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BPA WORLDWIDE BUSINESS

Price transparency remains murky

In the hopes of curbing rising costs, CMS issued a rule in November of 2019 expanding on the categories of price information that hospitals were already required to publicly disclose under the ACA. Now, new research has shown that out of 100 of the largest hospitals in the U.S., only about 22% of them are compliant with the new price transparency rule. At the other end of the spectrum, 65% of them were found to be "unambiguously noncompliant" — but is anyone surprised?

For decades hospitals have been increasingly incentivized to inflate the total gross prices reflected in chargemaster lists as a means to negotiate higher payments from their in-network insurance providers. These gross rates often fail to reflect the actual, end of day cost for consumers.

One of our new reporters, Robin Lasky, wrote about the new study on price transparency in our online news, but we weren't able to fit it in this issue, so I wanted to bring it up in my letter. Partly because it's interesting and partly because it's something all of us can relate to. It's basically impossible, in my experience, to have any idea how much a trip to the doctor is going to cost. Frankly, most of us just take that for granted.

For prominent healthcare stakeholders opposed to transparency initiatives (the AHA among them), one concern is that further transparency as prescribed by the rule would "confuse and frustrate" consumers, and potentially causes more avoidance of necessary care. The prevailing view of economists, however, is that empowering patients as consumers to shop around for services, may lead to increased price competition.

For me, price transparency fits neatly into the greater notion of value-based care. As much as I want to see it in this industry, it is hard — as a patient myself — to see how we're going to get there. But, one thing is clear: until further compliance can be achieved, how more price transparency may ultimately affect or reshape the healthcare landscape remains open to conjecture.

If you have any thoughts on what it will take to implement real price transparency in healthcare, I'd love to hear from you. Meanwhile, I hope you enjoy our cardiac imaging-themed April issue.

Thanks for reading,

Gus Iversen
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3D printing method yields organs and tissue 10-50 times faster

Posted online March 10, 2021 by John R. Fischer

Engineers at the University of Buffalo have 3D-printed a life-sized hand in minutes rather than six hours, like conventional methods.

Their method of choice was stereolithography, which they say produces 3D objects 10-50 times faster.

"Most of the 3D printing technologies we see today are extrusion and inkjet-based. To build a 3D object using these methods, you will need to first build a 2D planar layer in a pixel-by-pixel manner and then add multiple 2D layers to 3D. Our FLOAT technology is based on stereolithography printing, which deposits material through photo crosslinking of the resins in an entire 2D plane. So it is inherently faster than extrusion and inkjet-based methods," co-lead author Ruogang Zhao, associate professor of biomedical engineering at the University of Buffalo, told HCB News.

For their study, the engineers utilized the fast hydrogel stereolithography printing (FLOAT) method, which improved the stereolithography by automating the printing in the z-direction. This allowed the 2D layers to be continuously added to form a 3D object, thereby making the process faster but still accurate, compared to conventional printing methods.

The jelly-like materials used to develop the hand are hydrogels, which are currently used to create diapers, contact lenses and scaffolds in tissue engineering. The latter application was applied by the engineers to 3D-print organs and tissues accurately and at a faster pace.

Stereolithography enables them to produce centimeter-sized hydrogel models quickly, while reducing deformation and cellular injuries that are common with conventional 3D printing methods, due to prolonged exposure to environmental stresses. It is also considered to be particularly effective for printing cells with embedded blood vessel networks, which is expected to play a critical role in the production of 3D-printed human tissue and organs.

Zhao and his colleagues have filed a provision patent for the technology and established a startup company to work on commercializing the technology.

The findings were published in the journal, Advanced Healthcare Materials.

Read full story: dotmed.com/news/54197

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VIDEO INTERVIEWS

In a new segment called Five Minutes in Healthcare, HCB News publisher Phil Jacobus chats with industry leaders about the COVID-19 impact via Zoom.

Check it out at: dotmed.com/news/jacobus

Top trending headlines as we went to print:

Ultrasound vibrations can damage COVID-19 virus
dotmed.com/news/54314

Analysis finds 87% of US breast cancer centers begin screening at age 40
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Imaging reveals how COVID-19 makes the body attack itself

Posted online February 19, 2021 by John R. Fischer

Radiological images have revealed that COVID-19 is capable of making the body attack itself.

While muscle soreness and achy joints are common symptoms among COVID-19 patients, some individuals experience more severe and long-lasting conditions such as rheumatoid arthritis flares, autoimmune myositis or "COVID toes", a dermatological condition in which patients' toes become swollen and discolored, with blisters or pustules. Researchers at Northwestern Medicine say the radiological images confirm, for the first time, that the cause of these symptoms is the body itself.

"Mechanisms of musculoskeletal involvement in COVID-19 are not fully understood, but we now see evidence on imaging of immune-mediated damage," corresponding author Dr. Swati Deshmukh, assistant professor of musculoskeletal radiology at Northwestern Memorial Hospital and Northwestern University, told HCB News.

The researchers conducted a retrospective review of data from patients who were at Northwestern Memorial Hospital between May and December in 2020.

Multimodality imaging such as MR and ultrasound, according to Deshmukh, allowed doctors to distinguish aches caused by COVID-19 from those caused by the flu or other diseases. It also enabled them to examine tissues inside the body to see which tissues were affected by the virus and how severely; including muscles, nerves, and joints, and even small peripheral nerves. They could then determine the potential mechanisms behind injuries and send patients to the right specialist for treatment, such as a rheumatologist or a dermatologist.

Some COVID-19 diagnoses based on musculoskeletal imaging were made for patients who were not even aware they'd contracted the virus. Deshmukh says that symptoms can include edema and inflammatory changes of the tissues such as fluid and swelling, hematoma, and gangrene. The types of musculoskeletal injuries, however, can differ, with some patients presenting injured nerves and others experiencing impaired blood flows.

"COVID-19 and mechanisms of injury are not yet fully understood," she said. "The vaccine and virus variants add complexity. Further research is needed to optimize medical diagnosis, treatment, and hopefully one day, even prevention."

Read full story: dotmed.com/news/54009

European Commission gives nod for Siemens to acquire Varian

Posted online February 23, 2021 by John R. Fischer

The European Commission has approved Siemens Healthineers' $16.4 billion acquisition of Varian Medical Systems.

The deal marks Siemens direct return to the radiotherapy market 10 years after its 2011 exit.

"With the EU regulatory approval of the transaction, we have taken another important step forward on the path to combining our two companies. Together with Varian's strong team, we aim to do everything we can in the future to ensure that people around the world benefit from our efforts in the fight against cancer and to strengthen global healthcare," said Bernd Montag, CEO of Siemens Healthineers AG, in a statement.

The deal was first announced in August 2020, with the transaction being completed in December. Following this, the commission launched an investigation into the matter out of concern that the deal would cause competitors, the European Economic Area and the U.K., to foreclose on their supply of medical imaging solutions, especially CT, MR and PET scanners. It also feared foreclosures on supplies of radiotherapy solutions for treatment such as linear accelerators and proton therapy equipmen.

Read full story: dotmed.com/news/54061

FDA clears Siemens whole-body PET/CT scanner

Posted online March 08, 2021 by Lisa Chamoff

Siemens Healthineers has announced FDA clearance of its Biograph Vision Quadra PET/CT scanner, which has an extended axial field of view (FoV) that allows for simultaneous whole-body imaging from top of head to thigh.

The scanner, which is designed for both clinical and research use, features a 106-centimeter axial FoV that is four times the PET axial FoV of the company's Biograph Vision 600," said John Khoury, the U.S. vice president of Molecular Imaging at Siemens Healthineers North America. "The new scanner has the same 3.2-millmeter silicon photomultiplier (SiPM) detector technology and Time of Flight (ToF) performance, and the extended FoV allows clinicians to image all the vital organs simultaneously with higher sensitivity."

The large FoV allows clinicians to examine patient anatomy during radiopharmaceutical uptake in shorter periods of time and allows for radiation oncology planning for larger patients, Khoury said. Scans, particularly for pediatric patients, can also be done faster and at a potentially lower radiation dose. It also has applications in therapy research.

The market for this new scanner includes large academic research facilities and high-end oncology centers.

Read full story: dotmed.com/news/54183

Vaccine side effect may result in misleading mammography results

Posted online March 05, 2021 by John R. Fischer

A new study out of Massachusetts General Hospital reports that the COVID-19 vaccine can cause lymph nodes to swell similarly to how they would when breast cancer spreads to them. Some physicians are worried such an adverse event could create unnecessary worry and lead to false positives for breast cancer screening.

Some have recommended that patients who have received the vaccine delay mammograms, biopsies and additional imaging, while others say screenings should continue on as scheduled.

"Some have recommended waiting four to six weeks after your final vaccine dose before having a mammogram. That way, any lymph node swelling caused by the vaccine has time to go away. Others, including Mayo Clinic, recommend that mammograms continue as scheduled. But be sure to tell your doctor about your vaccination, the date it occurred and which arm was affected," Mayo Clinic posted on its website.

Swollen lymph nodes under the arm in which the vaccine is administered indicates that the body's immune system is responding and building up antibodies against the virus that causes COVID-19. Similarly, the spread of breast cancer can cause lymph nodes in the armpit to swell.

Out of the 70 million vaccinated already in the U.S., over 85% reported local reactions at the injection site and 75% reported systemic reactions. Axillary swelling or tenderness was the most common unsolicited adverse event reported, with 10.2% of patients experiencing it after the first Moderna vaccine and 14.2% of patients after the second. Known as palpable unilateral lymphadenopathy, the condition has also increased among those who received the Pfizer vaccine, according to the MGH study.

The Society of Breast Imaging recommends that women receive mammograms before they receive the vaccine and that those who already have wait four to six weeks before scheduling one and four to 12 weeks for follow-up imaging after receiving the final dose. "Breast radiologists will increasingly encounter axillary adenopathy as more patients become vaccinated, but the near to long term appearance of mammographic adenopathy following vaccination is currently unknown," it said in a statement, adding that "if axillary adenopathy persists after short term follow up, then consider lymph node sampling to exclude breast and non-breast malignancy."

The study's authors, however, advise against rescheduling imaging or vaccinations due to it potentially deterring racial and ethnic minorities from seeking medical support in the future. Such populations are more likely to suffer from both COVID-19 and cancer, write the authors.

Read full story: dotmed.com/news/54160

Lunit AI to be deployed in Philips X-ray systems

Posted online March 05, 2021 by John R. Fischer

Lunit Insight CXR, an AI software designed by startup Lunit and used to assess chest X-rays, can now be found as a component in Philips' diagnostic X-ray solutions.

The two companies announced the integration and their newfound partnership at the European Congress of Radiology virtual event.

"In times of higher patient throughput and increasing pressure to reduce costs, AI-based early detection and reading support can help drive faster decision-making about follow-up procedures and time to diagnosis. We also see a significant demand for early notification and decision-making at the point of acquisition directly at the modality, helping to improve the entire diagnostic imaging chain," Daan van Manen, general manager of DXR (Diagnostic X-Ray) at Philips, told HCB News.

Lunit Insight CXR chest detection suite is designed to identify 10 of the most common findings in a chest X-ray by mapping their location. It then shows scored calculations of the actual existence of a finding for accurate analysis. These findings include atelectasis, calcification, cardiomegaly, consolidation, fibrosis, mediastinal widening, nodule, pleural effusion, pneumoperitoneum, and pneumothorax.

It also can prioritize abnormal cases for faster triage and has an accuracy rate of 97% – 99% that has been validated in major publications. The solution will be made available for new products released by Philips and within its installed base of MobileDiagnost wDR, DigitalDiagnost, DigitalDiagnost, ProxiDiagnost N90 as well as CombiDiagnost R90 systems. Installations will not require costly modifications/upgrades for these existing systems.

For Philips, the partnership extends its AI sector further into precision diagnosis and enables it to provide better outcomes, improve patient and staff experience, and lowers cost of care. The deployment of Lunit Insight CXR is expected to help providers avoid complex IT projects and help lower barriers for adopting AI.

"Technologies providing more user-independent outcomes on a consistently high quality level can help caregivers stay on the clinical edge while managing costs," said van Manen.

Lunit INSIGHT is seeking FDA clearance in 2021.

Read full story: dotmed.com/news/54180

Abbreviated breast MR may enable quality diagnostic scans at reduced cost and time

Posted online March 11, 2021 by John R. Fischer

Abbreviated breast MR may save physicians more time and expense, while still being able to efficiently identify breast cancer.

That's according to researchers at Sungkyunkwan University School of Medicine in Seoul, South Korea. "Despite the high diagnostic performance of breast MR, its application as a cancer screening tool is hindered by high costs and longer acquisition and interpretation times," the group wrote. "Abbreviated MR protocols show equivalent diagnostic accuracy for cancer while reducing acquisition and interpretation times compared with conventional full-protocol MR."

Abbreviated breast MR reduces scanning time from 30 minutes to about 10 minutes, according to the authors. Data on its performance, however, is limited.

The authors assessed its use over three consecutive years on 1,975 women who underwent 3,037 exams between September 2015 and August 2018. They evaluated cancer detection rate, sensitivity, specificity, positive predictive value, abnormal interpretation rate, and interval cancer rates. Of the women examined, 14% were at high risk, 82.7% had an intermediate risk, and 3.3% were at average risk. The last of these three groups underwent breast MR either by patient request or surgeon recommendation.

Read full story: dotmed.com/news/54098

GE introduces pocked-sized wireless handheld ultrasound

Posted online March 17, 2021 by Gus Iversen

Vscan Air, a pocket-sized wireless ultrasound from GE Healthcare, is now available in the U.S. and Europe.

The system provides whole-body scanning capabilities, and will be priced at under $5,000, according to CNBC. It can perform both shallow and deep exams with a flip of the two-sided probe design (high-frequency linear and convex transducer probe), without switching probes.

