Exclusive Q&A with SNMMI 2017-2018 President Dr. Bennett Greenspan

Also in our Molecular Imaging issue

HOSPITAL SPOTLIGHT: MEMORIAL SLOAN KETTERING CANCER CENTER p. 26

PET GROWS AS SPECT ADAPTS
• Manufacturers are seeing tremendous expansion in the PET market with new opportunities in neurology and cardiology p. 50

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Will you be at SNMMI this year?

Not to take anything away from the other themes in our editorial calendar, but I have to say that molecular imaging is one of the, if not the single, most exciting imaging specialties in health care today.

Obviously, it’s no coincidence that we delve into these subjects just in time for the annual SNMMI meeting.

There is so much to talk about in molecular imaging and nuclear medicine and what we cover in the following pages can only offer a small glimpse at the wide range of discussions that will be taking place June 10-14 in Colorado.

Among other things, in these 96 pages you will discover the trends shaping the clinical PET and SPECT marketplace, the one-two punch of theranostics for both imaging and treating disease and the just-plain-cool potential of a whole-body PET scanner being conceived by a team of forward-looking researchers at UC-Davis.

Our Molecular Imaging Rewind, a section in which we recap a few major headlines over the last year, tells the story as well as any other section in the magazine: this is a rapidly evolving health care segment with seemingly endless potential.

In these pages you’ll also find our exclusive Q&A with Dr. Bennett Greenspan, the new SNMMI president. Read it to get his views on the ongoing Technetium-99m SPECT isotope supply uncertainty, as well as the major initiatives the society is currently focusing on and what Bennett is most excited about regarding the meeting.

We will have our senior correspondent, John Mitchell, attending the show on behalf of HealthCare Business News. In addition to being well versed in the forces impacting molecular imaging, John also happens to be a Colorado resident, so he was an obvious choice. If you’re attending SNMMI, look for John and let him know what you’ve found most interesting at the show.

We count on you, our readers, to make sure we’re covering the news that matters most to you. You can also just send me an email ... about molecular imaging or anything else for that matter.

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Top trending headlines
As we went to print:

- Varian unveils Halcyon linac for simplified, efficient radiotherapy
dotmed.com/news/story/37114

- Siemens reports progress with ultrasound business 'turnaround'
dotmed.com/news/story/37284

- Congressional hearing on ISO registration: What you missed
dotmed.com/news/story/37064

- Nuclear cardiology lab cuts radiation dose by 60 percent in past eight years
dotmed.com/news/story/37144

- Siemens mulls Healthineers spinoff plans
dotmed.com/news/story/37088

- Prostate cancer patients would pay $2,000 more for better, MR-US, biopsies
dotmed.com/news/story/36972

- Senate FDA user fee package excludes ISO registration
dotmed.com/news/story/37199

- GE and Partners HealthCare forge 10-year AI collaboration
dotmed.com/news/story/37343

- Alzheimer’s trial to study opening blood-brain barrier with focused ultrasound
dotmed.com/news/story/37054

- Elekta’s MR radiotherapy system Unity unveiled at ESTRO
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- Siemens Healthineers, Imricor form strategic partnership
dotmed.com/news/story/37159

- ISOs and HTMs across the U.S. issue strong opposition to FDA registration proposition
dotmed.com/news/story/37346

- GE to deliver 700 advanced health care units to Egypt’s hospitals
dotmed.com/news/story/37197

- Global artificial intelligence in health care market to hit almost $8 billion in 2022
dotmed.com/news/story/37083

- Trump’s DOJ sues UnitedHealth Group over Medicare payments
dotmed.com/news/story/37037

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Canon's Toshiba Medical Systems setting the stage for bigger health care market share

Since its 2016 Toshiba Medical Systems acquisition, Canon executives in major markets have been stressing that the synergy from the deal will put the company in a position to take on world leaders in the health care equipment and information technology sectors.

At a medical imaging trade show in Yokohama, Toshio Takiguchi, president of Toshiba Medical, told Nikkei Asian Review, “we hope to address the expanding variety of health care needs around the world by combining technologies.”

He added that, “synergies are significant in research and development, as well as production technology,” noting that the medical division should benefit from Canon’s existing expertise in image processing for a number of projects now on the drawing board, including one to find metastatic cancer, due to be launched in late 2017.

The Canon buy could inject new growth into the Tokyo-based firm, which has relied on camera and office equipment for much of its history — both sectors that have lacked growth momentum of late.

“It’s like starting a new business, so we don’t expect it to earn so quickly,” Canon CEO Fujio Mitarai said of the $6 billion deal.

While there may be some catch-up to be played to equal scanning leaders GE, Siemens and Philips, Takiguchi suggested that in IT, his team is already competitive. Toshiba Medical showed a cloud-based diagnostic image management system at the Yokohama show.

That is key because many believe that the next big leap forward for medical equipment will not be based on evolution of the technology as much as on interconnectivity and IT-related developments.

“We will enter a new stage of competition due to digitization,” Soichiro Tada, president of GE Healthcare Japan, told the Asian Review, as the company unveiled an efficiency-boosting service based on operating-rate analysis at the trade fair.

The new emphasis by Canon on Toshiba Medical Systems was also underscored by Asian Review reports in early April that the division had been raised to “core status” when Takiguchi was put in the top spot of the medical group, and also made a senior managing executive officer at Canon.

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U.S. urgent care clinic market hit $15 billion this year

The U.S. urgent care clinic market has risen from about $11.8 billion in 2011 to over $15 billion this year, according to a market report from Kalorama Information. There are more than 10,000 clinics in the country.

UCCs first appeared in the 1970s and have grown since then due to rising health care costs and the demand for convenient care.

Many health systems opened UCCs to take some of the load off of their emergency rooms. Other centers were started by entrepreneurial physicians to meet the market need and turn a profit.

The UCC business model is based on convenience — with wait times kept short and most visits taking 10 to 15 minutes. The majority are open seven days a week from 7 a.m. to 8 p.m. and are located in freestanding buildings with adequate parking.

UCCs are different from retail clinics in that they are staffed with physicians and treat a wider range of medical conditions. They are intended to supplement the care from the patient’s primary care physician.

“Most of the urgent care center market is related to cold, flu and throat [and that] will continue to represent the greatest single source of UCC revenue, followed closely by treatment of lacerations and wounds, and fractures and sprains,” Bruce Carlson, publisher of Kalorama Information, said in a statement.

UCCs can be a viable, more affordable alternative to emergency room visits in certain cases. A Health Affairs report from 2010 found that 27 percent of emergency room cases could be seen in UCCs.

A recent white paper from the Urgent Care Association of America estimated that cost savings of UCCs versus emergency departments could be as high as $18.5 billion per year.

The average UCC sees 294 patients per week and about 15,300 per year, according to the report. Patient volume is expected to rise through 2021 to about 300 patients per week, which will increase each UCC’s revenue to almost $1.7 million.

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Mammography screening dispute rekindled
Posted online April 19, 2017 by John W. Mitchell

In one of the great unsettled medical debates of our time, key medical groups continue to argue about the age at which women should be screened for breast cancer, and how often.

A recent research letter and accompanying editorial in JAMA Internal Medicine makes the case for earlier screenings at age 40.

Dr. Debra Monticciolo, chair of the American College of Radiology (ACR) Breast Imaging Commission, said that mammography screenings that commence at age 40 save lives.

“The ACR is not aware of any information that would cause us to change our recommendation that average-risk women begin annual mammography screening at age 40. In fact, recent data strengthen our recommendation,” she told HCB News.

She cited several studies, including a 2014 Pan-Canadian trial. The study involved nearly 3 million women and found a mortality reduction of 40 percent in screened women, including between the ages of 40 to 49.

The JAMA article highlights the difference in recommendations between several groups and the U.S. Preventative Services Task Force (USPSTF).

The USPSTF is an independent, volunteer panel of national experts in prevention and evidenced-based medicine, established in 1984. The new USPSTF guidelines issued last year recommend personalized screening decisions for women between the ages of 40 and 49 and biennial screenings starting at age 50 for women at average risk (no family history or other higher risk factors) for breast cancer.

A congressional panel delayed the USPSTF recommendations until the end of this year.

However, the ACR, the American Congress of Obstetricians and Gynecologists, The Society for Breast Imaging, and 81 percent of other primary care physicians surveyed (family and internal medicine) and cited in the JAMA article are in favor of the screenings starting at age 40.

The American Cancer Society splits the difference. They recommend personalized screening decisions for women 40 to 45, followed by annual screenings at age 45 and biennial screenings for women 55 and older.

Monticciolo said that even a USPSTF report for women aged 50-plus found that skipping a mammogram every other year would miss up to 30 percent of cancers.

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Varex completes $276 million deal for PerkinElmer's imaging business
Posted online May 03, 2017 by Thomas Dworetzky

Varex Imaging has closed on the previously announced acquisition of the medical imaging business of PerkinElmer.

The deal is for approximately $276 million in cash, depending on post-closing adjustments.

“This imaging business is highly complementary to Varex’s imaging detector business and has a similar financial profile. Customer overlap is minimal and we see revenue and cost synergy opportunities that we expect to achieve over time,” Sunny Sanyal, chief executive officer of Varex Imaging, said in a statement.

The Santa Clara, Calif.-based PerkinElmer business being acquired develops, manufactures and sells digital detectors for medical and industrial X-ray imaging systems.

It also has operations employing about 280 people in Germany, the Netherlands and the U.K.

Varex anticipates the deal will boost annual sales about $140 million and will “be transformative” to its digital detector operations.

“We are very excited about the opportunities and prospects of adding this imaging expertise into the Varex organization,” said Sanyal.

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GE Healthcare and Echosens partner to offer integrated ultrasound that manages liver disease
Posted online April 19, 2017 by Lauren Dubinsky

GE Healthcare and Echosens, a French diagnostics company, announced a partnership to offer an integrated ultrasound system that manages liver disease.

It’s called the LOGIQ S8 XDclear 2.0 ultrasound system, and it will be presented at the International Liver Congress in Amsterdam.

Liver diseases are the second-leading cause of mortality among all digestive diseases in the U.S., according to a study published in Gastroenterology.

It can be caused by hepatitis B or C, excessive alcohol consumption or poor dietary habits. The disease usually doesn’t present any symptoms and goes undetected until very late stages, which can result in liver cirrhosis and liver cancer.

GE’s LOGIQ S8 XDclear 2.0 ultrasound combines liver tissue quantification and ultrasound imaging. It can be used to screen, diagnose and monitor liver disease.

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The University of Texas MD Anderson Cancer Center and RaySearch announced a partnership to implement the new RayCare oncology information system at all of MD Anderson’s sites in the greater Houston area.

“I am proud that MD Anderson Cancer Center has joined us in the RayCare project,” Johan Löf, CEO of RaySearch, said in a statement. “Solving the coordination, safety and efficiency needs of one of the world’s largest cancer care providers is one of our most exciting challenges to date.”

MD Anderson treats about 130,000 patients per year and has more than 20,000 employees. A system like RayCare that consolidates the software systems in different departments can help their operations run smoother.

RayCare was designed specifically to support the complex logistical challenges in modern, large-scale radiation therapy centers. It includes the high-performance radiation therapy algorithms available in the RayStation treatment planning system and features clinical resource optimization, workflow automation and adaptive radiation therapy.

Integrating the medical oncology, radiation oncology and surgical oncology software systems saves time, reduces the rate of complications and risk of errors that can occur when transferring information between systems.

MD Anderson is also helping to develop RayCare — which is still under development and slated for launch in the second half of 2017 — and is planning to translate any research findings into practical solutions that other cancer clinics can use.

MD Anderson is also using the RayStation system to develop clinical treatment plans, which will be the first phase of the planned clinical rollout.

In 2015, MD Anderson signed a purchase agreement with RayStation for the treatment planning system, citing the importance of optimizing leading-edge hardware functionality while improving optimization and offering a modern working environment.

“Getting RayStation into MD Anderson and working with the team there is a great opportunity — we look forward to developing a research relationship that can lead to novel and exciting functionality.” Marc Mlyn, president of RaySearch Americas, said at the time of the agreement. “We are pleased to have the opportunity to show how RayStation can positively impact the center’s workflow and help it achieve its patient care goals.”

At that time, MD Anderson outlined intentions to implement approximately 30 licenses throughout the radiation therapy department, 20 for clinical use and 10 for research, to investigate which technologies have the biggest impact on practice.
Carestream sells dental digital business to two investment firms

Posted online April 17, 2017 by Lauren Dubinsky

Carestream, along with its parent company, Onex Corporation, announced an agreement to sell its dental digital business to two investment firms. The new, independent company will be called Carestream Dental.

Clayton, Dubilier & Rice, a leading global private investment firm, will invest 75 percent of the equity for the transaction. Hillhouse/CareCapital, a specialist investment platform focused on dental and consumer health in Asia, will provide the remaining 25 percent.

Carestream’s dental digital business holds positions in attractive, high-growth oral health care markets and CD&R and Hillhouse/Care Capital intend to build on the company’s leading positions, and foster further growth.

An iData Research market report found Carestream consistently among the top players in the European dental imaging device market, which is expected to exceed €430 million ($474 million) by 2023.

“Our investment in Carestream Dental lines up well with CD&R’s strengths, executing complex corporate carve-outs where there is meaningful transformation and growth potential,” Derek Strum, CD&R partner, said in a statement. “We are excited to partner with Hillhouse/CareCapital, which owns several dental platforms in China that will help Carestream Dental further capitalize on substantial emerging market growth opportunities.”

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Siemens Healthineers to acquire Medicalis Corporation

Posted online April 20, 2017 by Lauren Dubinsky

Siemens Healthineers announced an agreement to acquire Medicalis Corporation.

With solutions that streamline workflow and provide clinical decision support, the investment will enhance Siemens’ population health management portfolio.

“The acquisition of Medicalis will allow us to offer health care providers a powerful solution to define, implement, monitor and evolve their own standard of care for their diagnostic service line,” Robert Taylor, head of digital services population health management, digital health services at Siemens, said in a statement.

The Protecting Access to Medicare Act of 2014 (PAMA), which is expected to become effective on Jan. 1, 2018, will require health systems to check the appropriateness of certain advanced imaging exams.

Siemens believes that Medicalis’ clinical decision support solution will help providers achieve PAMA compliance, as well as evolve their standard of care based on evidence and direct health system experience.

Its imaging workflow management solution interprets the physician’s desktop and standardizes diagnostic pathways for high-impact disease states. Essentially, it prevents care gaps by ensuring the right specialist and tools are used.

Its referral management solution has appointment scheduling tools that allow patients to schedule exams within the health system’s network. That prevents existing patients from going to another health system.

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New Arizona research may aid proton therapy precision

Posted online April 18, 2017 by Thomas Dworetzky

The collaboration between Arizona State University and the Mayo Clinic that gave the state its first proton therapy facility is starting to pay research dividends.

ASU postdoc physics researcher Jason Holmes is designing devices that will help improve beam accuracy and make therapy safer.

Holmes is working on devices that will more accurately identify the location of protons in the patient’s body, and also the number that reach their target.

The Mayo Clinic’s Martin Bues, head proton physicist for its radiation oncology department, stressed the utility of the post-proton physicist for its radiation oncology program that reach their target.

“You can’t really use this to help the patient, today’s methods, which can determine the range of a proton to about a centimeter. “You can’t really use this to help the patient, to help their outcome, until you get within around a millimeter,” he told The State Press.

He also has a prototype proton counter. This works by first sending the beam through a diamond and then into the patient’s body.

“I’m literally talking about ‘there goes one proton, then another, there’s another,’” Holmes noted, advising that, “if you know how much energy is being deposited into a patient, and where it is being deposited, then you know basically everything you need to know,” and adding, “that’s what all of our projects are trying to do.”

His advisor, Ricardo Alarcon, noted that the range detector will mean that, “it’ll be the first time we will be doing this therapy and will be actually looking at what is happening while the treatment is being conducted.”

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Study: doctor-owned radiotherapy equipment means more use for prostate cancer

Posted online April 10, 2017 by Thomas Dworetzky

When prostate cancer is found in older men, they are more likely to get radiation therapy if their doctors own the equipment.

A new study looked at how “utilization and cost of care differ for men diagnosed with prostate cancer in a self-referral practice (SRP) compared to a traditional urologic practice,” according to senior study author Dr. Karen Hoffman of the University of Texas MD Anderson Cancer Center in Houston.

The findings appear in the journal Prostate Cancer.

The researchers found that in cases diagnosed by urologists who owned machines, patients were 61 percent more likely to receive radiation treatment, according to Reuters.

“For patients with very favorable prostate cancer, our findings suggest that urologist ownership of radiation equipment may contribute to unnecessary treatment,” Hoffman told the news service.

However, in those “patients with disease with aggressive features, our findings suggest that urologist ownership increases correct treatment, meaning that these patients who need treatment are more likely to receive it if they are diagnosed by a urologist with an ownership interest in radiation therapy,” she said.

The researchers looked at 17,982 men age 66 years and older diagnosed with localized prostate cancer from 2006 to 2009. They then evaluated 13 SRPs in Texas, looking for the distribution of different types of treatments for prostate cancer.

Men diagnosed in SRPs had upfront treatment (versus watchful waiting/active surveillance) at 92.7 percent, compared to those diagnosed by non-owner traditional practices, at 89 percent.

Those at SRPs were more likely to be treated with external beam radiation at 47.4 percent versus 34.1 percent at traditional practices, according to the study.

“This persisted for both favorable- and unfavorable-risk cancer,” noted the authors.

Annual care costs for prostate cancer at SRPs were also higher by an average of $2,460.

One limitation of the study was that patient preferences and other issues such as urinary, bowel and sexual functions weren’t taken into account.

The findings are in line with other studies about the impact on treatment options from equipment ownership.

“Allowing physicians to self-refer may lead to unnecessary treatment and added health care costs to society and patients,” Dr. Quick-Dien Trinh of Brigham and Women’s Hospital and the Dana Farber Cancer Institute Prostate Cancer Program told Reuters.

Trinh was not an author on the study.

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Cardinal Health has officially announced its agreement to make the acquisition of Medtronic's Patient Care, Deep Vein Thrombosis and Nutritional Insufficiency businesses for $6.1 billion in cash.

Saying that he was “thrilled about today’s announcement,” Cardinal Health Chairman and CEO George S. Barrett noted that some of the products to be acquired are already being distributed by his firm and that Cardinal and Medtronic “have been collaborative partners” in the past.

He also expanded on the reasoning behind the deal. “Given the current trends in health care, including aging demographics and a focus on post-acute care, this industry-leading portfolio will help us further expand our scope in the operating room, in long-term care facilities and in home health care, reaching customers across the entire continuum of care,” he said in a statement.

There will also be cash tax benefits from the deal of a minimum of $100 million, which are not factored into the stated purchase price. Plans call for the acquisition to use $4.5 billion in new senior unsecured notes and existing cash for its financing. Cardinal has obtained a commitment letter from Goldman Sachs Bank USA and Goldman Sachs Lending Partners LLC for an unsecured bridge loan for the deal.

Plans now call for the deal to close in Cardinal’s first fiscal quarter of 2018 pending the usual closing conditions and regulatory approvals.

The Medtronic businesses being acquired include its Patient Care, Deep Vein Thrombosis and Nutritional Insufficiency businesses will be folded into Cardinal Health’s Medical segment.

“Not only is this portfolio complementary to our existing suite of products, it enables us to build further scale on our established global platforms,” said Cardinal’s medical segment CEO Don Casey. “We are familiar with the talented team that will be joining us and have worked closely with many of them in the past. We believe this will help us execute an efficient and seamless integration after the transaction closes.”

Global orthopedic surgical robots market to hit roughly $687 million by 2021

The global orthopedic surgical robots market was worth $100.5 million in 2016 and is expected to climb to $687.2 million by 2021, according to a new Technavio market report. Hip and knee replacements are two of the major drivers of the market.

In 2016, knee surgery accounted for about 72 percent of the global market’s revenue. That’s expected to increase during the forecast period due to the prevalence of deteriorated joints and musculoskeletal disorders like osteoarthritis and degenerative hip disease among the elderly population.

Limitations in conventional surgeries are leading many facilities to purchase robotic surgical platforms. Minimally invasive surgeries are now becoming a preferred procedure in the orthopedic field, with arthroscopy being the most common procedure.

MIS are also being performed for joint replacements, to realign bone extremities and to reconstruct fractured bones. The market report predicts that minimally invasive spinal surgeries for stabilizing spinal joints and vertebral discs will start to gain traction.

ACR study rejects assertion that untreated breast cancer regresses or disappears

In case there was any doubt, the American College of Radiology (ACR) has published evidence refuting the assertion that breast cancer regresses or disappears if left untreated.

This surprising claim — which has persisted in recent years despite contrary evidence — prompted the study.

“The USPSTF states that a large part of the reason that they do not recommend screening in women under age 50, and recommend biennial rather than annual screening, is to decrease overdiagnosis. Several authors, notably Gilbert Welch, have stated that much overdiagnosis is due to cancers disappearing on their own,” Dr. Debra Monticciolo, chair of the ACR Breast Imaging Commission, told HCB News. “Our research shows that this is untrue.”

The study was published in the Journal of the American College of Radiology.

The study included 25,281 screen-detected invasive breast cancers and 9,360 cases of screen-detected ductal carcinoma in situ reported over 10 years. Among these cancers, there were 240 cases of untreated invasive breast cancer and 239 cases of untreated ductal carcinoma in situ. None were reported to have spontaneously disappeared or regressed at the next mammography exam.

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Catholic Health Initiatives announces 620 job cuts in Texas

Posted online April 03, 2017 by Thomas Dworetzky

Catholic Health Initiatives (CHI) St. Luke’s Health System will be cutting jobs in Texas.

It announced that it will reduce staff by 620 positions, according to KPRC Houston.

“Of the positions impacted, 161 were vacant positions that will not be filled and 459 employees are leaving our organization,” according to the company.

The cuts to positions were less than 4 percent of the overall workforce of CHI’s 17 hospitals, physician network, freestanding emergency centers and other facilities in the division.

“Like other hospital systems here in Texas and across the nation, we recently announced that we are working to restructure the CHI Texas Division to respond to continued changes in the health care environment,” the chain said in a statement.

It called “significant” the improvements made as a result of organizational changes in recent months, but stressed that “critical” further moves were needed to “realign our financial performance to sustain and grow our network of care across southeast Texas.”

In late March, Moody’s downgraded CHI’s long-term debt to Baa1 with an ongoing negative outlook.

“The negative outlook reflects the persistent decline in operating performance since 2012. The inability to show material improvement in operating performance, and failure to execute on turnaround strategies, or the continued weakening of balance sheet measures, would likely lead to a further downgrade of the long-term and short-term ratings,” noted the agency.

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Mayo Clinic and MRI Interventions partner to develop guided stroke treatments

Posted online April 26, 2017 by Lauren Dubinsky

The Mayo Clinic and MRI Interventions announced a partnership to design, develop and commercialize MR-guided minimally invasive therapies for stroke patients, with an initial focus on intracerebral hemorrhage.

The initial MR-guided product will build on MRI Interventions’ ClearPoint Neuro Navigation System. The company believes that the system’s intra-procedural visualization capabilities would create a “powerful foundation for minimally invasive therapies to treat ICH.”

The system is designed to provide stereotactic guidance for the planning and operating stages of neurological procedures. These procedures can be performed in a hospital’s existing MR suite and can be used with both 1.5T and 3T MR scanners.

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BIOTRONIK launches its Plexa ProMRI MR-conditional tachycardia lead

Published online April 19, 2017 by Lauren Dubinsky

BIOTRONIK launched its Plexa ProMRI MR-conditional tachycardia lead in the U.S. At 7.8-French, the company claims it’s the smallest lead of its kind.

“Plexa ProMRI is the only defibrillator lead in the U.S. market that offers both a small lead body and access to MRI diagnostics. Plexa’s small lead body minimizes the risk of vein occlusion or blockages,” Marlou Janssen, president of BIOTRONIK Inc., told HCB News.

“In addition, Plexa’s helical coil design is optimized to dissipate heat in the MRI environment, and allows defibrillator patients critical access to MRI scans,” she added.

This announcement came after almost 10 years of research and development. According to BIOTRONIK, it enrolls more patients in U.S. lead studies than any other global cardiac rhythm management device company.

Plexa ProMRI was approved by the FDA in February for use with implantable cardioverter defibrillators and heart failure devices.

The lead’s wire was designed for maximum durability. It extends to the area between the distal and proximal shock coil with only slight electrical impedance.

Plexa ProMRI’s suite of tactile design elements enable it to be used on various patient anatomies. The leads are available in DF4, DF-1 and DX configurations.

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GE Healthcare and Lantheus extend flurpiridaz F 18 agreement to 2020

Published online April 26, 2017 by Lauren Dubinsky

GE Healthcare and Lantheus announced a definitive agreement to continue phase III development and global commercialization of flurpiridaz F 18.

This news follows the signing of a term sheet, that was announced in February. At the time, there was no guarantee the deal would happen on the proposed terms.

But now, as part of the definitive agreement, GE will lead and fund the development program of flurpiridaz F 18, including the second phase III clinical study. It will also have exclusive rights to commercialize the agent worldwide.

“We are committed to strengthening and expanding our nuclear portfolio through this strategic partnership with Lantheus, and potentially offer a new diagnostic option to clinicians and patients in CAD,” Emmanuel Ligner, general manager of core imaging for GE Healthcare, said in a statement.

