharmaceutical sectors."

The facility represents PPD's initial investment toward continued growth of its contract research operations in Ireland, having already expanded its medical communications safety call center operations into Athlone.

PPD has already hired 21 employees in Athlone and plans to create approximately 250 jobs at the laboratory to include Ph.D.-level scientists, analytical laboratory staff and other clinical development professionals. The company is investing up to \$19 million (or 14 million) to develop the facility.

It has applied to the Irish Medicines Board (IMB) for manufacturer licenses to support both investigational medicinal products and marketed products and laboratory certifications for quality control of medicinal products. As of March 1, PPD's license applications have been assessed, and the quality system and premises inspected by the IMB. The progression of PPD's applications are under active

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*Deals roundup***Baxter agrees to acquire
ApaTech for up to \$330M****A Medical Device Daily Staff Report**

Baxter International (Deerfield, Illinois) said it has agreed to acquire all of the outstanding equity of **ApaTech** (London), a private equity-backed, orthobiologic products company, for up to \$330 million.

The agreement includes an upfront cash payment of \$240 million. Baxter may make additional payments of up to \$90 million related to the achievement of sales milestones. The transaction is expected to close in the first quarter, subject to customary closing conditions and expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. This deal is not expected to have a material impact on Baxter's 2010 financial results, the company said.

As a result of the acquisition, Baxter will acquire Actifuse, a silicate substitution calcium phosphate synthetic bone graft material which is currently sold in the U.S., Europe, and other select markets around the world, and manufacturing and R&D facilities in the U.K., U.S., and Germany.

"This is a significant step in enhancing Baxter's position in the rapidly growing orthobiologics space, and our leadership in regenerative medicine," said Ron Lloyd, VP and general manager of BioTherapeutics and Regenerative Medicine at Baxter. "Actifuse will allow us to immediately enter the emerging bone fusion category, and ApaTech's product pipeline is highly complementary to our existing commercial and technical capabilities in biosurgery."

ApaTech generated sales of about \$60 million in calendar year 2009, the company noted. Baxter said personnel from both companies would work to ensure uninterrupted operations, product distribution and ongoing support and service for ApaTech customers, distributors and business partners, and seamless integration of the business into Baxter.

"This is a great event for ApaTech, Baxter, our customers and our employees," said Simon Cartmell, CEO of ApaTech. "The combination of our market presence and insights with the resources of Baxter will enable us to deliver innovative new technologies to more patients worldwide. We are delighted to announce this transaction, and look forward to the future of our combined organizations with confidence and excitement."

In other dealmaking activity:

- **Solta Medical** (Hayward, California), a medical aesthetics company, said it has completed its acquisition of **Aesthera** (Pleasanton, California) for \$5.25 million in Solta common stock and cash, with potential additional base line milestones of \$750,000 for a total consideration of \$6 million. The deal brings together the Isolaz brand of products for the treatment of acne with Solta's brands for


skin tightening and skin resurfacing, Thermage and Fraxel, the company noted.

In addition, there are \$10 million of stretch milestones which would be paid to Aesthera shareholders if Aesthera achieves revenue ranging from \$14 million to \$21 million in the 12 months beginning April 1, Solta noted.

- **AbSorber** (Stockholm) said it is acquiring **NorDiag's** (Oslo, Norway) share of **Olerup** (Vienna, Austria). AbSorber said it is buying the company with **SSP Primers** (Carlsbad, California). After the transaction, AbSorber will own 50% of Olerup and SSP Primers will own the other half.

Olerup is selling the Olerup SSP HLA typing products and AbSorbers transplantation cross match test in the U.S. The American market also includes Canada and South America. Olerup will continue to sell NorDiag's product Arrow on the American market. Olerup has seven employees but will be increased as a consequence of the plans to further improve the presence in the HLA market, the company said.

- **BioMed Realty Trust** (San Diego) said it has acquired two life science buildings comprising roughly 82,400 square feet in Gaithersburg, Maryland. The company bought the property for about \$14.4 million, excluding closing costs. The property is 100% leased to two tenants: **MedImmune** (Gaithersburg), a subsidiary of **AstraZeneca** (London), and **GenVec** (Gaithersburg), a biopharmaceutical company. ■



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*HIMSS notebook***GE launches Qualibria with Intermountain and Mayo****A Medical Device Daily Staff Report**

GE Healthcare (Little Chalfont, UK) reported the launch of Qualibria, its new clinical knowledge platform designed to enable healthcare delivery organizations to improve performance against their quality targets. The company announced the launch Monday at the 2010 annual **Healthcare Information and Management Systems Society** (HIMSS; Chicago) conference in Atlanta.

According to GE, Qualibria gives clinicians more control over patient outcomes by bringing together real-time data from existing IT systems and comparing these data against shared baselines of evidence-based best practices. Qualibria is the result of a multi-year collaboration between GE, **Intermountain Healthcare** (Salt Lake City) and the **Mayo Clinic** (Rochester, Minnesota), the company said.

"As with many healthcare institutions, clinical excellence is a top priority at Intermountain," said Marc Probst, chief information officer of Intermountain. "We partnered with GE to build Qualibria because we needed an innovative platform that would continue Intermountain's history of clinical quality improvement while allowing us to share clinical best practices with other organizations who have a passion for improving their performance. We're very proud of the contributions we've made to Qualibria and we believe that it will allow our institution and countless others to achieve new levels of quality."

GE also reported that Mayo Clinic has agreed to an expanded collaboration on Qualibria. For the last two years, Mayo Clinic has contributed informatics and clinical expertise to build Qualibria's medical terminology management tools, GE noted. The result is a platform that will allow clinical knowledge and best practices to be shared across organizations in a new, open architecture, the company said. Through this expanded collaboration, Mayo Clinic will provide expertise in developing this platform for the delivery of best practice clinical content, including knowledge, protocols, and care guidelines that will be made available to other Qualibria customers.