"Now, more than ever, clinicians need smaller and smarter tools that increase access and efficiency both in and outside of the four walls of the hospital," said Anders Wold, president and CEO of global ultrasound at GE Healthcare, in a statement. "The Vscan Air exemplifies customer-driven innovation that enables more personalized care for patients worldwide."

GE Healthcare introduced the first color, pocket-sized ultrasound, Vscan, in 2010.

As clinicians treat more critically ill patients with limited resources, handheld ultrasound has emerged as a valuable tool, allowing clinicians to quickly collect images and triage patients while also providing the benefits of portability, cleanability, and workflow efficiency. Vscan Air has been verified for limited use outside of professional healthcare facilities.

Read full story: dotmed.com/news/54292

Varian appoints new CEO ahead of Siemens Healthineers acquisition

Posted online March 02, 2021 by John R. Fischer

Chris Toth is set to take the helm as CEO of Varian Medical Systems following its transition to a business segment under Siemens Healthineers.

Toth has served in multiple executive positions with Varian since joining the company in 2001. As of October 2020 he has been president and COO, overseeing the company's fiscal 2021 goals and strategic initiatives. Prior to that, Toth had been president of Varian Oncology Systems where he managed more than $3 billion in revenue and over 7,000 employees globally, and helped return Varian to double-digit growth.

After more than 16 years as CEO, Dow Wilson will be retiring from the role, but will remain involved as a special advisor to Siemens to help smooth the integration of the two companies. Wilson described his tenure with Varian as "the highlight of [his] career" and will leave behind a powerful legacy.

"I once took a tour of the Varian manufacturing facility in Palo Alto, California, and was impressed with how many people were on a first name basis with Dow," recalled Philip Jacobus, publisher of HealthCare Business News and a Varian business partner. "He seemed to not only be well thought of, but it's clear he inspired confidence."

As CEO, Toth will report directly to Dr. Bernd Montag, CEO of Siemens Healthineers.

Siemens announced its intention to purchase Varian in August for $16.4 billion, with the transaction completed in December. The deal marks Siemens' return to the radiotherapy market ten years after exiting in 2011 and pairs it with the leader in radiotherapy, with a market share of over 50%, according to Reuters. In exchange, Varian will work alongside a leader in medical imaging it has built a relationship with through previous collaborations.

Toth's appointment follows the completion of an investigation by the European Commission into the acquisition, out of concern that such a deal would cause competitors to foreclose on their supplies of medical imaging and radiotherapy solutions.

Read full story: dotmed.com/news/54134

Fujifilm to complete Hitachi imaging acquisition by end of March

Posted online February 19, 2021 by John R. Fischer

FUJIFILM Corporation has signed an agreement to acquire Hitachi's diagnostic imaging business in an absorption-type company split deal.

"By combining Fujifilm and Hitachi's diagnostic imaging businesses, we will be able to provide a more comprehensive healthcare solution that includes CT, MR, diagnostic imaging, enterprise imaging, endoscopy, endosurgery, ultrasound, and in-vitro diagnostics. This will dramatically enhance our ability to achieve our goal of delivering solutions across prevention, diagnosis, and treatment to healthcare institutions," Henry Izawa, vice president of modality solutions and clinical affairs at FUJIFILM Medical Systems USA, told HCB News.

Hitachi will split off its imaging business as a separate company that will be absorbed by FUJIFILM Healthcare, which Hitachi established to act as the successor. The transfer is expected to be completed by March 31, 2021.

The deal adds a large range of CTs, X-rays, ultrasound and MR systems to FUJIFILM's portfolio, and expands its medical business. It also will introduce a new portfolio that includes endoscopic ultrasound PACS, and is expected to put the company on equal footing with global medical imaging players such as Siemens, General Electric and Philips.

Read full story: dotmed.com/news/54012

IBM contemplating sale of Watson Health: report

Posted online February 24, 2021 by John R. Fischer

IBM Watson is considering selling its Watson Health business, which despite making up to nearly $1 billion annually, is not profitable.

IBM, which holds a market value of $108 billion, trails behind rivals Amazon and Microsoft in the cloud computing space. A sale of Watson Health would allow CEO Arvind Krishna to streamline the company and become a more competitive player in cloud computing, according to an article in The Wall Street Journal.

"Watson was one of IBM's highest-profile initiatives in recent years and a big bet on the growing healthcare sector, though results disappointed, in part, because physicians were hesitant to adopt artificial intelligence," read the article.

Despite bringing in nearly $1 billion annually, Watson Health is not considered profitable. The company's cognitive applications revenue, which includes Watson Health, for instance, came to $1.5 billion in the fourth quarter of 2020, a decrease of 2% year-over-year. Shares also slipped 6.6% due to poor cloud and cognitive software performance, with the company missing Q4 revenue estimates and posting its fourth straight quarterly revenue decline, reports Business Insider.

Read full story: dotmed.com/news/54060

FTC surrenders, announces no further attempts to thwart PA hospital merger

Posted online March 08, 2021 by Robin Lasky

In a surprising move, the Federal Trade Commission (FTC) advised on Monday that it will not be pursuing any additional challenges to the merger between Jefferson University Hospital and Einstein Healthcare Network, two Philadelphia based healthcare providers.

Last year, on February 27, 2020, the FTC filed an administrative complaint in the Eastern District of Pennsylvania alleging the merger constituted a violation of antitrust law and requested the court enjoin it from proceeding until its legality could be determined at an administrative trial.

"Patients in the Philadelphia region have benefited enormously from the competition between the Jefferson and Einstein systems," said Ian Conner, director of the FTC's bureau of competition, at the time. "This merger would eliminate the competitive pressure that has driven quality improvements and lowered rates."

Following evidentiary hearings, on December 8, 2020, district court Judge Gerald Pappert issued a scathing rebuke of the government's legal theory in his decision to deny the request for an injunction to halt the merger. Pappert's decision was, in part, based on finding the witness testimony from representatives of major insurance companies, which the government substantially relied on to make their case, inconsistent and otherwise not credible.

The health insurance market in the region, including only a handful of providers, is much more consolidated than the market for healthcare services, the court observed. Additionally, among these insurance providers, one controls over 50% of the market share. By contrast, there are dozens of alternative healthcare providers within a reasonable distance of Einstein and Jefferson, and Philadelphia has one of the most robustly competitive markets for healthcare in the country.

"Two nonprofit, anchor institutions coming together to preserve access to care and do the right thing by the residents of Philadelphia is a creative solution to ensure Einstein doesn't face the same fate as Hahnemann University Hospital," said Dr. Stephen K. Klasko, president of Thomas Jefferson University and CEO of Jefferson Health in a statement celebrating the FTC's announcement.

Read full story: dotmed.com/news/54182

GE Healthcare in search of buyer for Waukesha campus

Posted online March 03, 2021 by John R. Fischer

GE Healthcare is selling parcels of its Waukesha campus.

The sale will include 10 parcels and is part of a strategic decision to move operations to its West Milwaukee and Wauwatosa facilities, where it plans to invest $50 million to ramp up medical imaging production, reports the Milwaukee Journal Sentinel.

"If, after required bargaining with unions, we make a final decision to move manufacturing and related work, all proposed moves would be completed in two or more years," Ben Fox, director of global communications at GE Healthcare, told HCB News.

The company uses the 561-acre campus primarily for its MR, CT and X-ray businesses, according to the Milwaukee Journal Sentinel. It announced its intention in September to sell the campus, with the intent being to create a global showcase for CT manufacturing at the West Milwaukee and Wauwatosa facilities.

It plans to move roughly 1,500 employees from its offices and plant in Waukesha over a period of several years, though the MR unit and 600 GE employees at the Waukesha campus will remain at the campus, reports NBC-affiliate, TMJ4.

Read full story: dotmed.com/news/54135

HIMSS to pay $2.8 million settlement over unrefunded 2020 trade show fees

Posted online March 17, 2021 by John R. Fischer

HIMSS will pay $2.8 million to settle a proposed class-action lawsuit against it for unrefunded fees related to the cancellation of its 2020 annual conference and exhibition.

The settlement is between the Healthcare Information and Management Systems Society; HatchMed, a technology company that was registered to exhibit at the 2020 trade show; and Novarad, another healthcare technology company added later to the case as a plaintiff. HatchMed and Novarad are representing exhibitors who did not receive refunds following the cancellation of the show, according to Modern Healthcare.

"Unlike other industrywide tradeshows, HIMSS decided to utilize its cancellation as an unauthorized cash grab, as it unilaterally determined to keep the money that its exhibitors paid," HatchMed wrote in its June complaint.

HIMSS canceled its 2020 show days before it was to start due to COVID-19. Instead of refunding exhibitors and sponsors, the organization offered a deal where 15% of a company or individual's 2020 fees would go toward their participation in the 2021 conference and 10% in 2022.

The court will hold a hearing to determine whether to approve the settlement in June.

Read full story: dotmed.com/news/54285

USPSTF lowers age, expands access to lung cancer screening

Posted online March 10, 2021 by John R. Fischer

Current and former smokers should undergo annual lung cancer screenings starting at age 50, according to final guidelines issued this week by the U.S. Preventive Services Task Force.

The recommendation lowers the original age limit from 55 to 50 and redefines the definition of a heavy smoker as someone with a 30 pack-year history (one pack a day for 30 years) to a 20 pack-year history. Like the most recent 2013 version, the new guideline pertains to those who still smoke or have quit in the last 15 years and refers to those 80 or under.

"By screening people who are younger and who have smoked fewer cigarettes, we can save more lives and help people remain healthy longer," said USPSTF member Dr. Michael Barry in a statement.

Lung cancer is the number one cause of death in the U.S., with more than 200,000 people diagnosed annually. Smoking is the leading cause, and the Task Force expects the new recommendations to nearly double the number of people eligible for lung cancer screening to 15 million people, reports the Washington Post.

The changes are expected to especially be helpful for Black people, who have a higher risk of lung cancer than white people despite smoking fewer cigarettes than white men. They also are seen as potentially lifesaving for women, who also smoke less than white men.

"Lung cancer kills more people each year than breast, colon and prostate cancers combined. Particularly with the expanded screening thresholds implemented nationwide, this cost-effective test can save more lives than any cancer-screening test in history," said Dr. Debra Dyer, chair of the ACR Lung Cancer Screening Steering Committee, in a statement.

The guidance is a B recommendation, meaning that private insurers are required to cover it without levying a share of the cost on to the patient, as specified in the Affordable Care Act. The ACA mandates that private payers adopt updated USPSTF guidelines within one year.

Read full story: dotmed.com/news/54212

IBA teams with NorthStar to increase global access to Tc-99m

Posted online March 11, 2021 by John R. Fischer

IBA has joined forces with radiopharmaceutical developer NorthStar Medical Radioisotopes to help make technetium-99m more globally available.

The two plan to help non-U.S. companies access NorthStar's Tc-99m Generation Systems, high tech separation platforms that process non-uranium based Mo-99 as a step in the production of Tc-99m. They are used in conjunction with IBA's electron beam accelerators for reliable commercial-scale production of Mo-99.

"Reliable access to technetium-99m, the most widely used diagnostic imaging radioisotope, is increasingly important as the world's population expands and ages, and the TCM Generation System can help to reliably address these unmet needs on a global basis," Stephen Merrick, president and chief executive officer of NorthStar, told HCB News.

IBA and NorthStar's partnership builds on an existing contract under which NorthStar will use up to eight Rhodotron TT 300-HE electron beam accelerators developed by IBA for the production of non-uranium based Mo-99. It will then use this Mo-99 in its Tc-99m Generation System, RadioGenix to produce Tc-99m in the U.S. RadioGenix gained FDA clearance in 2018, making NorthStar the first U.S. source of Mo-99 in almost three decades.

Read full story: dotmed.com/news/54198

New proton technique enables more specific targeting of resistant cancer cells

Posted online February 25, 2021 by John R. Fischer

Researchers at Mayo Clinic have developed LEAP, a new technique that enables clinicians to more specifically target and administer proton therapy to cancer cells that resist other forms of treatment.

"We compared the effects of delivering the same amount of energy or dose into cancer cells using a dense energy deposition pattern with LEAP versus spreading out the same energy more diffusely, which is typical of conventional photon and proton therapy," said radiation oncologist Dr. Robert Mutter, co-principal investigator of the study. "Surprisingly, we discovered that cancers with inherent defects in the ATM-BRCA1-BRCA2 pathway are exquisitely sensitive to a new concentrated proton technique."

Using a dense energy deposition pattern, Mutter and his colleague, Zhenkun Lou, the other co-principal investigator, applied LEAP, which is an acronym for biologically enhanced particle therapy, to tumors with inherent defects in the ATM-BRCA1-BRCA2 DNA repair pathway. These types of defects are commonly found in cancer, with breast and ovarian cancer mutations in BRCA1 and BRCA2 repair genes being the most common cause.

Mayo Clinic did not respond for comment.

Read full story: dotmed.com/news/54019

Cardinal Health to sell Cordis for approximately $1 billion

Posted online March 17, 2021 by John R. Fischer

Cardinal Health is selling its Cordis business, a maker of cardiovascular technology, to global private equity firm Hellman & Friedman for approximately $1 billion.

Cordis designs a number of minimally invasive cardiovascular products, including stents, catheters, sheaths, closure devices and balloons. It expanded its portfolio in 2019 to offer solutions designed to facilitate the transradial approach (TRA) for interventional cardiology procedures.

"Our decision to divest Cordis demonstrates our disciplined approach to evaluating our portfolio and focusing our resources in our strategic growth areas where we are an advantaged owner. Looking forward, we remain committed to our medical distribution and global medical products businesses," said Mike Kaufmann, CEO of Cardinal Health, in a statement.

The company estimates the divestiture of the Cordis business will decrease Cardinal Health's medical segment profit by approximately $60 million to $70 million on an annual run-rate basis, upon completion of the sale. Most assets and liabilities associated with the Cordis business will transfer to H&F, with Cardinal Health retaining full authority for lawsuits and liability related to inferior vena cava filters in the U.S. and Canada.