Lantheus will participate in the development and commercialization process through a joint steering committee. The company also has the option to co-promote the agent in the U.S.

Through the deal, Lantheus will receive $5 million upfront in cash. If the launch is successful, it will also get up to $60 million in regulatory and sales milestone payments, as well as double-digit royalties on U.S. sales and single-digit royalties on sales outside the U.S.

Share this story: dotmed.com/news/36910
Global medical imaging software market on track to exceed $4.8 billion by 2021

Posted online April 25, 2017 by Lauren Dubinsky

The global medical imaging software market is expected to reach more than $4.8 billion by 2021 at an annual growth rate of 7 percent, according to a new market report from Technavio.

The market is carved up into radiographic imaging, ultrasound imaging, tomography, MR and nuclear medicine segments. A strong focus on preventive medicine and early diagnosis has contributed to the increased adoption of medical imaging software solutions in these segments.

The Americas account for 59 percent of the market, and the region will exceed revenues of $2.8 billion by the end of the forecast period.

One in five AEDs in four regions failed at least one phase of testing

Posted online April 27, 2017 by Lauren Dubinsky

When cardiac arrest happens, public AEDs are often the first line of defense in saving a life — but researchers have found that roughly one in five of these devices are not in full working order.

Currently there are no national standards for the maintenance of automated external defibrillators and Dr. Brad Sutton of the University of Louisville School of Medicine thinks that’s a major problem. He and his research team discovered a significant amount of variability in how AEDs are registered and maintained and as a result, the true risk for failure is unknown.

“Our study has helped to highlight a problem that is common sense in some respects but is much more widespread and potentially detrimental than I think has ever been reported,” Sutton, assistant dean for health strategy and innovation and clinical cardiac electrophysiologist at the university, told HCB News.

The research team evaluated 322 AEDs in 190 public, non-hospital settings in four geographically distinct regions: Seattle; Suffolk County, N.Y.; central Illinois; and Louisville.

They found that 21 percent of the devices failed at least one phase of testing. In addition, 5 percent had expired batteries and failed to power on at all, rendering them useless in the incident of sudden cardiac arrest.

Public access AEDs located in areas where there was a higher rate of registration were significantly more likely to pass testing. In Seattle and Suffolk County, the rate of AED registration was greater than 80 percent, with no battery failure found in Seattle and only 2 percent in Suffolk County.

Share this story: dotmed.com/news/36891
Japan’s Hitachi is “willing to work with Turkey to establish the country’s first particle beam therapy system,” according to its healthcare group’s CEO, Masaaya Watanabe.

At present, no similar therapy is in place in the Commonwealth of Independent States, Middle East and Africa, he told the Anadolu Agency. “We think that particle beam therapy will significantly strengthen Turkey’s place in health tourism,” he stressed.

Underscoring Turkey’s importance to the company, Hitachi recently closed a deal to acquire 75 percent of Turkish diagnostic imaging technology firm Kurt & Kurt.

That deal — which was announced last December — will have a major impact on Hitachi’s management going forward. “Turkey is positioned in the strategically and geographically important location to Europe, the Middle East and Central Asia,” Watanabe stated when the deal was announced, adding that, “after 33 years of successful partnership contributing to Turkey’s healthcare development, we recently have been providing not only our diagnostic systems, but also various kinds of solutions to medical facilities. Through this acquisition, we will further strengthen our partnership and collaborate together to deliver state-of-the-art solutions. I envision that our works will contribute to healthcare development and improve the quality of life in the region.”

He added, “we will manage our operations in 65 countries in [the] Caucasus, North Africa and the Middle East through Turkey, with Hitachi Healthcare Turkey.”

Dr. Teofilo Lee-Chiong, chief medical liaison for Philips and professor of medicine at National Jewish Hospital and the University of Colorado, told HCB News. “Newer technologies, such as the AVAPS-AE mode used in the study with Philips Trilogy, are more responsive to the patient’s ever-changing breathing needs.”

Patients suffering a common, often deadly, respiratory condition who went home from the hospital supported by more technologically advanced noninvasive ventilation (NIV) were less likely to be readmitted to the hospital — resulting in cost savings of nearly half a million dollars over 90 days — according to a study published in the journal Value in Health.

The study, sponsored by Philips, calculated the cost savings based on the home use of its advanced Trilogy 100 portable ventilator with AVAPS-AE mode on 250 patients with severe chronic obstructive pulmonary disease (COPD) following their discharge from the hospital. This was compared to patients who did not receive advanced care NIV treatments or did not receive NIV treatment at all.

“Noninvasive ventilation (NIV) assists patients with their breathing by providing a prescribed pressure or volume of air during inhalation,” Dr. Teofilo Lee-Chiong, chief medical liaison for Philips and professor of medicine at National Jewish Hospital and the University of Colorado, told HCB News. “Newer technologies, such as the AVAPS-AE mode used in the study with Philips Trilogy, are more responsive to the patient’s ever-changing breathing needs.”

Becton, Dickinson to acquire Bard for $24 billion

Becton, Dickinson (BD) is set to buy C. R. Bard in a $24 billion deal, according to the two companies.

This brings together both medical device makers in an acquisition, approved by the board of directors of both companies, that is set to pay $317 for each Bard common share in cash and stock. “Combining with Bard will accelerate our ability to offer more comprehensive, clinically relevant solutions to customers and patients around the globe, creating a strong partner for health care providers who are increasingly focused on delivering better outcomes at a lower total cost,” said Vince Forlenza, BD’s chairman and chief executive officer, in a statement, adding that expectations are for “the transaction to contribute meaningfully to BD’s plans for revenue growth and margin expansion, and generate outstanding value both near- and long-term for shareholders.”

The companies stated that the deal should combine BD’s management and infection prevention capabilities with Bard’s existing portfolio and pipeline of new products. “We also believe that we can expand our access to customers and patients through BD’s strategic selling capabilities, and that our fast-growing portfolio in emerging markets can significantly benefit from their well-established international commercial infrastructure,” said Tim Ring, Bard’s chairman and chief executive officer.

Philips study shows noninvasive home ventilation can reduce COPD readmissions

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ImagineSoftware and IBM’s Merge have strategically aligned in a deal that will have ImagineSoftware handle “front-line support” for Merge Financials and Merge Sentinel customers.

The arrangement will also allow customers to upgrade to Imagine’s platform for medical billing automation.

“The Merge-ImagineSoftware agreement is beneficial for our ambulatory customers in radiology and other specialties, and for both companies,” Anne Le Grand, vice president of imaging at IBM Watson Health, said in a statement. “Merge will focus on developing cloud-based, cognitively-enabled global imaging offerings — a growth area for our business — while ImagineSoftware remains focused on innovation in revenue cycle management and medical billing automation solutions.”

Since Merge Financials was originally built on an Imagine-Software platform, migration will be “simplified,” and the move will let Merge clients “enjoy the latest Imagine platform, with enhanced user experience, functionality and performance.”

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Loyola study: prostate cancer patients would pay $2,000 more for better, MR-US, biopsies

As the cost of health care spending shifts to patients through coverage limits and higher deductibles, researchers at Loyola University Medical Center found that men are willing to pay about $2,000 more out of pocket for a new, high-tech biopsy that significantly improves diagnostic and treatment accuracy.

The study centered around a relatively new imaging method for diagnosing prostate cancer, MR-US prostate biopsy. Loyola was the first center in Illinois to offer the procedure.

"We found that patients are willing to pay more for new technologies, for perceived benefits," Dr. Gopal N. Gupta, assistant professor of urology, radiology and surgery at Loyola Medicine, told HCB News. "We have had more and more patients willing to pay out of pocket for this technology when insurance denies it, and they are also angry with insurers who do not pay for this procedure."

The interdisciplinary study was conducted by the Loyola Stritch School of Medicine and the Loyola Chicago Quinlan School of Business. It was recently published in the journal Urology Practice.

The technique fuses MR images with ultrasound imaging to create a detailed, 3-D view of the prostate. This improved view helps physicians perform biopsies with much higher precision and increases prostate cancer detection. This compares to the less dependable standard biopsy protocol that requires 12 needle sticks into the prostate and, according to Gupta, has many inherent risks including bleeding and life-threatening infections.

The researchers surveyed 202 men age 55 to 70 in a urology clinic. They were asked to imagine that they had $2,000 of their money in a health savings account. These accounts are commonly linked with high-deductible insurance plans. The test subjects said they were willing to pay between $1,598 and $2,034 more for an exam that increased the likelihood of detecting prostate cancer at a higher frequency rate of between 8 to 20 percent.

SPECT/CT can assess kidney tumors without biopsies and surgery

A one-off study from the 1990s was the catalyst for a group of researchers at Johns Hopkins to find a noninvasive way to rule out benign kidney tumors.

"Just using CT or MR, we can only tell if there is a growth on the kidneys, not whether it's benign or not — there's no way to tell the difference," Dr. Michael Gorin, chief urology resident at the James Buchanan Brady Urological Institute and Department of Urology at Johns Hopkins University School of Medicine, told HCB News. "We thought — who wants to have a biopsy needle stuck in their back if the growth isn't cancer?"

Roughly 5,600 unnecessary surgeries are conducted annually in the U.S. to remove benign kidney tumors, according to Gorin.

To address this problem, his research team introduced the common nuclear isotope 99mTc-sestambibi in 48 patients, which lights up cancer cells in the SPECT/CT image. The highlighting qualities have been used for about 10 years to diagnose cardiac problems.

Eight of the 48 patients were initially diagnosed with benign tumors and did not require invasive biopsy or surgery.

Siemens partners with Ebit for Suitestensa cardio IT system

Siemens Healthineers announced a partnership with Esaote’s health care IT company Ebit to offer their German customers the Suitestensa cardiovascular information system.

Suitestensa gathers patient data from all cardiology modalities on a single platform. Siemens chose this solution because it can be integrated with existing systems within cardiology facilities.

When the patient arrives at the hospital, their data is recorded in the hospital information system and it’s then sent to the CVIS, which generates the interface that shows the exam modalities and location of the exam.

For example, if the location and extent of stenosis as well as the material used are documented in the CVIS during an angiography exam, the cardiologist will automatically receive this information as part of the diagnosis template.

Dr. Christoph Naber of the Elisabeth Hospital in Germany uses Suitestensa to compare ultrasound, CT, MR or angiography records, measurements and patient information without having to search for them on different systems.

"It is important to integrate a future-viable solution, especially when it comes to cardiovascular imaging and the enormous volume of associated data," Naber said in a statement.

As part of the agreement, Ebit agreed to offer Suitestensa within the Siemens Healthineers Digital Ecosystem. The platform connects health care providers and solution providers, as well as their data, applications and services.
Alzheimer's disease trial to study opening blood-brain barrier with focused ultrasound

Posted online May 03, 2017 by Thomas Dworetzky

Canadian scientists have begun clinical trials using focused ultrasound to breach the blood-brain barrier temporarily in patients with Alzheimer’s disease.

A safe, noninvasive way to open this barrier could prove key to “properly testing” future drug treatments for Alzheimer’s, according to Dr. Sandra Black, who holds the Brill Chair of Neurology at Sunnybrook Health Sciences Centre and University of Toronto, and is a co-principal investigator of the new trial.

“By opening up the [blood-brain barrier] using low frequency ultrasound, we’ve taken a small but important step that opens up a whole new vista of possibilities,” she said in a Sunnybrook statement. She explained that “the hope is there may be a way to eventually open up multiple little windows, in a gentle way, in order to get large molecules like drugs and even stem cells into the brain. But we need to take it one step at a time.”

The trial is studying the technique in patients with early to moderate disease. The hope is that the results will help “plan future clinical trials to establish what role focused ultrasound may play, whether alone or in conjunction with medical treatments, in the management of Alzheimer’s,” the study’s principal investigator, neurosurgeon Dr. Nir Lipsman, noted in a Focused Ultrasound Foundation statement.

The trial makes use of INSIGHTEC’s Exablate Neuro low-frequency platform.

In phase two of the trial, at one month, a similar approach will be taken targeting a larger frontal lobe area, and again images will be studied to see if the barrier was temporarily opened.

Sunnybrook researchers were first successful opening the barrier in this fashion in late 2015. Nearly 20 years of research by Dr. Kullervo Hynynen, director of physical sciences at Sunnybrook Research Institute, in conjunction with INSIGHTEC, led to the technology’s development and its present clinically ready state.

ARRS New Orleans meeting addresses DCIS overtreatment, overdiagnosis

Posted online May 03, 2017 by Lauren Dubinsky

Dr. Mai Elezaby of the University of Wisconsin School of Medicine and Public Health discussed the overdiagnosis and overtreatment controversy that surrounds ductal carcinoma in situ at the annual ARRS meeting in New Orleans.

“Overdiagnosis and overtreatment have typically been defined as cancers detected and treated as a result of screening tests that would not have otherwise been clinically apparent in a patient’s lifetime,” she told the audience in her session on breast imaging.

Elezaby noted that most of the data on DCIS overdiagnosis was calculated using historic data, prior to the introduction of the College of American Pathologists guidelines in 2009. Previously, there were multiple different classification systems, which resulted in significant variability in the interpretation of DCIS.

“There have also been technological advancements in the field of pathology that change the diagnosis of DCIS,” she added. “What we currently know as low-, intermediate- or high-grade DCIS might not apply to some of the data from new studies.”

Randomized control trials are the current gold standard for calculating overdiagnosis. The patients are randomly placed in either the screening or non-screening group and the researchers assess the incidence rates of breast cancer in both groups and subtract them to determine the rate of overdiagnosis.

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Siemens mulls Healthineers spinoff plans

Posted online May 05, 2017 by Thomas Dworetzky

While Siemens is “well advanced” with its plans to split off its Healthineers, the method of achieving independence for the $15 billion health care business is not yet certain.

“We have been preparing all the decisive steps and we are following three very interesting alternatives,” Ralf Thomas, chief financial officer, told Bloomberg TV.

The most apparent options would include a regular initial public offering, a spinoff or a reverse initial public offering involving a merger with an already-listed company.

The exact nature of the structure of the deal had never been discussed by the industrial giant — although it had suggested that it would keep control.

Whatever the nature of the final deal, it would serve the ongoing Siemens strategy of changing the company from a conglomerate to more of a holding company, according to the business news service.

Bloomberg Intelligence put the value of a classic initial public offering at roughly $33 billion to over $40 billion.

Siemens had already announced in February the possibility that it would list Healthineers in the U.S. and not Europe. “We don’t have a final view on this yet, but we are looking at it very closely,” Joe Kaeser, CEO of Siemens AG, said at the time.

But there was a possible change of heart in early March, when Kaeser told Swiss newspaper Finanz and Wirtschaft that “under President Donald Trump” he “will have to think twice” about where to list the health care unit, mentioning Frankfurt and Hong Kong as possibilities.

Moreover, the German industrial giant has to date not moved forward with any “mandated banks,” according to Reuters.

This puts a public listing this year, as anticipated, in some doubt.

Siemens held a conference call after its quarterly results were released and beat expectations. Thomas told reporters at that time that there had never been a certain date for listing and then revealed that possibilities existed other than a traditional initial public offering.

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MR and Hollywood special effects help create ultra-realistic surgical model

Posted online May 01, 2017 by Lisa Chamoff

MR imaging, 3-D printing and a bit of Hollywood magic helped a team of neurosurgeons, computer engineers and special effects experts create a way for surgeons to practice minimally invasive brain surgery.

The effort was recounted in an article recently published in the Journal of Neurosurgery: Pediatrics.

After an MR scan, the team created a full-scale reproduction of the head of a 14-year-old patient with hydrocephalus, a buildup of cerebrospinal fluid in the brain. After the brain, skull and scalp were 3-D printed, the special effects team brought in softer materials that mimicked the texture of the external and internal tissue, and the model included a basilar artery and ventricles that pulsed, and cerebrospinal fluid that moved in a realistic way.

The patient looked so realistic that the Journal said it needed consent to include the picture, said Dr. Alan Cohen, chief of pediatric neurology at Johns Hopkins Hospital and a senior author of the report.

A group of four neurosurgery fellows and 13 residents used the patient model to perform endoscopic third ventriculostomy (ETV), in which a small hole is created for the fluid to flow through, eliminating the need for implantation of a shunt, which comes with risks. ETV is performed via a small hole in the patient’s skull using an endoscope.

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Scopis taps Microsoft HoloLens for new mixed-reality spinal surgery platform

Posted online May 05, 2017 by Lauren Dubinsky

Scopis announced the launch of its Holographic Navigation Platform with integrated Microsoft HoloLens technology.

The platform is intended for use during open and minimally invasive spinal procedures.

“Scopis’ holographic solution has the potential to make spine surgery more effective, safe and precise,” Christian Wojciechowsky, chief of the Spinal Surgery Clinic at Vivantes Humboldt Hospital in Berlin, said in a statement. “Integrating mixed-reality tools into surgery is a huge technological advancement toward enhancing a surgeon’s vision and may provide greater benefits to patients.”

During multiple vertebrae fixation surgeries, the surgeons wear the Microsoft HoloLens glasses, which communicate wirelessly to the navigation platform. The surgeons see a mixed-reality overlay of the planned positioning of the pedicle screws on the patient.

With the platform, the surgeons are also able to use hand gestures to move virtual monitors into their field of view near the patient. That way, they don’t have to take their eyes off of the operative field.

The current standard for planning screw replacement positioning involves fluoroscopy, which exposes patients to radiation that can be avoided with the mixed-reality system. Since the platform can help surgeons align the pedicle screws more precisely, that also means better surgical outcomes and shorter hospital stays.

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Philips and B. Braun partner on ultrasound-guided regional anesthesia solutions

Posted online April 03, 2017 by Gus Iversen

Royal Philips and B. Braun have announced a new strategic partnership aimed at ultrasound-guided regional anesthesia — a rapidly growing alternative to general anesthesia — and vascular access.

The collaboration centers on a new ultrasound platform called Xperius, which will be available in a cart and ultra-mobile tablet version, and was designed specifically to support the point-of-care needs in regional anesthesia.

The multi-year agreement will allow for the joint development and commercialization of solutions to support anesthesiologists with enhanced needle visualization and guidance, as well as optimize procedure workflow and resource planning.

"Some of our existing ultrasound systems, such as our Sparq system, have a functionality to support ultrasound-guided regional anesthesia procedures," a Philips spokesperson told HCB News. "Contrary to Sparq, which is a multipurpose ultrasound system for acute care settings, Xperius has been specifically designed for ultrasound-guided regional anesthesia and vascular access at the point of care."

Xperius complements B. Braun’s offerings in the field of ultrasound-guided regional anesthesia which includes the newly launched peripheral nerve block portfolio comprising Stimuplex Ultra 360 and Contiplex Ultra 360. It has also been specifically designed to support future innovations for needle visualization and guidance.

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GE Healthcare inks deal with HealthTrust to supply SPECT and PET tracers

GE Healthcare announced an agreement that commenced in early March with group purchasing organization HealthTrust to supply low-energy SPECT and high-energy PET radiopharmaceuticals to HealthTrust’s members throughout the country.

"GE Healthcare is focused on providing health care providers choice in contrast media options," a GE spokesperson told HCB News. "Given that HealthTrust’s member institutions are required to purchase from compliant contracted vendors, our agreement will expand availability of these diagnostic tools for health care providers and patients at these member institutions."

HealthTrust is headquartered in Nashville and has about 27,600 members including acute care facilities, ambulatory surgery centers, physician practices, long-term care and alternate care sites. As a GPO, they negotiate discounts with manufacturers to help its members realize savings.

Overall, about 72 percent of purchases that hospitals make are done through GPO contracts, according to the Healthcare Supply Chain Association. These GPO contracts save hospitals up to $33 billion each year.

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Hartford HealthCare and GE announce seven-year deal to reduce waiting

GE Healthcare and Hartford HealthCare announced a collaboration to launch a series of projects over the next seven years.

The projects that the organizations are planning to roll out will aim to help patients avoid unnecessary wait times and other factors that can delay care.

"We are redesigning the way we organize and deliver care," Elliot Joseph, CEO of Hartford HealthCare, said in a statement. "We are focused on ensuring patients get the care they need, where they need it, and to coordinate that care so it is faster, safer and, ultimately, more affordable."

Hartford HealthCare is a comprehensive health care network located in Connecticut. It comprises two teaching hospitals, two community hospitals, an acute-care hospital and trauma center, a primary care physician practice group and five cancer centers.

As part of the collaboration, GE will help implement and activate Hartford HealthCare’s new Care Logistics Center. The center’s goal is to improve communication between health care providers and facilities, and reduce wait times.

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Johns Hopkins University seeding startups to keep health tech companies in Baltimore

Tired of seeing most of the $1 billion-plus it raised for startup funding leave the state, Johns Hopkins University has opened a new state-of-the-art technology incubation hub, part of a $65 million expansion project.

The space — called FastForward 1812 — features 8,000 square feet of office and meeting space, with an additional 15,000 square feet of lab space to accommodate a broad range of biological and chemical work. Since opening, the facility has welcomed 19 innovative startups working in medical fields ranging from telemedicine platforms, treatment for Type 2 diabetes and cell therapies for cancer treatment.

"For too long, Baltimore hasn’t had robust infrastructure in place to support the number and types of life science startups spinning out of our academic and research institutions,” Christy Wyskiel, senior advisor to the president of Johns Hopkins University, told HCB News. "Our FastForward spaces and the resources they provide are making it easier to keep startups in the city."

The new location is the third FastForward location, and doubles Johns Hopkins’ innovation space footprint in the city. The program, which is part of a network of other incubation hubs in the city, also provides support to some off-site companies.

According to Wyskiel, the FastForward program has already resulted in either launching or retaining several technology companies in Baltimore. These include:

• Protenus, a startup that improves the security of patient electronic records. The company has 20 employees working to protect 44 million patient records, and is headquartered in Baltimore.
• Personal Genome Diagnostics, a startup that has raised more than $20 million to support the development of personalized cancer therapies. The company is building a new headquarters in the city.
• Sonavex, a company that uses imaging technology to visualize clinical data at the point of care. The company just put aside $3 million to help it get FDA approval for a device that detects blood clots. It was named the 2016 Maryland Incubator Company of the year, and is also moving to a larger space in the city.

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Upcoming Events

AAMI 2017 Annual Conference
Location: Austin Convention Center
Austin, Texas
Dates: June 9–12
Years in existence: 48
Average attendance: 2,300+
Who should attend: Health care technology management professionals.

SNMMI 2017 Annual Meeting
Location: Colorado Convention Center
Denver
Dates: June 10–14
Average attendance: +5,400
Who should attend: Imaging and nuclear medicine physicians, radiologists, cardiologists, pharmacists, scientists, lab professionals and technologists.

AHRA 2017
Location: Anaheim Convention Center
Anaheim, Calif.
Dates: July 9–12
Years in existence: 45
Average attendance: 1,000
Who should attend: Radiologists and physicians involved in medical imaging.

NATCO 2017
Location: St. Louis Union Station Hotel
St. Louis
Dates: Aug. 2–5
Years in existence: 42
Average attendance: 400+
Who should attend: Transplant and procurement professionals as well as professionals involved in hospital development and administrative work.

FIME 2017
Location: Orange County Convention Center
Orlando
Dates: Aug. 8–10
Years in existence: 27
Average attendance: 50,000
Who should attend: Physicians, nurses, technicians, senior hospital executives.

ESMRMB 2017
Location: Congress Center
Barcelona, Spain
Dates: Oct. 19-21
Years in existence: 34
Who should attend: Radiologists and physicians and others involved in MRI.
Hospital Spotlight: Memorial Sloan Kettering Cancer Center

Locations: Facilities throughout the New York metropolitan area, including Manhattan, Brooklyn, Long Island, Westchester County and New Jersey
Year founded: 1884
Number of beds: 473
Number of employees: 15,697, including 1,091 attending physicians, 2,864 registered nurses and 131 senior laboratory investigators
President’s name: Craig B. Thompson, M.D.

1. Main entrance of Memorial Sloan Kettering.
2. Former Vice President Joe Biden paid a visit to an MSK lab before a roundtable discussion on his Cancer Moonshot Initiative.
4. Nursing staff and MSK leadership celebrate as they find out they achieved Magnet recognition.
5. Pediatric oncologist Dr. Richard J. O’Reilly was featured in the Humans of New York photo blog series on pediatric cancer (Photo courtesy of Brandon Stanton).
6. A cancer scientist in one of MSK’s more than 100 labs.
7. MSK’s Ambulatory Care Art program at MSK Monmouth features a new exhibit, ‘Reinventions.’
Noteworthy distinctions: Memorial Sloan Kettering Cancer Center is the world’s oldest and largest private cancer center and has devoted more than 130 years to exceptional patient care, innovative cancer research and outstanding educational programs. One of 47 National Cancer Institute-designated Comprehensive Cancer Centers, MSK is committed to compassionate, evidence-based, patient-centered cancer care, ensuring patients have access to the newest treatments through the hundreds of clinical trials MSK offers and the state-of-the-art science MSK researchers conduct in more than 100 labs on MSK’s campus. According to U.S. News & World Report Best Hospitals, MSK has ranked as one of the top two hospitals for cancer care in the country for more than 25 years and among the nation’s top pediatric hospitals for cancer care. In 2016, MSK nursing received Magnet® recognition, the nation’s highest honor for excellence in nursing, and in 2017, MSK was recognized in Glassdoor’s Annual Employees’ Choice Awards 2017, honoring the best places to work and highest-rated CEOs.