"At GE, we strive to offer solutions that can help our customers thrive in a performance based world," said Vishal Wanchoo, president/CEO of GE Healthcare IT. "Leveraging the deep clinical knowledge at Intermountain Healthcare and Mayo Clinic, we are confident that Qualibria will allow healthcare institutions to succeed in a performance-based world."

In other news from HIMSS:

- **Motion Computing** (Austin), a provider of integrated mobile computing solutions, reported new peripherals and solutions for its tablet PCs. The new ReadyDock with Ethernet and Mobile Dock with built-in lock for the Motion C5 mobile clinical assistant (MCA) and F5 Rugged Tablet PC

offer more storage, charging and management options while the Motion Medical Dictionary streamlines documentation processes for healthcare professionals, according to the company.

"Adding an integrated Ethernet connection to the ReadyDock provides significant value to the solution's usability in healthcare," said Dan Hurd, co-founder of **Complete Tablet Solutions**, a value-added reseller of Motion Tablet PCs, services and solutions. "Now IT can continuously update and manage the devices without interrupting clinical workflows, efficiently ensuring that the tablets are continuously charged and ready for clinician use."

- **Eclipsys** (Atlanta) reported the addition of an integrated suite of mobility applications designed for the Apple iPhone and Apple iPod touch. The mobility applications are built on Helios by Eclipsys, the company's recently reported open platform. Featuring a differentiating user interface built specific for mobility, constituent-specific devices and native integration with Eclipsys' Sunrise Enterprise suite of healthcare information technology solutions, Eclipsys' mobility applications bring a next-generation approach to smart phone technology in healthcare.

The company said it is previewing its suite of mobility applications this week at HIMSS.

- **Concerro** (San Diego) unveiled its new iPhone application in support of its RES-Q scheduling solution. According to the company, the new iRES-Q iPhone application was designed to allow users of RES-Q Labor Resource Management to view their schedules, self-schedule, request shift swaps and review/request open shifts across all units for which they are qualified to work. The iRES-Q application continually updates and displays the most up-to-date information synchronized with each facility's RES-Q scheduling database, Concerro noted.

- **Welch Allyn** (Skaneateles Falls, New York) is showcasing two products at the meeting designed to address the costly issues of patient vital signs errors and the complexities surrounding electronic health record (EHR) implementation. Designed to help caregivers improve data accuracy and realize greater efficiencies surrounding EHR functionality, the company's Connex Data Management System and new EHR Preparation and Selection Services program will be on display at HIMSS, the company said.

Now available in version 2.0, the company said the Connex system works with a wide range of Welch Allyn devices to capture and document patient vitals easily and accurately. The system sends the most up-to-date patient vitals data to electronic health records, which dramatically reduces the time spent on documentation, reduces errors and minimizes delays. Connex also minimizes the chance of human error by automating patient identification using barcode-driven processes and eliminating the need for

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*Agreements/contracts***iSOFT partners with Lumetra on incident management software****A Medical Device Daily Staff Report**

iSOFT Group (Sydney) reported a strategic partnership with Lumetra PSO, a division of **Lumetra Healthcare Solutions** (San Francisco). Lumetra agreed to provide iSOFT's AIMS incident management software to U.S. healthcare organizations that are seeking to reduce the complexity and cost of their patient safety and risk management programs.

Under the agreement, iSOFT appointed Lumetra PSO to market, support and distribute AIMS in the U.S. PSOs provide consulting services to U.S. healthcare organizations that are seeking to minimize the safety risks of delivering care. Information used by PSOs has been afforded protection by the U.S. Government as healthcare providers seek to better understand and prevent medical errors.

"The PSO market in the U.S. is at an exciting and critical point as healthcare providers seek to partner with PSOs that can help them to understand and address patient safety problems," said Gary Cohen, iSOFT executive chairman and CEO. "The AIMS application is one of iSOFT's key offerings in the important U.S. market. It is proven across organizations such as NSW Health, serving a population of nearly 7 million people in Australia."

AIMS incident management software provides an

integrated electronic solution for collecting, tracking, reporting, and managing patient safety activity. The software captures adverse event and near miss information across acute care, community care, disability care, mental health, and residential aged care. Used by more than 400 Australian hospitals, as well as at sites in South Africa, New Zealand, and the U.S., AIMS includes a standardized classification (taxonomy) that is recognized by the World Health Organization and the U.S. Institute of Medicine.

In other agreements/contracts news:

- **APC Group** (Fairbanks, Alaska) reported that terms have been reached with **Orthoscan** (Scottsdale, Arizona) to provide MedReel's OEM with their new HD Mini C-ARM. APC Group estimates sales over four to five years at \$350,000 globally.

- **Allscripts** (Chicago) said that **Hospital Sisters Health System** (HSHS; Springfield, Illinois) has selected the Allscripts Electronic Health Record and Practice Management solution to automate and connect clinical and business functions for their 130 employed physicians and the more than 3,300 independent physicians affiliated with the health system's 13 hospitals in Illinois and Wisconsin.

- **Greenway Medical Technologies** (Carrollton, Georgia) reported a partnership to supply the company's integrated electronic health record and interoperability solution PrimeSuite to **Take Care Health Employer Solutions** (Deerfield, Illinois), a provider of worksite health and wellness services and pharmacy. ■

*Financings roundup***Awarepoint raises \$10 million for new technology research****A Medical Device Daily Staff Report**

Awarepoint (San Diego), a maker of real-time location systems (RTLS) for U.S. hospitals, said it has raised \$10 million of expansion capital led by Jafco Ventures (Palo Alto, California), and joined by existing investors, Cardinal Partners (Princeton, New Jersey), and Venrock Associates (Palo Alto, California).