Cardinal Health's entry into a definitive agreement requires that it classify the Cordis business as held for sale, resulting in an expected pre-tax loss of up to $120 million in the third quarter of its fiscal year 2021. In addition, Cardinal Health was authorized to incur costs associated with the planned divestiture of up to $125 million, primarily for its fiscal years 2021 and 2022.

"We at Ajax Health and Zeus Health are ecstatic about injecting growth into Cordis' powerful platform, and will do so through investments in the core business and through an independent R&D engine — the 'Cordis Accelerator' — to develop and commercialize a new pipeline of products exclusively for Cordis," said Duke Rohlen, CEO of Ajax Health and Zeus Health, partners to H&F in the transaction, and executive chairman-designate of Cordis. He will also serve as CEO of Cordis Accelerator.

Read full story: dotmed.com/news/54255

Walmart may be scaling back healthcare operation plans

Posted online March 02, 2021 by John R. Fischer

Walmart, which announced in September its intention to open up more clinics, may now be downsizing that number along with plans to expand into imaging and other healthcare services.

Initially planning to build 125 clinics this year as part of its goal to open 4,000 by 2029 at a cost of $11 billion, the retail giant now plans to open only 22 this year, according to Insider.

"There is less commitment to the strategy," one Walmart employee close to the healthcare operation, told Insider on the condition of anonymity. "What you have today is an organization that's playing the waiting game — waiting for a core strategic choice to be made."

The slowdown was chalked up to leadership changes, competing business priorities during the COVID-19 pandemic and the complexity involved with building up a large healthcare operation. While two current employees said Walmart did not plan to build a set number of clinics this year, several say that healthcare is still a priority for the company.

Read full story: dotmed.com/news/54109

New X-ray scanner 2.5x better at detecting cancer in breast-conserving surgery: study

Posted online February 22, 2021 by Robin Lasky

A new scanner that combines the benefits of X-ray phase contrast imaging (XPCI) with the 3D image mapping capabilities of a CT scan may significantly reduce the incidence of reoperations among breast cancer patients.

Researchers at University College London (UCL) published the results of a study on the effectiveness of their breadboard XPCI-CT imaging system on breast-conserving surgeries, which showed 2.5 times superior detection of cancer in the soft tissue margins versus traditional imaging.

"I am terribly excited about these results, as they are likely to lead to the first clinical use of XPCI," said lead author of the study, professor Alessandro Olivo, in a statement. "The technology has tremendous potential, and I am sure once people see what it can do many other clinical areas will follow suit."

Unlike conventional X-ray, XPCI measures changes to the speed the X-rays travel as they encounter different types of tissue allowing for greater detection of faint soft tissue differences that may indicate cancer. Combining this advantage with the rapidly rendered 3D mapping may allow surgeons to target significantly more cancerous tissue intraoperatively, thereby reducing the rate of reoperations.

Read full story: dotmed.com/news/54034

Lack of reimbursement limits availability of mobile stroke units

Posted online March 15, 2021 by John R. Fischer

Limited reimbursement makes operating mobile stroke units financially challenging and has made them widely unavailable.

That's according to preliminary research to be presented this month at the American Stroke Association's International Stroke Conference 2021. The main issue, says lead author Kenneth Reichenbach, is that there is no established means for the government or private insurers to reimburse the cost of mobile stroke unit care, especially for CT scans and medication administered outside hospital.

"We need overwhelming, united support for this to change within federal entities, including the Centers for Medicare and Medicaid Services, to explore appropriate pathways for Medicare reimbursement for the full range of advanced mobile stroke unit services," Reichenbach, program director of the Mobile Stroke Unit at Lehigh Valley Health Network in Pennsylvania, said in a statement.

All 20 U.S. mobile stroke programs are partially funded through personal gifts, grants or institutional support. A blind survey by Reichenbach and his colleagues from June 2019 found that out of 19 mobile units, 18 had a negative financial status based on the last 12 months of their operation. The sole one with a positive status classified itself as an outpatient clinic rather than an ambulance. The 20th did not respond.

The programs together administered clot-busting medications to stroke patients 72 times a year on average, and each was open nearly every day of the month. This led to 600 responses per year, on average, among all of them. All are equipped to perform CT scans and had an average of four staff members: a CT technologist, paramedic/emergency medical technician, stroke nurse, and either a doctor or advanced practice healthcare professional as a stroke expert. For 47% of programs, telemedicine connected patients remotely to a stroke expert.

The need for support is backed by the American Heart Association's 2019 Recommendations for the Establishment of Stroke Systems of Care, which suggests that reimbursement for mobile stroke units is an issue that warrants further investigation.

Read full story: dotmed.com/news/54240

Philips to incorporate classic Disney characters in Ambient Experience for MR

Posted online March 04, 2021 by John R. Fischer

Children may soon expect to see Mickey Mouse, the Avengers and other animated Disney characters pop up in front of their eyes when undergoing an MR exam at a hospital equipped with Philips Ambient Experience.

Designed to create a relaxed atmosphere, the solution has become the center of an upcoming pilot study that will investigate its ability to reduce anxiety and fear among children during MR scans by offering stories and adventures that incorporate classic Disney animations.

"During the procedure, the child's theme of choice appears throughout the process, meaning Mickey Mouse might appear on the wall near the MR system, casting spells as the Sorcerer's Apprentice from atop a mountain. Or Spiderman might swing into view, in scenes with other Marvel characters. Yoda might float peacefully in the bore as the child is being scanned or Ariel, the Little Mermaid, might swim with characters from Finding Nemo. The child's choice of story — each including an array of beloved characters — guides their experience," Mr. Werner Satter, general manager of Philips Healthcare Experience Solutions, told HCB News.

Read full story: dotmed.com/news/54159

Pyrus to streamline distribution of RP Canon's medical imaging portfolio

Posted online March 04, 2021 by John R. Fischer

RP Canon Medical Systems, a subsidiary of Canon, has appointed Pyrus to oversee the streamlining of digital processes for the distribution of its medical imaging solutions.

Pyrus, a low-code platform, will manage the internal processes of Canon's CT, MR and ultrasound systems, from development stages to distribution, at medical practices in more than 150 countries worldwide. "Fast and proper functioning of these operations is considered essential at this time, as the world continues to combat the COVID-19 pandemic," says Denis Cherednichenko, general director at RP Canon Medical Systems.

"Having one single system to facilitate seamless collaboration across teams in different offices and countries, and with field and remote employees, contractors, and customers will be a game-changer in our fight against COVID," he said.

The first stage of the project will include automation of product configuration, service desk, and contract approvals processes. RP Canon sales will be able to interact with customers on-site through the Pyrus mobile apps; while commercial proposals, contracts, purchase orders and other documents will be generated automatically, in just a few clicks, based on the templates.

Read full story: dotmed.com/news/54138

Caption AI allows inexperienced sonographers to obtain quality images: study

Posted online February 24, 2021 by John R. Fischer

A multicenter study is touting Caption Health's Caption AI platform for its ability to help inexperienced healthcare workers capture quality diagnostic cardiac ultrasound scans.

Caption AI is the first and only AI-guided medical imaging acquisition software to obtain FDA clearance for cardiac ultrasound exams at the point of care, according to the company.

"There is a shortage of professionals with this level of training. That shortage, in turn, limits access to imaging at the point of care. The intent of Caption AI is not to replace skilled sonographers, but to expand the number of healthcare professionals who can perform focused cardiac ultrasound at the point of care to enable timely diagnosis and management," Charles Cadieu, CEO and co-founder of Caption Health, told HCB News.

Caption AI is integrated onto a full-service ultrasound system and utilizes Caption Guidance, which provides real-time guidance on how to position and manipulate the transducer on a patient's body; and Caption Interpretation, which automatically calculates ejection fraction from any combination of parasternal long-axis (PLAX), apical 4-chamber (AP4), and apical 2-chamber (AP2) at the point of care.

The study, titled Utility of a Deep-Learning Algorithm to Guide Novices to Acquire Echocardiograms for Limited Diagnostic Use, was the basis for the February 2020 Authorization of Caption Guidance through the FDA's De Novo pathway, and included 240 patients between 20 and 91, with 42% female; 17.6% black or African American; and 33% with a BMI of 30 or greater. Each underwent an ultrasound performed by a nurse with no prior experience and one from an experienced registered diagnostic cardiac sonographer. Experienced cardiologists assessed their diagnostic quality and made diagnostic assessments.

The platform produced quality diagnostic scans to assess left ventricular size and function in 98.8% of patients, right ventricular size and function in 92.5%, and the presence of pericardial effusion in 98.8%. Results showed at least 92.5% agreement between the nurse and sonographer scans in diagnostic assessment.

The findings were published in JAMA Cardiology.

Read full story: dotmed.com/news/54071

Demand for proton therapy systems half of what it was five years ago: report

Posted online March 15, 2021 by John R. Fischer

Demand for new proton therapy systems is half of what it was in 2015, with the market slowing by 3% each year since 2018, according to MEDraysintell's Proton Therapy World Market Report & Directory, Edition 2021.

The slowdown has been attributed in the past to several factors, including negative publicity and cost barriers to treatment. One of the biggest challenges has been resistance from health authorities and private insurers to reimburse providers for the treatment.

"Proton therapy, like any business in the medical field, is directly affected by reimbursement policies, which differ in each country or region worldwide, Paul-Emmanuel Goethals, co-founder of MEDraysintell, told HCB News. "Generally, countries that have a proton therapy center have a reimbursement policy for proton therapy implemented by their national health insurance system and/or covered by private insurances."

Fewer than 280 particle therapy treatment rooms — most of which are PT-based — were available for patients as of February 2021. There are 0.4 particle therapy treatment rooms per ten million people, compared to a rough equivalent of 20 radiotherapy systems worldwide.

Read full story: dotmed.com/news/54200

Intelerad acquires LUMEDX

Posted online February 22, 2021 by John R. Fischer

Intelerad Medical Systems has acquired LUMEDX, a developer of healthcare analytics and cardiovascular information systems.

The deal enables Intelerad to offer customers greater cardiovascular expertise and analytical skills through its enterprise imaging applications, especially for those tending to heart-related diseases during the COVID-19 pandemic.

"As we work through the integration, Intelerad customers will have access to an expanded suite of connected PACS, CPACS, CVIS and worklist solutions, as well as deeper analytics capabilities, increasing automation and ease-of-use that enables them to drive clinical efficiency and focus on providing improved patient care. This acquisition will, over time, provide for deeper analytics expertise that can be leveraged for other specialties as well," Mike Lipps, CEO of Intelerad, told HCB News.

Among the solutions LUMEDX brings to Intelerad are HealthView Analytics, which provides performance insights embedded into the EHR; CardioPACS, a fully integrated cardiovascular PACS solution; and HealthView ECG Manager, a cloud-based ECG management system that can oversee different data types from different vendors in more than 10 modalities and capture, store and annotate patient monitoring strips.

Read full story: dotmed.com/news/54032

Cutting edge imaging technology provides new insights into schizophrenia

Posted online March 01, 2021 by Robin Lasky

Use of synchrotron radiation nanotomography has allowed researchers to produce uncorrupted 3D images of neurons and blood vessels for the purposes of studying schizophrenia's effect on brain tissue.

Schizophrenia is a chronic mental disorder which can cause a range of debilitating cognitive and psychiatric symptoms, such as paranoid delusions, depression, disordered thinking, and auditory and visual hallucinations. Despite it long being the subject of medical research, which has produced various psychiatric treatment options, Schizophrenia continues to frustrate scientific discovery into precise underlying causes. However, various genetic, environmental, and other physical factors have been identified as correlating with an increased likelihood of developing the disorder.

A new study from the University of Tokai, in Japan, in conjunction with other institutions, published in Translational Psychiatry on January 13th, seeks to shed more light on the physical differences of brain tissue in people afflicted with this disorder, in the hopes of eventually contributing to a better understanding of its causes and impact on the brain.

"The current treatment for schizophrenia is based on many hypotheses we don't know how to confirm," Ryuto Mizutani, professor at Tokai University, said in a statement. "The first step is to analyze the brain and see how it is constituted differently."

For the study, four brains of deceased patients with schizophrenia were obtained, along with four healthy brains to serve as the control group. Researchers focused on an area of the brain associated with having a role in processing spoken language and other auditory stimuli.

Through the use of an advanced 3D imaging technique, they were able to discern marked differences between the structure of the neurons in the brains of patients with schizophrenia compared with the control samples that may indicate association with the disorder.

Over the years, researchers have used various brain imaging systems to contrast the differences between healthy brains and the brains of patients with schizophrenia in order to better understand its effects on the brain.

Read full story: dotmed.com/news/54102

SpinTech acquires MR Innovations

Posted online February 25, 2021 by John R. Fischer

MR software developer SpinTech has acquired Magnetic Resonance Innovations, a medical imaging research and technology manufacturer.

The deal adds a group of Ph.D. and master's-level engineers and physicians, as well as 10 of MR Innovations' patents, to SpinTech, which will rebrand its current business name from SpinTech Imaging to SpinTech MRI.

"With the integration of MR Innovations into our team, SpinTech has a full, end-to-end technology development platform. This means that researchers and engineers on the front end of the process can listen and understand end-users' specific challenges before developing practical tools to meet those needs," SpinTech CEO Ward Detwiler told HCB News.

In addition to its expertise, MR Innovations brings more than 300 published papers and a network of over 50 global collaborators. It also provides protocol development for medical imaging scans, image processing services, clinical research organization consulting and innovation in imaging hardware and software.

Both companies previously worked together to design technology for solutions such as STAGE, a standardized MR software program designed by SpinTech that enables AI-assisted detection and completes MR acquisitions of the brain 40% faster.