Specialties: MSK physicians have an extraordinary depth and breadth of experience in diagnosing and treating all forms of adult and pediatric cancers, from the most common to the rarest. Each year, they diagnose and treat patients with more than 400 different subtypes of cancer. MSK’s world-class physicians have specialties that range from surgery, chemotherapy, immunotherapy, precision medicine and radiation therapy to imaging, pathology and clinical trials.

Recent developments: In 2016, MSK expanded its footprint by opening its second New Jersey outpatient center, MSK Monmouth, as well as the Josie Robertson Surgery Center, which can accommodate 60 outpatient surgeries a day — more than any other freestanding outpatient cancer surgery center in the tri-state area. Also last year, MSK’s Department of Pediatrics was featured in the popular Humans of New York photo blog, resulting in a fundraiser that generated more than $3.8 million for pediatric cancer research, and MSK hosted former Vice President Joe Biden for a roundtable discussion about his Cancer Moonshot Initiative.
Radiochemist Jason Lewis is the director of the Center for Molecular Imaging and Nanotechnology at Memorial Sloan Kettering Cancer Center (MSK) in Manhattan. He recently took some time to talk about the work being done in his lab and some of the exciting advances in medicine.

**HCB News:** What inspired you to become a scientist?

**JL:** I just found it intriguing. As a child, there was a program in the U.K. called “Tomorrow’s World” that I watched and was inspired by. I really can’t remember a time I didn’t want to be involved in science.

**HCB News:** How long have you been with MSK?

**JL:** I’ve been here nine years, coming here after 12 years at Washington University School of Medicine in St. Louis.

**HCB News:** What attracted you to a career at MSK?

**JL:** The fact that there was the clear ability to translate novel molecular probes into patient use. Memorial Sloan Kettering is second to none in that regard due to the strong support they give to research. Clinical translation is one of MSK’s main missions and there’s a great infrastructure for it.

**HCB News:** I saw that the MSK lab is called “The Jason Lewis Lab.” Was it started up under you?

**JL:** When I joined MSK, there was already an active radiochemistry program, but I was given three main tasks. The first was to build a new GMP cyclotron facility. The second was to lead a team of faculty, at 12 members now, as their service chief. The third was to start my laboratory. I think I have been able to build all three to meet MSK’s radiochemistry and molecular imaging probe research needs. I’ve also been named the vice chair for research of the Department of Radiology, which is somewhat unusual for a non-M.D. to be vice chair of a clinical department, and that brings its own set of challenges and possibilities.

**HCB News:** A lot of news was offered about your work with imaging agents. Can you discuss some of the advancements you’re most excited about?

**JL:** We have an extensive investigational new drug or IND list. There are 35 different tracers we can use in clinical trials here. We average about four to five new imaging and therapy probes into the clinic per year. One recent example is our work with carbon-13 pyruvate as a hyperpolarized MRI probe. All the pharmacy work is done in the new GMP facility, supporting the manufacture and supply of all manners of molecular imaging probes.

Dr. Christian Lohrmann will present on one of the new agents, MVT-2163, for the first time at the Society of Nuclear Medicine’s annual meeting this year. Using an antibody labeled with zirconium-89, it’s imaging a serum biomarker for pancreatic cancer. There has been three or four years of preclinical work done on this and Christian’s presentation will be the first to present the human data from our trial.

'I was given three main tasks. The first was to build a new GMP cyclotron facility. The second was to lead a team of faculty, at 12 members now, as their service chief. The third was to start my laboratory.'
HCB News: What challenges do you face?

JL: I would say the very unsettled fiscal and political climate is a challenge. As scientists, we are so unsure about whether funding will be maintained or provided. I also don’t think that science necessarily gets the respect that it should. Another challenge is that human disease constantly provides a new set of questions that need to be answered. Also, especially in the U.S., not enough young people are going into science, and this has profound ramifications for the future.

HCB News: What opportunities do you see ahead?

JL: The fact that we can make a profound difference in how we treat and pursue personalized medicine. If you want to treat someone with cancer, you had better know where the cancer is. A picture speaks a thousand biopsies.

Still, the imaging community has been its own worst enemy. If there are 10 probes to look at the same target, we need to make the decision to get behind one or two, to look at the data objectively and collectively push to get the regulatory approvals and reimbursement. Most probes are coming out of academia or small pharma. Big pharma does some, too, but academic laboratories are the main source. Those labs survive by getting published and landing grants. So they constantly have to have an influx of funding for new projects and clinical trials. When someone finds a great target, others recognize that and then pursue it, too. We have to change our mindset and pick winners and support them together.

HCB News: How do you predict PET will change in the next decade?

JL: It will change in a number of ways. It will become more important as advanced cancers become more common. It will have more of a role in determining the efficacy of therapy at an earlier point. It will help physicians translate new therapies and ask better-defined questions and be a much stronger part of clinical trials. Finally, when UC-Davis introduces their whole-body PET it will lower dose, especially important in the imaging of children.

HCB News: You mentioned advanced cancers. What do you mean by that?

JL: We’ve gotten very good at treating cancer. However, if a treatment cures or destroys 99 percent of the tumor, that leaves 1 percent of the tumor that's potentially resistant. When it comes back, it’s then a cancer we may not be used to seeing or treating. As this “evolution” happens, the questions change and we have to find new answers.

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The need to mitigate data breaches and cyberattacks

By Sanjaya Kumar and Chandrashekar Bilugu

Today’s health care industry depends on information systems — from clinical applications such as EMR/CPOE systems, to specialized radiology, pharmacy, laboratory systems, to billing and scheduling systems, etc.

The accessibility of data and interoperability from such systems is resulting in increased productivity, efficiency, improved quality of care and ensuring safe patient care. Health care organizations are a top target for hackers due to their inherent vulnerability, with cyberattacks becoming more focused and sophisticated. Health care records are a treasure trove of data for identity thieves. Health records are popular targets for their high potential for exploitation through identity theft, insurance fraud, stolen prescriptions, ransom attacks and dangerous hoaxes.

According to Reuters, on the black market, medical information is sold for more than 10 times your credit card number. Continuous dependency on information systems also makes health care organizations prime targets for ransomware attacks. The “wannacry” attack encrypted key patient data within hospital systems, crippling operations.

Several assessments and surveys have highlighted that health care organizations in the U.S. are at great risk today for cyberattacks and there are limited mitigating safeguards in place to ensure continuity of operations. However, with significant HIPAA fines and penalties being enforced for PHI data breaches and noncompliance with established standards, health care organizations are left with few choices but to enforce compliance and strengthen key processes to plug vulnerabilities and mitigate cyberattacks.

There are nearly 250 HIPAA privacy and security controls that require continuous monitoring by covered entities and their business associates (who, in turn, are now also liable for inadvertent exposure of PHI).

The top three major gaps in processes and failures at health care organizations are related to:

• Not establishing and maintaining required documentation (49.4 percent).
• Lack of evidence of adequate data and information management (26.5 percent).
• Lack of notification, training and responsiveness (10.5 percent).

Data on breaches also highlight that data security failures originate from both inside and outside of the organization given the dependency on a varied number of business associates and vendors that health care organizations contract with.

In 2016, 43 percent of data breaches were the result of insiders — either the result of simple human error or actual malicious wrongdoing. Hacking and ransomware were responsible for 26.8 percent of breaches, although this number is likely underreported and very much on the rise. While covered entities are not technically liable for security breaches at a business associate, there are many reasons why it pays to select business associates who take data privacy seriously.

Consider the following five key safeguards and processes to establish for mitigating data breaches and cyberattacks:

• Establish continuous security control compliance assessments, evaluation of gaps and remediation due diligence processes at your health care organizations systemwide. Health care organizations currently only do periodic assessments of their controls. Vulnerabilities are identified, but required remediation to fix the gaps is not acted upon in a timely fashion. It would be ideal to have health care organizations establish a SWAT team-like approach to identify gaps and get them fixed.

• Exercise your audit rights with your business associates. While most business associate agreements include the right for a covered entity to audit the business associate’s security compliance processes, many do not do this. Utilizing a closed-loop, third-party auditing software is ideal for this as all the information, communication and evidence of compliance will be logged and trackable. Document all PHI sent to third parties and pay special attention to the management (and appropriate renewals) of business associate agreements across the health care system.

• Require approval for subcontractors. Often, business associates have the discretion to utilize subcontractors to fulfill the work. This adds another layer in an already complex relationship, and subcontractors are not always bound by the same guidelines of the BAA signed by the covered entity. Require notification and consent with the option to terminate the agreement, if needed.

• Be proactive as opposed to reactive with what devices are on your network and their state of compliance. Establish tools that can identify threats at your endpoints and protect them continuously. With very few good solutions on the market, endpoint security is emerging as the next frontier for health care organizations to address.

• Conduct good governance both internally and externally. The work doesn’t end with a signed business associate agreement or an assessment of your organization.

About the authors: Sanjaya Kumar, M.D., is the chief medical informatics officer and Chandrashekar Bilugu is the chief technology officer at Aegify, Inc.

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By Sanjaya Kumar and Chandrashekar Bilugu

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WWW.ASTRO.ORG/ANNUALMEETING
The fiscal year 2018 Medicare Fee Schedule Proposed Rules have started to be released for comment.

Here is a preliminary “scorecard” to help you navigate the 2018 Proposed Rule cycle over the summer and be ready to prepare comments:

**Hospital Inpatient Prospective Payment System**

On April 14, 2017, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would update 2018 Medicare payment and policies when patients are admitted into hospitals. Comments are due on June 13, 2017.

The proposed increase in operating payment rates for general acute care hospitals paid under the IPPS that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users is approximately 1.6 percent. CMS projects that the rate increase, together with other proposed changes to IPPS payment policies, will increase IPPS operating payments by approximately 1.7 percent, and that proposed changes in uncompensated care payments will increase IPPS operating payments by an additional 1.2 percent for a total increase in IPPS operating payments of 2.9 percent.

Other additional payment adjustments will include continued penalties for excess readmissions, a continued 1 percent penalty for hospitals in the worst performing quartile under the Hospital Acquired Condition Reduction Program and continued upward and downward adjustments under the Hospital Value-Based Purchasing Program. CMS projects that total Medicare spending on inpatient hospital services, including capital, will increase by about $3.1 billion in FY 2018.

In addition to the payment and policy proposals, CMS is releasing a Request for Information to welcome feedback on positive solutions to better achieve transparency, flexibility, program simplification and innovation. This will inform the discussion on future regulatory action related to inpatient and long-term hospitals.

**Quality Payment Program/ Medicare Access and CHIP Reauthorization Act of 2015 Year 2**

This proposed rule is in the final stages of clearance at the Office of Management and Budget (OMB) and will contain the proposed requirements for physician participation and reporting in the Merit-Based Incentive Payment System (MIPS) and in Advanced Alternative Payment Models. It will discuss quality measures, cost measures, clinical improvement activities and use of electronic health records by physicians. These requirements will include proposed scoring systems and how penalties and bonuses will be apportioned. This proposed rule should be published no later than early June and will have a 60-day comment period.

**Physician Prospective Payment System**

Around July 4, CMS will issue a proposed rule that updates payment policies, payment rates and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after Jan. 1, 2018. This proposed rule could have several new physician fee schedule policies. It will also address misvalued services and it will have proposed payment changes on codes that have been evaluated for 2018. Payments are based on the relative resources typically used to furnish the service.

Relative value units (RVUs) are applied to each service for physician work, practice expense and malpractice. These RVUs become payment rates through the application of a conversion factor, updated each year as specified in the statute. This proposed rule will also have a 60-day comment period and comments usually are due right after Labor Day.

**Hospital Outpatient Prospective Payment System**

Also, around July 4, CMS will release the Calendar Year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System policy changes, quality provisions and payment rates proposed rule.

Again, this year, a key proposal will be the continued implementation of Section 603 of the Bipartisan Budget Act of 2015, which will impact how Medicare pays for certain items and services furnished by certain off-campus outpatient departments. There may also be proposals regarding payment policies on the packaging of services and the continued use of comprehensive APCs. CMS may also propose new or reconfiguration of the payment classifications for various services. This proposed rule will also have a 60-day comment period and comments usually are due right after Labor Day.

About the author: Jill Rathbun is managing partner at Galileo Consulting Group.

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Preserving practice revenues in a multitasking world

By Kellye Sherbet

Anyone who has ever worked in a physician office knows that multitasking isn’t just a “nice-to-have” skill: it’s an essential requirement.

At any one moment, you might be scheduling a patient, locating a proper billing code for a physician and running the latest A/R report.

Unfortunately, most of us aren’t as good at multitasking as we think. In fact, only about 2 percent of the population is considered good multitaskers. For the rest of us, multitasking actually decreases our productivity, by as much as 40 percent.

As someone who has spent most of my career working with physician offices, I am very familiar with the endless interruptions and task-juggling that staff face on a daily basis. While many people might find such an atmosphere exhilarating, the reality is that productivity does indeed take a hit when staff must constantly start and stop different tasks. And, if the individuals who are multitasking are responsible for billing and collections, the financial security of the practice could very well be at risk.

Nothing is more crucial to the long-term viability of a practice than effective billing and collections. Often the staff that handles these tasks is also responsible for other vital activities, such as scheduling, answering phones or managing the practice. When employees are stretched too thin, it’s easy for certain financial tasks to fall through the cracks.

For example, most practices have little difficulty collecting about 80 percent of the monies due from insurance and patients. The last 20 percent, however, requires more time and dedicated resources to uncover the reasons for claim rejections or why a patient hasn’t paid their portion of a bill. If staff is unable to make billing and collections a top priority, the practice may end up leaving a good portion of its revenue on the table.

Providers, especially those in small to medium-size practices, can rarely afford to dedicate staff solely to revenue cycle management (RCM) activities, especially in the face of shrinking reimbursements and rising overhead costs. For practices that are committed to maximizing their revenues, but struggle with resources, one alternative is to partner with a professional RCM company.

By partnering with an RCM company, practices can remain focused on the delivery of safe and effective patient care, while delegating billing and collection responsibilities to individuals who are highly trained and credentialed. Though not all RCM companies offer the same level of service and expertise, most reputable organizations are staffed by experienced billers, including certified coders, and are able to collect more money in less time than the average practice.

Consider a few of the ways RCM companies differ from the typical physician office:

- **Dedicated staff.** Unlike employees in many physician offices, RCM personnel are solely focused on maximizing revenues for their medical practice clients. They are typically charged with the responsibility of proactively addressing revenue-impacting changes, such as updated coding requirements for a specific payer or specialty. This is an add-on responsibility of the in-house billing staff and could easily be put off due to other priorities. Because RCM companies are staffed with multiple billing and collection experts, a practice also doesn’t need to worry that an unexpected turnover or that a vacation in the billing department might lead to a short-term cash flow problem.

- **Industry expertise.** An RCM company is much more likely to have expertise in areas that will positively impact a practice’s bottom line, such as CMS medically necessary rules, prepayment audits, insurance recoupments, ICD-10, MACRA/MPIS, PQRS and more.

- **Best practice mindshare.** Individual practices tend to operate in a silo, with little exposure to what other physician offices in their area or specialty are doing to maximize reimbursements or increase efficiencies. Because RCM companies provide services to numerous practices in multiple specialties, they have greater visibility to unique billing and coding nuances that can impact reimbursement. They are able to offer “best practice” guidance as needed to help practices create streamlined workflows and implement procedures that enhance both financial and non-financial operations.

For example, RCM specialists can:

- Spot likely coding omissions, such as forgetting to bill for equipment use.
- Compare payments to contract allowables in order to spot underpayments.
- Educate the practice on regulatory changes that could impact the bottom line.

Because RCM personnel are not practice employees, physicians and office personnel may view their feedback and advice more objectively and without misplaced emotion. For example, a physician may be more receptive to a recommendation to complete chart notes on a timely basis if the suggestion comes from an RCM employee and not the office manager. Similarly, by having an RCM professional handle patient collection issues, office staff and physicians are better able to preserve their relationships with patients. In addition, RCM professionals are well-trained to resolve even the most difficult collection cases.

About the author: Kellye Sherbet is the president of RCM Services at Aprima Medical Software.
Bacteria hits the floor

By Thom Wellington

Research concerning high-touch objects in patient rooms has led to many product advances and innovations. They include new cleanable TV remote controls, copper-embedded IV poles, washable keyboards and even silver-impregnated privacy curtains all designed to reduce the bacteria burden. A study published in the American Journal of Infection Control detailed a survey of five Cleveland-area hospitals where samples were collected from patient room floors and found to be contaminated with dangerous pathogens.

You may be thinking: are the pathogens just going to jump off the floor?

According to Hicks, “the law of gravity turns the patient and visitors. Hand hygiene is recognized by IPs as the most important intervention in decreasing the spread of infection. Hands are vectors for transmission between both people and objects. According to the World Health Organization (WHO), health care workers should practice proper hand hygiene before touching the patient, after touching the patient and after touching inanimate objects in the patient’s surroundings. The principles of the safety protocol should be taught to the patient as well as others entering the room. The additional data presented concerning contamination transference from touching items that were picked up from the floor means a review of education practices is necessary immediately.

Since new research and testing data are putting questions in the minds of infection preventionists and EVS managers, new products and education programs will likely be developed or promoted. The cost of health care associated infections (HAIs) to both the patient and the hospital is driving the intense focus on the patient environment, and with the new research comes better practices to improve patient safety and healthier outcomes.

About the author: Thom Wellington is the CEO of Infection Control University.

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Infection Control Corner

Bacteria hits the floor

By Thom Wellington

Just when you thought things were improving with hospital safety and health care associated infections (HAIs), new research shows health care associated pathogens remain active on all types of surfaces for extended periods of time.

Based on this new research, an infection preventionist at a large hospital demanded the environmental services (EVS) department change the floor cleaning chemical to a disinfectant to combat the active pathogens. Soon, patients and staff were complaining of the floor’s “stickiness” from the disinfecting solution and a psychological feeling that something inappropriate was spilled on the floor.

According to Darrel Hicks, EVS director at GCI Certified and author of Infection Prevention for Dummies, the issue of whether the floor should be disinfected is unresolved. According to Hicks, “the law of gravity turns floors into depositories of everything from soiled tissues, dust and microscopic organisms.”

Hicks commented that combining a good neutral cleaner with a microfiber mop and a properly trained EVS technician would be just as effective and about one-tenth the cost of an in-use dilution of disinfectant.

“Of course, arming the technician with a bottle of an intermediate-level disinfectant should reduce microorganisms to a safer level,” he said.

The CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities states that reasons exist for using a detergent alone on floors because noncritical surfaces contribute minimally to endemic health care-associated infections, and no differences have been found in HAI rates when floors are cleaned with detergent rather than disinfectant. Changes to health care floor care guidelines will likely be coming considering this referenced study whereby of the 100 occupied rooms which were studied, 41 percent had one or more high-touch objects that came into contact with the floor. Cultures were collected from the floors and from hands that had touched items which had come into contact with the floor. Contamination identifying Clostridium difficile was recovered from floors in 48 percent of the surveyed rooms. MRSA and VRE were also present in patient room floor samples, but at a significantly lower rate.

Samples were taken from hands to determine the frequency of transference of pathogens from the floor to hands in the patient room after touching an item that was on the floor. Of the 31 bare hand or glove cultures, MRSA was recovered from 18 percent, VRE from 6 percent and C diff 3 percent.

The best defense for the patient is making sure everyone in the room is washing their hands after touching items including the patient and visitors. Hand hygiene is recognized by IPs as the most important intervention in decreasing the spread of infection. Hands are vectors for transmission between both people and objects. According to the World Health Organization (WHO), health care workers should practice proper hand hygiene before touching the patient, after touching the patient and after touching inanimate objects in the patient’s surroundings. The principles of the safety protocol should be taught to the patient as well as others entering the room. The additional data presented concerning contamination transference from touching items that were picked up from the floor means a review of education practices is necessary immediately.

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The virtual health assistant

By Bipin Thomas

In my previous column, I introduced the emerging relevance of artificial intelligence (AI) in the health care industry.

This article is the continuation of the AI series in which I’m outlining specific applications of AI in health care. While there are a number of applications within health care where AI can deliver incredible value, health care executives must evaluate and see if they can adopt some or all of them in order to begin their journey in the AI space. The following is one of the four areas in which artificial intelligence in health care is gaining steam.

With most of today’s U.S. adolescents, adults and seniors owning a smartphone, they are likely to have access to an intelligent personal assistant on their device. The likes of Cortana and Siri are backed by powerful systems with robust AI capabilities. These systems have the potential to provide tremendous value when combined with health care apps.

Virtual health assistants are going to see increasing use in the health care arena, where they can do everything from answering billing questions to encouraging patients to remain adherent to treatment and wellness regimens. They can save companies money while empowering patients to achieve better outcomes. Infinitely scalable, they can help millions of people navigate all kinds of information and deliver the high-touch, proactive engagement that call centers can’t afford to offer.

The case for virtual health assistants

Patients often make small mistakes that impact their health in big ways. Those simple mistakes include everything from forgetting to take their medicine on time to delaying to failing to schedule important health tests like mammograms and colonoscopies. There are already several technology-driven solutions, such as phone applications, medication text reminder systems, smart medication bottles and shipments of medication and goods that are automatically sent when an old prescription is due to run out. Those help, but they don’t go far enough.

The application of AI in the form of a personal assistant can have an incredible impact on monitoring and assisting patients with some of their needs when clinical personnel are not available. Virtual health assistants won’t replace humans. In fact, they work in conjunction with them. They are an engagement technology that is infused with the knowledge of a specific domain, therapy or wellness regimen as deciphered by each client. They are infinitely scalable, therefore saving money by addressing issues once reserved for call centers and health care professionals. When they can’t answer a question, they are programmed to direct you to the person or place that can.

For instance, virtual health assistants can track individual health needs and send out reminders with the full consent of patients as often as a patient needs them. They can then communicate with health care providers to help doctors figure out treatment plans. As the number of patients outstrips the number of health care professionals available to serve them, these virtual assistants will allow scalable, effective provision of wellness, prevention and disease management care pathways.

Establishing a relationship with patients

Virtual health assistants can converse and empathize with patients using real language, thereby developing relationships with them. That ability changes the whole equation. In addition to being able to converse with people, they use personal data and context to establish emotional and social relationships by delivering valuable information.

For instance, the virtual health assistant might start a conversation by telling the local weather and traffic conditions, which it knows because it has access to data sites through a patient’s smartphone. Once it is talking to you, it might quiz you about what you ate for breakfast and when you planned to exercise. You understand that it is a computer program, but because it gives you real information you can use, you begin to trust it, just as you would a real person.

Virtual assistants also have an advantage of being with patients 24 hours a day, with the ability to engage them at the precise moments they want and need to interact. There is no easier way to connect with patients than by talking to them. It’s the one, natural way of gathering real, unfiltered patient data. That’s something that our current inefficient call-center patient service models cannot provide, and virtual health assistants are already being deployed to transform health care.

About the author:
Bipin Thomas is a renowned business-technology innovator and thought leader on consumer-centric health care transformation. Thomas is a board member of HealthCare Business News magazine and strategic advisor to HealthTap. Thomas is a senior executive at Flex, where he is leading business innovation by enabling intelligent products and connecting stakeholders across industries. Thomas is a former senior executive at Accenture and UST Global, where he implemented strategic digital initiatives across the care continuum.

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SNMMI Preview

Over 5,000 expected in Denver for SNMMI meeting

The Society of Nuclear Medicine and Molecular Imaging’s 2017 annual meeting takes place in Denver June 10-14.

It will bring together more than 5,000 physicians, technologists, scientists and exhibitors from around the globe to learn about cutting-edge research and advance their knowledge through continuing education sessions.

The focus is on science, including: improving patients’ lives by creating new equipment or probes to diagnose earlier and more accurately; delivering the most effective therapy for a specific patient’s disease; and how to monitor and adjust treatment to ensure optimum results.

There will be tracks for scientists, physicians and technologists, covering the latest advances, including the growing role of nuclear medicine and molecular imaging in precision medicine.

The opening plenary session on Sunday, June 11, will feature theranostics. The Henry N. Wagner, Jr., M.D. Lecture, titled “Theranostics: Looking Back and Moving Forward,” will be given by Richard Baum, M.D., Ph.D. In addition, Johannes Czernin, M.D., editor-in-chief of The Journal of Nuclear Medicine, will speak about “Imaging with a Purpose: The Future of Nuclear Medicine, Molecular Imaging and Therapy.”

The opening plenary will also introduce the society’s new value initiative, which addresses five critical domains that will guide the society’s strategic plan over the next several years: quality of practice; research and development; workforce pipeline and lifetime education; advocacy; and outreach.

SNMMI is an international organization that relies on collaboration across borders.

Germany’s latest advances in research, technology and clinical practice.

Additional meeting highlights include sessions on new tracers and applications, emerging technologies, a fluciclovine live reader training, updates on appropriate use criteria and coding and reimbursement, and Mo-99 production and availability. The exhibit hall will be a one-stop showcase for cutting-edge molecular imaging devices, products and services.

The CT and MRI case reviews, presented in collaboration with the University of Colorado Denver, will provide 12 hours of review over two consecutive days and include 52 CT studies and 48 MRI case studies.

Patient Education Day, June 11, will feature breakout sessions on neuroendocrine tumors, prostate cancer, thyroid cancer and Alzheimer’s disease.

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HealthCare Business News had a recent opportunity to speak with Dr. Bennett Greenspan to learn more about him, his goals as society president and some of the challenges and opportunities facing nuclear medicine, molecular imaging and SNMMI members.