"We are very excited to be a part of the Awarepoint team. Awarepoint's dramatic growth, seasoned management team and focus on customer success make it truly unique in the RTLS market. We look forward to supporting the company's continued growth and market leadership in creating an outstanding company for the long haul," said Jafco's general partner Tom Mawhinney.

The capital infusion will be used to accelerate Awarepoint's development of new technology, products and client success capabilities. As part of the financing, Mawhinney of Jafco Ventures will take a seat on Awarepoint's board.

Awarepoint offers location, status, condition and

movement visibility of both equipment and people, allowing for real-time remote monitoring of critical resources in hospitals. Awarepoint's networked Real-time Awareness Solutions include its ZigBee wireless mesh network, application software, firmware, connectivity bridges and multipurpose tag form factors to support asset and people tracking and condition-sensing applications (e.g., temperature monitoring and autoclave cycles).

ZigBee is the wireless language connecting dramatically different devices to work together and enhance everyday life. The ZigBee Alliance is a non-profit association of more than 300 member companies driving development of ZigBee wireless technology.

In other financings news, **Tech Coast Angels** (TCA; Irvine, California), an angel investment network, completed seven rounds of new investment deals and 17 follow-on deals in 2009, raising \$4.7 million through direct Tech Coast Angels investment and an additional \$57 million through other sources of venture capital and angel capital for the network's entrepreneurial companies.

A number of the invested companies in 2009 were in the high technology arena, a TCA focus, however many other markets were represented. Young companies in entertainment, industrial applications, retail,

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HIMSS

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issues that healthcare faces.

To illustrate his point, Chaiken told the story of the inbox and how it has changed throughout its 40 year-existence. Years ago an inbox was considered as a tray where various papers and documents were placed. Now inboxes have grown and are features on a phone or someone's computer. The paper aspect of the inbox, has almost completely been eliminated, Chaiken said.

"The story of the inbox tells the story of the economy of our country," Chaiken said. "The story of the inbox tells of how a manufactured-based-economy transformed to an electronic information-based-economy. But healthcare in many ways remains frozen in time."

Chaiken added that "in many respects, the U.S. healthcare system still operates like the typical business of 1969; it is still largely paper-based, it ignores information tools that can facilitate evidence-based best practices, and it functions without analytics to qualify and quantify the care we provide. Medical decisions are made according to implicit criteria – hidden internal knowledge – rather than explicit criteria – external knowledge that can be checked, evaluated, and updated. He pointed out that "the Dartmouth Atlas of Healthcare provides documented proof of glaring, unacceptable variations in how healthcare is provided and sheds light on disparities existing across the country. Too many providers are not taking advantage of 21st-century technologies to access 21st century information, choosing instead to provide care the same way it was done 40 years ago.

The healthcare system is plagued with inefficiencies that significantly impact its effectiveness, Chaiken told the audience. According to statistics he cited from the **World Health Organization** (WHO; Geneva) U.S. Healthcare costs 50% more per capita than in any other country. He added that the only way to stop this is to have a greater adoption and use of healthcare IT solutions.

"While these healthcare challenges are daunting, I believe the solutions to them must and will come from the professionals sitting in this room and from our colleagues across the country and around the world, he said. "Healthcare information technology is the instrument that will transform healthcare and it is we – the informaticists, clinicians, management engineers, senior IT executives, IT specialists and the diverse talents of so many others – who will create the applications, processes and workflows that will improve quality, safety, access and cost-efficiency."

Chaiken told the audience that they would be at the forefront in developing technologies that would help bring healthcare into the 21st century.

"It's no longer about what others are doing or have done," Chaiken said. "It is you who will transform healthcare. It's your job to act now upon the message in your inbox and to place your contribution to a transformed

American healthcare system in your outbox in due time."

Keynote Speaker Dan Hesse CEO of **Sprint** (Reston, Virginia) said that he couldn't agree more. Hesse, who spoke after Chaiken, said that the coming year was going to bring wireless patient monitoring to the forefront and the adoption of a 4G communications network was going to change the landscape of how medicine is practiced in general.

The term 4G refers to the fourth generation of cellular standards.

"Now what if I had been talking to you about wireless in 1986," Hesse asked. He then picked up a huge cell phone from that era to illustrate his point. "You would've laughed me off the stage."

He then picked up a smart phone, which fit in the palm of his hand.

"The cell phone is the most rapidly adoptive technology on this planet and its presence is growing in healthcare," Hesse said.

He pointed out that the inclusion of applications with cell phone is helping this change take place and is transforming healthcare.

"Have you ever accidentally coughed into your cell phone? Well you might want to on purpose because there is now an (application) that can analyze the cough," he said.

Hesse also mentioned that there was an application called Flu Radar, which gives helpful tips regarding the disease.

But beyond applications, perhaps the most transformative piece of technology to revolutionize healthcare will come from a physician's increased ability to remotely monitor patients.

Hesse held up a pill and said that in the future, smart chips could be added to the pill and once it was ingested it would give the physician the ability to monitor if a patient is taking their medicine or not, or what kinds of issues the patient would suffer from.

These chips could be added to pretty much anything and provide wireless connectivity," Hesse told the audience.

"As the population grows we believe that home healthcare will grow," he said. The 4G network will help with that because it will bring in a higher resolution for imaging at greater speeds."

Hesse said that while much has changed with wireless technology since 1986, even greater changes are coming in the next few years. He urged the audience to seek out innovation and look for even better ways to improve the healthcare industry.

"Healthcare faces what I believe is a once in a lifetime combination," Hesse told the audience. "It faces great challenges and great opportunities. Even the best technology company can't seize that opportunity on its own. We need all of you to take part in this." ■

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Thrombolysis

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directly into spontaneous IVH or ICH to facilitate evacuation of the hemorrhage with the aid of ultrasonic waves.