Read full story: dotmed.com/news/54085

Swiss researchers 3D-print high-res X-ray detectors

Posted online February 23, 2021 by John R. Fischer

Scientists at the School of Basic Sciences in Switzerland's École polytechnique fédérale de Lausanne (EPFL) have 3D-printed cost-effective, high-resolution X-ray detectors that can be integrated into standard microelectronics to improve performance and reduce radiation exposure in medical imaging scanners.

They used aerosol jet-printing, a new 3D-printing technique used to manufacture electronic components. The materials used to make the detectors were graphene and perovskites, which may help to decrease required X-ray doses for forming an image by more than a thousand times, according to Dr. Endre Horváth, scientific assistant of InSTI-HEPIA and guest scientist at LQM-EPFL.

"Lead halide perovskites are soluble in various solvents which is a great advantage for printing based techniques to apply for future industrial production of solar cells, LEDs and various detectors based on this peculiar semiconductor. This family of materials contain heavy elements such as lead and iodine that have a large X-ray scattering cross section, one of the basic requirements to create high-sensitivity X-ray detectors."

The scientists' work was published in ACS Nano.

Read full story: dotmed.com/news/54033

Global MR imaging market expected to rack up $4.5 billion by 2024

Posted online March 02, 2021 by John R. Fischer

The global MR imaging market is poised to take home $4.52 billion in revenue in 2024, according to a Frost & Sullivan report.

Point-of-care, pediatric, dry-magnet and compact MR are among the factors driving this growth, along with fusion imaging and an expected increase in sales of portable MR. Growing public-private partnerships and an increase in near-replacement time in public domains are also expected to increase MR system installations.

"Enhanced image acquisition and reconstruction techniques, and speed of acquisition have led to clinical benefits in interventional imaging, vascular, abdomen, oncology and cardiac," Poornima Srinivasan, industry analyst for medical imaging, healthcare and life sciences at Frost & Sullivan, told HCB News. "Portable or point-of-care MR is a game-changing technology that is expected to influence and make scanning accessible to patients in ER, ICU, and other critical-care units across the location of care."

He adds that the MR segment is expected to continue to shrink with the wider adoption of 1.5T and 3T MR systems that incorporate increased field of view and radiofrequency (RF) channels, and enhanced signal-to-noise ratio for optimized patient throughput. The current MR market earned $3.99 billion revenue-wise in 2019 and is predicted to have a compound annual growth rate of 2.5% by 2024. COVID-19, however, has slowed the market down, and it is likely to not reach pre-COVID levels until 2023.

Growth is slated to be diverse among different regions. For North America, a 3%-4% boost in MR procedural volume over the past three years has been seen in the U.S. and 0.9% growth has been seen in Canada. Western Europe has seen moderate growth in 1.5T and 3T MR for brain, MSK, and oncology imaging, with public hospitals accounting for 70% of traditional imaging procedures, and private and imaging centers performing 80% of emerging applications.

"In terms of adoption, countries with low MR penetration will continue to evolve toward expanding their MR with 1.5T and replacement with high-field MR systems in developed economies," said Srinivasan.

Read full story: dotmed.com/news/54072

FDA gives nod to Akesis Galaxy RTi radiosurgery system

Posted online March 12, 2021 by John R. Fischer

The FDA has given Akesis the green light to move forward with the sale of its Akesis Galaxy RTi, an advanced gamma stereotactic radiosurgery system.

The scanner is equipped with continuous 360 degree rotational technology and real-time, in-line CBCT + kV/kV imaging that helps it perform automated intrafractional skull tracking and corrections.

"For the first time, the patient can be imaged and treated without time-consuming patient movements between imaging and treatment positions. This dramatically enhances the speed and accuracy of the whole procedure," Tim Prosser, director of Global product management at Akesis, told HCB News.

Akesis Galaxy RTi is set up on a rigid ring gantry at the treatment place that eliminates the need to move patients or stop treatment to image them. This, and the fact that the treatment and imaging beams are designed to coincide with one another, reduces time spent on the table by the patient.

Akesis Galaxy RTi is expected to be attractive among institutions with high-throughput workflows, small cancer centers and value-based reimbursement models.

Read full story: dotmed.com/news/54228

Michigan woman who contracted COVID-19 from lung transplant dies

Posted online February 26, 2021 by John R. Fischer

A woman in Michigan died after contracting COVID-19 from a double-lung transplant she received from a donor who showed no signs or symptoms of the virus.

Officials at the University of Michigan Medical School say it may be the first proven transmission of COVID-19 via an organ transplant in the U.S. "We would absolutely not have used the lungs if we'd had a positive COVID test," said Dr. Daniel Kaul, director of Michigan Medicine's transplant infectious disease service, who co-authored a report about the case, in a statement.

The transplant took place in fall 2020 at University Hospital in Ann Arbor, where a woman with chronic obstructive lung disease received the lungs of a Midwestern woman who died from severe brain injury in a car accident. Samples from the donor's nose and throat prior to the procedure came back negative for SARS-CoV-2.

The recipient experienced a fever, a drop in blood pressure and labored breathing three days later, and eventually developed septic shock and heart function problems.

The report on the case was published in the *American Journal of Transplantation.*

Read full story: dotmed.com/news/54064

Upcoming Events

Due to ongoing coronavirus outbreak, all events may be subject to change or cancellation

Society for Imaging Informatics in Medicine 2021 Annual Meeting

Location: VIRTUAL
Dates: May 24-27
Years in Existence: 41
Average attendance: 1000+
Who should attend: Physicians, all Imaging Specialties such as Dermatology, Pathology, Cardiology, Radiology, Surgery, ER, Imaging Informatics Professionals, Researchers & Scientists, Vendors

The AAMI Exchange

Location: Charlotte, NC
Dates: June 4-7
Average attendance: 2,300+ (at live events)
Who should attend: HTM Professionals, biomedical and clinical engineers, technicians, cyber security and sterilization experts, hospital admins and managers, industry service and solution providers

The Society of Nuclear Medicine and Molecular Imaging Virtual Annual Meeting

Location: VIRTUAL
Dates: June 11-15
Average attendance: 5,400 +
Who should attend: Imaging & nuclear medicine physicians, radiologists, cardiologists, pharmacists, scientists, lab professionals and technologists.

The Association for Medical Imaging Management 49th Annual Meeting and Exposition

Location: Nashville, TN
Dates: August 1-4
Years in Existence: 49
Average attendance: 1,000
Who should attend: Medical imaging leaders

The Florida International Medical Expo, by Informa Markets

Dates: August 1- October 1 (Online), September 1-3 (live)
Location: Miami Beach Convention Center, FL
Years in Existence: 31
Average attendance: 17,000
Who should attend: Medical device and equipment distributors and manufacturers

Q&A with Dr. Kernesha Weatherly

Interim co-senior director of Radiology
University of Alabama at Birmingham (UAB)

By John W. Mitchell

Kernesha Weatherly's journey to leadership has its roots, in part, in not being heard as a frontline radiology technologist. That frustration, along with a love for learning, launched her journey to earn her master's degree in hospital administration/operations and just recently, a Ph.D. in healthcare quality and analytics. She advocates that leaders need self-awareness about themselves and tolerance for different styles, in order to thrive in the diverse space of imaging leadership.

HCB News: Please tell us about your leadership journey.

Kernesha Weatherly: I started as a volunteer in our organization, which led to my going to UAB as an undergraduate student and attending their radiology school. I wanted to be on the front line, taking care of patients. My co-workers and I would have questions about the work process, and I decided early on I wanted to be part of the change, which meant being a leader — you can't just sit around and complain. Thankfully, leadership wasn't foreign to me — I had been in charge when I worked in the retail sector. Eventually, I wanted to do more. I went from working as a technologist to being the clinical educator for the department. After only eight months, I was offered a management position to help evolve an imaging department. My director at the time said, "Hey, I want you to go into mammography and make changes." And together, with the physician support, we transformed the mammography into an inclusive breast imaging department. After two years, I got the opportunity to be the director of inpatient imaging services and breast imaging. Throughout that experience, I went on and got my master's and just recently my Ph.D. A lot of what I have learned in those programs has helped me throughout my career. Our senior director recently transitioned to another department, and my colleague and I were granted the position of interim department co-leaders. My trajectory in the past ten years had been amazing and I feel fortunate to be able to enact change a little more in each position that I've been in. I think I offer a lot as I've moved into leadership positions with hands-on, frontline experience. I can impact change at a whole different level.

> I can't stress enough how vital self-awareness is when you're responsible for other people.

HCB News: What are some of the most important skills a leader should model, and is there anything unique to medical imaging?

KW: For any leader, integrity and self-awareness are essential. I can't stress enough how vital self-awareness is when you're responsible for other people. When a person doesn't know who they are and who they can be, they go from being an asset to a liability for a department and ultimately, an organization. Self-awareness allows you to identify your weaknesses to make them strengths. Everything we do is based on a delicate balance between perception versus intent — how your peers, colleagues, and superiors perceive you. If you're not self-aware, it's a form of tone-deafness and lack of emotional intelligence that can negatively impact change and impede your department's productivity. Which is why I say a leader can make or break your division. For example, when I started working, I would see some of the things other leaders were doing and how it would negatively impact their surroundings. Leaders need to be authentic and present, and that requires self-awareness about weaknesses. I realize leaders are busier now, more than ever, however, something as simple as listening to their staff's needs can easily be tied to the department's productivity.

HCB News: Conversely, how does poor leadership manifest itself in the imaging department?

KW: Imaging services all the other areas — ortho, cardiology, neurology, etc. — and if, for example, a CT scanner goes down, you're not just impacting imaging, you're affecting the whole hospital's operations. People who feel heard and informed will rise to the day-to-day challenges as a well-

oiled machine. Poor leadership can affect the overall morale and manifest in high turnover. Employee empowerment is vital. I have more than 10 people directly reporting to me, and I have to respect their differences, as we have to create a culture where they can work together for a common goal. Transparency and being honest is an essential part of good leadership — and that starts with self-awareness.

HCB News: Tell me about the different managerial types and what self-management means?

KW: Self-management starts by establishing baseline metrics for each department. I'm not an overbearing or micromanaging leader, but I do ask my direct reports to own whatever they decide. I require all my new leaders to go through an onboarding series through the UAB leadership development team. I also created my own imaging training plan so every leader — no matter their leadership style — learns base-level expectations and standards. I have no desire to change any of my managers from their authentic self. My goal is to help them be effective and implement necessary change, while navigating fluid situations. This cannot be done without self-management.

HCB News: Are there certain hallmarks/metrics of a department with excellent leadership?

KW: I would say the most important metric is to actually have access to palpable metrics. For example, if someone asks what is your next available MRI appointment, can you tell them? Do you know the employee turnover percentage for every department? What are your trends or highest use? What are your areas of opportunity and how long has this been a trend? Often, people don't know their story, to adequately make a case based on the data. They go off emotions, and you can't make cases to senior leadership or present emotions in a PowerPoint presentation.

HCB News: For leaders who recognize the need for change in their department, what first steps can they take to improve?

KW: It goes back to introspection, with which most people are not comfortable. Leaders have to ask themselves what they are not doing well. I suggest anonymous 360 reviews. But you have to be able to receive it, and that can be uncomfortable. I personally do this often for myself as I like feedback on how my actions may be affecting others. However, when you do this, you're stepping out there and allowing people to unload on you. And once received, pick a couple of things and be honest and transparent with yourself on the validity of their claims. Although you may not agree, can you see what they're saying? This process can also apply to evaluating operations within a department, and is one of the reasons I rely on quarterly Stoplight Reports for all managers. I tell my managers to connect with the person in their department who is the most vocal and let them vent. Let them know you might not make every change they think is needed, but the act of just listening to them can and does go a long way.

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Selecting an effective risk management solution

By Lauren Dubinsky

It's important for clinical engineers and biomedical teams to assess their medical device security program and select a risk management solution for their connected devices. But what's the best way to go about that?

An integrated delivery network, software solution provider, and service provider discussed this topic during the AAMI Summer Learning Series. **Cory Brennan**, attorney and security adviser at Hall Render Advisory Services, started things off by describing an ideal risk management program.

A risk management program should provide: An active, up-to-date inventory of all connected devices and a vast amount of attributes for each of those devices, including their specific risk profiles; vulnerability and risk prioritization, which includes identifying all active vulnerabilities affecting a connect device and analyzing how those vulnerabilities could be exploited and what the impact of that is; the means to contain and segment a device on the network to isolate it from other devices if its risk profile requires it; consistent anomaly and event detection, as well as continuous intrusion monitoring; communication to the health system to notify the right team when anomalous behavior has been discovered on the network or from a medical device, analyze the risk factors of that anomalous behavior, and provide risk mitigation options right off the bat; assistance with recovery measures after responding to an event or an incident, as well as identifying areas of opportunity for improvement in response time and communication protocols.

"After a program assessment has been completed and the results have been reviewed including any gaps identified, the health system should begin to remediate those gaps and to incorporate security best practices into their overall medical device management program," said Brennan.

You can then use that program assessment to assemble a team and develop a set of use case criteria to evaluate and select a risk management solution. This involved assembling a team of diverse experts, reviewing proposals from a variety of vendors, doing demonstrations, performing a final evaluation internally and then awarding a contract.

"One of the things I recommend is to discuss a detailed implementation plan or project plan with the vendor before you sign a contract because that is where you have the most opportunity to leverage what you want out of that partnership," said **Priyanka Upendra**, quality and compliance director at Banner Health.

That plan should include where you want to install the solution, the deployment model and the cost. When it's time for implementation, Upendra recommends a multiphase approach, because it allows for the continuous evaluation of important success factors.

She stated that an effective solution identifies the different medical devices, builds a risk profile around them, consolidates all that data to provide meaningful information, detects anomalies and unauthorized behavior happening on your network, communicates risk recommendations to the stakeholders and enforces policies in your risk mitigation plan.

"From a health system side, one of the suggestions I provide is that you want to plan your processes before you implement a solution, otherwise you're going to end up with a multimillion dollar, fancy solution that's giving you huge amounts of data sets, but you don't know how to use it," said Upendra.