**HCB News: What inspired you to get involved in medicine?**

**BG:** My father was an internist subspecializing in hematology and oncology, so I grew up with medicine in the house. In high school, he said I should go into medicine, as it offered so many opportunities. I resisted as a teenager, because that’s what teenagers do. In college, though, I studied microbiology with the aim to go into medicine. I focused on radiology and nuclear medicine in med school.

My father actually suggested nuclear medicine as a career while I was still in high school, but I didn’t know anything about it. In medical school, I looked into it. It didn’t click right away, but it did eventually make sense.

**HCB News: How did you get involved and get to where you are today in SNMMI?**

**BG:** Somewhere along the line I got involved in one or two committees. I liked it and was good at it, so I got more involved. I became a member of several committees and councils and the chair of the Academic Council. I was elected to the board of directors and served two terms. I ran for vice president-elect two years ago and was elected.

**HCB News: What major initiative or initiatives do you plan to support during your time as president?**

**BG:** There are a number. First, we’ll be presenting our value initiative from our board of directors at the annual meeting. It will support our revised strategic plan.

Second, promoting radionuclide therapy and theranostics. These have a lot of promise, especially with radionuclides that can function in both therapy and diagnostic studies.

Third, we’ll be promoting a reasonable approach to radiation safety. The linear non-threshold hypothesis that’s used for radiation protection isn’t even correct.

Fourth, we’ll be supporting development of Appropriate Use Criteria (AUC) and updating our procedure standards. In its role as a qualified provider-led entity (PLE) under the Medicare AUC program for advanced diagnostic imaging, SNMMI is developing a series of new AUCs for some of the most commonly used nuclear medicine procedures. These AUCs are intended to assist referring physicians and ordering professionals in fulfilling the requirements of the 2014 Protecting Access to Medicare Act.

Fifth, we plan to reinstate the future leadership academy. It’s important for the future of the society to engage young talent and encourage them to be active participants.

And finally, I want to support the development of medical physicists who specialize in nuclear medicine physics by supporting increasing the number of medical physics residencies. I would also like to support mid-level opportunities for nuclear medicine technologists.

**HCB News: As president, what unique experience and perspectives do you bring to the table?**

**BG:** I’ve been heavily involved in committees for many years and have a broad range of experience in that respect. I have worked with scientists, technologists, radiologists and nuclear medicine physicians. I also have training in radiology and nuclear medicine, and am certified in both.

**HCB News: What are the biggest challenges facing SNMMI today?**

**BG:** There are three main challenges. The first is handling regulations and reimbursement. Second is raising awareness among clinicians about the value of nuclear medicine. The third is the concern about a shortage of Technetium-99m. There is no domestic supply of Mo-99. The Canadian reactor shut down routine production of Mo-99 in 2016, and backup emergency support will cease in 2018.

However, the good news is that a study by OECD’s Nuclear Energy Agency stated that the supply chain capacity should be sufficient to manage an unplanned outage of a reactor or a processor until 2021. Also, the High Flux Reactor in Petten has undergone upgrades, and has significantly increased production of Mo-99, and ANSTO has ramped up Mo-99 production at its OPAL reactor in Australia. Companies working in partnership with the
U.S. Department of Energy’s National Nuclear Security Administration on non-high energy uranium production of Mo-99 will also soon be part of the supply chain.

**HCB News:** What are the biggest opportunities?

**BG:** It goes back to the value initiative of nuclear medicine and radionuclide therapy that is key to advances in the field, especially in cancer therapy. There are also new radiopharmaceuticals which have been or will be receiving FDA approval that are very promising.

**HCB News:** Did the introduction of the ACA have any significant impact on your members?

**BG:** I don’t have numbers, but I think in general, more patients could afford to get tests, so it did probably increase the volume of tests being done.

**HCB News:** Are there any concerns about repeal/replacement?

**BG:** Doing the right study for the right patient helps them get the care they need. PET studies can determine if they have cancer and at what stage, so it can prevent unneeded surgeries. By providing the right information, it lowers costs by directing physicians toward the most promising therapy. So cutting reimbursement or increasing copays reduces the chance of getting care when treatment could be more successful. Therefore, cutting reimbursement or increasing copays could lead to an increase in health care costs.

**HCB News:** What are you most excited about at the upcoming annual show and conference?

**BG:** I’m looking forward to seeing the data on the new agents to see how successful they are. Presenting our value initiative about how nuclear medicine provides value to patients and health care overall will also be exciting.

Our value initiative covers five domains:

- Quality of practice, which provides focus on improvement in quality of studies and interpretations, and use of diagnostics and therapeutics, to promote better patient outcomes.
- Research and development, to develop new radiopharmaceuticals in a wide range of diagnostic procedures, and new radiopharmaceuticals for radionuclide therapy.
- The workforce pipeline, to attract high-quality candidates to nuclear medicine. Also to get radiology residents more interested in nuclear medicine.
- Advocacy, explaining to legislators, regulators and payors the value of nuclear medicine and molecular imaging.
- And outreach to referring clinicians, patients and the public.

The value initiative will help direct our development of the new strategic plan of the SNMMI for the next three to five years.

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The following are just some of the products and services on display at SNMMI 2017. To view these products online, or to share with colleagues, visit dotmed.com and enter the code DM 37247 in the search window, or enter the address www.dotmed.com/news/37247 in your browser.

**SNMMI PRODUCT SHOWCASE**

**Nuclear Medicine Products**  
*Lantheus Medical Imaging, Inc.*  
*Booth 709*

Lantheus Medical Imaging provides a broad portfolio of nuclear medicine products that help healthcare professionals identify disease and improve patient treatment and care. Our products assist physicians in the diagnosis of conditions affecting the heart, brain, lungs and other organs. Please visit us at the SNMMI 2017 Annual Meeting or lantheus.com to learn more about our suite of nuclear medicine products, including TechneLite® (Technetium Tc99m Generator), Xenon 133 (Xenon Xe133 Gas) and NEUROLITE® (Kit for the Preparation of Technetium Tc99m Bicisate for Injection).

**Lead Lined Laboratory Furniture**  
*MarShield*  
*Booth 361*

MarShield manufactures a wide range of Standard or Custom Designed Lead Lined Laboratory Furniture suitable for Nuclear Medicine or Radiochemistry laboratories. MarShield has worked extensively with architects, engineers, contractors and end-users like doctors, hospitals, laboratories and medical and veterinary clinics to ensure that our designs are functional and harmonious with their surroundings while meeting radiation code requirements. Please refer to our Cabinet/Furniture quotation and information guidelines at marshield.com to design one for yourself today!

**NuPET™**  
*Cubresa*  
*Booth 922*

Cubresa’s NuPET™ is a revolutionary PET scanner that empowers you with simultaneous molecular and functional imaging by bringing PET into the bore of an existing MRI. Hybrid PET/MR imaging is gaining momentum for preclinical and translational research, enabling better understanding of complex biological mechanisms. Fields such as neurology, oncology and cardiology benefit from the ability to correlate time-dependent molecular mechanisms to functional response with significantly shorter acquisition times and maximized throughput. NuPET™ combines the superior anatomical, structural and functional information of MRI with the molecular sensitivity of PET and eliminates registration errors when an animal is moved from one scanning system to another, boosting confidence in your data and adding new insights to your preclinical research.
Mediso AnyScan S large FOV SPECT camera Absolute Imaging Solutions Booth 431

The Mediso AnyScan® S large FOV SPECT camera is a small footprint, vendor neutral system, designed for ease of use, patient safety and integration into any practice. Image patients up to 505 lbs. via the ergonomic and open design, maximize the proximity of the variable angle detectors for increased resolution and implement half-time and dose reduction in your market. Maximizing system uptime, the AnyScan also lowers your total cost of ownership from acquisition to long-term service costs and we do not install expensive encryption keys. The AnyScan® S, a solution in efficiency, improving patient comfort and safety, one patient at a time.

PET/MR 3T Bruker BioSpin Booth 939

The latest breakthrough in PET detector technology, together with the proven superior soft tissue contrast of translational field strength MRI, is now combined in one compact, easy-to-use instrument. Featuring homogeneous, constant PET resolution over the whole field of view, a newly developed 3T cryogen-free magnet and a motorized animal transport system, the PET/MR 3T simplifies your workflow and supports a broad spectrum of application fields.

The Lara™ System Lucerno Dynamics Booth 472

Lucerno Dynamics’ first commercial product, The Lara™ System, focuses on quality control and quality assurance of the radiotracer injection process. By placing Lara™ sensors on a patient’s arms prior to injection of radiotracer, clinicians can easily assess the quality of injections during the uptake period, prior to a PET/CT scan. For quality assurance, Lucerno Dynamics offers proprietary Ellexa™ software to identify contributing factors impacting injection quality, make appropriate adjustments and improve quality. Do you know which of your PET/CT patients experience radiotracer infiltrations? Lara™ knows.
AIS — Absolute Imaging Solutions, Booth 431
Prior to making imaging services or purchasing decisions, have you contacted Absolute Imaging Solutions™? AIS, one of the most respected and battle-tested molecular/nuclear imaging providers, provides something that you won’t get from other molecular imaging partners: The Absolute Guarantee™. AIS is the exclusive U.S. source of the vendor neutral AnyScan® S, single- or dual-head large FOV general purpose SPECT camera. Feature rich with half-time and half-dose options, the AnyScan® S is designed and developed by Mediso Medical Imaging Systems. Please visit us at the SNMMI 2017 Annual Meeting for an exclusive introduction to the Mediso AnyScan S and to learn more about AIS!

Bruker BioSpin, Booth 939
Bruker offers advanced preclinical imaging solutions for a broad spectrum of application fields, such as oncology, neurology, cardiology, inflammation, infectious diseases, cancer research, functional and anatomical neuroimaging, orthopedics, cardiovascular imaging and stroke models. Our range of techniques includes PET/SPECT/CT imaging, MRI, PET/ MRI imaging, Optical Imaging, micro-CT, MPI as well as MALDI Imaging.

Our team of experts will be available to chat about applications, technology updates, product specifications or even service offerings. Stop by to also discover our PET/ MR 3T on display!

Cubresa, Booth 922
See Cubresa’s NuPET™, a revolutionary in-bore PET scanner for your existing MRI instrument that empowers you with multimodal, simultaneous molecular and functional imaging. NuPET™ can be installed in the widest range of MRI magnets, including dedicated preclinical 7T and 9.4T models and even clinical 3T magnets where you may wish to add preclinical capability. Boost confidence in your data and add new insights to your research with true simultaneous PET/MR imaging.

Lantheus Medical Imaging, Inc., Booth 709
Lantheus Medical Imaging is a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products. Lantheus provides a broad portfolio of products that help healthcare professionals identify disease and improve patient treatment and care. Our pioneering products assist physicians in the diagnosis of conditions affecting the heart, brain, lungs and other organs. Please visit us at the SNMMI 2017 Annual Meeting to learn more about our suite of nuclear medicine products, including TechneLite® (Technetium Tc99m Generator), Xenon 133 (Xenon Xe133 Gas) and NEUROLITE® (Kit for the Preparation of Technetium Tc99m Bicisate for Injection).

Lucerno Dynamics, Booth 472
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Do you know which of your PET/CT patients experience radiotracer infiltrations? Lara™ knows. Don’t keep flying blind! Enter a drawing to win a free Lucerno Dynamics Lara™ System two-month radiotracer injection process quality assessment for your center. The prize includes complementary use of Lucerno Dynamics hardware, software and related training.

Marquis Medical, Booth 861
Marquis Medical is an ISO 13485 Certified Company and the industry leader in providing pre-owned PET/CT systems. Primarily recognized as a service company because of our extensive technical knowledge of Siemens and GE products, Marquis Medical is one of the few in the PET/CT marketplace that can offer a true turnkey solution.

Visit us at SNMMI to learn about our large selection of PET/CT systems and parts. When it comes to Siemens or GE PET/CT systems and service, Marquis Medical has the expertise to help you and your practice succeed.

MarShield, Booth 361
MarShield is a global leader in radiation shielding products for the health care industry. We manufacture high-quality custom lead-lined cabinets for isotope storage. Our in-house design assistance team will custom design and manufacture X-ray rooms and booths to your exact specifications.

MarShield also offers a complete range of standard and custom modular radiation barriers, storage containers, lead curtains and lead/Silflex blankets. We are the experts in the application of sheet lead, lead glass, lead bricks, lead drywall and lead-lined doors/windows used in the construction or renovation of medical clinics, dental offices and health care facilities. For 38 years... MarShield — Every Solution in Shielding.

MOLECUBES NV, Booth 910
MOLECUBES NV is an innovative company developing, manufacturing and selling benchtop preclinical imaging PET, SPECT and CT cubes enabling researchers and biologists to achieve high quality multimodality images supported by fast and simple workflows and intuitive wireless users’ interface.

The X-CUBE, Gamma-CUBE and Beta-CUBE are respectively the best-in-class benchtop small animal CT, SPECT and PET designed both for high throughput and advanced applications.

Thanks to its truly benchtop design, total ease of use and breakthrough service concept, MOLECUBES paves the way to the next generation of whole-body mouse and rat imagers. Please visit us at our SNMMI booth #910 and see for yourself.

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In recent years, medical imaging, including magnetic resonance imaging (MRI), X-ray, computed tomography (CT), ultrasound, optical and positron emission tomography (PET), has reached the forefront of indispensable tools used by medical doctors to diagnose, treat and monitor the cellular and molecular underpinnings of diseases on a patient-by-patient basis.

With the increasing need for more information to be gained from each individual diagnostic test, scientists have been harnessing the characteristics of diseases unique to each patient to aid in determination of treatment planning. Surveys of the distinctive chemistries of individual tissues within a living organism cannot be accomplished with classic anatomical imaging techniques, such as X-ray, CT and ultrasound, but require molecular imaging techniques, such as PET. No other individual test can be claimed to be more influential for the growth of PET above 2-deoxy-2(18F)fluoro-D-glucose or [18F]FDG.

Early studies found that synthetic analogs of glucose containing a fluorine in place of a hydroxyl group in the 2 position of the carbohydrate backbone were easily and rapidly taken up by cells, but became trapped within the cells as the normal glucose metabolic pathways could not progress past the first phosphorylation event. This resulted in an accumulation of these glucose analogs within the cell and could, by extension, be seen within cells with elevated glycolytic activity, such as rapidly proliferating cancer cells. By replacing the normal fluorine atom in these compounds with the radioactive isotope fluorine-18, [18F]FDG PET was born. First administered to healthy human volunteers in 1976, the compound quickly gained favor as an imaging agent for a variety of neuropsychiatric disorders, but arguably found its greatest utilization in the world of oncology.

With the rapidly evolving technology of both producing [18F]FDG and detecting the radioactivity produced in a three dimensional field of view, the supply of the drug has far outweighed the demand in recent years. One could argue that the technology involved in the production of [18F]FDG, primarily the cyclotron production of the raw fluorine-18 and the automated synthetic units used to produce the drug, has outpaced the demand for the drug in such a way that the field has been flush with availability, causing a dramatic downturn in the price per dose in recent years. In reality, the relatively low cost per dose of [18F]FDG has been a benefit for facilities that purchase the drug from commercial vendors, but has been highly detrimental to the facilities that prepare the drug for internal use and rely on reimbursement to subsidize the cost of production and auxiliary research and development.

The utility of [18F]FDG, although shown to be useful in a variety of circumstances, is limited for visualization of the brain due to high background uptake in normal brain tissue. For example, the determination of amyloid plaques associated with neurodegenerative disease requires the development of alternative imaging agents. In recent years, several new PET imaging agents have been brought to market through commercial entities and academics alike.

The first major effort was undertaken by Avid Radiopharmaceuticals for the commercialization of [18F]Florbetapir (known as AMYVID or AV-45). With FDA approval being granted in early 2011, [18F]Florbetapir showed great promise of becoming a sustainable new PET imaging agent. However, the proper utilization of the drug hinged on a therapeutic agent also coming to market, which to date, has not been the case.

Even though the future of [18F]Florbetapir remains uncertain, release of new amyloid imaging agents has not been hampered. The most recent approval for a novel PET imaging agent has been [18F]Fluciclovine (known as 18F-FACBC), gaining FDA approval in May 2016. This agent has gained interest in the oncology community, especially in prostate cancer, and is currently gearing up for large-scale production and distribution through a partnership with Blue Earth Diagnostics (the developer of [18F]Fluciclovine) and Siemens’ PETNET Solutions. Lastly, one cannot ignore the success of [18F]Florbetaben (formerly known as BAY-949172), which was originally developed by Bayer and gained FDA acceptance in 2015.

With all three of these agents competing for the top spot as the next highly used PET imaging agent, the future of this field does indeed look promising. Additionally, a large number of new PET agents are being reported and tested each day in both pharmaceutical companies and academia, utilizing other PET isotopes, including carbon-11, gallium-68 and zirconium-89. With the advent of new radiopharmaceuticals and increasing utilization in the pursuit of precision medicine, future applications of PET are nearly unlimited.

About the authors: Michael L. Nickels, Ph.D., is the technical director of the PET Radiochemistry Research Laboratories, Radiology and Radiological Sciences at Vanderbilt University. Michael Schulte, Ph.D., is a research instructor at Vanderbilt University. H. Charles Manning, Ph.D., is the director, Vanderbilt Center for Molecular Probes and Molecular Imaging Research.

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Focus on Axumin

Q&A with
Jonathan Allis
CEO of Blue Earth Diagnostics and
Barry Scott
global head of PETNET Solutions, Inc.

Axumin, a PET imaging agent for men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment, has seen rapid adoption in the U.S. since receiving FDA approval in May 2016. The tracer was developed by Blue Earth Diagnostics in the U.K. and is being distributed in the U.S. by PETNET Solutions Inc., a subsidiary of Siemens Healthineers.

HealthCare Business News spoke with Jonathan Allis, D. Phil., CEO of Blue Earth Diagnostics, and Barry Scott, global head of PETNET Solutions, Inc., about Axumin’s busy year — and what we can expect in the months to come.

HCB News: How does Axumin help physicians?
Jonathan Allis: Approximately 161,000 men are diagnosed with prostate cancer each year in the U.S., so it’s a very common disease. Fortunately, it’s a disease that, if caught early, can be cured in lots of patients, and for those who cannot be cured, they still typically live for a long time — so that’s a good thing.

What is not a good thing is that about one-third of patients — potentially many years after their treatment, whether it was surgery or radiotherapy — will experience a rise in their blood level of prostate specific antigen (PSA) and that means the cancer has probably recurred somewhere.

If you don’t find out where it has recurred you cannot treat it — so you want to have an imaging test that tells you if it has recurred in the prostate bed or near the prostate, or if it’s further away somewhere in the abdomen or in bone, for example. If you can work out where the cancer is, then you can do something about it.

HCB News: What has been the response to Axumin from the PET imaging community since its FDA approval last year?

Jonathan Allis: The problem is that current imaging methods are pretty bad at finding where this cancer has recurred. Most people will have a CT scan, but the chance of a CT scan finding the site of prostate cancer recurrence is about 10 to 15 percent, so most of the time physicians and patients are faced with the unpleasant dilemma where the patient has a rising PSA, but they can’t find or treat the disease.

If you don’t treat it at that stage, the patient may develop metastatic disease and that’s an extremely dangerous form of prostate cancer compared to the average. So, that’s where Axumin comes in. It allows you to inject a radiopharmaceutical agent into the patient. It travels to the site of cancer and allows you to see it on a PET scanner.

Axumin will detect this recurrence between 60 and 80 percent of the time — so it allows the disease to be localized so it can be treated appropriately and the disease can be stopped from spreading.

HCB News: What has been the response to Axumin from the PET imaging community since its FDA approval last year?

Barry Scott: ‘Axumin will detect this recurrence between 60 and 80 percent of the time, so it allows the disease to be localized so it can be treated appropriately and the disease can be stopped from spreading.’
JA: When you introduce a new product, you hope that it has an unmet medical need and that when you tell people about it, that they won’t look at you in a really bored way. We are happy to say we’ve not had that response with Axumin. It addresses a fundamental unmet medical need and we’ve been pleasantly surprised by how rapidly the uptake has gone in the U.S.

HCB News: Is Axumin currently being reimbursed?

JA: When we started the company in 2014, we weren’t overly worried about technical issues or regulatory approval. We were worried it wouldn’t be paid for. If you look at the history of reimbursement for PET imaging agents, it hasn’t been pretty. It’s taken a long time to get reimbursement for certain PET agents while others are not reimbursed.

So, we were very fortunate to have the reimbursement process go smoothly for Axumin. We put together dossiers on how it works and contacted local Medicare contracting committees and presented the data and got a very positive response. We’ve had a permanent HCPCS code (A9588) since the beginning of this year, meaning it is covered by CMS for the Medicare population across the U.S., so that removes a big barrier from product adoption.

People hear about Axumin and say, ‘Yes, we need that.’ Then they say, ‘Well, is it available near me?’ And, of course, PETNET is doing a lot to turn that answer into, ‘Yes.’ Then they ask, ‘Is it reimbursed?’ And the answer to that is, ‘Yes’ as well.

It speaks to the utility of the product — you don’t get products that are not useful reimbursed and we’re extremely pleased that this has all gone so well.

HCB News: What is the half-life of Axumin? Must it be administered to patients within a tight time frame? Did these factors influence your decision to choose PETNET Solutions, Inc., as the radiopharmaceutical’s exclusive U.S. commercial manufacturer and distributor to imaging centers?

JA: Axumin is labeled with fluorine-18 which has a half-life of 110 minutes so it’s the same isotope that is used for FDG, which is the most common PET imaging agent by far — so Axumin plugs directly into the same distribution network. With FDG, you wait an hour or so after injecting the patient, but with Axumin you inject and scan within three to five minutes, so it’s a different process.

There are a number of radiopharmacy networks in the U.S., but I think PETNET has the largest footprint, so that factored into our decision to partner with them. They also have a genuine passion for PET — you want a partner who believes in your product as much as you do, and is not just doing it as a job, but as a mission — we love working with PETNET.

BS: As of right now, Axumin is available from 16 production sites, and PETNET Solutions plans to add several more sites in the next year. With the success we’ve had with product adoption, we’re going to step up expansion, but even as of today, we can provide Axumin to a majority of U.S. imaging centers.

HCB News: Do you plan any other indications for Axumin?

JA: As you know, we’re indicated for biochemically recurrent prostate cancer, but we’re interested in how it might apply in a range of prostate cancer indications as well as other cancers.

We have work going in a number of interesting areas. The data we have in brain tumors, particularly gliomas, looks pretty good and we’re starting to pull all that together to file for that indication. We currently have an orphan drug designation from the FDA as well as the European Community for glioma.

Also, some types of breast cancer are not imaged well with existing radiopharmaceuticals, and we think Axumin may be interesting in those areas, so we will continue to investigate them.

Share this story: dotmed.com/news/37250
HealthCare Business News recently caught up with Tiffany Olson to discuss supply chain issues in the radiopharmaceutical industry.

**HCB News:** There have been molybdenum-99 (Mo-99) supply interruptions in the past. Does the supply chain in the U.S. look stable now, or are there weaknesses to keep an eye on?

**TO:** When I started in the radiopharmaceutical industry in 2013, I was astonished at the complexity of the supply chain. It truly impacts the business, and industry as a whole, more than I’ve seen in other industries in which I’ve worked. Technetium-99m (Tc-99m) is the daughter of molybdenum-99 (Mo-99) and is used in approximately 80 percent of the nuclear medicine procedures worldwide. Tc-99m has become the principal radioisotope used for medical diagnostic imaging because of the manageable half-life, low radiation exposure to patients and health care providers and clarity of images provided.

Tc-99m is critical to how physicians make diagnoses and direct patient care, and we are therefore dedicated to managing the complicated dynamics in the Mo-99 supply chain. Many factors combine to make the current supply chain for Mo-99 complex, including:

- The short half-life of Mo-99 at 66 hours, and Tc-99m at six hours.
- The U.S. does not have a domestic source of Mo-99, which can create difficult transportation and customs issues.
- The advanced age of most of the international reactors creates concern.
- The Mo-99 supply shortage in 2009 created an impetus for the industry to focus on enhancing the reliability of supply. Over the last several years, the industry has increased outage reserve capacity and added extra targets at current reactors. Generator manufacturers, downstream to reactors, have diversified their supply chains and incorporated multi-source agreements for Mo-99. Industry groups such as the Organisation for Economic Co-operation and Development (OECD) are meeting with groups to ensure reactor maintenance schedules are coordinated. Mo-99 production has become more reliable with these additional reactors and processing capacity. We continue to monitor these conditions closely, and feel confident in the plans the industry has in place to minimize interruptions and ensure continuous supply for patients.

**HCB News:** You raised the issue of the U.S. not having a domestic supply of Mo-99. How is this progressing?

**TO:** Cardinal Health and others in the industry are closely following these projects for the creation of a domestic Mo-99 supply. We need continued support from the U.S. government to assist commercial entities in establishing a reliable domestic supply of Mo-99.

In January 2013, the American Medical Isotope Production Act (AMIPA) was enacted to help establish a reliable domestic supply of LEU Mo-99. Making gains in this area, in December 2016, the U.S. Department of Energy’s National Nuclear Security Administration (DOE/NNSA) announced that it entered into follow-on cooperative agreements with three commercial entities to establish a reliable domestic source of molybdenum-99 that will be produced without the use of highly enriched uranium (HEU).

**HCB News:** When will conversion to low enriched uranium (LEU) become

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**Q&A with Tiffany Olson**

**President, Nuclear Pharmacy Services, Cardinal Health**

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mandatory? What does that mean to the industry?