"If you Google sonophoresis [using ultrasound to increase drug absorption] there are two decades of research," Robert Hubert, president/CEO of **Ekos** (Bothell, Washington), the company behind the study and ultrasonic accelerated thrombolysis technology, told *Medical Device Daily*. "The science is extremely well vetted. Clots are made of fiber and strands; a tightly woven substance. When you apply rt-PA it has to go to a receptor. Ultrasound opens up the clot and thins out the fiber and strands and makes it porous so when the drug hits the clot you have more surface area. Ideally if you can get the drug to all receptor sites immediately, you can dissolve the clot."

Newell reported that 35 patients presented at SNI with ICH and IVH who were screened between November 2008 and July 2009 for entry into the study. Entry criteria included the spontaneous onset of ICH and/or IVH producing ventricular obstruction. Nine of the patients who met the entry criteria were entered into the trial.

A ventricular drainage catheter and an ultrasound microcatheter were stereotactically delivered together, directly into the IVH or ICH. rt-PA and 24 hours of continuous ultrasound were delivered and gravity drainage was performed. In patients with IVH a total of 3 mg of rt-PA was injected, and in patients with intraparenchymal hemorrhages a total of 0.9 mg rt-PA was injected, in three doses over 24 hours.

All of the patients had significant volume reductions of the treated hemorrhage. The mean percentage volume reduction after 24 hours of treatment, compared to the pre-treatment stability scans, as determined by CT, were 59% for ICH and 45% for IVH. One ICH patient was excluded from analysis due to catheter breakage.

There were no intracranial infections and there were no significant episodes of re-bleeding by clinical or CT assessment. One patient died within 30 days after admission.

"The data are pretty compelling," Hubert said. "I would suggest that we move further with this as a result. We will now develop a device specific to hemorrhagic stroke. Today there is no good therapy for hemorrhagic stroke. When you contrast it to ischemic stroke, the patient needs to be treated within six to eight hours. With hemorrhagic, it's the pressure from bleeding that does the damage and data show you can delay therapy up to 72 hours, so patients have a lot more time to get to the hospital for treatment."

In a more remarkable case that was part of the study, and a best result, a police officer, age 38, was enrolled at 71 hours post stroke.

"A couple of weeks later, he walked out of the hospital and is now back on the job," Hubert said. "It's very encouraging. It's a small study and now there needs to be a larger study. This could be a major paradigm shift in how we treat stroke.

The technology and the science are well grounded. Nobody disputes that ultrasound has a positive effect."

Ekos developed the same technology it uses for peripheral vascular disease for stroke.

"We took the ischemic catheter and used it for hemorrhagic using image guidance and then delivered rt-PA," Hubert said. "But it's not ready for prime time or the average surgeon. We will likely start development [of the final product] in a month and in 18 months we'll have a product. We may have a couple of iterations come out to start some trials sooner."

The company's technology is already being used successfully in peripheral vasculature with more than 16,000 devices sold. ■

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transcription of vitals signs data, Welch Allyn said. As a result, the typical hospital med/surg floor can save hours of documentation time daily, allowing for more time for caring for patients.

- **Merge Healthcare** (Milwaukee) introduced its Merge Patient Kiosk and deployed this new patient engagement tool in several imaging centers in the U.S. According to the company, the Merge solution combines the best of kiosk technologies already present in other industries and the specific requirements of healthcare consumers to create a new way for imaging practices to stay connected to their customers.

- The Enterprise Mobility Solutions division of **Motorola** (Schaumburg, Illinois) reported its newest advanced data capture solution for healthcare – the_DS6878-HC cordless 2D imager. According to the company, the product extends the access of critical information to the patient's bedside, the nurse's station, operating room and beyond with the highest levels of reliability and performance. Specifically designed to withstand the rigors of everyday use in demanding healthcare environments, the DS6878-HC helps to prevent medical errors, improve patient safety and increase caregiver productivity by providing real-time and convenient access to information, Motorola said.

The device is also designed to reduce the spread of germs and protect patients and caregivers against dangerous and deadly illnesses, the company said. ■

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Will FDA resume imaging facility audits?

One of the topics that arose during Friday's hearing in the House Energy and Commerce's health subcommittee was the mammography quality standards regulations, a series of regulations that went into effect in 1994. This series of rules is widely credited for having ramped up enforcement and compliance for issues such as image phantom quality control and technician licensure. However, it appears that FDA's oversight has either resulted in much better compliance over the past few years or that this oversight has flagged in the past decade.

FDA issued only four warning letters in all of 2009 that are labeled by the agency as dealing with mammography quality standards, a sharp drop from the dozens the agency hammered out every month toward the beginning of the decade. In just the month of February 2002, the agency dropped warning letters on at least 15 mammography clinics, citing them for violations ranging from personnel who did not obtain the required number of continuing medical education credits to lack of a system to provide timely medical reports and lay summaries of imaging studies. However, it should be pointed out that FDA had help from state and local jurisdictions in conducting these inspections.

FDA also has a history, however lean, of inspecting other radiological facilities, and at least one regulatory consulting attorney believes the agency will soon resume such inspections. John Manthei, a partner in the regulatory law firm of **Latham & Watkins** (Washington), said makers of radiological equipment can expect more inspections and more warning letters for their installed units. "This FDA has

promised greater enforcement, and they've delivered," he said, adding, "there will be more warning letters and I think industry needs to be prepared for that."

An example of perhaps the most relevant warning letter in the context of CT equipment that is inspected on site is the letter dated Oct. 31, 2002, to **General Electric Medical Systems** (Pewaukee, Wisconsin), which cites the company for findings associated with a field test of an X-ray machine in a healthcare setting. Information on the model number and the location of the installation were redacted. Among the findings in this warning letter is that X-ray production "was possible with the primary protective barrier in the park position (outside of the primary X-ray beam)."