She also recommends implementing different solutions at pilot sites and assessing the data to determine which solution meets your program and organization's long-term goals. That will help you determine whether what the vendor is showing in the scripted demonstration is what is truly going to happen.

Shankar Somasundaram, CEO and founder of Asimily, concluded the session by outlining how data from the risk management solution can be used to improve the security posture of the health system.

> Discuss a detailed implementation plan with the vendor before you sign a contract.

"What people forget is that medical devices risk management is really about vulnerability management," he explained. "The challenge with medical devices is that not all devices have the same risk."

Even across devices with the same legacy operating system, the risks may be different. Whether an unpatched vulnerability affects a device depends on the exploitability of the vulnerability for the device in that environment, the impact of the vulnerability, how the device is connected, the device's security capabilities and any other mitigating security controls.

Health systems can use the risk management solution to dig deep into the root cause of an anomaly. Once an anomaly is detected, they can set rules to take corrective action as well as preset certain rules to determine the root cause and take preventive action.

These solutions can also be used to understand the priority for different vulnerabilities, patch the device to ensure it has the latest solution version and/or operating system, and implement workarounds such as network-level authentication.

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Data and evidence anchor healthcare's financial renaissance

By Dr. John Cherf

Even as brighter days appear to lie ahead for healthcare providers, COVID-19 continues to strain our healthcare system. The American Hospital Association estimates $323.1 billion in financial losses for U.S. hospitals and healthcare systems in 2020. These losses, coupled with increasing supply and labor costs, are cause for concern to hospital leaders responsible for their organization's financial viability. It is important that healthcare providers prepare for the post-COVID-19 era now.

The challenge that faces healthcare providers is not simply navigating the pandemic's ongoing financial impact, but simultaneously forging a path to recovery. In response, many hospital leaders have accelerated cost reduction initiatives to meet financial targets. Prior to the pandemic, a study published in JAMA found the cost of waste in the U.S. healthcare system ranged from $760 billion to $935 billion annually, accounting for 25% of total healthcare spending annually.

Controlling product variation represents one of the greatest financial opportunities in the months and years ahead, yet few hospitals have a thorough understanding of where that variation lies. Thriving in a post-COVID environment will be contingent on how well an organization uses data and evidence to fully understand cost-per-case, cost-per-discharge, and patient encounters. This insight will enable healthcare providers to establish process improvements that will optimize savings while maintaining the highest level of patient care.

Data to draw upon

Thankfully, we have an abundance of data in healthcare, from product and price to use, performance and outcomes. Better yet, we can put that data and clinical evidence to use to tackle a sensitive and personal cost issue: physician preference items (PPI). Today, up to 60% of a hospital's total supply spending comes from PPI. In healthcare, we have learned that variation is often unwarranted, drives up costs and can even affect the quality of care we deliver. Most other industries have effectively managed variation or standardization for decades. It's time for similar advances in healthcare.

The aim to rein in this spend isn't uniformity; it's standardization. While patient care remains paramount, physicians are beginning to understand the financial pressures facing hospitals, which have only been exacerbated by COVID-19. Data and evidence can facilitate the right conversations between supply chain, financial and clinical teams to reduce variation and standardize products without sacrificing quality of care, the imperative for physicians.

For example, during the peak of COVID-19 lockdown, a large health system in the mid-Atlantic region used the "downtime" to achieve reduction goals that would help offset the pandemic's financial impact. The supply chain team initiated vendor reduction strategies as a cost saving method. They first targeted high-spend orthopedic categories, including hip, knee and shoulder replacements. The team shared real-time data that drilled down into device utilization, cost-per-case variation and outcomes. Access to this information helped engage surgeons in the product and vendor decision-making process. Together, the teams selected a single vendor for joint replacement implants. The standardization then opened the door for additional contract negotiation with the vendor, resulting in significant price cuts due to volume. The collaboration resulted in more than $12 million in annual savings. The supply chain and clinical teams then used the same approach for breast reconstruction surgery. Data and clinical evidence along with surgeon insight allowed them to identify a single source for two categories (mesh and implants). By reducing the number of vendors from four to one for these categories, the team was able to cut the organization's annual spend for these items in half — a net saving of $3 million. Furthermore, there is no high-level research evidence suggesting these sourcing changes will have any impact on clinical outcomes.

Evidence and data can also help us identify situations in which a technology or device no longer has meaningful impact. Not long ago, use of Continuous Passive Motion (CPM) machines following lower extremity surgery was a mainstay of postoperative care. Clinical literature has since proved CPM machines don't have a meaningful impact on successful rehabilitation or postoperative function. The same is true regarding the use of antibiotic loaded cement to prevent against postoperative infection in reconstructive joint surgery. Clinical evidence now indicates antibiotic cement should only be used in cases that produce higher risk of infection or on patients who present a high risk of infection, not all joint replacement patients.

Healthcare's road to financial recovery will be a group effort and the first place to start is around reducing wasteful spending to help us recover millions of dollars. Hospitals and health systems can draw insights from the marriage of supply chain, financial and clinical data teams to source supplies that demonstrably deliver the best quality care at the lowest cost. Forward thinking physicians will welcome these conversations and become active participants when provided accurate data and reliable clinical evidence.

About the author: Dr. John Cherf is the chief medical officer at Lumere.

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Trends in cardiac angiography and ultrasound

By Krys Lee and Camille Allred

Cardiac angiography continues to be a robust clinical area that has seen significant improvements in intravascular imaging and artificially intelligent software solutions for image-guided systems. Minimally invasive procedures continue to attract high levels of interest and technological advancement as the COVID-19 pandemic continues, driven by the urgent need to decrease length of hospital stays for non-COVID patients across the U.S. Minimally invasive valvular procedures, endovascular repairs, PFO closures, and Left Atrial Appendages are all candidates for minimally invasive procedures. These procedures can be done with limited hospital stays or, in some cases, on an outpatient basis through the use of angiography labs.

The use of valvular imaging software is available on many systems and allows for a reduction in both contrast and radiation dose per procedure. This advancement in safety for both staff and patients while maintaining a high level of accuracy is the biggest improvement in this area. TAVR continues to gain popularity among both patients and doctors. In 2019, TAVR was approved for low-risk aortic stenosis patients as well as the previously approved high-risk patients. TAVR procedures minimize the recovery time for patients when compared to SAVR and can contribute to shorter hospital stays when there are no complications with the initial procedure.

Although COVID-19 caused a sharp decline in new equipment purchases for interventional labs, we saw a comparable increase in service agreement renewals for the same equipment. Budgets nationwide are tight, with the regional restriction of elective procedures and COVID-19 numbers across the country still high. It seems most hospitals are holding off on replacing angiography equipment if it is still functional, opting instead to extend existing service contracts, even on equipment reaching end of service. This trend is likely to continue until concrete data on the end of the pandemic and future reimbursement rates are settled.

Interventional cardiology continues to be a robust clinical area. We can expect to see purchasing return to the levels we saw pre-pandemic once hospitals recover financially from the impact of COVID-19.

Cardiac ultrasound

With its high rate of cardiovascular disease and the impact of COVID-19, North America remains the largest market for cardiac ultrasound. Cardiovascular ultrasound uses 2D, 3D, 4D, color, and pulsed wave doppler to acquire diagnostic images of the heart, vascular system, and, in some instances, the lungs for prognosis, tracking, and treatment of patients.

The advantages of echocardiography versus invasive cardiac diagnostic procedures, coupled with the rising incidences of cardiovascular disease, are driving market growth. At the same time, innovations and technological advancements and a surge in preventive medicine have boosted market growth even more. Vendors have introduced new performance models that offer streamlined ergonomics and software that combine the strength of their premium models with some of the mobility features of compact, portable systems. COVID-19 has led to increased use of point-of-care ultrasound (POCUS) in the screening, monitoring, and treatment of patients, with attention focused on the lung and heart.

The increased demand saw providers who were not trained ultrasound technologists performing exams. In response, vendors created tutorials, authored whitepapers, and equipped systems with COVID-19 protocols to improve diagnostic exam accuracy and patient outcomes. Ultrasound guidance in transesophageal (TEE), interventional, and vascular procedures has led to an increase in software updates being offered by vendors for current systems, with discounting seen ranging from 60% to 100% for software upgrade purchases.

Unfortunately, there have been FDA recalls on some TEE transducers, specialized transducers, and cardiac model systems' pulse doppler features. This has not diminished or derailed innovation and advances in technology. Some vendors introduced new cardiac system models, and others introduced updated and new software and components, including more sensitive transducers. Transducers with varying ranges of field of view, higher frequencies with less loss of spatial resolution, and more depth penetration have been seen.

Heart wall motion tracking, or strain imaging, is also a growing trend. It is one of the primary ways to track heart wall damage to preserve cardiac function, prevent heart failure, and tailor efficacy of treatment. Strain imaging expert Marielle Scherrer-Crosbie, M.D., Ph.D., director of echocardiography at the Hospital of the University of Pennsylvania, and chair of the 2019 ASE sessions said, "Strain is a very hot topic. It is an index of myocardial function. It seems in many pathologies strain decreases earlier than the ejection fraction, and there is a better prognostic valve of the strain than the ejection fraction."

About the authors: Krys Lee (pictured left) and Camille Allred are clinical advisors at TractManager, now a part of symplr.

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Is data a liability or asset for supply chain departments?

By Lauren Dubinsky

Dr. Randy Bradley, associate professor of information systems and supply chain management at the University of Tennessee, believes that data is the "invisible chink in supply chain's armor." In a virtual session at last year's virtual AHRMM annual meeting, he said that the way to repair that armor is through understanding the most common types of data and implementing a data strategy.

The most recent challenge to affect the healthcare supply chain field is the COVID-19 pandemic. It exposed the fragility of the supply chain and highlighted the need for greater transparency and visibility.

"We do need better visibility, but I need us to understand that transparency and visibility are not the same thing," said Bradley. "When we talk about them, I like to view them from an inside-out and from an outside-in perspective."

He explained that transparency refers to an organization's willingness to share information, whether it's about their operations transactions. Visibility is the degree to which you can see upstream in the supply chain and downstream to the point of consumption.

But visibility hinges on a trading partner's ability and willingness to be transparent. According to Bradley, you could have a good trading partner that's willing to share information, but they may not have the technological infrastructure in place to do so.

He suggested taking a step back and looking at the supply chain's traceability and integrity, but cautioned that they are only means to an end.

"What we should be striving for and what we should endeavor to build is a sustainable supply chain," said Bradley. "I'm talking about a supply chain that to some degree is pandemic and natural disaster resilient [as well as] agile, adaptive, responsive, forward-looking, such that you are able to responded to prompts and triggers as they happen rather than sometime after they happen."

The foundation for building a sustainable supply chain is risk management and risk mitigation. Visibility, integrity, transparency and traceability are the pillars that will support the supply chain into the future.

Although data is often perceived as an asset, it can actually be a liability due to the tremendous cost associated with cleaning, integrating and leveraging it. Bradley stated that the industry needs to change its perspective in order to treat it like an asset.

The first step is digital connectivity, which involves extracting data from systems and integrating it seamlessly across the healthcare organization. Once that is achieved, organizations can then look into implementing artificial intelligence tools to analyze that data.

However, a common hurdle that Bradley encounters is the lack of a data strategy. He stated that less than 10 percent of organizations have what he calls an "articulated data strategy."

"I think part of that has to do with the fact that they thought they did [have a data strategy]," he added. "They may have had a big data strategy, a digital strategy or an analytic strategy, but those things, though they are strategic in nature, are not the same."

A true data strategy involves "an integrated set of guiding principles that foster a set of behaviors and guide decisions that allow an organization to better govern and manage data assets throughout their full life cycle", said Bradley.

"When we look at it from this vantage point, it becomes abundantly clear that the vast majority of organizations don't have it because they haven't really thought about it," said Bradley.

He stressed that organizations need to think about the data they already have and the data they might need to acquire in the future.

He referred to one source of data as "breadcrumbs" because it is fragments of data within an organization, that in isolation, have little to no meaning. However, this data can yield insights when those "crumbs" are stitched together with AI tools.

There is also derivative data, which involves taking one data element and extracting additional value from it. And lastly, there is proprietary data or data that only the organization has or has access to.

Other organizations don't know that those data elements exist or that there are sources of that type of data. That allows the organization to gain an advantage and is an example of how data can move from being a liability to an asset.

"[This journey is] part innovation, but it's also part continuous improvement and checking to make sure we have everything we need before we go on this journey," concluded Bradley. "Do we have the right human talent? Do we have the right technical infrastructure? Do we have the appropriate strategy? And most importantly, do we have the right stakeholders on the team to get us there?"

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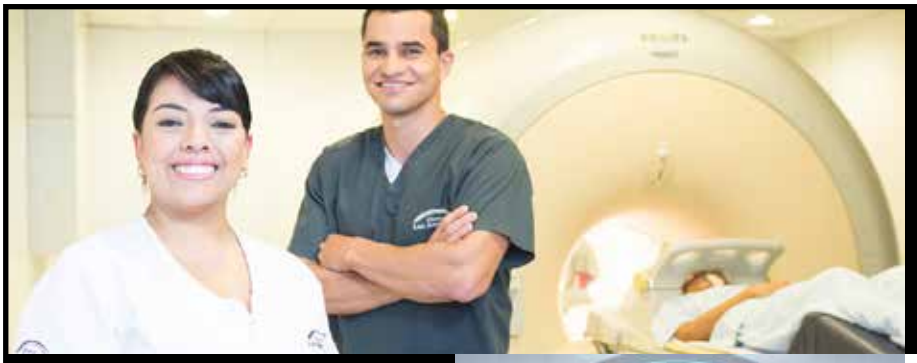

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Imaging heart disease in the era of COVID-19

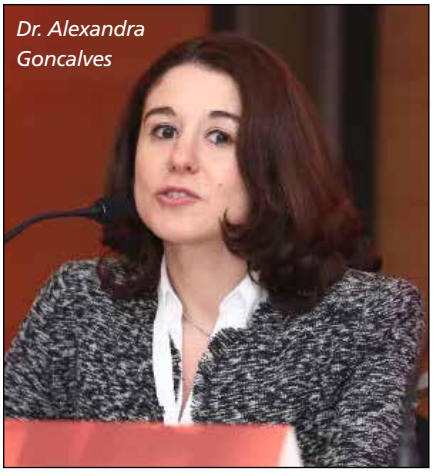
By Lauren Dubinsky


Dagfinn Saetre


Hila Goldman-Aslan


Michael McElroy


Elizabeth Oakes


Dr. Alexandra Goncalves

A growing body of research is revealing that the connection between COVID-19 and heart problems is significant.