TO: Since 1978, the International Atomic Energy Agency and U.S. Department of Energy have led focused programs to convert research reactors from using HEU to LEU to reduce the potential risk of terrorists accessing HEU. In 2007, 140 research reactors were using HEU fuel, and in 2016, this number was down to 74 research reactors using HEU. This includes eight reactors in the U.S. HEU continues to be used in producing Mo-99, as fuel for reactors and as targets. However, many producers utilize LEU fuels in their reactors, but continue to rely on HEU targets. The National Nuclear Security Administration (NNSA) also works with international Mo-99 producers to convert their facilities to LEU targets. The goal is to eliminate the use of HEU in civilian applications worldwide, including in research reactors and medical isotope production facilities. It is key for the government to invest in these programs, otherwise the timelines will be very drawn out.

HCB News: What is the state of the radiopharmaceutical market today and what does the near-term future look like?

TO: We continue to see solid demand for myocardial perfusion imaging (MPI) due to the prevalence of cardiovascular disease and MPI’s ability to assist a physician in determining a course of action.

In 2016, we saw new radiopharmaceutical products enter the market, and this brings a sense of optimism to the industry as we continue to provide patients and healthcare providers effective tools to diagnose and treat patients. The pipeline for radiopharmaceuticals is a strong indication pharmaceutical manufacturers continue to invest in our industry.

The radiopharmaceutical industry is full of passionate individuals focused on improving patient care. I believe that through continued investment in research through public and private organizations, along with government grants, we’ll continue to see new developments that will grow our industry. The IDEAS study is a great example of financial investment from both industry and government to advance diagnosis and treatment.

HCB News: What other dynamics are impacting the radiopharmaceutical industry?

TO: We continue to be optimistic about therapeutic radiopharmaceuticals in the drug development pipeline. The unique aspects of radioisotopes, combined with new pharmaceuticals, make this a cutting-edge area that will truly improve patient care.

We continue to experience industry changes of acquisitions and divestitures. This year Cardinal Health acquired North American rights to Lymphoseek from Navidea. We are thrilled with how the integration is moving, and are driven by the goal of providing continued access of the product to our hospital and clinic customers who have found great value in using Lymphoseek.

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Treatment Availability

How fast will the U.S. market get access to $^{68}$Ga?

By Richard Zimmermann and Paul-Emmanuel Goethals

The nuclear medicine world is slowly preparing for the introduction of gallium-68-labeled ($^{68}$Ga) tracers.

The first $^{68}$Ga-labeled molecules ($^{68}$Ga-DOTATATE and $^{68}$Ga-DOTATOC) obtained their marketing authorization in the course of 2016, but their use will become more obvious in connection with the associated therapeutic agent, $^{177}$Lu-DOTATATE (marketing expected in 2017). A series of new $^{68}$Ga tracers, in particular for imaging metastasized prostate cancer, will soon enter late-stage clinical trials. The manufacturing world needs to prepare for these new products. Nowadays, $^{68}$Ga-labeled tracers rely only on $^{68}$Ge/$^{68}$Ga generators and synthesis automates. Both the source of $^{68}$Ga and the preparation process are already challenged by new technologies while the market will have to adapt to the growing needs.

The use of gallium-68 as an alternative to fluorine-18 ($^{18}$F) in the development of new tracers for positron emission tomography (PET) took off mainly in Europe over recent years. Although in absence of tracers with marketing authorization, the routine use of $^{68}$Ga and the preparation process are already challenged by new technologies while the market will have to adapt to the growing needs.

In Europe, and most countries other than the U.S., each hospital has developed an access to a dedicated preparation room which is equipped with a hot cell that is generally operated by technologists under the control of the hospital pharmacy. This department is preparing the final doses from cold kits and generators, while only long half-life tracers and fluorinated tracers are delivered from central places. Such an infrastructure can, without difficulty, adapt to $^{68}$Ge/$^{68}$Ga generators.

However, when considering the current use of $^{68}$Ga, especially using synthesis automates, this local hospital radiopharmacy structure remains expensive as it requires a proportionally high number of dedicated experts (radiochemist, radiopharmacist), local investment as well as local handling authorizations which are still only accessible for a limited number of the hospitals (<25% in Europe). The recent introduction of cold kits, allowing the production of $^{68}$Ga tracers as easily as with technetium-99m ($^{99m}$Tc), will definitely reduce the time of preparation and the overall cost for $^{68}$Ga tracers. However the presently high price of generators makes this local product interesting only if all doses of gallium can be used daily in patients.

In the U.S. and a few other countries, the vast majority of customers rely on industrial radiopharmacies. This structure is more pragmatic as it concentrates both investment and experts on central sites. In theory, those sites should also show better profitability. These sites run several large $^{99m}$Tc generators from which they produce individual tracer doses sometimes even as pre-filled syringes directly shipped to hospitals and clinics. They buy large amounts of other radionuclides from which they prepare final products.

When $^{18}$F-FDG started playing an important role, these same centers became equipped with cyclotrons as their geographic distribution fit well with the customer density. Additional centers were created to fill the distribution gaps. Four major players control the largest areas with their networks, which are now adapted to radionuclides with the half-life of fluorine-18 (108 minutes). These centers are located in the most populated areas and, if required, can ship doses at up to six hours distribution distance.

Four major players control the largest areas with their networks, which are now adapted to radionuclides with the half-life of fluorine-18 (108 minutes). These centers are located in the most populated areas and, if required, can ship doses at up to six hours distribution distance.
$^{68}$Ga due to its shorter half-life, while in Europe, the market is not yet ready for buying ready-to-use tracers when such tracers can be prepared on-site from a generator with the existing staff and infrastructure.

There are an estimated 2,300 PET cameras installed in the U.S., actually largely underused equipment, that will easily cope with new tracers. This figure has to be compared with an estimated 870 PET cameras installed in the European Union countries and an estimated 5,600 PET cameras installed worldwide.

Additionally introducing a new $^{68}$Ga tracer on any market will need to account for new parameters, including:

- Very soon there will be new sources of germanium-68 ($^{68}$Ge) available, the parent isotope for gallium-68. This will increase competition among manufacturers, and sooner or later, directly impact the price of generators. It will favor individual generator implementation, but providing that the final authorized product is based on cold kits, otherwise it will become too costly in terms of local marketing authorizations. Cost of goods (CoGs) calculations have shown that single doses of $^{68}$Ga could reach levels that tend to be almost competitive with generator-produced $^{99m}$Tc, reducing the price of the PET modality to the price of the Single Photon Computed Tomography (SPECT) modality.
- A new way to directly produce very large amounts of pure gallium-68 (more than 50 times the capacity of a generator) based on standard cyclotrons (the same cyclotrons as the ones used to produce fluorine-18) will become available. This will favor centralized production, but also have the double advantage of being independent of the decay of $^{68}$Ge which reduces over time the generator capacity, and being clean of $^{68}$Ge as a potential contaminant. Depending upon the number of single doses that could be produced and distributed per batch, the price of cyclotron-produced $^{68}$Ga could even be competitive with generator-produced $^{68}$Ga when the price of $^{68}$Ge will have dropped.

From the final customer side there should be no major changes or investment to be required. Providers will have to guarantee a smooth supply of the new $^{68}$Ga-labeled tracers and generators or bulk $^{68}$Ga. Using gallium-68 as PET tracers instead of fluorine-18 labeled tracers will not need new equipment. Software will have to be adapted to this tracer and new indication, which is actually the case for any new tracer brought on the market. All PET imaging centers equipped for fluorine-18 will be able to use the new $^{68}$Ga tracers. This means that the installed PET customer base will remain the same.

There are an estimated 2,300 PET cameras installed in the U.S., actually largely underused equipment, that will easily cope with new tracers. This figure has to be compared with an estimated 870 PET cameras installed in the European Union countries and an estimated 5,600 PET cameras installed worldwide. The density implementation of PET cameras is very high in the U.S., with a ratio of 210 installed cyclotrons. Only daily capacity production will define profitability while new local regulation hurdles may slow down the implementation.

For countries with a well-developed cyclotron installed base, such as the U.S., it would make sense to use this equipment to partially supply customers with $^{68}$Ga through this channel. Almost any cyclotron able to produce $^{18}$F could, in theory, be able to produce $^{68}$Ga, providing some small investment. Like for cameras, the U.S. market has a large and underutilized installed base of cyclotrons: some 240 cyclotrons with energy below 25 MeV (mega-electron volts), able to be used for producing gallium-68, are in operation in the U.S. The density vs. cameras is even higher in the European Union with 210 installed cyclotrons. Only daily capacity production will define profitability while new local regulations may slow down the implementation.

So far, no radiopharmacy company has taken a decision to invest in one or the other technology, but such decisions need to be made soon. Both in Europe and the U.S., the structures will have to adapt. Eventually, the owners of the new proprietary $^{68}$Ga tracers will force their own way of access to market on the basis of the most cost-effective solution. The first cost of goods evaluations have shown that centralized cyclotron production could fit with both markets, but a timeframe of about two years will be needed for full implementation. Let us see how this market will develop, but in any case, $^{68}$Ga tracers will become available very soon.

About the authors: Paul-Emmanuel Goethals and Dr. Richard Zimmermann are co-founders of MEDraysintell, providing first-rate strategic intelligence in nuclear medicine, proton therapy and brachytherapy. MEDraysintell offers the most comprehensive set of reports and directories, with over 1,900 pages of unrivaled intelligence covering some of the most exciting healthcare technologies using radiation for diagnosis and treatment.

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PET grows while SPECT adapts

Within the nuclear imaging space, manufacturers are seeing tremendous growth in the PET market, a mainstay imaging modality for oncology, with new frontiers in neurology and cardiology.

By Lisa Chamoff

As for SPECT, facilities are migrating from SPECT-only systems to SPECT/CT, with the ability for the machines to do double duty and act as a CT backup.

Here's what's new from several companies.

Digirad

In September 2016, Digirad introduced its Cardius X-ACT+, a refresh of its dedicated SPECT myocardial perfusion imaging (MPI) system first launched in 2009.

“The new system is more ergonomically friendly, based on feedback from clinicians and patients,” says Jessica Schwarz, the director of commercial operations at Digirad.

For the new model, the company changed the design of the chair and footrest for better patient comfort and to make it easier for the technologist to use. It incorporates a new handrail and lower step to get up to the platform, and adjustable footrests at three different levels to cater to each patient’s height. The system can also accommodate patients up to 500 pounds.

“With our upright imaging, the chair moves, keeping the heart in the center of the field of view throughout the entire scan,” Schwarz says.

The X-ACT+ has an advantage over other systems with its fully integrated low-dose fluorescence attenuation correction, which Schwarz says provides a better image of the heart without using higher-dose CT.

“The X-ACT will do the nuclear emission scan first, then another one-minute transmission scan, without moving the patient,” Schwarz says. “The images are fused together.”

Last year, Digirad also became a dealer of products from Danish company DDD Diagnostic, including the CorCam, a dedicated cardiac SPECT camera, and QuantumCam,
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Molecular Technologies

a small, general-purpose nuclear medicine camera that can fit in a room as small as 10 feet by 10 feet. This allows Digirad to offer a full line of nuclear medicine products, says Virgil Lott, the company’s president of diagnostic imaging.

“In the past, we were very niche oriented in dedicated cardiac and portable planar imaging,” Lott says. “We wanted to add variable angle cameras so we could offer a full line of products to our customers. This allows us to be able to do all nuclear studies.”

GE Healthcare

Last June, GE Healthcare announced two molecular imaging systems: the Discovery MI platform, a premium PET/CT scanner with a high-end diagnostic CT; and the Discovery NM/CT 670 CZT, a SPECT/CT system.

The company says the Discovery MI, which received FDA clearance in October 2016, has the potential to help in the early diagnosis of cancers.

“If you can see it smaller and you see it earlier, you can better guide the patient to a more effective treatment strategy,” says Amy Burris, GE’s marketing leader for PET/CT. “It was also designed with the hope of pushing the boundaries of PET and conducting more compelling research within oncology, cardiology and neurology.”

The Discovery MI allows for the detection of smaller lesions, Burris says, and its high sensitivity allows enhanced utilization of limited-access tracers. It also has a 20-centimeter axial field of view option, which provides a more comfortable patient experience with short scan times with less dose, according to Burris.

For the Discovery NM/CT 670 CZT, which uses cadmium zinc telluride (CZT)-based digital technology, the most significant feature is the ability to further optimize dose and acquisition time along with smaller lesion detectability, says Luke Chrusciel, GE’s marketing leader for SPECT/CT.

“The reduction in time means the patients can have more comfortable exams, and therefore, exams are less likely to be compromised due to potential patient movement associated with prolonged imaging times,” Chrusciel says.

The company’s Discovery TM 670 DR can be upgraded at a customer site to the CZT technology, which Chrusciel calls the “future of nuclear medicine,” in two days.

“GE Discovery MI

“This is the beginning of a new era in nuclear medicine, going from analog to digital in general purpose imaging,” Chrusciel says. “We are proud again to lead the industry in this space like we have done so previously by being the first to market with a hybrid SPECT/CT system.”

In the PET/MR space, GE earlier this year received FDA clearance for the follow-up to its SIGNA PET/MR system, called SIGNA PET/MR with QuantWorks. The technology includes Q.Clear reconstruction that improves image quality and quantification of tracer uptake with personalized attenuation correction in the head.

Mediso

Mediso’s newest release is the AnyScan TRIO SPECT/CT, a system that blends preclinical and clinical technology with a three-headed scanner, which scans the patient faster and provides better angular positioning, says Gabor Nemeth, director of preclinical imaging for Mediso.

This is an upgrade from the original AnyScan, which has a dual-headed scanner.

“In a dual-headed system, the sensitivity is lower because the surface of the crystal is

GE Discovery MI
less,” Nemeth says. “Three heads provide better coverage of the body in a single shot.”

With the AnyScan TRIO, Mediso is the first SPECT manufacturer to release a clinical system with multiple pinhole aperture technology, which provides much higher spatial resolution and sensitivity.

“It brings the benefits of preclinical imaging technology, which has extremely high resolution and sensitivity, to the clinical imaging space,” says Jeff Sumeracki, regional sales manager for Absolute Imaging Solutions, Mediso’s U.S. distributor. “This technology brings near-PET-quality imaging to the SPECT world.”

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Molecular Technologies

Last year, the company installed the first AnyScan TRIO systems in Europe. Absolute Imaging Solutions intends to assist with installation and delivery of the first TRIO systems in the U.S. in conjunction with the application for FDA 510(k) clearance.

Philips

Philips introduced its Vereos digital PET/CT in 2013. Kirill Shalyaev, vice president and general manager for advanced molecular imaging at Philips, says the system provides twice the volumetric resolution, improvement of sensitivity gain and quantitative accuracy, leading to smaller lesion detectability and a lower radiation dose.

At this year’s SNMMI annual meeting, the company plans to present a number of abstracts showing early indications of the system’s clinical benefits.

Shalyaev says he has seen the overall PET/CT market expand by double digits in the last two years, calling PET/CT the “fastest-growing imaging modality” due to continued adoption and the emergence of new radiopharmaceuticals, including agents for oncology as well as amyloid imaging.

While FDG PET is the gold standard for cancer staging, Shalyaev points to growing applications for early therapy planning and response assessment.

“Oncology, in particular, is a big area of growth,” Shalyaev says. “Dementia and neuro is a new frontier.”

SPECT, on the other hand, is seeing “a little bit of a cannibalization from other imaging modalities,” and in some areas, is being taken over by PET.

“We see more growth [in PET], so we’ve doubled down on our investment,” Shalyaev says.
Positron
Positron’s primary product is the Attrius PET camera, along with its cfrQuant software package.

Offering PET without CT allows the company to provide a system at a lower price point and smaller footprint, says Aaron Hargrave, clinical applications specialist at Positron.

The company’s primary focus is the cardiac space, though the Attrius does have applications within oncology and neurology.

“We have a site that is primarily doing beta amyloid research,” Hargrave says.

Hargrave sees a market that’s moving away from SPECT for cardiac applications to PET, which can detect what is called hibernating myocardium, or viable heart tissue that is not able to be seen with perfusion imaging.

“Hibernating myocardium will take up FDG,” Hargrave says. “Scar tissue won’t take up anything.”
Molecular Technologies

Toshiba Medical
Toshiba Medical has released new software for PET/CT that speeds up reconstruction for both PET and CT scans and improves throughput. The software is available on the company’s Celesteion PET/CT system, which was unveiled in 2014 at SNMMI.

“We do have faster reconstruction than we had a year ago,” says Jim McCann, product manager for oncology at Toshiba America Medical Systems, Inc.

The company started delivering the software in the fall of 2016.

“Everyone has either received it already or is on the drawing board to receive it in a few months,” McCann says. “The response has been positive.”

Toshiba Medical anticipates releasing additional software enhancements at SNMMI this month.

Siemens Healthineers
The latest FDA-cleared nuclear medicine product from Siemens Healthineers is Symbia Intevo Bold, a SPECT/CT system that is the latest addition to the company’s Symbia Intevo product line, introduced in 2013.

The Bold, which has a 16-slice CT scanner, enhances dual-use capabilities at a time when facilities continue to move toward SPECT/CT, says Collin Schaeffer, global product marketing manager for SPECT/CT at Siemens.

“We continue to see customers migrate from SPECT-only systems to SPECT/CT,” Schaeffer says. “If they’re going to invest in adopting the technology, they want to make sure they’re getting the best system for both the SPECT and the CT.”

The scanner can be used as a standalone CT, or can act as a backup and handle overflow from radiology or the emergency department.

The system also comes with enhanced CT capabilities, including Siemens’ SAFIRE itera-
itive reconstruction and iMAR metal artifact reduction to enable high image quality at the lowest possible dose.

“It brings some of these capabilities to SPECT/CT for the first time,” Schaeffer says.

In PET, Siemens has also introduced the Biograph Horizon Flow edition, a PET/CT system that is pending FDA clearance. The system features Siemens’ unique FlowMotion continuous patient bed motion technology, which previously was only available on the company’s premium PET/CT platform, the Biograph mCT Flow.

“FlowMotion enables PET images to be acquired in a continuous motion of the patient, similar to a spiral CT scan,” says Regis Monticeli, global product marketing manager for PET/CT at Siemens. “Our customers now have a lot more opportunity to personalize their acquisition protocols to each patient and clinical indication. Every customer that has FlowMotion utilizes it in almost 100 percent of the relevant protocols.”

One of the biggest clinical benefits of the technology is enabling the routine use of respiratory gating technologies, which help detect lesions in the chest and abdomen, areas that are subject to respiratory motion, Monticeli says.

On the software side, the FDA has cleared a new version of Siemens’ syngo.via VB20 for Molecular Imaging. The new version has a feature called Multi-Foci Segmentation (MFS) that allows one-click calculation of a patient’s whole-body tumor burden. This is used to see a patient’s response to therapy.

Previously, clinicians would have to look at all the images from different parts of the body at different points in time, which can take as long as an hour, depending on the extent of the disease. MFS can take from a few seconds to a minute, says Karin Barthel, global product marketing director for Siemens.

“This automated approach is much faster while being as sensitive,” Barthel says.

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Toshiba Celesteion

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PET/CT, PET/ MR & PET
PRODUCT SHOWCASE

PET/CT, PET/MR and PET manufacturers are constantly working to improve the offerings available in the marketplace. The products appearing on the following pages represent some of the best innovations available. Look for the companies in this space to continue rolling out enhancements that will improve patient experience and outcomes.

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**PET/CT**

**Bruker Bio Spin**

**Albira Si**

PET imaging is at the forefront of this revolution, and Albira Si, the first commercial SiPM-based PET, is delivering the promise of this technology, full field of view accuracy (FFA), in imaging and quantification. Reinforced by high performance, seamlessly integrated SPECT and CT, and fully compatible with MRI, Albira Si is setting the new standard in what you can expect from the best molecular imaging technology.

**GE Discovery™ MI**

Created to help you diagnose and stage disease earlier and better guide your treatment strategies, help expand your diagnostic service offerings and provide a more comfortable patient experience with short scan times. LightBurst Digital Detector: Significantly better small lesion detectability, ½ the time or ½ the dose, up to 2× improvement in volumetric resolution. Quantitative SUV you and your patients can trust. Enhance your clinical excellence in oncology, or expand PET’s impact on neurology and cardiology and beyond. Meaningful insights. From your patient to every patient.

**GE Discovery™ IQ**

Enabling the best possible patient outcomes to more people in more places. Discovery IQ was designed for a personalized approach to patient care — from disease detection through treatment assessment.

- LightBurst PET Detector: Scans in ½ time and ½ dose. Highest NECR & NEMA sensitivity. Largest Axial FOV.
- Quantitative SUV you and your patients can trust.
- 4× lower dose.

Discovery IQ. Image Quality. Intelligent Quantitation.
**NEW PRODUCT SHOWCASE**

**MOLECUBES X-Cube (CT)**

The X-CUBE, innovation by MOLECUBES, is the best-in-class benchtop small animal CT designed aiming at modularity and simplicity of use. Whole-body mouse and rat applications benefit from fast acquisition speed and low animal dose, while iterative reconstruction guarantees high image quality. Intuitive and wireless user-interface together with a functional animal bed allow for easy and reliable multimodal imaging in combination with the Gamma-CUBE (SPECT) and Beta-CUBE (PET).

**Mediso nanoScan PET/SPECT/CT**

The nanoScan preclinical PET/SPECT/CT imaging system is a fully integrated molecular imaging system designed to provide solutions for small animal life science, molecular imaging research and drug discovery. Best performance in the industry for all subsystems: fully integrated, large field of view small animal triple modality whole-body tomograph for quantitative in vivo imaging with complete animal handling system. From starting laboratories with a constrained budget to highest-end combinations where the available space is limited, we can offer many combinations with the continuous on-site upgrade possibility and wide array of accessories.

**Mediso MultiScan LFER 150 PET/CT**

Large FOV Extreme Resolution Portable Research Imager. The MultiScan LFER 150 PET/CT is a large bore research PET/CT in vivo imaging system dedicated to research applications for both clinical and preclinical imaging. The LFER 150 (Large Field of view Extreme Resolution) with 20 cm axial and 15 cm transaxial field of view (FOV), sub-mm PET resolution and 5 percent PET sensitivity is aimed at a wide range of translational imaging applications. The system features the most versatile PET/CT gantry ever built. Besides the horizontal lying position for anesthetized subjects, the system supports a vertically sitting position for the scanning of awake subjects.

**GE Discovery™ MI DR**

A premium PET/CT system with the added flexibility of a standalone diagnostic CT. Delivers accurate, reproducible results referring physicians require and added clinical versatility needed to expand beyond FDG and oncology. LightBurst LBS Detector: Designed for speed and efficiency. High PET sensitivity and count rate performance to image all tracers. Combination of Time-of-Flight and Q.Clear: Most innovative reconstruction technology available. Future ready: Easy upgrade path to Discovery MI to deliver LightBurst Digital Detector technology. Get ready for meaningful insights.
**PET/CT, PET/ MR & PET**

**PRODUCT SHOWCASE**

**Philips Healthcare**
**Vereos PET/CT**
The world’s first and only true digital PET/CT system provides approximately twice the volumetric resolution, sensitivity and quantitative accuracy compared to analog systems. Philips’ proprietary Digital Photon Counting technology helps physicians to manage dose, reduce scan times and enhance lesion detectability. These improvements can ultimately be translated into high image quality, increased diagnostic confidence, improved treatment planning and faster workflows.

**Philips Healthcare**
**Ingenuity TF PET/CT**
Leverages the Philips Astonish TF technology for enhanced image contrast, resolution and quality. The system also features Philips’ proprietary xPand5 quantification tools, to assist with measuring and monitoring disease progression. And built with the proven technologies of the Ingenuity CT platform, the system also offers the benefits of high-resolution visualization coupled with dose management techniques to manage image quality in both imaging modalities. Breakthroughs such as iDose and O-MAR (orthopedic metal artifact reduction) provide ways to produce high image quality with reduced artifacts, while the advanced iPatient platform simplifies complex procedures by automating routine tasks.

**Photo Diagnostic Systems**
**NeuroPET/CT**
The “self shielded” NeuroPET/CT includes a PET subsystem designed from the ground up with modern solid-state sensor technology, and a diagnostic quality eight-slice CT scanner. The motor-driven system is easily taken from the research area to a preclinical imaging setting. No special siting requirements, uses 120V 20A or 208V 20A power. This device is available for research use only until pre-market clearance from the FDA.
**Siemens Biograph mCT**

Biograph™ mCT brings accurate and reproducible quantification to PET/CT imaging by optimizing each element of the measurement chain. Starting with the industry’s finest volumetric image resolution*, Biograph mCT features unique daily quality control, SMART registration technologies and intelligent software to bring accuracy and reproducibility to PET/CT imaging. In addition, innovative CARE technologies help ensure the lowest possible dose is administered and the large, patient-friendly 78-cm bore with five-minute, ultra-fast scanning offers exceptional patient comfort.

*Based on competitive literature available at time of publication. Compared to PMT-based devices. Data on file.

**Siemens Healthcare Biograph Horizon**

Small, cost-efficient PET/CT system with low power requirements addresses clinical indications in oncology, neurology and cardiology. Possesses 4 mm LSO crystals for faster scintillation, faster and higher light output than BGO crystals¹, resulting in high resolution and better image quality and enabling Time-of-Flight acquisition.² Fits into virtually any existing PET/CT exam room. Offers low operating and maintenance costs with automated technologies such as gentle system warm-up and automatic standby that extend the system’s economic life and reduce power consumption.