A warning letter addressing a different function for X-radiation equipment is the Nov. 30, 2001, letter to **Perkin Elmer Instruments** (Long Beach, California) for a tabletop screening system for packages and bags installed in a prison in Yankton, South Dakota. The agency has also exerted jurisdiction over laser light shows, as the Feb. 5, 2001, warning letter to **Lowell Products** (Marysville, Washington) indicates.

FDA wrote **Omega Medical Imaging** (Sanford, Florida) an Aug. 4, 2000, warning letter dealing with the firm's cardiac imaging systems, but this letter is alone in a category dealing with cardiac and vascular imaging systems, while **Control-X Medical** (Columbus, Ohio) sits alone in the category of "diagnostic X-ray equipment/Altered" thanks to an April 18, 2001 warning letter.

FDA was unable to respond to calls for comment on whether the agency intends to resume such inspections, but promised to provide an update.

— Mark McCarty, Washington Editor

Washington

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intended to ward off accidental overexposure (*Medical Device Daily*, March 1, 2010). Recent events may also spur FDA to reinvigorate its on-site inspections of radiological equipment, a point of enforcement that has ebbed over the past few years if the number of warning letters is any indication (*see sidebar above*).

One of the oft-heard recommendations during last Friday's hearing, that of a schedule of standard, procedure-determined doses, may prove more difficult to forge than might be commonly appreciated inasmuch as variable factors, such as body mass, can decidedly torque the required radiation dosage for a procedure.

Rep. Frank Pallone (D-New Jersey) stated at the beginning of Friday's hearing, "I was reading in the *New York Times* a front page story about a radiation oncology group that raised a lot of the issues." He added, "particularly disturbing is the fact that this group practice apparently had physicians who were overseas and were billing on the assumption that those physicians were present" while services were rendered, although it was not clear from his

remarks what procedures were involved.

Pallone acknowledged that "medical radiation has saved lives," adding that it is "important that patients not stop getting their treatments" over the issue. The hearing, he said, was "to examine what the driving factors are when things go wrong." While "the benefits are enormous," he said, CT procedures "can deliver as much radiation as 300 chest X-rays," adding that in his view, "a procedure with such a small margin of error should be stringently monitored."

Pallone also noted that it is "shocking to me that individuals in many states" do not have to be licensed to perform radiological procedures. He also claimed that enforcement is sometimes lacking in states where licensure is mandatory.

"The problem could be that no single agency" has jurisdiction over radiological practice, Pallone said, adding that he is unaware of any guidelines "especially in terms of radiation dosage and lifetime exposure."

Pallone also highlighted the dilemma of duplicate scans, a subset of redundant procedures that are seen as a huge driver of excess healthcare costs. "I know from my

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Melanoma

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Institute (Bethesda, Maryland), nearly 68,720 new cases of melanoma were reported in the U.S. last year and about 8,650 deaths were attributed to the disease.

According to the Johns Hopkins researchers, doctors look for subjective clues such as the size, shape and coloring of a mole in order to identify a mole that may be melanoma – but the process is imperfect.

“The problem with diagnosing melanoma in the year 2010 is that we don’t have any objective way to diagnose this disease,” said Rhoda Alani, adjunct professor at the Johns Hopkins Kimmel Cancer Center and professor and chair of dermatology at the **Boston University School of Medicine**. “Our goal is to give an objective measurement as to whether a lesion may be malignant. It could take much of the guesswork out of screening patients for skin cancer.”

With this goal in mind, Alani teamed with heat transfer expert Cila Herman, a professor of mechanical engineering in Johns Hopkins’ Whiting School of Engineering. Three years ago, Herman obtained a \$300,000 **National Science Foundation** (Arlington, Virginia) grant to develop new ways to detect subsurface changes in temperature. Working with Muge Pirtini, a mechanical engineering doctoral student, Herman aimed her research at measuring heat differences just below the surface of the skin.

Because cancer cells divide more rapidly than normal cells, they typically generate more metabolic activity and release more energy as heat, the researchers said. To detect this, Herman uses a highly sensitive infrared camera on loan from the Johns Hopkins Applied Physics Laboratory. Normally, the temperature difference between cancerous and healthy skins cells is extremely small, so Herman and Pirtini devised a way to make the difference stand out. First, they cool a patient’s skin with a harmless one-minute burst of compressed air. When the cooling is halted, they immediately record infrared images of the target skin area for two to three minutes. Cancer cells typically reheat more quickly than the surrounding healthy tissue, and this difference can be captured by the infrared camera and viewed through sophisticated image processing, the researchers said.

“The system is actually very simple,” Herman said. “An infrared image is similar to the images seen through night-vision goggles. In this medical application, the technology itself is noninvasive; the only inconvenience to the patient is the cooling.”

The pilot study is designed to determine how well the technology can detect melanoma. To test it, dermatologist-identified lesions undergo thermal scanning with the new system, and then a biopsy is performed to determine whether melanoma is actually present.

“Obviously, there is a lot of work to do,” Herman said. “We need to fine-tune the instrument – the scanning system and the software – and develop diagnostic criteria for

cancerous lesions. When the research and refinement are done, we hope to be able to show that our system can find melanoma at an early stage before it spreads and becomes dangerous to the patient.”

Alani, the skin cancer expert, is also cautiously optimistic.

“We, at this point, are not able to say that this instrument is able to replace the clinical judgment of a dermatologist, but we envision that this will be useful as a tool in helping to diagnose early-stage melanoma,” Alani said. “We’re very encouraged about the promise of this technology for improving our ability to prevent people from actually dying of melanoma.”