"As the pandemic progressed, so has understanding of the impact the virus can have on a patient's heart," **Dagfinn Saetre**, general manager of cardiovascular ultrasound at GE Healthcare told HCB News. "Doctors and researchers have observed a particular connection between COVID-19 and strain on the heart's right ventricle."

A study conducted last year by Mount Sinai Heart found that hospitalized COVID-19 patients with right ventricular dilation might be at a higher risk of poor outcomes and even death. Another recent study published in *JAMA Cardiology* found that heart problems were the cause of death among 50% of the 416 COVID-19 patients in Wuhan, China.

In response, the American Society of Echocardiography (ASE) and the European Association of Cardiovascular Imaging (EACVI) recommended that clinicians perform limited echo exams on COVID-19 patients at the point-of-care to monitor their left and right ventricles for cardiac dysfunction.

Saetre reported that clinicians have been relying on GE's Vivid ultrasound systems to assess the left and right ventricle throughout the pandemic. In October, the company received FDA approval for its Vivid Ultra Edition system, which features AI-driven algorithms for 2D and doppler echo imaging.

DiA Imaging Analysis has also seen an increase in the use of its products, especially its cardiac artificial intelligence (AI) tools. This uptick is the result of point-of-care settings triaging and monitoring COVID-19 patients' hearts.

The downside of point-of-care ultrasound

Point-of-care ultrasound (POCUS) is number two on ECRI Institute's 2020 list of Top 10 Health Technology Hazards. That's because these systems are not being used appropriately, leading to misdiagnoses, and there is an overreliance on this modality when a more comprehensive exam by an imaging specialist is needed.

Additionally, there is a lack of universal guidelines or recommendations for POCUS and training for this modality is inconsistent. ECRI recommends that healthcare facilities create a multi-disciplinary POCUS committee to oversee the standardization of this technology within the facility.

DiA launched two FDA-approved and CE-marked AI solutions in 2020 that help make cardiac ultrasound exams easier to perform. The new LVivo RV assesses the size and function of the right ventricle (RV) to check for cardiac dysfunction such as pulmonary embolism and pulmonary hypertension as well as potential heart failure.

"The RV has always been very difficult to evaluate, due to its unique structure and location," said **Hila Goldman-Aslan,** CEO and cofounder of DiA. "Additionally, RV analysis using 2D ultrasound is currently done visually or manually, making the process time-consuming, error-prone and highly dependent on the user's experience."

"DiA's technology is based on advanced pattern recognition, deep learning and machine learning algorithms that automatically imitate the way the human eye detects image borders and identifies motion," said Goldman-Aslan.

Philips Healthcare also has a stake in this market with its newly FDA-cleared 3D Auto RV application that leverages AI-based techniques. This product was the fruit of the company's acquisition of TOMTEC in 2017.

"Until recently, analysis of the right heart was relatively uncommon, but the advent of new, A.I.-based techniques is helping to give greater confidence to sonographers and cardiologists that are seeking to add RV measurements to their analysis in a reproducible and efficient manner," said **Dr. Alexandra Goncalves**, head of the medical office for precision diagnostic at Philips.

The rise of GLS

In January 2019, myocardial strain earned a category 1 reimbursement code in the U.S. The use of strain imaging as a prognostic indicator of left ventricular function is now widely recognized as a clinical best practice.

"The global longitudinal strain (GLS) of all the different strain methodologies that we've had has become the one that people use," said **Michael McElroy**, solutions marketing senior manager at Canon Medical Systems USA. "We finally have a standard of strain."

Strain imaging provides an earlier prediction of cardiac issues before the ejection fraction (EF) changes. By the time the EF changes, that's the indicator of major issues with myocardial function.

Last year, Canon released its Auto EF with GLS tool for its Aplio a-series and i-series ultrasound systems. By hitting one button, this tool automatically provides the clinician with the EF and GLS number.

Finding the right views in each echo exam and EF and GLS is also a cumbersome process. This task typically takes stenographers a couple of minutes to complete, but they can get those numbers in a couple of seconds with this tool.

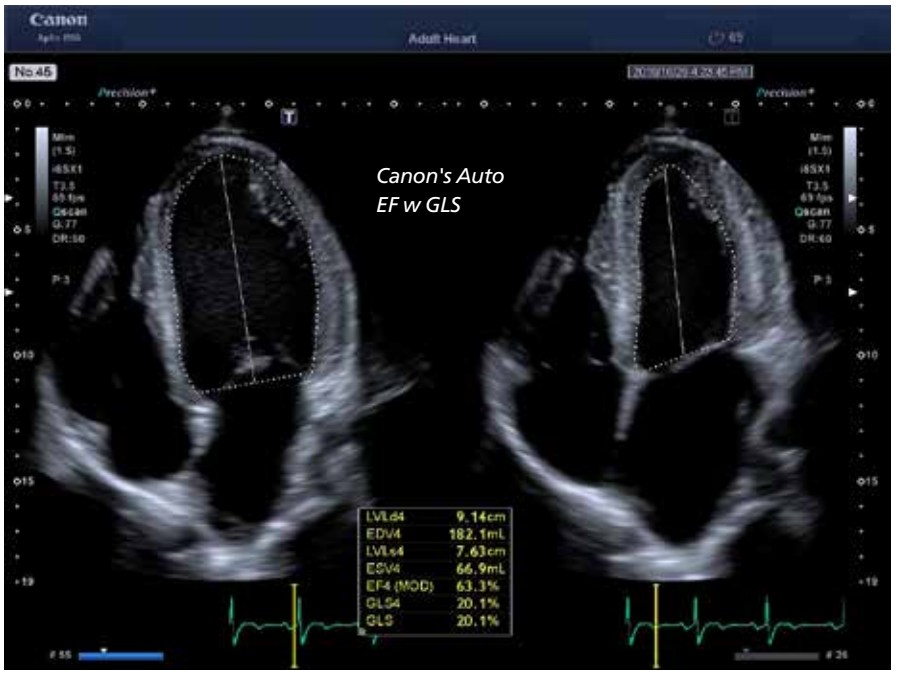
DiA also launched a new tool for this called LVivo Seamless. It automatically obtains optimal views and cardiac measurements for every cardiac ultrasound exam in the echo lab.

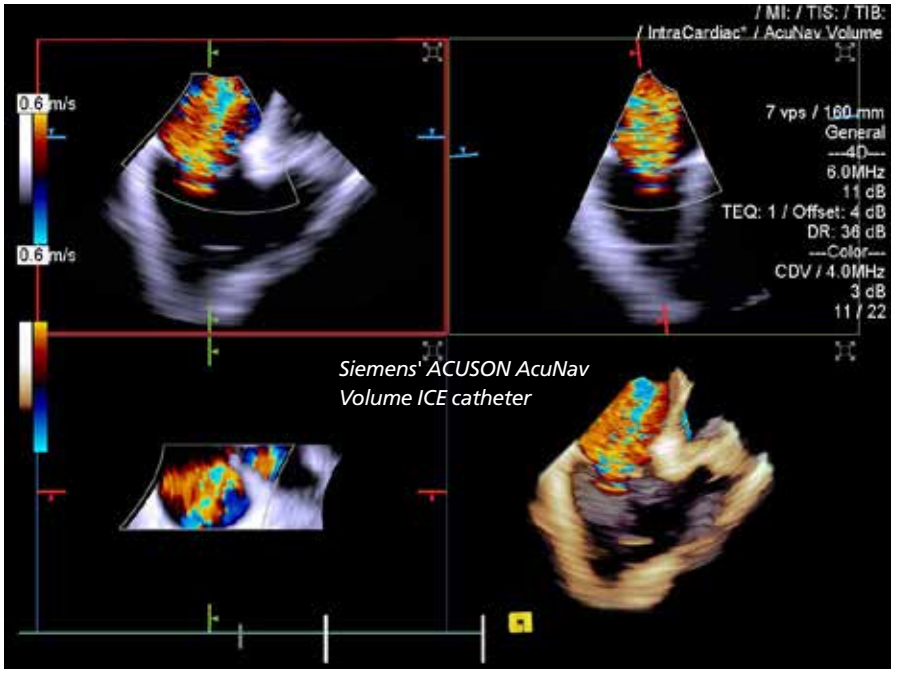
There are usually between 50 and 60 views in a standard echo exam and this tool pre-selects the optimal views for the calculation of EF and GLS.

An area that GLS is showing promise in is chemotherapy. Many chemotherapy agents can damage the heart muscle, so GLS is being used with the highest sensitivity to assess any potential damage.

"The tightrope that the oncologist is walking is whether they can use the agent and not put the patient in unrecoverable heart failure because of the myocardial toxicity of the agent," said McElroy.

GLS strain imaging provides an earlier indication of chemotherapy toxicity before the EF changes. It's thought that once the EF goes down, the damage is permanent, but if the clinician spots the change in strain GLS early on, they can adjust the chemotherapy regimen and preserve the EF and have good oncological and cardiological outcomes.





Despite its benefits, adoption remains slow. According to McElroy, the routine use of strain imaging among cardiologists is within the 20 to 30% range, and its use in doctor's offices is about 10%..

Structural heart disease

The global structural heart devices market is projected to reach $13 billion in 2027, according to a new Transparency Market Research report. New procedures for aortic stenosis and mitral regulation are driving this trend, as well as the rising geriatric population.

"Considering the growing number of structural heart procedures, innovations in this area are game changers," said **Elizabeth Oakes**, senior director, clinical strategy at Siemens Healthineers.

The company recently launched a product that has the potential to greatly improve procedural efficiency in this area. The latest ACUSON SC2000 PRIME 6.0 ultrasound system features 4D Volume Intracardiac Echocardiography (ICE) capability with the ACUSON AcuNav Volume ICE catheter.

This is currently the only commercially available 4D Volume ICE catheter on the market as of February 2021. It provides more real-time information in one view to accurately navigate, guide and measure with multiplanar reconstruction planes (MPRs).

This technology also has the potential to reduce the need for general anesthesia as well as scheduling effort, staffing needs, procedural time, and cost compared to transesophageal echocardiogram (TEE)-guided procedures.

A 2017 study published in JACC: Cardiovascular Interventions found that left atrial appendage closure procedures performed with ICE led to 57 percent time savings per case compared to TEE.

4D Volume ICE allows physicians to offer treatment to patients that would otherwise have no options for structural heart disease procedures. These patients cannot undergo TEE or general anesthesia, or any procedure that requires optimal imaging of the tricuspid valve.

Philips is also making headway in this field with its new automated tools for mitral valve and left atrial appendage measurement, Auto MVA and LAA solution, and its new visualization tools, TrueVue Glass. These tools are for use with the company's EPIQ CVx ultrasound system.

"[Our new tools] provide a unique way of analyzing the heart structure and function with transparency," said Philips' Goncalves.

During interventional echo procedures, the system visualizes the morphology of the left atrial appendage (LAA) and automatically measures the ostium. It also automatically assesses the mitral valve and obtains multiple measurements and functional data.

"2020 was a year of innovation with exciting new features for assessment of structural heart disease and procedure guidance," said Goncalves. "3D techniques have been evolving to provide better visualization, efficient quantification and safe guidance for the challenging structural heart disease procedures."

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The continuing evolution of the cath lab

By John R. Fischer

From valve replacements to coronary low-risk angioplasty, catheterization labs have become the center of many minimally invasive procedures for the heart. Once just the room where heart trouble was diagnosed, cath labs of today see a larger range of patients, with the complexity of their conditions only rising. **Dr. Zagum Bhatti**, a vascular and interventional radiologist at Modern Vascular, which operates a number of these sites in the U.S., told HCB News, that patients prefer when the cath lab is in outpatient settings or ambulatory surgical centers (ASC) versus the hospital.

"You can now undergo a cutting-edge, minimally invasive endovascular procedure in an outpatient lab and be able to go home to recover and be with your family the same day," he said, adding that "more importantly, they are not exposed to other illnesses that are present in a hospital setting."

Le Bonheur Children's Hospital: Cath labs can treat conditions that once required open heart surgery with minimally-invasive operations that allow patients to be discharged the same day (Photo courtesy of Le Bonheur Children's Hospital)

Le Bonheur Children's Hospital: Cath labs today are equipped to both diagnose patients and perform therapeutic procedures such as coronary low-risk angioplasty (Photo courtesy of Le Bonheur Children's Hospital)

Further, the continuing COVID-19 pandemic makes patients even more inclined to seek care outside of the hospital, out of fear of contracting the virus. It is changes like these that are forcing cardiologists and radiologists to question what role the cath lab will play in the future.

Modern Vascular: Cath labs today can perform fluoroscopy but also intravascular imaging, intravascular physiology, integrated CT imaging to guide procedures, and are equipped with newer left ventricular support devices. (Photo courtesy of Modern Vascular)

A one-stop shop

The original cath lab, 30-40 years ago, diagnosed disease and referred patients to open heart surgeries that were followed by a month-long recovery. Today, percutaneous coronary intervention, innovations like TAVR (transcatheter aortic valve replacement), mitral valve clips, atherectomy for calcification and more recently, intravascular lithotripsy, have expanded treatment options for complex coronary, valvular and structural heart diseases in the lab itself.