² Optional

Biograph Horizon is not commercially available in all countries. Due to regulatory reasons its future availability cannot be guaranteed. Please contact your local Siemens organization for further details.

**Siemens Biograph mCT Flow**

Biograph mCT Flow™ is a groundbreaking new system that, for the first time ever, overcomes the limitations of conventional bed-based PET/CT thanks to FlowMotion™, Siemens’ revolutionary technology that moves the patient smoothly through the system’s gantry, while continuously acquiring PET data. Biograph mCT Flow with FlowMotion takes routine image quality to a new level by enabling imaging protocols based on the organ’s need. FlowMotion expands accurate and reproducible quantification in all dimensions for precise disease characterization in therapy monitoring, while enabling physicians to offer as low as reasonably achievable dose to every patient. Additionally, the combination of a 78 cm bore with five-minute, ultra-fast scanning and a continuous sense of progress throughout the scan provide patients with a more comfortable exam experience.

*Biograph mCT Flow is not commercially available in all countries. Due to regulatory reasons its future availability cannot be guaranteed. Please contact your local Siemens organization for further details.
### PET/CT, PET/MR & PET

#### PRODUCT SHOWCASE

**MOLECUBES**

**Beta-Cube (PET)**

The β-CUBE, innovation by MOLECUBES, is the best-in-class benchtop small animal PET. Sub-millimeter image resolution is achieved thanks to monolithic scintillators, advanced photon detection and iterative image reconstruction. THE β-CUBE is optimally designed for whole-body mouse and rat imaging, from high throughput to advanced workflows. Intuitive and wireless user interface together with a functional animal bed allow for easy and reliable multimodal imaging in combination with the X-CUBE and Gamma-CUBE.

**Positron**

**Attrius**

Positron’s Attrius offers a new perspective for cardiac imaging. The Attrius is optimized for myocardial perfusion imaging, enabling physicians to provide superior proven technology while delivering an accurate diagnosis. The market’s only new, dedicated PET system, it provides high system uptime, minimal radiation exposure and a proprietary cardiac specific software package designed to ensure effortless interpretation for today’s most challenging clinical cases. The Attrius was designed with the private practice in mind with a small design footprint and a significantly lower operating cost when compared to PET/CT.

**Oncovision**

**Mammi**

Dedicated breast PET. Mammi offers high sensitivity and high spatial resolution (1.6mm) 3-D imaging. Indicated for a second look and inconclusive breast diagnosis (dense, high-risk patients, recurrences). Thanks to the ring configuration, Mammi visualized early response monitoring for therapy follow-up. The prone position allows no breast compression, pain-free.
**Cubresa NuPET™**

Cubresa’s NuPET™ is a revolutionary PET scanner that empowers you with simultaneous molecular and functional imaging by bringing PET into the bore of an existing MRI. Hybrid PET/MR imaging is gaining momentum for preclinical and translational research, enabling better understanding of complex biological mechanisms. Fields such as neurology, oncology, and cardiology benefit from the ability to correlate time-dependent molecular mechanisms to functional response with significantly shorter acquisition times and maximized throughput. NuPET™ combines the superior anatomical, structural and functional information of MRI with the molecular sensitivity of PET and eliminates registration errors when an animal is moved from one scanning system to another, boosting confidence in your data and adding new insights to your preclinical research.

**GE Healthcare SIGNA™ PET/MR with QuantWorks**

Built with pioneering TOF and integrated with a 3.0T MR, its impressive quantitative accuracy and high count rate combined with innovative Q.Clear reconstruction delivers 2x improvement in image quality. In addition, SIGNA PET/MR with QuantWorks includes a comprehensive suite of applications and flexible research tools to pursue ideas that could influence the future of medicine.

**Bruker BioSpin PET-MR 3T**

The latest breakthrough in PET detector technology, together with the proven superior soft tissue contrast of translational field strength MRI, is now combined in one compact, easy-to-use instrument. Featuring homogeneous, constant PET resolution over the whole field of view, a newly developed 3T cryogen-free magnet and a motorized animal transport system, the PET-MR 3T simplifies your workflow and supports a broad spectrum of application fields.

**Mediso nanoScan PET/MRI (3T)**

Integrated whole-body preclinical PET/MRI(3T) system with cryogen-free, translational 3T MRI capable to image mice and rats. The compact nanoScan PET/MRI(3T) combines the superior small animal sub-millimeter PET subsystem with variable MR field strength between 0.1T and 3.0T 3T and superior soft-tissue contrast. Proven, reliable and compact with installation in North America, Europe and Asia. The system can be placed anywhere in a research facility. No costly site preparation or shielding is required.

**Siemens Healthcare Biograph mMR**

Biograph mMR allows simultaneous whole-body data acquisition from MR and PET to enable generation of the location, function and metabolic activity of organs in one image at the same time. Potential clinical applications include early identification and staging of malignancies, therapy planning and treatment.
SPECT & SPECT/CT

PRODUCT SHOWCASE

SPECT and SPECT/CT manufacturers are constantly working to improve the offerings available in the marketplace. The products appearing on the following pages represent some of the best innovations available. Look for the companies in this space to continue rolling out enhancements that will improve patient experience and outcomes.

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DDD Diagnostic

CorCam™

Optimized for quick and seamless myocardial perfusion imaging. Highly reliable and well-proven gamma camera. Truly open gantry allows for greater patient comfort. Integrates with hospital infrastructure, DICOM modality work list. Like the other camera systems from DDD Diagnostic A/S, CorCam™ has been designed as a workhorse camera for nuclear cardiology imaging procedures.

DDD Diagnostic

Solo/SoloMobile

Solo™, a versatile, cost-efficient and compact gamma camera designed for hospital use, outpatient clinics and private clinics. Low-profile detector positioned to perform planar procedures, imaging of the thyroid gland, parathyroid, multigated cardiac and sentinel node. Requires minimal space and offers unobstructed access between detector and patient. Easily mounted on the floor. SoloMobile™ can be moved in patient rooms for bedside imaging.

DDD Diagnostic

QuantumCam™

The QuantumCam™ from DDD Diagnostic is a general-purpose nuclear medicine camera with minimal room size requirements, fitting in rooms as small as 10’x10’. In fact, no other SPECT system on the market has such a small footprint and full flexibility in detector positioning, offering versatile use for whole-body, SPECT, cardiac SPECT and planar imaging procedures. QuantumCam’s patient-focused open design provides ultimate comfort, especially for those with claustrophobia.
**NEW PRODUCT SHOWCASE**

**Digirad Ergo™ Imaging System**
Digirad’s Ergo™ Imaging System is the only solid-state, large field-of-view (LFOV), portable general-purpose gamma camera available in the market. The single-head gamma camera is compact, lightweight and designed to offer maximum clinical versatility and flexibility for performing nuclear medicine studies (planar, gated and dynamic) in a variety of hospital settings (general nuclear medicine department, ICU, CCU, ER, OR, pediatrics, trauma units, patient floors, ambulatory services, women’s health), imaging centers and outpatient service centers.

**Digirad Cardius® X-ACT+**
Digirad’s Cardius® X-ACT+ diagnostic imaging system raises the bar in nuclear cardiology with its advanced SPECT/FAC technology, nSPEED™ 3D-OSEM and TruACQ count-based Imaging™ for customized SPECT MPI. Its triple-head, solid-state detectors and fully integrated ultra-low dose Fluorescence Attenuation Correction allow for high specificity imaging, reduced patient dose, excellent image quality and superb reliability. Its patient-friendly, open gantry design helps to comfortably image bariatric patients up to 500 pounds, as well as claustrophobic and COPD patients.
SPECT & SPECT/CT
PRODUCT SHOWCASE

GE Healthcare
Discovery™ NM/CT 670 CZT
Bring theory to life with CZT!
The world’s first commercially available general purpose SPECT/CT system powered by CZT technology. Help bring your theories to life with a system designed to leverage all that CZT can do. Engineered for improvements in lesion detection, image quality and patient comfort, and combined with advanced quantitative applications provided through Xeleris™, this system renews the promise of nuclear medicine’s potential for true discovery.

GE Healthcare
Discovery™ NM530c
• The Discovery NM530c, with CZT-based Alcyone technology, redefines what’s possible in nuclear cardiology.
• An innovative, dedicated cardiac gamma camera, with up to 4 times lower injected dose compared to conventional detector technology.
• Alcyone’s heightened sensitivity and zero equipment motion improve both image quality and energy resolution, enabling the potential for new clinical applications including 3-D dynamic acquisitions and simultaneous dual isotope imaging.

GE Healthcare
Optima™ NM/CT 640
Advanced technology that builds off the potential of SPECT with the anatomical precision of CT. It gives you the image quality you need to make critical decisions at a low dose to patients. And because we understand the importance of making strong investment decisions, it was designed to deliver a low cost of ownership for your needs today and the ability to support your clinical SPECT/CT needs over time. It’s the right balance of precision and performance, and the accessible starting point you need to start making true discovery part of your routine care.
MOLECUBES
Gamma-Cube (SPECT)

The Gamma-CUBE, innovation by MOLECUBES, is the best-in-class benchtop small animal SPECT unique in modularity and simplicity of use. The Gamma-CUBE offers high sensitivity and sub-millimeter resolution for whole-body mouse and rat imaging. Patented loft hole pinhole technology supports compactness. State-of-the-art reconstruction guarantees excellent image quality. Intuitive and wireless user interface, together with a functional animal bed allow for easy and reliable multimodal imaging in combination with the X-CUBE (CT) and Beta-CUBE (PET).

Mediso AnyScan® S

The Mediso AnyScan® S is the alternative small footprint OEM SPECT system, allowing for easy integration into various clinical settings at a low cost of ownership, saving on construction costs, service costs and those expensive service encryption keys. With an ergonomic open design, outer room and stretcher mode imaging capabilities, the AnyScan® S is the solution in efficiency while improving patient comfort.

Oncovision Sentinella

Sentinella is an intraoperative portable gamma camera to detect sentinel lymph nodes in real time in the operating room. Sentinella allows the surgeon to locate the SLN and confirm the excision of all SLNs by obtaining post-excision scintigraphic images. Approved for radio-guided surgery in most of the worldwide affected tumors, such as breast, melanoma, parathyroid, oral cavity, urological and gynecological cancer.
**SPECT & SPECT/CT**

**PRODUCT SHOWCASE**

**Oncovision Wprobe**


**Philips Healthcare BrightView X**

- BodyGuard: Automatic body contouring with user-defined scan distance for each type of scan.
- Patented concurrent imaging feature that allows the user to acquire up to 15 simultaneous data sets to reduce the total number of separate acquisition steps, thereby improving workflow.
- Improve collaboration with enterprise-wide access to NM review and processing with IntelliSpace Portal.
- Fits into a room as small as 15’ 6” x 11’ 7” (4.72 x 3.53 M).

**Philips Healthcare BrightView XCT**

- High resolution CT (0.33 mm) at low dose.
- Isotropic voxels provide high resolution transverse, coronal and sagittal slices for SPECT/CT functional anatomical mapping.
- Attenuation correction with registration confidence with co-planar acquisition and matched tidal breathing protocols between SPECT and CT.
- In-room CT acquisition control option.
- Improve collaboration with enterprise-wide access to NM review and processing with IntelliSpace Portal.
- Fits into a room as small as 15’ 6” x 11’ 7” (4.72 x 3.53 M).
**NEW PRODUCT SHOWCASE**

**Siemens Healthineers**

**Symbia Intevo**

Symbia Intevo™ is Siemens’ premium hybrid platform. It is the world’s first xSPECT* system to fully integrate SPECT and CT data during reconstruction. The resulting complete integration sets a new standard in image quality with xSPECT Bone* and, for the first time in nuclear medicine, absolute quantitative images with xSPECT Quant*. Now, with Symbia Intevo, physicians have the ability to not only image disease, but characterize it with confidence while also leveraging the unique quantitative capabilities to monitor and adjust treatments earlier.

*Symbia Intevo, xSPECT, xSPECT Bone and xSPECT Quant are not commercially available in all countries. Due to regulatory reasons their future availability cannot be guaranteed. Please contact your local Siemens organization for further details.

**Scandia Medical Imaging**

**Scandia-45**

The Scandia-45 is a high-resolution digital SFOV planar gamma camera designed for thyroid and small organ imaging. It can be used as a standalone, or interfaced to any workstation and PACS system. Available integrated cardiac gate and a comprehensive selection of optional collimators allows the Scandia-45 to perform virtually all planar studies with ease.

**Siemens Healthineers**

**Symbia Intevo Bold**

SPECT/CT system combines high-performance CT with the company’s proven SPECT technologies to maximize dual-use capabilities. Add additional CT slice reconstruction with Interleaved Volume Reconstruction to better evaluate small structures, SAFIRE iterative CT reconstruction for lower dose and iMAR metal artifact reduction for CT and SPECT/CT. Established SPECT options include high-resolution xSPECT Bone and automated, accurate and reproducible quantification of 99mTc, 123I, 111In and 177Lu isotopes with xSPECT Quant.

1 177Lu is not commercially available in some countries, including the U.S. 177Lu is not currently recognized by the U.S. FDA as being safe and effective and Siemens does not make any claims regarding its use. Due to regulatory reasons, its future availability cannot be guaranteed. Please contact your local Siemens organization for further details.
NEW PRODUCT SHOWCASE

SPECT & SPECT/CT

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1 Based on competitive literature available at time of publication. Data on file.
2 Patients up to 500 lbs (227kg).
*Symbia Evo Excel is not commercially available in all countries. Due to regulatory reasons its future availability cannot be guaranteed. Please contact your local Siemens organization for details.

Spectrum Dynamics Medical
D-SPECT® and D-SPECT-L™

Spectrum Dynamics Medical revolutionized the practice of nuclear cardiology with the first clinical and commercially available CZT imaging scanner. The D-SPECT® and D-SPECT-L™ nuclear cardiology imaging systems allow for flexible patient imaging — upright, supine or anything in between. Both cameras incorporate BroadView™ Technology, which enables an increase in sensitivity and energy resolution, thus dramatically enhancing the image quality, improving workflow, allowing the ability to reduce radiation exposure by implementing unique low-dose protocols and providing the platform for advanced imaging protocols, i.e. Dynamic SPECT (CFR) and Simultaneous Multi-Isotopes.
**NEW PRODUCT SHOWCASE**

**Hermes SUV SPECT**

The HERMES SUV SPECT revolutionizes quantitative imaging by converting recorded counts per voxel into activity per unit volume with SUV calculations, providing essential and accurate quantitative results. Combined with attenuation correction from a hybrid SPECT-CT scanner or SPECT-only camera (utilizing an independent CT) and a Monte Carlo-modeled scatter correction, HERMES SUV SPECT brings SPECT-CT scanners from any manufacturer to the next level. More than 6,000 studies performed, 100 global partners. Visit us to learn more about this breakthrough clinical application (FDA, CE, Health Canada, CFDA-China) supporting Tc99m, I123, In111, Tl201, Ga67, Lu177 tracers and more.

**MIM Encore**

A single platform solution for general nuclear medicine, PET/CT, SPECT/CT and PET/MRI. Vendor neutral multi-modality image fusion and processing with advanced application for therapy response assessment. Greater accuracy for PET tumor segmentation with PET Edge, an innovative gradient-based segmentation method. Available on Windows and MAC as well as thin-client platforms.

**MIM MIMcardiac**

MIMCardiac provides quantitative analysis of PET and SPECT for generating left ventricular functional parameters. Image fusion can be performed for stress/rest and perfusion/metabolism. These functional images can also be fused to CCTA or MRA.

**MIM MIMneuro**

MIMneuro is a fully automated and quantitative PET/SPECT analysis package that assists in the detection of various neurological disorders and includes databases of normals for FDG, Amyvid™, HMPAO, Neuraceq™, Vizamyl™ and DaTscan™. Statistically significant differences from the normals are highlighted for each voxel in the brain or for anatomical brain regions. Brain atlas regions can also be used to calculate SUV ratios (SUVR) comparing at-risk brain regions to reference structures such as the cerebellum. An automated neuro subtraction workflow is included for highlighting differences in serial exams or baseline and activation studies.
A new type of clinical brain imaging: nuclear neurology

By Robert S. Miletich

Much of the historical development of medical imaging after the time of Wilhelm Rontgen was fueled by a quest for an image of the brain.

Even with the use of X-rays, the brain in the intracranial vault remained a secret place, as it was not readily examinable by clinical practitioners because of its encasement in the bony box called the skull. The development of computed assisted tomography, now called CT, revolutionized the practice of clinical neurology in the 1970s. CT was soon overtaken by nuclear magnetic resonance imaging, now called MRI, in major part because of the better soft tissue contrast that MRI affords. CT and MRI show the anatomic structure of the brain, which is clinically important because nervous system diseases or illnesses often affect that structure, though not always. In contrast, brain disorders always affect the functioning of the brain. We are now entering into a new era, wherein we clinically have the capability of creating images of the functioning brain. This is the focus of nuclear neurology (NN), a 21st century diagnostic field now available for clinical medicine.

NN uses the techniques of nuclear medicine in order to examine the brain. Its modalities include positron emission tomography (PET), single photon emission computed tomography (SPECT) and scintigraphy. NN is also called neuromolecular imaging, because the source of its signal is from a radioisotope tagged to a molecule which demonstrates or traces some physiologic process. NN is also cellular imaging as we are measuring physiological processes, many of which reside within the brain cells. The improved diagnostic accuracy of NN directly results from this characteristic of measuring physiology through both molecular and cellular imaging.

Diagnosis of neurologic syndromes is particularly difficult because it is a two-step process. First, any particular set of neurologic signs and symptoms can be due to pathology at multiple sites in the nervous system. This, in part, is related to neural redundancy in the mediation of function. It is also due to the fact that for a neural signal to gain expression to the outside world, it must traverse through multiple levels of the nervous system. Second, there are a large number of diseases that can cause any neurologic syndrome, hence the differential diagnosis is quite wide. Since brain disorders always affect physiologic function, by assaying the appropriate physiologic process, NN provides increased sensitivity for disease detection. Since each disease process has its own functional profile, NN provides increased specificity for distinguishing between illnesses. Increased sensitivity plus increased specificity equates to increased diagnostic accuracy. The main advantages of NN over conventional imaging are: early diagnosis in the pre-diagnostic and even pre-symptomatic phases of chronic disease; differential diagnosis; and evaluation of therapy efficacy.

There are two general classes of NN exams, separated by the type of physiologic process measured, what I call basal and specific physiology. Basal physiology refers to those processes which all cells of the body engage in. All cells require intermediary metabolism in order to generate stored energy. All cells need blood perfusion for the delivery of nutrients and for the elimination of waste products. Specific physiology refers to processes which are not ubiquitous, but rather are specific to certain types of cells. There are different arrays of NN exams for different disorders. These will now be briefly reviewed.

The remarkable prevalence of dementia and cognitive impairment in the older population is creating a public health epidemic for the aging U.S. population. Dementia is a syndrome and has a wide differential diagnosis. Dementia is also the result of chronic illness. Early diagnosis improves management outcomes. Each disorder which causes dementia has its own basal physiology pattern. Thus, basal physiology imaging with cerebral perfusion SPECT (CPS) and glucose metabolism PET (FDG-PET) can have major roles. In addition, the diagnosis of Alzheimer’s disease can be aided by PET amyloid imaging, of which there are now four FDA-approved radiopharmaceuticals. The exact diagnosis...
of dementia is important in that drugs which are currently used in cognitively impaired patients can have adverse effects if given to the wrong patient. For instance, neuroleptics given to dementia with Lewy bodies patients or acetylcholinesterase inhibitors given to frontotemporal lobar degeneration patients can cause clinical destabilization.

Grading of brain tumors for degree of malignancy guides therapy which is offered to patients. Grading is performed with FDG-PET and slightly less effectively with thallium-SPECT. Although MRI is highly sensitive for pathology, it has poor specificity and many times cannot distinguish between tumor recurrence or treatment effect. This is the main indication for FDG-PET in brain tumors.

Epilepsy affects 1 percent of the population. It is often unclear what the underlying disorder is in patients presenting with episodic neurologic syndromes. There can be changes in the epileptic brain even when patients are seizure-free, or interictally. This can help distinguish epilepsy from transient ischemic attack or other manifestation of cerebrovascular disease and even somatization psychiatric illness. Many epilepsies can also be cured by surgically resecting the seizure focus. CPS during a seizure (ictus) is a standard diagnostic method of epilepsy centers throughout the world.

Epidemiologic studies have shown that parkinsonism is just as prevalent as dementia and cognitive impairment in the older segment of the population. It also has just as broad of a differential diagnosis as dementia. Basal physiology imaging with CPS and FDG-PET has roles in both the early diagnosis and the differential diagnosis of parkinsonism. There is also a specific physiology imaging exam available which allows us to assay the density of dopamine transporters which are present on dopamine nerve terminals. This assay is helpful for the diagnosis of Parkinson’s disease and atypical parkinsonian syndromes.

Stroke remains the No. 4 killer of humans. What is not revealed in this statistic is the prevalence of morbidity in the population because of cerebrovascular disease. We are starting to become aware of the shocking prevalence of small vessel disease in the U.S. population. Because it is a cell-based imaging method, CPS has high sensitivity for the detection of ischemia in viable cells and in distinguishing viability from cell death. The latter is an important consideration for decisions on using invasive endovascular therapies. This exactly replicates management decisions faced in cardiology.

There has been recent disturbing press on patients with disorders of consciousness. Brain injury from trauma, hypoxia or ischemia can result in impaired consciousness, the recovery from which is uncertain. As basal physiology NN shows brain function, it can be used as a tool for prognostication in such cases.

Following closed head injury, patients often have persistent symptoms which are poorly explained by conventional imaging. Basal physiology imaging of NN can identify dysfunction in this post-concussive syndrome and help facilitate entry into appropriate treatment regimens.

Patients presenting with neurologic syndromes usually carry comorbidities of systemic illness which often cloud the diagnostic picture as to causation. These illnesses may even be inducing a low grade toxic or metabolic encephalopathy. Polypharmacy related to these disorders may even be a major factor. Basal physiology NN with CPS or FDG-PET can be helpful in this differential diagnosis as metabolic encephalopathies have a pattern revealed in NN.

A major element of many differential diagnoses for the above disorders is psychiatric illness. Somatization related to affective disorders, anxiety disorders and even psychotonic disorders can mimic various neurologic disorders. These can be distinguished by NN as there are patterns on basal physiology NN which identify these.

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Developments in Technology

The concept of personalized medicine has been influencing patient care since at least the dawn of Western medicine more than 2,000 years ago.

Hippocrates, an early proponent of this concept, is said to have observed, “It’s far more important to know what person the disease has than what disease the person has.”

It was not until the 19th century that developments in chemistry, histochemistry and microscopy enabled scientists to understand the underlying causes of diseases. Those breakthroughs ushered in the innovations of the pharmaceutical and medical device industries of the 20th century and gave rise to genetics, imaging and data mining.

More recently, the ability to sequence the human genome finally put the concept of personalized medicine into practice, making it possible for scientists to develop technology that curates diagnosis and treatment for each individual patient.

Theranostics, a combination of therapy and diagnostics, is a form of personalized medicine. While it usually refers to genome and RNA sequencing, molecular theranostics is a uniquely promising specialty that is gaining momentum.

“Theranostics involving molecular nuclear medicine is a very small field within the whole...
field of medicine, but I think it has the most interesting, practical applications for theranostics,” says Dr. Richard Baum, professor of nuclear medicine and chairman and clinical director of the Theranostics Center for Molecular Imaging and Molecular Radiotherapy at Frankfurt University Hospital in Germany.

Molecular theranostics typically involves a PET/CT exam in combination with a diagnostic radiotracer to determine whether a cancer patient would benefit from a specific therapeutic drug.

The field is not new, but it didn’t gain traction until recently. The radiotracer iodine-131 was used in 1941 at the Massachusetts Institute of Technology to treat metastatic thyroid cancer, but it wasn’t until 2011 that Frankfurt University Hospital launched the first world congress for molecular theranostics.

To date, the Theranostic World Congress has been held four times. In 2013, it was held in India. In 2015, it took place in the U.S. Last November it was in Australia.

The current gold standard

Most cancer patients are still treated based on their symptoms. The physician makes a diagnosis and then selects the treatment using data from large clinical trials, which predict with some certainty if the patient will respond to the treatment.

“It is common for physicians to use a trial-and-error strategy until they find the treatment therapy that is most effective for the individual patient,” says Baum.

Following chemotherapy, lab testing and CT or MR exams are performed after several weeks or months to determine if the cancer is shrinking. In many cases, the therapy doesn’t work and the patient has to endure another round of chemotherapy.

“Of course, it is based off of large clinical trials with thousands of patients where you know the drug is working in 70 out of 100 patients,” says Baum. “But if you are the individual patient, no one knows if you belong to the 70 percent or to the 30 percent that are not responding.”

The difference between the standard approach and the theranostic approach is that a test is performed before the therapy is administered. That informs the physicians that the drug will bind to the cancer cell, which means the treatment should be effective.

Baum explains to his patients that the diagnostic radiotracer fits like a key in a lock into the tumor cell, which allows him to predict if the same peptide will carry the therapeutic radioisotope into the tumor cell and kill it.

Neuroendocrine tumors

Each year, about 8,000 people in the U.S. are diagnosed with a neuroendocrine tumor, according to the American Society of Clinical Oncology. These tumors originate in the gastrointestinal tract and frequently localize in the lung, pancreas and small intestine.