Ultimately this research could lead to a hand-held scanning device that dermatologists could use to evaluate suspicious moles. The technology also might be incorporated into a full-body-scanning system for patients with a large number of pigmented lesions, the inventors said. ■

Financings

Continued from Page 5

communications, healthcare, biotechnology and even home improvement received investment dollars.

According to Richard Sudek, TCA chairman, “We want entrepreneurs to know that there is still a vibrant investment environment in Southern California. We take our responsibility to foster and develop new enterprises very seriously.”

While the total investment money available in 2009 declined from the previous year and fewer new deals were completed, 2009 actually saw an increase in the number of follow-on investments. Sudek said, “Clearly our members feel deeply committed to our invested companies and believe in their growth. We not only continue to raise money for them, we also provide day-to-day operating assistance and mentoring that company executives tell us often make the biggest difference in their success.” ■

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Washington

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own experience that healthcare providers are quick to order another CT scan" without discussing lifetime exposure with the patient, Pallone said, noting that when he was helping his mother through her cancer, physicians would tell Pallone that her scans from other providers were useless. "Nobody would actually use the previous one. They always had a reason why they couldn't use it," he commented. He closed by musing that some overuse is a driver of excess healthcare costs, but added, "I have to wonder if there are not health implications as well."

Pallone finished the hearing by telling the witnesses who appeared, "as valuable as your responses were, I felt that we ended up with more questions," meaning that the committee is "going to have to have an additional hearing," especially given the ramifications of recent events on pending legislation.

Pallone made reference to the CARE (Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy) Act of 2009 (H.R. 3652), authored by Rep. John Barrow (D-Georgia), a bill the intent of which is to impose accreditation standards for all who practice imaging that is billed to Medicare. The bill is purported to call for standards for all imaging, rather than just the 30% said to be covered by similar requirements imposed by the Medicare Improvements for Patients and Providers Act of 2008.

One of the witnesses at Friday's hearing was James Parks of Gulfport, Mississippi, who told the panel about his son Scott, who "died from an overdose of radiation by a team of inept therapists," describing Scott's fate as "a horrible way to die."

Scott Jerome-Parks was the subject of the Jan. 24 article appearing in the *New York Times*, which spurred Pallone's interest in the subject. Jerome-Parks died in 2007 after radiological treatment for tongue cancer resulted in a lethal dose of radiation delivered via intensity-modulated radiation therapy at **St. Vincent's Hospital** (New York) in 2005.

"What was to be a minimally invasive procedure turned out to be a nightmare for the whole family," James Parks said, adding that Jerome-Parks "rapidly became blind and deaf, had constant pain and vomiting. His jaw was calcifying and his teeth were falling out," he added.

Steven Amis, Jr., MD, of the **American College of Radiology** (Reston, Virginia), told the committee that "a formal accreditation process must be mandatory" for all radiological services performed in hospitals and freestanding imaging facilities. These standards, he said, should "encompass all clinical settings and radiation therapy modalities," and he voiced support for the CARE Act.

"Since CT scans are a growing source of exposure," Amis said, a CT registry might be appropriate "A required dose index registry would be a critical new component that could measure ongoing performance of the accreditation

baseline and may have helped identify many of the problems covered in media reports far sooner," Amis contended. He also said ACR "has been working with industry to develop such a registry but a congressional mandate would aid this process." ■

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Europe

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consideration by the IMB.

PPD is a global contract research organization that provides discovery and development services. Its clients and partners include pharmaceutical, biotechnology, medical device, academic and government organizations.

NovaStent gets CE mark for SAMBA stent

NovoStent (Mountain View, California) reported that it has received the CE mark for its SAMBA Stent and Delivery System for the treatment of peripheral artery disease. The SAMBA Stent was designed to treat the highly varied presentation of atherosclerotic disease in the superficial femoral (SFA) and popliteal arteries by providing a unique combination of strength, flexibility and vessel coverage.

CE mark approval was supported by data from NovoStent's SAMBA trial which enrolled patients in Germany in 2009. Partial 6-month results of the SAMBA trial were presented in January at the International Symposium on Endovascular Therapy by Michael Dake, MD, of the **Stanford University** (Stanford, California) School of Medicine. Lesions treated in the trial included a wide spectrum of disease such as total occlusions, eccentric calcified plaque, ulcerating lesions and thrombotic occlusions. Also included in the trial were several isolated popliteal lesions. Physicians typically avoid placing stents in the popliteal artery for fear of stent fracture.

MiMedX garners CE mark for HydroFix

The **MiMedx Group** (Marietta, Georgia) reported that it received the CE mark for its HydroFix Spine Shield device and was certified for design, development, and production of post-surgical adhesion inhibiting barriers. The HydroFix is indicated for use in specific locations as a cover of the spine to provide a plane of dissection during a revision surgery. The proprietary, patented, and biocompatible polyvinyl alcohol polymer (PVA) membrane may reduce the risk of injury that may be associated with anterior vertebral surgeries. By covering the spine at the surgical repair site in anterior spine surgeries, HydroFix Spine Shield creates a plane of dissection for revision surgeries.

The HydroFix is a permanent and biocompatible implant that is suitable as an adhesion inhibiting barrier or plane of dissection between anatomical structures. ■

Product Briefs

- **Citius Tech** (Sarasota, Florida) reported the launch of BI-Clinical MUSE – an enhanced version of its healthcare business intelligence framework. BI-Clinical stand for “Meaningful Use” Analytics & Reporting compliance. The BI-Clinical framework provides an integrated approach for clinical, operational, financial and regulatory performance management in healthcare for hospitals, physician practices and managed care organizations – covering over 600 measures. BI-Clinical hospital module includes acute care reporting (e.g., AMI, pneumonia and stroke) and measures for CMS, JCAHO, P4P, and NCQA. Citius Tech practice areas include healthcare software engineering, healthcare interoperability, healthcare business intelligence and CRMM. Citius Tech says it brings strong healthcare domain expertise – across technologies, applications and standards.