"The equipment has become smaller, lower profile, and easier to use," said **Dr. Anna Bortnick**, attending interventional cardiologist and program director of the interventional cardiology fellowship at Montefiore Health System. "Image guidance in coronary arteries using live intravascular ultrasound or optical coherence tomography (OCT), CT scans and echocardiography for preplanning of valve procedures, allows interventional cardiologists to integrate more detailed information in their treatment plan for patients. The goal is to achieve better results and discharge patients home with faster recovery."

These advancements mean conditions that once required open surgery are now treatable with minimally invasive procedures, where patients can go home the same day.

"We don't have to cut a patient open or stitch them up, so there's a big trend to doing everything less invasive," **Dr. Shyam Sathanandam**, director of the cardiac catheterization laboratory at Le Bonheur Children's Hospital in Memphis, told HCB News. "As a result, the number of procedures performed in current cath labs throughout

the country are going up, so more and more hospitals is building new cath labs. Even existing hospitals that have cath labs are adding more."

And while regulatory changes have been a long-standing and difficult to overcome barrier, they have finally caught up to the science and permit ASC cath labs to grow in the therapeutic space, says **Dr. Rick Snyder**, an interventional cardiologist and president of HeartPlace, a cardiology and cath lab practice in Dallas. "Private payers started to pay for therapeutic procedures first years ago but Medicare was very resistant. Medicare did not even cover PCI (Percutaneous coronary intervention) until 2020 for the first time."

Heading out of the hospital

Most patients want to avoid hospitals as much as possible, instead preferring ambulatory and outpatient settings, where they can typically receive the care they need at a lower price and closer to home.

"Especially in the COVID era, patients do not want to go to the hospital to have procedures performed. If procedures can be accomplished in the ambulatory setting, you can more carefully control that only COVID negative patients come through the doors; that's not true in a hospital," said **Dr. J. Jeffrey Marshall**, chief of the Northside Cardiovascular Institute. "In the future, due to technology like coronary CTA/FFRCT, the diagnostic procedures will and are starting to move out of the hospital and into the ambulatory surgical settings. Low-risk therapeutic procedures may stay in the ambulatory surgery centers, with only higher-risk therapeutic procedures being performed in the hospital."

Support from professional societies and experts in the field has paved the way for procedures to be performed in outpatient settings, including low-risk coronary angioplasty. Many payors and self-insured employers also prefer the affordability of outpatient and ambulatory labs, compared to ones in hospitals. Still, some patients, like children, are still better off undergoing cath lab exams and operations in a hospital.

"They need the backup of cardiac surgery and cardiac anesthesia and other subspecialists that an ambulatory setting may not have," Sathanandam said. "Some cath labs for adults have transitioned but I would still say that's a minority. You need an infrastructure that a tertiary hospital will provide, especially if the patients are very complex."

Wearing multiple hats

Most modern cath labs are hybrids that can operate as ORs to perform both open-heart surgeries and cardiac catheterization, according to Sathanandam. "Some of these patients that should have had open-heart surgery are now undergoing a minimally invasive procedure in the cath lab. But obviously if they need to have open-heart surgery during their minimally invasive procedure for some reason, you need to be able to do it."

Other hybrids are beginning to combine peripheral procedures, traditionally found in ambulatory settings, with coronary ones that are just beginning to be performed in labs, according to Marshall. In addition to fluoroscopy, modern-day cath labs are equipped to perform intravascular imaging and intravascular physiology. Some also have integrated CT imaging to guide procedures and newer

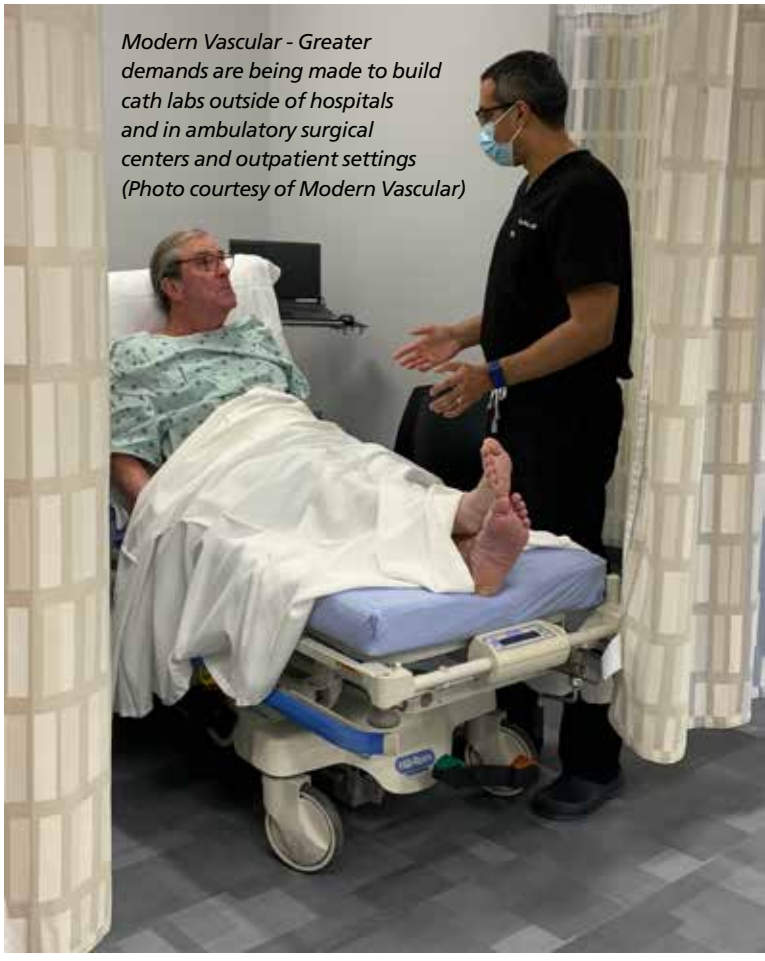
left ventricular support devices that make them well-suited to care for critically ill patients.

Bortnick's team at Montefiore used these technologies to transform their own cath lab into a hybrid ICU that could care for both heart and COVID-19 patients at the height of the pandemic. "We take care of the highest number of heart attack patients in all of the boroughs of New York City," said Bortnick. "We organized ourselves to not only take care of COVID patients, but to keep critical cath lab services available for people coming in with a heart attack or chest pain."

A future of evolution

Better dosing and radiation reduction technologies have decreased risk for overexposure by ten times compared to five years ago. Sathanandam sees this trend continuing. "Five years from now, I think X-rays will be replaced with other modalities in imaging, especially MR, which has no radiation," he said. "I think, eventually, [cath labs] will perform procedures with MR guidance rather than X-ray guidance."

On the therapeutic side, Bortnick is already seeing new devices that she believes will further the number and complexity of conditions that can be addressed in the cath lab. "There are new innovations in mitral and tricuspid valve technologies for valve repair and replacement. There will be an array of devices to support failing hearts. Those are areas I already see blossoming."



Modern Vascular - Greater demands are being made to build cath labs outside of hospitals and in ambulatory surgical centers and outpatient settings (Photo courtesy of Modern Vascular)

Marshall says all these factors will be the catalyst for the cath lab's biggest change: its transition from a diagnostic unit to a therapeutic place. "One of the worst things that inadvertently happens to patients is peri-procedural bleeding. With new access techniques, like radial access, you're much less likely to have a bleeding complication. These techniques make it safer to do outpatient procedures with same-day discharge."

Cath labs will also grow outside the hospital in more outpatient and ambulatory settings that will be well equipped to handle low-risk and some complex conditions. "As technologies and our techniques become more refined, less invasive endovascular procedures will continue to replace traditional open surgeries," said Modern Vascular's Bhatti. "Considering the reimbursement, enhanced convenience for both patients and providers, and access to the same, and sometimes better, tools when compared to the hospital, I see this trend of providing vascular care in an outpatient setting continuing."

Ultimately, the modern-day cath lab is in several transitions that are expected to change the options and locations in which cardiac trouble can be diagnosed and treated, says Snyder. "We are kinda at the same stage where colonoscopy was 10-15 years ago when they were mostly done in the hospital outpatient department setting. Now most are done in an ASC."

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When it comes to non-labor spend, consider calling a friend

By Eric Slimp

Financial health is a top priority for every healthcare organization, even in the best of times. But hospital operating margins have plummeted due to COVID-19-related revenue losses and sky-high expenses. According to Kaufman Hall, hospital operating margins for the first 11 months of 2020 were 56% lower, compared to the same period in 2019. Compounding the problem, staff reductions have left fewer contracting and supply chain staff available, and they must scramble to meet demands for supplies and outsourced services while working remotely.

To survive this financial crisis, healthcare organizations need to control their non-labor costs. Supply-chain spending accounts for one third of the typical hospital's overall operating expenses. An analysis by Navigant revealed that the average hospital spends $12.1M more than it needs to on med/surg and pharmaceutical supplies, medical and implantable devices, and maintenance supplies.

One approach that has yielded meaningful results is to ensure that your health system is focusing on the right categories that will yield significant savings rather than merely reacting. This requires visibility and digestible data related to your current spend, as well as data-driven approaches to create a roadmap of categories that lets you strike when the time is right. To achieve savings goals and displace lost revenues, hospital supply chains must transition from only tactical activities, such as negotiating contract renewal quotes, into proactively attacking categories and sourcing strategically.

One way understaffed hospital personnel can address this urgent problem is by enlisting the services of an outside organization to act as a consultant and unbiased advisor to the provider as they negotiate with their suppliers. That's what happened in the case of a large children's hospital in the Southeastern U.S. that was spending vast sums on a life-saving therapy for newborns and children with cardiorespiratory problems.

Pediatric healthcare is a dynamic industry that changes quickly and requires specialized — often expensive — equipment and supplies to diagnose and treat children with a large variety of needs. One such item in this client's budget was iNO therapy, which is used extensively in children's hospitals for the management of neonates and children with cardiorespiratory failure. This important therapy was expensive because of an orphan drug designation that impeded competition.

The hospital's outside sourcing analysts identified iNO therapy during a review of the hospital's spend as a "category to watch" for high savings opportunities. The hospital and its consultants shared intel over the years, resulting in quick action when exclusivity expired on the orphan drug.

The consultant's advisory team worked with the hospital's Strategic Sourcing and Respiratory personnel and provided product evaluation, further data analytics, and targeted negotiation points for a successful, competitively priced new agreement with an emerging iNO therapy supplier. Specifically, the consulting team was able to identify what alternatives were emerging into the market, what type of fee structures they offered, and what a competitive price was for the therapy based on visibility into what other providers were paying. This level of insight and transparency into these specialized and rapidly changing markets is not and cannot be available without leveraging a third party with access to an extensive database of market pricing that is updated in real time.

With its market intel and expertise in spend management, the consulting organization helped the hospital achieve cost savings of more than $350,000 annually. The effort underscored the hospital team's commitment to obtaining a critical service for its patients at a lower cost, without impacting patient care.

Working with a knowledgeable partner allows hospitals to analyze data and develop spend insights for immediate action. Categories with the most opportunity for savings include purchased services, med-surg, and capital equipment and projects.

Every budget cycle comes with ambitious savings targets. But even after consolidating vendors and optimizing price, aggressive management of leakage, off-contract spend, and misbilling still needs to take place. This is especially difficult — and often mismanaged — when it comes to non-PO spend, which cannot be validated via a 3-way match in an ERP system. A combination of spend analytics and monitoring, coupled with contract negotiations and proven purchasing strategies, can help transform cost centers into savings opportunities.

Spend Analytics takes a goal-driven approach to how hospitals and health systems manage their supply chain spend and contract negotiations. It starts with a technology-enabled analysis into every dollar a health system spends (excluding payroll), and is guided by a team of spend analytics experts to achieve the organization's savings goals.

Working with its spend analytics consultants, clients like this children's hospital can determine the best opportunities for savings. Then, they are guided along the way with roadmaps and support to ensure that contract goals are met and savings are achieved. Such a true collaborative effort can yield meaningful results.

About the author: Eric Slimp is purchased services director for TractManager, a part of symplr.

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Q&A with Dr. Y.S. Chandrashekhar

Editor-in-chief

Journal of the American College of Cardiology: Cardiovascular Imaging

By Sean Ruck

The American College of Cardiology's 70th Annual Scientific Session & Expo will take place virtually from May 15 – 17. In advance of the show, we spoke to Dr. Y.S. Chandrashekhar, editor-in-chief of the *Journal of the American College of Cardiology: Cardiovascular Imaging* and professor of medicine at the University of Minnesota.

Dr. Chandrashekhar offered insight into the changes and challenges wrought by COVID-19 and talked about some of the exciting advances that are happening in cardiac imaging today.

HealthCare Business News: How has the role of cardiac imaging evolved over the course of the pandemic?

Dr. Y.S. Chandrashekhar: The greatest difficulty was how to calibrate imaging volume with the ebb and flow of the pandemic. Even with curtailed imaging, we had a lot of challenges — which patients do we bring in for imaging? How do we choose the tests that are the most efficient and expose both patients and technicians to the least risk?

Our labs also had to be configured to accommodate for social distancing. There were lots of things that we normally don't think of. Then, of course, we have to do something called focus studies instead of our full regular protocol. In some cases, answering very targeted questions. And we had to innovate sometimes. For example, our patients used to be in the ICU in a prone positon, and if you had to do an echocardiogram on them, that's a tough thing to do. So there was a group in England that created a workaround where they positioned the probe between the bed and the patient and they could create an echo picture with reasonable utility.

Lastly, we found things in the imaging tests that we didn't know about and are still fretting about now — something you see on an MRI for a patient who was asymptomatic, was it myocardic? Should I worry?

HCB News: One post-COVID-19 ailment that crops up is heart issues. Is that something that has required new learning for clinicians or was it something that professionals were reminded to be more aware of looking for?