The research on treating neuroendocrine tumors with molecular theranostics was pioneered in Europe. The diagnostic compounds are labeled with gallium-68 (Ga-68) and the therapeutic compounds are labeled with lutetium-177 (Lu-177).

The physician has the patient undergo a Ga-68-DOTATATE PET/CT exam to see if the target is expressed in the body. If it’s expressed, the patient then qualifies for therapy and is treated with the Lu-177-DOTATATE compound, which is on the market as Lutathera.

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Prostate cancer

Prostate cancer is far more prevalent than neuroendocrine tumors. The American Cancer Society estimates that there will be about 161,360 new cases of prostate cancer and about 26,730 deaths from the disease this year.

“When talking about prostate cancer that recurs and becomes hormone resistant, you have to lock all of the hormones in the body, which is usually done with medication, but even with these medications the tumors reoccur,” says Czernin.

The prostate-specific membrane antigen (PSMA) protein, which is found on the surface of prostate cancer and metastatic cells, was first discovered in the 1980s. It was originally labeled with Ga-68 and only used for diagnostic purposes, but eventually it was labeled with Lu-177 to also be used to treat metastatic prostate cancer.

A study from June 2015 investigating a PSMA-inhibiting theranostic agent called PSMA-617 was presented at the 2015 annual meeting of the Society of Nuclear Medicine and Molecular Imaging. The researchers imaged mice with Ga-68 to assess the diagnostic value of PSMA-617.

Then they used Lu-177 to deliver a more powerful dose of radiation to penetrate and destroy the tumor cells when combined with PSMA-617. That preclinical research was followed by the first human clinical trial, which found that this therapy can reduce the prostate-specific antigen (PSA) level from 38 to 4.6 nanograms per milliliter.

Pioneering the PSMA-targeted theranostic field in Europe, a research group in Germany produced the imaging and therapeutic compounds and they were later approved for clinical use. They have been used to image thousands and treat over 1,000 patients with prostate cancer.

There’s a single-center trial underway at Frankfurt University Hospital that’s investigating PSMA for imaging and therapy, and a multi-center trial will soon begin in Germany. Most of the university hospitals in Germany are now offering this therapy to patients, says Baum.

“It’s a specific situation in Germany because we can use new radiopharmaceuticals in hospitals, especially in university hospitals, without approval by German authorities because we have a law that allows us to administer new radiopharmaceuticals to end-stage cancer patients,” he adds.

“IT just tells you that the cancer cells [have] increased metabolism,” says Baum. “It is very sensitive to find the disease, but it cannot determine if it’s a breast cancer cell, lung cancer cell or lymphoma cell because they all take up FDG very heavily.”

Since most tumors don’t express cancer cell-specific receptors, there is an increasing need to find other ways to deliver image-guided targeted molecular medicine. Sources such as metabolism, angiogenesis, inflammation, the tumor microenvironment and stromal cell receptors are being explored, according to a study published in the European Journal of Radiology.

The researchers concluded that although cancer cell receptors are the easiest targets for theranostics, future areas will include targeting specific microenvironments, cancer stem cells and imaging, and targeting preventive microenvironmental niches for cancer stem cells.

What about other cancers?

In 2013, 232,924 people in the U.S. were diagnosed with breast cancer, 212,584 with lung cancer and 136,119 with colon cancer, according to the Centers for Disease Control and Prevention.

There aren’t any markers specific enough to be used to treat those cancers. F-18 FDG, which is the main radiopharmaceutical used for PET/CT imaging, is an unspecific biomarker, says Baum.

“It just tells you that the cancer cells [have] increased metabolism,” says Baum. “It is very sensitive to find the disease, but it cannot determine if it’s a breast cancer cell, lung cancer cell or lymphoma cell because they all take up FDG very heavily.”

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Q&A with
Ramsey D. Badawi and Simon R. Cherry

Ramsey D. Badawi, professor and molecular imaging chair in radiology at the University of California, Davis, and chief of nuclear medicine, and Simon R. Cherry, Ph.D., a distinguished professor of biomedical engineering and radiology at UC-Davis, are two men with a single vision: to build a PET scanner large enough to image an entire human in a single scan. The mission to create this “whole body” PET scanner became their passion — and now they’re on the verge of seeing that vision come true. HealthCare Business News interviewed the two men so they could detail how they are meeting this challenge.

HCB News: How did this whole body PET project initially get started?
Badawi & Cherry: In the fall of 2005, we were discussing future projects that we could collaborate on. I mentioned that I had done some simulations of long PET scanners in the past and that we should try to build one, perhaps 60 cm long or so. Simon replied that if we were to do this, we should go the whole hog and build a two-meter one that would cover the entire body! We both got very excited about this idea and decided to pursue it. We launched the project in 2006, when Simon described the idea at the Henry Wagner Jr. lecture at the SNMMI annual meeting. It took us 10 years from the time of the initial idea to finally obtaining funding from the NIH to build the first prototype.

HCB News: What are the perceived benefits from whole body PET compared to conventional PET imaging?
B & C: There are two main features that lead to a range of benefits: for total body applications, one can collect ~40x as much signal as with a conventional scanner (or about 5x more signal if one is only interested in a single organ) and one can scan the entire body simultaneously.

Due to the increased sensitivity to signal, one can either:
• Scan faster for the same image quality, reducing a 20-minute scan to perhaps 30 seconds and a single breath-hold. This should reduce the effects of motion blurring and allow many more patients to be scanned in the same amount of time. It also reduces the need for anesthesia in pediatric patients, which is a major plus.
• Scan better. We can use the extra signal collected to make much clearer images, allowing us to see smaller and more subtle changes due to disease, and to use more complex models to describe radiopharmaceutical behavior in the body.
• Scan longer. PET scans involve injecting a small amount of radioactive material (such as a sugar analog) and using the scanner to see where it goes. These materials decay with a certain half-life. The most commonly used materials decay with a roughly two-hour half-life, but some have a 75-second half-life and some have a three-day half-life. Current scanners can image for about three half-lives before the signal gets too weak. EXPLORER should be able to scan for ~eight half-lives. This is very exciting and has not been attempted before. What will we learn about the human body when we can scan so long after injection of the radioactive material? We don’t know yet.
• Scan more gently. We can use the sensitivity to use less radioactive material. This is very important for pediatric patients, or for doing scientific studies where we want to scan the same patient many times to look for changes. Examples would be learning more about the biology and cures for arthritis, or diabetes or obesity, where the diseases have time courses of many years.
In addition, one can scan everything. The ability to scan the entire body at the same time allows us to make movies showing, for example, how drugs move around inside the body. This allows us to see to what degree new drugs hit their target, and to what degree they hit non-target organs, causing side effects. We can also learn about interactions and signaling between different organ systems. For example, the brain and the gut. This could prove to be very important for Parkinson’s disease, for Alzheimer’s disease, and for obesity, among others.

**HCB News:** What hurdles stand in the way of completing this project? Do you have a completion date in mind?

**B & C:** This will be the biggest, most complex PET scanner for human use yet built. The scanner has over 560,000 detector elements and almost 54,000 light sensors and channels of electronics. There will always be engineering problems of scale-up that we will have to address. But likely the most challenging issue will be the very large amount of data we are going to generate, possibly up to 40 TB per day. This all has to be rapidly processed to produce images we can work with.

**HCB News:** You’ve already constructed a small-scale preclinical scanner in partnership with Siemens. What did you learn from that project?

**B & C:** We learned that the standard methods for calibrating the scanner will probably not work. We had to develop some new approaches even for our smaller-scale device. However, we are not expecting any major hold-ups there. In some ways, the extra sensitivity will allow us more flexibility with making data corrections. More importantly, the smaller-scale prototype will allow us to learn more about possible applications that we can try once we have the full-size device. This work has only just begun. We have scanned our first patient with the preclinical device, a pet dog with osteosarcoma that needed the scan to see if her cancer had spread. And we look forward to scanning many more.

**HCB News:** In early 2017 you announced some new partnerships that would help bring your vision to life. Can you tell us about those?

**B & C:** We announced a joint partnership with United Imaging America, a young medical imaging company with a track record of developing new PET imaging devices, and SensL, a company that builds solid-state light detectors known as silicon photomultipliers (SiPMs). SensL will be providing the light detectors that United Imaging will be using to build the radiation detectors that will go in the scanner. The SensL detectors offer better performance than conventional vacuum photomultiplier tubes, and in addition, this technology will reduce the power consumption by close to a factor of 10, an important consideration for a device of this scale. United Imaging has a strong team of engineers working on the scanner, and very importantly from our point of view, they have a very solid quality control system for their detector manufacturing. This kind of quality control is almost impossible for us to replicate in the lab and should go a long way toward ensuring reliability for the final device. There also is a high probability that these partnerships will lead to the availability of a commercial system, allowing the technology to be disseminated around the world.

**HCB News:** What issues are you currently working on with relation to developing the scanner?

**B & C:** Critical issues are: speeding up the data processing and image reconstruction so that we can handle the massive amounts of data that we will be generating; and testing the various components in a second small-scale system. We hope to have our hands on this small-scale device in the next three months or so.

**HCB News:** Do you ever hear from skeptics who question the clinical value of your research? What do you tell them?

**B & C:** Absolutely! I would say that when we started, probably three-quarters of our colleagues in the field questioned us on the value of this. However, as we have kept making the arguments, that number has probably gone down to about 20 percent, and there are now multiple sites across the world that have expressed an interest in obtaining a total-body PET scanner.

Actually, we welcome skepticism. It ensures that we stay on track with our arguments and helps prevent us from engaging in sloppy thinking. The biggest argument we hear is that the device will be just too expensive. But when all the installation requirements are factored in, this device won’t be very much more expensive than a very-high-field (e.g. 7 tesla) MRI scanner, and we believe it opens up many more avenues of research. We are looking forward to using this scanner to try to answer a whole range of questions that we could not hope to look at before, and to finding out who is right! Also, as with all new technologies, initial costs often are high, but if we can demonstrate clear benefit that, in turn, generates demand, then there will be pressures and opportunities to reduce cost.

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Use of molecular imaging modalities like PET/CT, SPECT and SPECT/CT is likely to increase in the next 10 years, driven by new indications for these procedures, new tracers being released and expanded insurance coverage.

When facilities are planning to purchase these molecular imaging modalities, they should look for system features and options that fit their facilities’ needs and pricing limits. They should also look to make sure the system’s software can be easily upgraded as technology changes throughout the years.

SPECT and SPECT/CT markets continue to evolve with advancements in treatment and diagnosis. Systems should incorporate three key areas: integrated patient data; improved workflow and automation; and the ability to identify the disease in the early stages and devise a treatment plan. In the MD Buyline database, we are seeing facilities purchase a SPECT/CT scanner and using the CT scanner as a backup scanner for overflow procedures. We also note that customers tend to be purchasing multi-systems or multi-modality systems for a lower purchase price based on a bundled system purchase.

The MD Buyline database shows that hospitals tend to be brand loyal, continuing with vendors that provide excellent performance and reliability as well as service and support. Purchasing departments should include the radiologist, department director and technologist(s) when looking to purchase a system. Reimbursement procedures are changing all the time, so facilities should have an “all hands on deck” approach to aid in their purchasing decisions. When making large capital purchasing decisions, facility personnel need to research every aspect of the vendor and system offered and whether the system will be used for cardiology, neurology and/or oncology purposes. Some vendors are now offering digital PET/CT, which has been demonstrated to provide approximately twice the volumetric resolution, sensitivity gain and quantitative accuracy of analog systems.

When considering vendors and PET/CT systems, facilities need to look closely at FDA recalls, reading and understanding each recall. Get a written statement of the status and resolution actions taken by the vendor. Use recalls as leverage in your negotiations. Check out the ratings of the system. Make sure the vendor has the proper contact point for further recalls. Finally, always negotiate uptime guarantees.

Every system purchase should be accompanied by a point-of-sale service contract. The best time to purchase service is at the time of the capital purchase. Historically, purchasing service when the warranty has expired is a lot more costly. Many vendors offer American College of Radiology (ACR) support packages, education, software upgrades and support. Make sure the service support level and time period covered are in line with the facility’s departmental needs.
Quantitative methods improve the role of imaging

By Robert Nordstrom and Hyunsuk Shim

Clinical trials are used to determine the safety and efficacy of drugs prior to FDA approval and market entry.

The success of such trials depends on the organization of the trial, the protocols used and the ability to predict the drug response and measure accurate final outcomes. The advent of quantitative methods to extract information from clinical images has significantly refined and improved the role of imaging as a reliable tool in clinical trial measurements. The degree of variability arising from uncertainty in scanner quality, image acquisition, processing and analysis degrades the data quality and requires more patient accrual, and can lead to inconclusive results. This translates directly into additional costs for drug development. Going beyond the simple RECIST linear measurements of tumor size, quantitative imaging is now capable of defining tumor volume, heterogeneity, metabolic activity, entropy and other measures of staging.

PET is a quantitative functional imaging technique and a powerful method for assessing early response to new cancer therapies in multi-center clinical trials. Unfortunately, the reliability of this quantitative information is degraded by substantial variability. The addition of CT and the development of more sophisticated instrumentation, reconstruction and compensation methods has improved accuracy, but the physical variations between systems from different vendors and institutions is a problem. Scanner manufacturers compete in the marketplace by promoting improvements in image quality and ease of operation without serious consideration of quantitative reliability. This leads to variations in measurement bias and variance between the instrument manufacturers and even within individual scanner overtime.

If we were to achieve a prominent role in building multi-site clinical trial productivity through quantitative imaging, it is essential to resolve the lack of calibration/standardization among imaging scanners. In 2008, the NCI established the Quantitative Imaging Network (QIN) to bring together research teams nationally to find solutions. In another effort supported by the NCI, several academic research groups have joined forces with the major PET/CT scanner manufacturers and SNMMI to generate standard calibration methods using a NIST traceable $^{68}$Ge/$^{68}$Ga phantom. The SNMMI Clinical Trials Network (CTN) has designed a PET/CT phantom imaging program to validate scanners across sites.

There has been a major focus on standardizing PET imaging, especially for FDG. In addition, the Clinical Trials Working Group within the QIN has focused on methods to report quantitative results from PET and other modalities to develop standardized reporting criteria and evaluate variability across performance sites. These results have shown good comparability in SUVmax measurements, but leave room for improvement in the SUVpeak and other metrics. Currently, QIN members and others are piloting a software solution called Auto PERCIST to improve the repeatability of quantitative PET metrics. Overall, these efforts by the QIN and other organizations are promoting the standardization of PET imaging.

Other nuclear medicine modalities such as SPECT have also been used in a variety of clinical trials. Originally, SPECT imaging was not quantitative, due to the lack of compensation for image degrading factors. The development of compensation methods for hybrid SPECT/CT has opened the door to clinical quantitative SPECT. Studies performed as part of the QIN have helped establish the accuracy and repeatability of quantitative SPECT. However, standardization of acquisition protocols and reconstruction, compensation, calibration and analysis methods to reduce variability is still needed. The RSNAs Quantitative Imaging Biomarker Alliance is in a process of drafting a profile for quantitative imaging of I-123 ioflupane, and the SNMMI CTN is developing a standard for assessing quantitative capabilities of imaging sites.

The question is not about how to standardize quantitative imaging methods, but rather how to bring these standards into clinical practice. Equipment manufacturers need to be brought on board to implement a full set of quantitative imaging settings, and national protocols must be established in order to bring quantitative imaging into multi-site clinical trials. Imaging technologists must be trained to use the quantitative settings and protocols as needed, and radiologists must be made aware that ringing quantitative procedures to clinical trials will help reduce costs and improve accuracy of trial outcome.

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Financial Management

Precision-based medicine improves outcomes and reduces costs for patients

By Paul Crowe

As health care costs continue to skyrocket, oncologists are looking for ways to effectively treat their patients without the added burden of enormous medical bills.

According to the National Cancer Institute, the U.S. spends approximately $157 billion on cancer care per year. In 2014, spending on oncology medication surpassed $100 billion worldwide. As patients are footing the bill for more of their medical expenses, they are increasingly aware of these escalating costs. According to a survey by Premier, Inc., 56 percent of C-suite hospital executives plan to invest more in cost-cutting avenues to meet patient demand.

Despite the exorbitant price tag, traditional cancer screenings and therapies are often ineffective or unnecessary. Cancer screenings may involve the potential for serious complications (perforation with colonoscopy) or result in false positives, which unnecessarily lead to anxiety and further invasive testing. Chemotherapy and radiation poison the body and may eventually lead to heart problems, lung disease and increased risk of other cancers, among other conditions. These treatments and diagnosis tools are decades old and do not utilize the significant genetic knowledge and data we have gathered in recent years. In effect, radiation and chemotherapy is a “throw everything against a wall and see what sticks solution,” rather than a personalized and targeted approach.

As patients demand less invasive and less costly diagnosis and treatment, innovators in the health care system are turning to precision-based medicine. By targeting the specific genetic abnormalities that cause cancer, precision medicine can diagnose and treat with much greater accuracy. In a study of juvenile brain cancer, researchers discovered that 56 percent of the tumors studied had genetic abnormalities that could influence how the disease was diagnosed or treated by drugs already in the market or in clinical trials. Research and testing using new technology have been successful in clinical feasibility studies reporting > 90 percent accuracy in diagnosing impacted males.

Unfortunately, the insurance industry has hesitated in covering some of the genetic tests available. This may be because precision medicine is often made from biological materials instead of synthesized chemicals, which makes it more expensive to initially develop. But, as precision medicine becomes part of the standard of care over the next five years, that is likely to change.

Insurers may be more apt to approve precision medicine techniques when considering a cost-benefit analysis. For cancer patients, expenses will drop as they receive targeted medication within days of diagnosis, and are able to skip more toxic treatments that result in hospitalization, intravenous lines, complications of those, steroids and other medications to lessen side effects and nursing. For example, a report by PricewaterhouseCoopers indicates that a genetic test on breast cancer patients could save an estimated $1,900 per patient because it can reduce chemotherapy use between 20 and 35 percent. Likewise, increased diagnostic accuracy for cancer screenings will reduce the costs and morbidity associated with false positive tests.

In hospitals, where insurance reimbursement rates depend upon patient experience and satisfaction, and expenditures are always closely monitored, precision medicine is already improving outcomes. In one study, precision medicine was shown to reduce readmissions by 52 percent, reduce visits to the emergency department by 42 percent and decrease deaths by 85 percent. Hospitals have a responsibility to their patients (and shareholders) to proactively promote new advancements in medicine. They should utilize their considerable clout to support research and development companies during FDA trials to ensure their physicians have access to the latest precision therapies once approved.

With the passage of the 21st Century Cures Act, precision medicine has received the backing of the U.S. government. The bill, which provides $4.8 billion in funding to initiatives aimed at matching patients to treatments based on their genes, signals a shift toward creating new health care standards. With the ability to fund more genetic sequencing, it is my hope that we can develop new treatment and diagnostic approaches for a wide range of cancers.

About the author: Paul Crowe is chairman and CEO of Nuview Life Sciences. Crowe is an experienced health care executive who, over the past 40 years, participated in the commercialization of new diagnostic imaging technologies such as diagnostic ultrasound, magnetic resonance imaging and positron emission tomography (PET). These technologies provided physicians with better tools to more effectively diagnose, and subsequently treat, chronic human diseases, improved patient outcomes and lowered health care costs.

Share this story: dotmed.com/news/37261
HealthCare Business News caught up with Richard Biehl, who discussed the challenges facing health care systems engineers.

HCB News: What is a health care systems engineer?
RB: Systems, in the sense we’re discussing, are fairly large-scale collections of interacting parts, the combination of which produces outcomes or results that would be beyond the capabilities of individual component parts. Systems engineers work to design and optimize those systems with an emphasis on the interactions as well as the components. A health care systems engineer does that work across the societal-scaled system that is our health care system. Unlike a mechanical systems engineer who works with system components of mechanical systems, the health care systems perspective encompasses large-scale institutions, facilities, knowledge, professions, regulatory models, supply chains, social services, biomedical research and education, and the general public. Whatever might affect the delivery of health care to patients could be within the focus of a health care systems engineer.

HCB News: What are some of the most pressing issues that systems engineers are helping to address?
RB: There are so many, with the highest number involving economics and the most important dealing with safety. Everyone talks about reducing health care costs, and costs are often the business justification for a systems engineering project, but cost is rarely the focus of our engineering efforts. We know that an efficient optimized system will operate at its lowest cost. Our focus is on that efficiency and optimization, even if our management teams only want to talk about cost.

To improve systems, we usually look for disruptions at the system level. As we find ways to provide health care access to more people, we have to address disruptions in supply. We know that there won’t be enough doctors in the future to meet the demand, particularly in some geographic locations and some clinical specialties. Making sure there’s an adequate supply of health care in the right places, in the right specialties, and at the right times, is a health care systems engineering challenge.

Among the safety concerns that systems engineers focus on are medication errors and continuity of care, as well as the general overuse, underuse or misuse of key health care procedures. We address these by improving specific aspects of the practice of health care in organizations, including increasing the use of evidence-based practices, improvements in the capture and flow of patient information and an increased focus on population-level trends and patterns. Improving health care requires even rethinking what we mean by a health care organization as we include more and broader stakeholders in our initiatives.

HCB News: Why are we facing a doctor shortage and how can we prepare for this growing crisis?
RB: The problem of doctor supply is very complex and has many dimensions. The number of new doctors entering the field is limited by the capacity of our medical schools. Of those entering practice, many choose to work in geographic locations or clinical specialties that don’t address the actual patient demand curves adequately. Many doctors leave the field because of economic pressures, liability concerns or simply the pursuit of more advantageous opportunities. Many doctors are baby boomers who will simply reach retirement over the next decade. All of these factors combine to cause the supply of doctors not to keep up with the ever-growing demand for care.

There are many opportunities to address this problem at the system level. Policy changes can reduce some of the burdens of being a doctor and cause more to stay in practice. Incentives can be designed to shift some practices to higher-demand specialties in underserved geographic areas. We can make it easier for immigrants to obtain medical licenses in states. These options represent system tinkering that can have a short- or medium-term effect, but won’t fix the problem long-term.

Systemically, we’re already addressing the problem in several ways. First, we’re rethinking the provision of care so that more of it can be provided by professionals not traditionally seen as doctors. This is
one reason we use the term provider rather than physician (or doctor), because increasingly the person providing care isn’t a physician. This spreading of care across a broader sector that includes stakeholders outside of hospitals and physician practices dramatically increases the system’s capacity even though the number of doctors is declining.

Additionally, we’re working to engineer out waste. Unnecessary procedures take up valuable capacity without improving health outcomes. Reapplying that capacity can increase the yield of our system with the same supply. Ultimately, we make health information more broadly available so that patients make better life choices, further reducing the demand on doctors to provide care. A patient developing a disease that could have been prevented is even more wasteful to our system than a doctor ordering an extra blood test. Waste of any kind reduces useful capacity, and systems engineering looks at all of these dimensions.

**HCB News: Why do we need to have health care systems engineers for all of this?**

**RB:** Health care systems engineers are specialists, bringing knowledge, skills and tools to bear in distinct ways that are unlikely to be included in many organizational change initiatives otherwise. Many health care organizations include quality or process improvement activities that work to address many of the problems being encountered across the system. These initiatives can successfully improve efficiency and effectiveness in meaningful ways. The people conducting these activities are well-meaning and hardworking, but they often concentrate too easily on symptoms of problems rather than causes of problems. They fix components of systems, and problems often then pop out in other components. Systems engineers are educated and trained to focus on the system as a whole, and to implement changes in components that actually optimize the whole system. The people in the system need to be involved because they know their patients, processes and interfaces better than any engineer could. It’s the synthesis of all of that knowledge with systems thinking that will improve our health care system for the future.

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Molecular Imaging Rewind

HCB Daily News (www.dotmed.com/news) covers the biggest announcements in molecular imaging all year round. In this section you will find a small sampling of the most interesting stories we’ve published over the last 12 months. These are the current events impacting the molecular imaging marketplace today and the practical research innovations poised to improve patient care tomorrow. For more stories like these, visit our Molecular Imaging news silo online.

Technetium 99m shortage led to more invasive cardiac stress-test procedures: study

Posted online July 07, 2016 by Thomas Dworetzky

Shortages of technetium Tc-99m had clinical impact — it drove up usage of cardiac catheterization to measure exercise stress, according to a recently published report.

“Shortages of important medical compounds can have substantial clinical consequences,” researcher Dr. Venkatesh L. Murthy from the University of Michigan in Ann Arbor reported to Reuters. In a study of the use of technetium 99m (Tc-99m) during the 2010-2012 period based on Medicare data, a shortage of the radioisotope at the time “appears to have led to a nearly 10 percent increase in heart catheterizations after stress tests,” he told the news agency.

The study determined that there were over 5,700 extra cardiac catheterizations for the patients in the study. Technetium 99m use dropped almost 25 percent during that period.

“In this particular case, shifting to thallium-201 during future shortages of technetium-99m may not be the optimum strategy, and greater use of other tests, such as positron emission tomography (PET), magnetic resonance imaging (MRI) and computed tomography (CT) may be a better alternative,” he advised.

The production challenge is well-known in the industry. Technetium Tc 99m is made largely from "weapons-grade" highly enriched uranium, according to the study published online in JAMA Cardiology, which noted that "none of the nuclear reactors that produce molybdenum Mo 99, the parent isotope of Technetium Tc 99m, are located in the United States and all are at least 50 years old, with repeated shortages of Technetium Tc 99m occurring, owing to required repairs."