- The **Cook Medical** (Bloomington, Indiana) Hercules 3 Stage esophageal balloon has received FDA clearance and CE mark certification for the treatment of gastrointestinal strictures. The Hercules 3 Stage Esophageal Balloon is made with P.E.T. FLEX technology, a new material that optimally combines the high tensile strength and flexibility necessary for a strong balloon that inflates accurately to three distinct and increasing diameters. Already available as a non-wire guided balloon, Hercules has been used by clinicians to successfully treat benign and malignant strictures in the esophagus. With the addition of the wire-guided version, Cook says it now offers a Hercules Balloon option for the entire GI tract including the pylorus, duodenum and colon. GI strictures are treated endoscopically by passing a deflated balloon into the strictured area, inflating it to dilate the passage, and then deflating and removing the dilator. A balloon dilator can also be used to open the lumen so other procedures can be performed, such as biopsies or stent placement. The preloaded wire-guided Hercules dilator facilitates the navigation of narrowed passageways.

- **Corindus Vascular Robotics** (Natick, Massachusetts) said that its CorPath vascular robotic system was the subject of a podium presentation last week at ‘CRT 2010’ by George Vetrovec, MD, of Virginia Commonwealth University Medical Center, in which he concluded that CorPath “can potentially raise the standard of care in PCI by improving standardization, reproducibility and accuracy” of the procedure. The Corpath system precisely drives coronary guidewires and stent/balloon catheters during percutaneous coronary intervention procedures performed in a cath lab. “The CorPath vascular robotic system can potentially foster a new standard of care for precise stent deployment—which is a big challenge today due to the limited precision associated with manually controlled PCI procedures,” said Vetrovec.

- **Emdeon** (Nashville, Tennessee) reported the introduction of a mobile application for its medical claim management platform Emdeon Vision. The Emdeon Vision

Mobile application offers healthcare providers an on-the-go snapshot of their claims and related cash flow and is compatible with the iPhone, Android, Windows Mobile, Palm and many other “smart” portable devices. Emdeon Vision for Claim Management is a web-based program that enables end-to-end visibility of healthcare claims from the point of submission to Emdeon through payer adjudication as well as fifteen months of historical claims data. It can be used in a standalone mode but may also be integrated with a number of leading physician office systems. Emdeon Vision Mobile is an extension of the web-based program and offers healthcare providers a quick glimpse into the claim management side of their practice from their portable handheld device.

- **TomTec** (Hamden, Connecticut) will be exhibiting their multi modality CPACS solution Image-Arena at HIMSS in Atlanta. Image-Arena is a scalable solution for cardiovascular imaging and reporting to meet the needs of hospitals, and group practices. Existing IT infrastructures (i.e. PACS, HIS) can be used resulting in efficient workflow scenarios available for on- and off-site image and report distribution. The web-based reporting solution helps practices create high-quality medical procedure reports.

- **TriReme Medical** (Pleasanton, California) has received FDA clearance for the Glider balloon catheter, for percutaneous transluminal angioplasty (PTA) of lesions in the peripheral vasculature including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. The Glider PTA catheters have shaft construction reinforced for torque transmission and an a-traumatic tapered tip configuration. Designed to be delivered through the complex peripheral anatomy to cross long and tight lesions and to restore blood flow in the vessels, Glider PTA catheters provide physicians a powerful new tool to treat patients with PAD.

People in the News

- **Cardima** (Fremont, California) has named Peter Wong, MD, to the board. Wong is a professor at the University of British Columbia, Faculty of Medicine with a specialization in pediatric clinical neurophysiology. Cardima makes diagnostic catheters.

- **Delcath Systems** (New York) has named Michael Dellario to the newly-created position of VP, Global Marketing. Dellario was most recently a marketing consultant for startup medical companies in the early stages of marketing development. Delcath Systems makes a treatment method for primary and metastatic cancers to the liver.

- The **West Wireless Health Institute** (San Diego) said that Amir Jafri has joined the Institute as its COO. Jafri joins WWHI from Cardinal Health. West Wireless Health Institute is a medical research organization that seeks to cut the cost of health care by identifying, creating, validating and accelerating the use of wireless technologies to transform medicine.

MDD'S CARDIO EXTRA

ADDITIONAL DEVELOPMENTS IN ONE OF MED-TECH'S KEY SECTORS

TUESDAY, MARCH 2, 2010

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Keeping you up to date on recent headlines in cardiovascular healthcare.

Study reinforces value of MTWA to identify patients at risk of SCD . . .

Cambridge Heart (Tewksbury, Massachusetts) said that results of a clinical study presented at the 29th annual scientific meeting of the **Belgian Society of Cardiology** (Brussels, Belgium), reinforce the value of the Microvolt T-wave Alternans (MTWA) as an accurate non-invasive test to identify patients at risk of arrhythmic events and sudden cardiac death (SCD). The study, conducted at **Jolimont Hospital** (Haine Saint Paul, Belgium), prospectively evaluated MTWA in 73 consecutive patients who met criteria for implantable cardioverter defibrillator implantation for primary prevention of SCD. At a mean follow-up time of 39 months, the incidence of arrhythmic events in patients with an abnormal MTWA test was 7.6 times that for patients who tested negative. SCD was 4.8 times more common in those with an abnormal MTWA result. "The aim of the study was to find a test with a very good predictive value in terms of life-threatening arrhythmic events," said Antoine de Meester, MD, lead author of the study. "Results show that Microvolt T-wave Alternans is that test."