As HCB News reported in June, the U.S. government has an “interest” in “ensuring a reliable supply” of molybdenum 99 (Mo-99), according to an address by Dr. Matt Heavner, Ph.D., assistant director for global security for the White House Office of Science and Technology Policy, at the San Diego SNMMI meeting.

“Even though the health of Americans relies heavily upon the availability of this isotope … there have been times in recent years when it has been in short supply,” he acknowledged to the SNMMI attendees.

Part of the challenge is that the materials used to make it carry weapons risks. Regarding these, Francie Israeli, press secretary with the National Nuclear Security Administration (NNSA) told HCB News, “Current supply challenges derive from two types of problems … Mo-99 production facility outages and problems associated with transporting Mo-99 from production facilities to Tc-99m generator producers — particularly across international borders.”

One way to combat the proliferation risks is the government-advocated switch to the use of low-enriched uranium (LEU) for production. “In the case of medical isotope production this has not been a trivial matter,” said Israeli. “These issues are being successfully addressed by current producers who are expected to complete conversions over the next three years.”

LEU and HEU production methods produce clinically equivalent Mo-99, she told HCB News.

The scope of the challenge to switch was also noted by the researchers in the JAMA report. “There are efforts to address this issue by many groups,” Murthy said. “Several companies have developed technologies to produce the technetium without using weapons-grade uranium. What is not completely clear yet is whether they will be able to operationalize these technologies and ramp up supply quickly enough.”

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Michael J. Fox Foundation puts up $2 million prize for Parkinson’s disease PET tracer

Posted online June 15, 2016 by John W. Mitchell

At the opening SNMMI plenary session, the Michael J. Fox Foundation (MJFF) announced that it is offering a $2 million prize for the discovery of a viable alpha-synuclein PET tracer — which could be key in creating a cure for Parkinson’s disease.

“This prize of $2 million is a small expense of our total budget, but a big step in accelerating research to find a cure,” Jamie Eberling, senior associate director of research programs at MJFF, told HCB News.

That type of radiotracer would aid in progressions tracking and testing therapies, according to MJFF sources, but finding a tracer that attaches to the Parkinson’s protein has eluded researchers.

In a video, Fox told the 6,000 attendees in the crowd that even though he knew the money was not their motivation in helping to find a cure for Parkinson’s, “it doesn’t hurt.” The prize, which has no time limit, also stipulates that the researcher who finds the tracer would have to share it with other scientists.

Fox’s goal in establishing the association was to succeed in developing a cure for the disease, said Eberling, and the $2 million prize is intended to help achieve that goal.

Alpha-synuclein accumulates in the brains of people with Parkinson’s disease, and researchers believe that is the cause of cell degeneration and death.

The lack of an objective biomarker of Parkinson’s slows testing of new treatments. If physicians could visualize alpha-synuclein in the brain, they would be able to confirm diagnosis earlier, intervene earlier, monitor disease progression and determine a patient’s response to treatment in clinical studies.

MJFF has long supported the pursuit of an alpha-synuclein PET tracer — in addition to funding of alpha-synuclein therapies and projects investigating peripheral measures of this key protein. In 2011, with little activity in the field, MJFF established a public-private entity to begin work toward such a tool.

Eberling said that Fox set up the organization to spend to a zero balance every year, so that funding the prize is in keeping with the organization’s mission. Last year, the MJFF raised nearly $90 million for research, according to Eberling.

Share this story: dotmed.com/news/31411
Mallinckrodt completes $690 million sale of Nuclear Imaging business to IBA Molecular

Mallinckrodt announced that it has closed the sale of its global Nuclear Imaging business to IBA Molecular (IBAM) for approximately $690 million before tax.

The Nuclear Imaging business encompasses two manufacturing facilities and a total of more than 800 employees in locations around the globe, including nearly 350 in the St. Louis area.

The business is a prominent global producer of the key medical isotope molybdenum-99, from which the workhorse SPECT isotope, technetium-99m (Tc-99m), is derived. Mallinckrodt’s decision to divest Nuclear Imaging was announced last August, and is a decision aligned with the company’s strategy to transform its portfolio with specialty pharmaceutical assets that are “durable, innovative and have significant volume growth potential,” according to a statement.

“The divestiture of our Nuclear Imaging business is another important step toward the evolution of our portfolio,” said Mark Trudeau, president and CEO of Mallinckrodt. “Our Nuclear Imaging business is an excellent strategic fit for the IBAM organization and we believe the expanded global reach of the combined business will enable IBAM to substantially increase its ability to meet the needs of patients around the world. With this transaction, we are pleased to welcome IBAM to the St. Louis area.”

The total price tag consists of approximately $574 million of up-front consideration, the assumption of approximately $39 million of long-term obligations and approximately $77 million of contingent consideration.

“We have created a new world-class nuclear imaging business. We have over 1,500 skilled employees across four continents, an unrivaled global manufacturing footprint comprising 21 leading-edge production facilities, a commercial presence in over 60 countries serving more than 6,000 customers, and very complementary product portfolios and technical capabilities,” said Renaud Dehareng, chief executive officer of IBAM.

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PET tracer study confirms tau brain tangles may drive Alzheimer’s disease pathology

A German team of researchers presenting at the annual SNMMI meeting in San Diego presented findings examining the correlation between amyloid, tau aggregation and metabolic activity in those suffering from Alzheimer’s.

While such a correlation has long been suspected, previous evidence has relied on post-mortem study obtained through autopsy. The new research provides confirmation in living patients, and that evidence contributed to the group receiving the SNMMI Image of the Year Award for their work.

“Adding tau-imaging may help us now to understand factors leading to the actual onset of neurodegeneration and possibly also to document effective treatment,” Dr. Alexander Drzezga, professor and chair in nuclear medicine at the University of Cologne, Germany, told HCB News. “Our results indicate that tau-pathology may be very tightly linked to neuronal dysfunction in Alzheimer’s disease … and could possibly be causally involved.”

According to Drzezga, the findings suggest that targeting the build-up and propagation of tau-pathology in the brain may impact the progression of the disease. He also said that monitoring the development of tau-pathology (in amyloid-positive patients) might represent an interesting biomarker to aid in the prevention of the symptomatic onset of Alzheimer’s disease.

“Using the three PET tracers in living patients offered a unique opportunity which has not been available in the past,” he told HCB News. “Tau-imaging seems to be closely linked to actual onset of neuronal injury, whereas amyloid-imaging may allow us to detect a predisposition to disease years ahead of the onset symptoms.”

SNMMI received more than 2,200 abstracts for the 2016 Image of the Year competition. The winner is selected by a vote of reviewers and the SNMMI society leadership.

“I was extremely honored and proud of my team,” Drzezga said. “This work has only been possible on the basis of an interdisciplinary effort involving several clinical and scientific partners and this award represents a great motivation for this entire group. I am particularly happy that the young investigators of our group involved in this study are now so specially rewarded for their work.”

According to Alzheimer’s Disease International, the economic cost of Alzheimer’s globally will reach $1 trillion by 2050. Currently 46 million people worldwide suffer from Alzheimer’s.

Share this story: dotmed.com/news/31412
White House representative Heavner sees 'tremendous progress' in Mo-99 availability

Posted online June 20, 2016 by John W. Mitchell

To illustrate the U.S. government’s “interest to develop and efforts to help ensure a reliable supply” of Molybdenum-99 (Mo-99), Dr. Matt Heavner, Ph.D., assistant director for global security for the White House Office of Science and Technology Policy, addressed an open meeting at the SNMMI conference in San Diego.

Heavner noted that about 80 percent of the medical isotope is “used in nuclear medical diagnostic procedures that you perform every day.” He also noted that America consumes about half the world’s supply of Mo-99.

“Even though the health of Americans relies heavily upon the availability of this isotope … there have been times in recent years when it has been in short supply,” he acknowledged to the SNMMI attendees.

He said that many of the facilities that produce Mo-99 are outdated and aging. Heavner added that the materials to produce Mo-99 could be used for nuclear weapons if in the wrong hands.

Heavner referred specific questions to a spokesperson at the National Nuclear Security Administration (NNSA).

“Current supply challenges derive from two types of problems,” Francie Israeli, press secretary with the NNSA, told HCB News. “Mo-99 production facility outages and problems associated with transporting Mo-99 from production facilities to Tc-99m generator producers — particularly across international borders.”

Heavner asserted that current patient needs can be met by current producers. “Even when Canada stops producing later this year, U.S. supplies have been strengthened,” he added.

Heavner said that the Department of Energy’s commercial partners are expected to offer further production options in the coming months, although he offered no specifics. He also said that the U.S. was working with Canadian sources to make emergency supplies if necessary, to head off any shortages.

Heavner added that commercial insurers must follow the precedent set by CMS to be willing to reimburse more for Mo-99 due to higher costs associated with developing the new sources.

A major concern for the government is that the same highly enriched uranium (HEU) used to make Mo-99 can be used to make nuclear weapons. So the government is advocating the switch to low-enriched uranium (LEU).

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PET beats SPECT for coronary disease diagnosis

Posted online September 07, 2016 by John W. Mitchell

A Dutch team presented results of its research concluding that PET is superior to diagnosing obstructive coronary artery disease in patients when compared to CT, SPECT or a combination of imaging tests.

“Ninety percent of what cardiologists do is to evaluate if chest pain is caused by coronary artery disease.” Dr. Paul Knaapen, M.D., Ph.D., principal investigator and senior author of the study, as well as interventional cardiologist and researcher at VU University, Amsterdam, told HCB News.

“For years I’ve been going around the globe telling the story that the combination of coronary anatomy obtained with CT and flow measurements with nuclear techniques should provide the best noninvasive diagnostic accuracy for our patients. The biggest surprise is that combination testing is not superior, but that PET as a single modality is significantly more accurate on its own.”

In the study, 208 patients with suspected coronary artery disease underwent angiography with pressure measurements of all arteries (FFR), the gold standard protocol. Angiography is an invasive test requiring threading a catheter into the patient’s coronary artery to obtain X-rays and to measure arterial pressure. The angiography indicated that 44 percent of the patients showed signs of coronary heart disease.

Patients next received noninvasive PET, SPECT and CCTA as well as combinations of nuclear and CT techniques. The results were that PET was significantly more accurate (85 percent) for diagnosing coronary ischemia compared to SPECT (77 percent) and CCTA (74 percent). CCTA had more false positive findings, where SPECT had more negative findings. The combination of tests did not add to the diagnostic accuracy.

Knaapen said that the cardiologists in attendance at the 2016 European Society of Cardiology, where he presented the study, were “surprised and stunned” at the findings — as was he.

“It makes it credible that I changed my opinion as a result of this study,” he said. “But that’s science — it helps you to challenge your own beliefs.”

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Researchers: PET agent, flurpiridaz F 18, shows promise over SPECT for cardiac imaging

Posted online September 26, 2016 by Lauren Dubinsky

Researchers have pitted PET and SPECT against each other yet again, and PET was crowned the victor.

More specifically, flurpiridaz F 18, Lantheus’ investigational PET agent for myocardial perfusion imaging (MPI), was found superior to SPECT for evaluating patients with coronary artery disease (CAD) during exercise stress testing.

PET MPI is usually used in combination with pharmacological stress testing because of the short half-lives of the radiotracers that are currently available, including 13N-ammonia and Rubidium-82 chloride. Conducting PET exams with exercise stress helps clinicians gather important additional clinical information.

“We believe improved diagnostic accuracy, coupled with reduced radiation exposure and potential for quantification of coronary flow reserve, provide great promise for flurpiridaz F 18 to become the diagnostic imaging agent of choice for evaluating coronary artery disease,” Dr. Cesare Orlandi, chief medical officer of Lantheus Medical Imaging, said in a statement.

A team of researchers led by Dr. Rob Beanlands of the University of Ottawa Heart Institute conducted a multi-center international Phase 3 study. They enrolled about 800 patients with known or suspected CAD who were scheduled for coronary angiography and conventional SPECT.

Among those patients, 221 with known or suspected CAD underwent exercise stress flurpiridaz F 18 PET and SPECT imaging and coronary angiography.

They found that flurpiridaz F 18 PET imaging has greater sensitivity than SPECT imaging, but lower specificity. In addition, a statistically higher percentage of flurpiridaz F 18 PET images were rated as either excellent or good quality compared to the SPECT images.

This is not the first time that flurpiridaz F 18 has shown promise. In a previous study presented at the American College of Cardiology’s annual scientific session in 2016, it was found to be superior to MPI with SPECT for assessing CAD in obese patients.

“SPECT image quality and accuracy decreases as BMI increases, due to a number of factors including more scatter, more attenuation and lower counts,” Dr. Timothy Bateman, cardiologist at Mid America Heart Institute and the presenter of the study, told HCB News at the time. “PET instrumentation reduces scatter and corrects for attenuation. PET quality is preserved as BMI increases, especially with F 18 tracers.”

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University of Virginia: polarized nuclear imaging may be the next big imaging modality

Posted online October 14, 2016 by Lauren Dubinsky

Take note of a new technique called polarized nuclear imaging (PNI), because it may just be the next big imaging modality. Researchers at the University of Virginia have developed the technique and are now in the process of refining it.

“We view this as a platform technology that might provide physiological information about a variety of different organ systems, much like MR and nuclear medicine now,” Wilson Miller, one of the researchers and a physicist at the university, told HCB News.

Instead of imaging protons in water, which is what MR does, PNI images a radioactive isotope of xenon that has been polarized using laser techniques. It obtains the spatial information from MR and collects image information by detecting gamma rays generated by xenon.

Since it’s possible to detect a gamma ray from even one atom, PNI offers much better image sensitivity and greatly reduces the amount of material required to perform the MR techniques, according to the researchers.

A paper covering the new imaging modality has recently been published in the journal, Nature, along with the first-ever published image using the technique. The researchers stated that the quality of that image is much greater than the first image ever produced using MR.

Once the technique is refined, it could provide a relatively inexpensive way to visualize the gas space of the lungs. Patients would inhale a gas that contains the isotopes and PNI would be used to generate the image.

The technique could also be used to image targeted areas of the body by injecting the isotopes into the bloodstream. It only requires a small amount of tracer material, so the radioactivity would be of little to no danger to the patient.

“In the longer term, we hope that it will enable enhanced imaging of organ systems beyond the lungs, although challenges associated with agent delivery must be overcome to realize that hope,” said Miller.

The researchers noted that “considerable work” still needs to be done to illustrate the usefulness of the technique in living subjects. In order to develop it for practical use, the size of the detector or the amount of tracer material needs to be increased.

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New cyclotron supplies FDG to Royal University Hospital in Canada as three-year project concludes

Posted online June 29, 2016 by Lauren Dubinsky

The Saskatchewan Centre for Cyclotron Sciences in Canada is supplying Royal University Hospital with FDG-based radioisotopes for PET/CT exams — marking the end of the facility’s three-year capital project.

“It will allow the hospital to increase the number of patients they can see on a regular basis,” Matthew Dalzell, partnership manager at Fedoruk Centre, which operates the Saskatchewan Centre for Cyclotron Sciences, told HCB News. “Before that, our supplies had to be flown in, which means it was subject to the vagaries of air travel.”

The hospital previously received radioisotopes from Hamilton, Ontario, which is about 1,794 miles away. Now that the cyclotron is on the campus, the clinic is open earlier and there will be fewer missed appointments due to transport delays.

The radioisotopes will also be used for Parkinson’s disease research, to understand how it develops and the effectiveness of different treatment options. The cyclotron is able to produce fluorodopa, which is used for looking at neurodegenerative conditions like Parkinson’s.

Researchers at the university will also be radiolabeling antibodies to investigate tailored treatments and ways to diagnose cancer, like drug-resistant forms of breast cancer. The antibody can point out the cancer cells that are resistant to initial chemotherapy.

“It lights [the cells] up, which gives someone the opportunity to assess treatment and also realize that they need to use different forms of treatment,” said Dalzell.

Hospitals all over North America have their own cyclotrons, but what makes this cyclotron unique is that it can be used for research.

“There are turnkey solutions that are basically cyclotrons in a box that you can buy, that allow you to produce FDG, but that’s about all it lets you produce,” said Dalzell.

The Fedoruk Centre is currently working toward getting a drug establishment license from Health Canada so it can supply radioisotopes to other hospitals in the area. They are looking to be either a direct or back-up supplier.

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GE Healthcare announces FDA clearance of Discovery MI digital PET/CT system

Posted online October 04, 2016 by Gus Iversen

GE Healthcare has announced FDA clearance of its Discovery MI digital PET/CT system, saying the new scanner may help clinicians diagnose and stage disease earlier.

“We are extremely excited about the FDA clearance of Discovery MI, and are proud to demonstrate the clinical performance of the scanner, with one of the first studies on the scanner demonstrating a new level of PET image quality,” said Bich Le, general manager of GE Healthcare PET/CT, in a statement.

The first unit has been installed at the Stanford University School of Medicine and GE has shared images captured with the system.

While the Discovery MI is intended to help guide treatment strategies, it will also enable research to be conducted using more novel, faster decaying tracers.

The system includes Discovery MI’s Light-Burst Digital Detector, which is a key component of its benefits as well as a central element in GE’s vision for a digital future for PET. The detector delivers up to two times improvement in volumetric resolution so that even smaller lesions can be detected.

The scanner also has the highest NEMA sensitivity of any Time-of-Flight (TOF)/PET system in the industry.

“Discovery MI is the industry’s only PET/CT system that brings together the sensitivity of digital detection, with the most innovative reconstruction technology available, the combination of Time-of-Flight (TOF) and Q.Clear,” said Le.

Q.Clear is a GE solution to help assess how effectively a patient is responding to treatment.

Discovery MI features diagnostic CT innovations to deliver dramatically improved spatial resolution with no increase in image noise with ASiR-V. With Smart Metal Artifact Reduction (MAR), Discovery MI also reduces streaks and shadows from metal artifacts. The system’s ability to increase low-yield tracer capability with protocols that reduce dose by up to 50 percent may also expand PET’s impact in neurology, cardiology and beyond.

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Each month, we visit Dr. Blaufox’s Museum of Historical Medical Artifacts to take a look back at the medical equipment that cleared the way for what patients encounter in doctors’ offices and operating rooms of today. Some equipment may be recognizable, while other featured inventions have since become obsolete or have had their usefulness discredited.

The picture and description appear courtesy of Dr. M. Donald Blaufox, M.D., Ph.D, from his website: www.mohma.org.

**Estimated Date:** 1915  
**Name:** Thomas Cone  
**Manufacturer:** Unknown  
**Description:** This radioactive block was inserted into a crock of water and became a radon emanater, generating radioactive water that was thought to have medicinal properties.

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This Month in Medical History

Remembering Alois Alzheimer

With longer life expectancies and a large cohort of Americans moving into their golden years, some diseases that impact the elderly will take a more prominent role in health care discussions in the coming decades.

Perhaps one of the most frightening was first detailed to an audience of medical professionals in 1906. It would be four years later that it would be named in honor of the doctor who discovered the disease.

Alois Alzheimer was born in Germany on June 14, 1864. His father was a notary, so Alzheimer didn’t model his professional life on examples he grew up with. However, his parents instilled a sense of purpose in him, teaching him that it was honorable to look after the less fortunate.

Alzheimer took a strong interest in science and went on to attend the universities of Berlin, Tübingen and Wurzburg. He graduated from Wurzburg with a medical degree in 1887. By the following year, he was into his residency at the Hospital for the Mentally Ill and Epileptics in Frankfurt, Germany. His mentor, Emil Sioli, encouraged Alzheimer to expand his knowledge and branch out his efforts professionally. Alzheimer consequently studied psychiatry and neuropathy, which was of particular interest. He partnered with neurologist Franz Nissl to carry out studies of the pathology of the nervous system. These efforts culminated in the six-volume work “Histologic and Histopathology Studies of the Cerebral Cortex.”

At the age of 32, he married Cecilia Geisenheimer, a banker’s widow. His wife’s wealth meant Alzheimer didn’t have to struggle to pay bills, allowing him to focus more on his research. Still, he found time for other pursuits, with the couple having three children. Just seven years after they married, however, Cecilia passed away. Alzheimer’s younger sister, Elisabeth, moved in to help raise the children.

In 1901, the same year his wife died, Alzheimer met Auguste Deter, a 51-year-old woman with odd psychological symptoms and a deteriorating memory. Deter would become a major focus of Alzheimer’s research. Yet, he would continue to branch out even as he studied the puzzling and troubling case. Alzheimer would continue to investigate diseases like Huntington’s chorea and epilepsy. In 1903, he was asked to come to Munich as the research assistant of psychiatrist Emil Kraepelin. In Munich, he created a research lab to allow him to continue his studies of the brain. Just three years later, in 1906, Deter died at the age of 55. Through an agreement with Deter’s husband, Alzheimer had petitioned on her behalf to keep her in the better psychiatric hospital that would have otherwise been beyond her husband’s financial means. In exchange, her husband would allow him to receive her records and her brain upon her death.

Alzheimer worked with two Italian physicians with knowledge of a new stain for preparing tissue to examine under a microscope. The autopsy of Deter’s brain showed various pathological conditions, including shrinking of the cortex and the presence of neurofibrillary tangles and neuritic plaques. The tangles and plaques, able to be investigated better due to the new stain, stood out as particularly unusual discoveries in a woman of her age and Alzheimer studied them extensively, determining that they were the cause of her dementia. Later that year, Alzheimer would give a lecture about his findings, and in 1907 would write a paper extensively detailing his findings. However, it was Kraepelin’s book, “Handbook of Psychiatry,” published in 1910, that would give the disease its name, although American Solomon Carter Fuller reported similar findings five months before Alzheimer’s lecture.

In 1912, King Wilhelm II of Prussia appointed Alzheimer as professor of psychiatry at the University of Breslau. It was during his train ride to his new post that he fell ill. He never fully recovered from his illness and it ultimately contributed to his death three years later from cardiac failure at the age of 51.

More than 75 years after his death, some medical professionals raised questions regarding his findings and reviewed his notes and papers to develop their own hypotheses. Some critics questioned whether Deter did indeed have the disease named for Alzheimer rather than other similar, albeit rare conditions. In 1998, the original microscope slides from the autopsy of Deter’s brain were rediscovered and based on studying those slides, it was confirmed that Deter’s postmortem diagnosis was, in fact, correct.

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Value. It’s both a concept and goal that is driving our health care industry forward today, putting emphasis on more personalized care delivery, improved patient outcomes and reduced costs.

It’s also advancing nuclear medicine imaging modalities that have a long history of providing clinicians unique views into their patients’ cellular and molecular levels, driving earlier diagnoses. Current innovation is bringing unprecedented specificity and sensitivity to molecular imaging, resulting in many benefits.

With value-based care changing the way health care organizations approach care delivery, there is a greater need for easy to use, fast and precise imaging. And with expanding access to data, clinicians are looking for ways to make that data actionable, whether in their own workflow or for customizing treatment for a patient. Molecular imaging accomplishes that, allowing physicians to make decisions based on the specific molecular and cellular patterns of disease in addition to the patient’s anatomy.

For example, being able to determine the exact measurements of a tumor versus just having a visual interpretation of its size can translate to better outcomes. Physicians have already begun to look at molecular imaging technologies as more than just scanners, but as solutions that have a broader impact on patient care and the industry at various stages along the health care continuum.

As health care organizations more fully shift to value-based care in the coming years, nuclear medicine and molecular imaging will continue to see expanded use to provide more personalized care. Over the next five years, we can expect:

Innovations that provide greater detail and accuracy. Advancements in imaging technology, such as digital PET/CT and CZT-based SPECT, will drive better lesion detectability, quantitative accuracy and lower dose. Digital PET/CT will bring the Time-of-Flight PET imaging to the next level of performance in clinical sensitivity, volumetric resolution and quantification as the clinical community aspires to see the disease states earlier and monitor therapy effectiveness better than before. We do expect that PET/CT, with its high sensitivity and specificity, will continue to grow rapidly and play an increasingly important role among the diagnostic imaging modalities.

Emergence of new radiopharmaceuticals. As technology evolves, new radiotracers are developed and approved, opening doors to new applications in both clinical and academic capacities. While radiotracers have a number of barriers to overcome before they come to market for use, they are greatly improving the ways in which molecular imaging can be used. Molecular imaging technology is already well established in current clinical applications, like oncology and cardiology, but we are seeing growth in areas such as neurology and new oncology applications as new molecules and imaging agents are identified. Advancements in imaging technology, in turn, will open additional possibilities for new radiopharmaceuticals to emerge.

Improved integration within the broader health continuum. With an aging population and the continuing rise in multiple chronic and complex diseases, molecular imaging’s high detail and qualitative results will play a key role in transforming population health. Population health management requires more integrated and interdisciplinary approaches, and as clinicians look to implement more preemptive and definitive treatment programs, they will require access to integrated, comprehensive data on the patient’s diagnostic history, not just an image.

Nuclear medicine and molecular imaging will continue to advance and develop as an integral part of radiology and diagnostic imaging, expanding to bring physicians one step closer to personalized care. Despite its significant growth in past years, the opportunity for further innovation and growth remains, continuing to maximize nuclear medicine’s value and impact.

About the authors: Kees Wesdorp, Ph.D., is the business group leader, Diagnostic Imaging at Philips. Kirill Shalyaev, Ph.D., is the business leader, Advanced Molecular Imaging at Philips. Share this story: dotmed.com/news/37263
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