HeartWare concludes patient enrollment in ADVANCE trial . . . Heart-

Ware (Farmingham, Massachusetts and Sydney, Australia) reported the conclusion of patient enrollment in its ADVANCE trial. The FDA approved IDE study is designed to evaluate the HeartWare Ventricular Assist System as a bridge to heart transplantation for patients with end-stage heart failure. The primary endpoint of the trial is survival at 180-days, defined as alive on the originally implanted device or transplanted or explanted for recovery. Secondary endpoints include adverse events such as bleeding and infection, as well as functional status, hospitalization, assessment of neuro-cognitive function and patient quality of life. "We witnessed a growing enthusiasm from investigators during this study, and we are grateful for their continued support," said HeartWare President/CEO Doug Godshall. "We also had an unexpected acceleration to the completion of the enrollment phase of the trial. During routine discussion with the FDA, we were asked to change the definition of 'enrolled' in our IDE protocol to include patients who were consented to enter the trial, as opposed to those who were consented and met all inclusion and none of the exclusion criteria. With two additional implants scheduled, this modification will result in 30 U.S. clinical sites implanting a total of 140 patients, making ADVANCE the largest bridge-to-transplant pivotal trial to date." The company expects the final patient to reach the 180-day follow up by the end of August. As a result, HeartWare said it now anticipates submitting a PMA application to the FDA in early December, rather than late December or early January as the company had previously said. HeartWare is seeking FDA approval to implant additional bridge-to-transplant patients under a continued access protocol (CAP) in any U.S. center that implanted a patient under the trial. While there is no guarantee that a CAP will be granted, the FDA has allowed CAPs following full enrollment in prior VAD trials, as it makes the technology available to patients and clinicians while also providing additional safety data for the FDA to evaluate, the company noted.

Study does not support use of platelet function tests to guide clinical practice in low-risk patients undergoing PCI . . .

An analysis of six tests that are used to measure platelet function and help gauge the effectiveness of antiplatelet drugs for patients undergoing a cardiac procedure such as a coronary stent implantation found that only three of the tests were associated with a modest ability to predict outcomes such as heart attack or death, according to a study in the Feb. 24 issue of the *Journal of the American Medical Association*. Dual antiplatelet therapy with aspirin and clopidogrel (antiplatelet agent used to inhibit blood clots) reduces vascular obstruction complications in patients undergoing percutaneous coronary intervention (PCI; procedures such as balloon angioplasty or stent placement used to open narrowed coronary arteries) with stenting. However, the individual response to dual antiplatelet therapy is not uniform, according to background information in the article. There currently is no consensus regarding the most appropriate method to quantify the magnitude of effect an antiplatelet agent may have on platelet reactivity. Nicoline Breet, MD, of **St.**

Antonius Hospital and **St. Antonius Center for Platelet Function Research** (Nieuwegein, the Netherlands), and colleagues conducted a study to evaluate the ability of multiple platelet function tests to predict atherothrombotic events, including stent thrombosis (blood clot within the stent), in 1,069 clopidogrel-pretreated patients undergoing elective coronary stent implantation. Using blood samples, platelet reactivity was measured in parallel with six platelet function tests. The primary outcome measured was a composite of all-cause death, nonfatal heart attack, stent thrombosis and ischemic stroke. The researchers found that at one-year follow-up, the primary outcome occurred more frequently in patients with high platelet reactivity when assessed by the tests light transmittance aggregometry, VerifyNow and Plateletworks, which also had modest ability to discriminate between patients having and not having a primary event. The three other testing methods (IMPACT-R, Dade PFA collagen/ADP, and Innovance PFA P2Y) were unable to discriminate between patients with and without the primary outcome, according to the authors. None of the tests identified patients at risk for bleeding. "In conclusion, of the platelet function tests assessed, only light transmittance aggregometry, VerifyNow, and Plateletworks were significantly associated with the primary end point. However, the predictability of these three tests was only modest. None of the tests provided accurate prognostic information to identify patients at higher risk of bleeding," the authors wrote. "Thus, [this study] does not support the use of platelet function testing to guide clinical practice in a low-risk population of patients undergoing elective PCI."

High-risk cardio patients in Australia undertreated in general practice, study shows . . .

According to a study published in the *Medical Journal of Australia*, patients at high risk of a cardiovascular event are substantially undertreated in Australia. Emma Heeley, MD, senior research fellow at the **George Institute for International Health**, and her co-authors conducted a nationally representative, cross-sectional survey of 322 GPs, who were asked to collect data on cardiovascular disease (CVD) risk factors and their management in 15-20 consecutive patients aged 55 years and over. Their study found low uptake of absolute risk-based care in general practice, with just 63% of GPs reporting using CVD risk calculators. There were also substantial differences between patients' CVD risks as perceived by GPs and when calculated using Framingham risk equations and different guideline adjustments, leading GPs to underestimate their patients' absolute risks. "The AusHEART study shows that large evidence-practice gaps exist in primary and secondary prevention of CVD for older Australians," Heeley said. Of the 1,548 patients with established CVD, only half were prescribed a combination of a blood pressure-lowering medication, a statin and an antiplatelet agent, despite evidence for the benefit of this combination of therapy being well established in this group, Heeley said. "When stratified by absolute risk category, around two-thirds of patients at high risk of a first CVD event were not prescribed a combination of a BP-lowering medication and a statin," she said. Heeley said the findings were not only related to individual clinicians; they were also attributable to system failure. "Because around 85% of Australians visit a general practitioner every year, primary care is the ideal setting for CVD prevention . . . A stronger effort to rationalize the many guidelines for assessment and management of CVD risk factors is needed, accompanied by simple tools to help general practitioners implement them," Heeley said. The study authors recommend that GPs assess the absolute CVD risk of their older patients and ensure that high-risk patients receive evidence-based pharmacotherapy.

**– Compiled by Amanda Pedersen, MDD Staff Writer
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