YC: There are two sets of issues. Most of these problems we've seen with other diseases, but here what happens is that they're concentrated in a sick patient. The second thing, while some of these changes, like the inflammation of the heart, are seen in other diseases, what to do with the COVID patient is continually evolving with no strongly established guidelines. But yes, they're problems we're familiar with and we're on the lookout more for them.

HCB News: As the editor of JACC: Cardiovascular Imaging, did you feel extra responsibility to highlight the right research in the early days of the pandemic? If so, can you tell us about that experience?

YC: JACC: Cardiovascular Imaging is one of the top journals on imaging for the entire world. So we felt a special pressure, when people were finding all these changes, to bring out all the information about what was happening, what the cause is, and what should be done. It was a difficult time for my journal as well as other journals I'm sure. Everyone had to figure out the path they felt was best with the rush of papers coming in. We had a 35% increase year-over-year in the number of papers submitted to us — both COVID-related and non-COVID-related. So lots of people were doing research despite the difficult environment. However, most of these papers were small, they were observational studies… They needed to be confirmed with better studies before we could act on them. Even during a pandemic, though, it's our responsibility to maintain quality. Papers have to be robust, they have to have sizable data. We, as a group, felt most of the submitted papers would not pass the traditional metrics of quality. Throughout the whole year, we only published four original papers on COVID. We may have gotten two or three hundred COVID-focused submissions and found just the four that cleared the bar. Our usual acceptance rate is about 5%.

HCB News: Aside from the pandemic, where is cardiac imaging making the biggest impact in clinical practice?

YC: Lots of areas. Some of the biggest impact immediately seen would be marrying imaging with structural intervention, like putting an aortic valve through a catheter or closing a leaky valve through a catheter. These techniques need a lot of imaging support. Similarly for electrophysiology procedures, where to burn, where the focus of the scar is, becomes very important.

Then of course, there are new things happening in CT. Especially with CT perfusion gathering good data. In one test you can get anatomy, physiology and blood flow at the same time.

PET scans are coming up in a big way as well, because they allow you to measure blood flow and that, coupled with new neurotracers, will allow us to get better answers. CMR is the other that tops the list. There are lots of new things coming there. At this time, there isn't much uptake, but in the next few years, it will be a very powerful tool.

HCB News: Despite lots of research showing its value, cardiac CT is underutilized and perhaps under-reimbursed. Has that been your impression?

YC: Very true. CT is probably the area with the strongest emerging evidence for its use. It is data-based, clearly showing where it's useful and where it has limitations. We are gathering more knowledge about that faster than we have for technologies like echo and nuclear. CT has provided similar kinds of information in a much shorter time. And an important thing to note is that the evidence has been gathered from contemporary patients. It's easy to do and it acts as a great gatekeeper to more invasive procedures.

HCB News: Are there any emerging use cases for cardiac imaging that researchers are particularly excited about?

YC: There are lots of questions we can answer now that we couldn't in the past. One area that stands out is cardiotoxicity. We give radiation to patients with cancer to help them, but there's a risk we may end up damaging the heart, which, in some cases can be permanent. That means it can be a very heavy decision. So being able to identify the potential for damage, and if there is early evidence of damage, you can stop the chemotherapy and protect the heart, is incredibly valuable.

Then, there are questions regarding things like ventricular stiffness. That's an epidemic itself. Of course, there's always the question of how to measure how well the heart is pumping. The metric we have now is called ejection fraction. It's not very good. There are better techniques coming out that measure myocardial mechanics, so that's very exciting. Lastly, there are some advances in CMR which allow you to extract a bunch of parameters from one single scan. That's going to be a game changer. My journal has been fortunate to showcase a lot of the outstanding papers in this area.

HCB News: What are some of the big cardiac imaging topics to look forward to at the upcoming ACC virtual meeting?

"This is something that comes up in discussions with my colleagues all the time — what will be the role of doctors in the future? We will probably farm out the low-level things to machine technology and add more value to the high-end tasks."

YC: The program for this year hasn't been released yet, but I expect to see a fair amount of machine learning AI. There will be a lot of discussions about how to evaluate patients with chest pain and ischemia since the ischemia trials came out a few months ago with some very interesting results that the imaging community may or may not have been expecting. There will be all the usual topics as well — CT and CMR will feature prominently.

HCB News: We think of cardiac MR as a somewhat sophisticated exam that is not available in the routine clinical environment. Is that changing?

YC: It is, but very slowly. We are a little behind compared to Europe — especially Germany and the United Kingdom. There's a big opportunity here to enhance utilization of CMR. It provides so much information, it can become a one-stop shop for most diagnostic conditions. It also provides something unique that most other tests don't have — or even if they have, it's extremely difficult to get — and that is tissue signatures.

HCB News: How much of a role is AI playing in cardiac imaging today and how much growth do you expect in the coming years?

YC: It's already playing a fairly large role in the background in how machines analyze data and how they produce models of the heart, but we're moving into uncharted territory. It's extremely exciting, but also potentially unnerving, with what AI can and cannot do. The imaging leaders of the future may not necessarily only be the doctors. Of course doctors will still be there, but a lot of imaging technology may move from companies that are currently in health care to companies who are experts on handling large amounts of data: Facebook, Alphabet, Amazon, Microsoft.

There is also some mind-blowing technology coming up. There's one called GAM (generalized additive model) which gives you the ability to take a data set generated for say, a CT, and without having to repeat the test, you can convert that into an MR image or an echo image.

HCB News: So GAM could take something in one modality and translate a difficult case into a modality where an organization has an absolute superstar available to offer expertise?

YC: Totally. But the experts for GAM aren't sitting in universities. They're sitting in big data mining companies. This is something that comes up in discussions with my colleagues all the time — what will be the role of doctors in the future? We will probably farm out the low-level things to machine technology and add more value to the high-end tasks. We'll probably be concentrating on things that make a big difference to the patient rather than spending as much of our time acquiring or interpreting images.

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The benefits of hospital-grade wearable remote patient monitors

By Dr. Arik Eisenkraft

For decades, patient blood pressure (BP) has been measured using standardized oscillatory inflatable-cuff monitoring devices. The measuring process requires a healthcare practitioner to wrap a cuff-based BP monitor around a patient's upper arm, which then inflates and deflates to manipulate blood flow, creating detectable vibrations within the arteries. These vibrations are then recorded and analyzed to help clinicians understand patient cardiovascular health. Unfortunately, due to the fact that inflating cuff-based monitors often startles patients and that monitoring BP solely on circumstance as opposed to patient lifestyle can lead to less-than-ideal patient results, these readings do not demonstrate a holistic view of patient heart health.

With advancements in both connectivity and vital-sign tracking capabilities of patient monitoring technologies, wireless wearable remote patient monitoring (RPM) devices unfold new opportunities within the cardiovascular space and healthcare overall. These devices enable us to look at real-time patient data — including BP — unencumbered by cuff-based monitors, allowing clinicians to holistically view patient status, even from a distance.

A year into the COVID-19 pandemic, healthcare professionals continue to turn to new, innovative RPM devices to prevent unnecessary hospital admissions and limit the spread of the virus. In a recent report, Insider Intelligence estimated that 30 million U.S. patients, or 11.2% of the population, will use RPM tools by 2024 — marking 28.2% growth from 23.4 million patients in 2020.

This highlights an additional benefit, in that medical-grade RPM devices allow providers to aggregate patient results over long periods of time without constraining patient lifestyles. This means that vital-sign measurements can be taken and analyzed while patients are eating, walking and sleeping, resulting in accurate readings that properly portray patient health correlating with their actual lifestyle, not only when they have a BP cuff on their arm in a clinician's office or breaking from their daily activities to self-monitor.

With the development of AI and Big Data analysis capabilities, RPM devices play a more pivotal role than ever before within the realm of patient care. In aggregating patient health data from millions of patients, RPM systems can act as guides for clinicians and provide highly attuned patient data insights, helping health professionals care for generic patient populations as well as patients with specific morbidities, including cardiac diseases. By providing precise point-of-care instruction, RPM systems can alert physicians to patient deterioration and assist in preventing adverse health events.

While the concept of instantaneous results is one that the world has become more accustomed to, the introduction of instantaneous and continuous patient health within the healthcare sphere is truly revolutionary. This culmination of AI insights enabled by big data and advanced wearable patient monitoring capabilities has empowered caregivers with patient health insights unlike ever before. Now, clinicians and researchers can fully understand what makes one's heart work harder, the direct correlation between patient status and medication intake and the health journey that individuals take during the provision of care.

More recently, these capabilities have proved to be crucial in the fight against COVID-19. As hospitals face overflooding and medical personnel experience exhaustion and burnout, the unfortunate reality is that unintentional human error is inevitable. These mistakes can be detrimental to patient outcomes, which is significant when patient conditions are as fragile as they are during COVID-19.

The introduction of wearable RPM devices limits the need for clinicians and nurses to spot-check patients and monitor their vitals, helping to mitigate viral exposure and spread. RPM systems also serve as a useful tool in discovering deeper patient nuances of COVID-19, allowing providers and scientists to seamlessly conduct studies on the impact of the pandemic in remote care settings, including the home. These RPM systems also offer opportunities for pharmaceutical companies and CROs to conduct decentralized clinical trials, which may become the new normal as we move forward into a post COVID-19 era.

With all of this in mind, it is time for antiquated patient monitoring methods, like cuff-based BP monitors, to take a back seat to new and improved AI-powered wearable RPM systems. By providing truly holistic, accurate and reliable patient health data, these devices are changing the scope of patient monitoring throughout the turbulent COVID-19 climate and beyond, offering a new dimension into the world of patient care based on real-time data from real-life activity. As we look ahead, we can be excited at the prospect of RPM systems elevating the standard of patient care and becoming the standard of patient monitoring, especially BP, in hospitals and in the home.

About the author: Prof. Arik Eisenkraft, M.D., MHA is the chief medical officer of Biobeat, developer of wearable AI-powered remote patient monitoring solutions.

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C-arms move into 3D, guided by touchscreens, AI

By Lisa Chamoff

Manufacturers of fixed and mobile C-arms continue to seek out the holy grail of radiology — providing the clearest images at the lowest possible dose. Several companies are achieving this with the use of high-definition and 3D imaging, coupled with artificial intelligence (AI) to decrease radiation exposure.

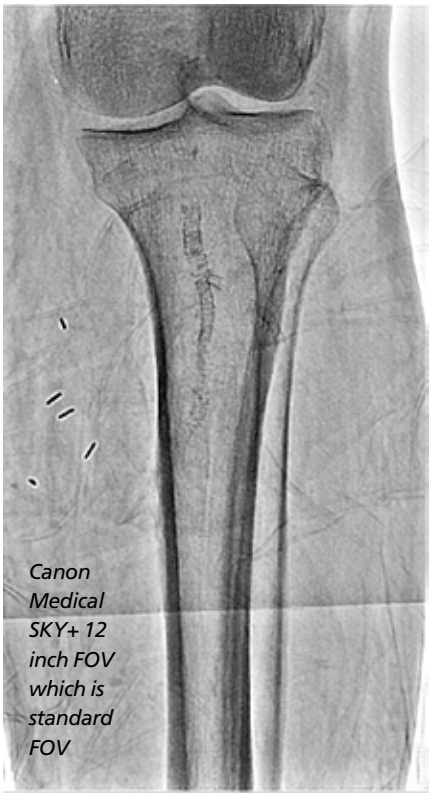
At the same time, they're looking to make C-arms more mobile than ever with intuitive touch-screen user interfaces.

Here's a look at what's new in the C-arm space from several manufacturers.

ControlRad Select

Canon Medical Systems

At last year's RSNA annual meeting, Canon Medical Systems announced that it was making its 12-inch-by-16-inch True Hi-Def Detector available on the Alphenix Sky+, a ceiling-mounted fixed C-arm and 4D CT, combined CT/angiography room. The technology was previously available on the Alphenix Core+ and Alphenix Biplane, which were released two years ago. The technology allows for magnification with 76 micron pixel resolution at 3 inches, 2.3 inches and 1.5 inches.



Canon Medical SKY+ 12 inch FOV which is standard FOV

"This expands the applications for this technology," said **Kevin Maguire**, managing director of the vascular business unit at Canon Medical Systems USA. "We believe the high definition technology may be very beneficial in supporting challenging interventions" across a variety of interventional radiology procedures.

A study of over 6,300 neurointerventional procedures comparing the use of high-definition technology to standard imaging technology on Canon Medical's 12-inch-by-12-inch detector quantified a decrease in both cumulative dose and total procedure time with the use of high definition imaging, according to Maguire.

ControlRad

In September 2020, ControlRad announced FDA clearance for use of the ControlRad Trace solution, designed to reduce radiation exposure on the GE OEC 9900 Elite, one of the most commonly used mobile C-arm models in the U.S.

Last month, the company announced FDA clearance of ControlRad Select, its new radiation-reducing platform in the angiography and cath lab space.

ControlRad Select is a retrofit for the Siemens Artis zee interventional imaging system. In preparation for commercial release this spring, ControlRad has entered into an exclusive agreement with Boston Scientific to sell the ControlRad Select technology.

"With the reach of the Boston Scientific sales team, every cath, EP and IR lab in the country that has a Siemens Artis zee will now have the opportunity to reduce their radiation dose by 85 percent without compromising image quality," said **Guillaume Bailliard**, chief executive officer of ControlRad.

The technology for ControlRad Trace and Select utilizes proprietary semi-transparent filters, image processing algorithms and a tablet-based user interface to reduce radiation exposure to the patient and medical staff.

"We believe our technology is vital to reducing radiation exposure in the clinical set-

ting and releasing these two products were huge milestones in offering this potentially lifesaving technology to even more healthcare professionals," said Chris Fair, executive vice president and president of ControlRad.

GE Healthcare

Last year, GE Healthcare released a 31-centimeter-by-31-centimeter flat-panel detector for its OEC One CFD C-arm. The field of view is ideal for imaging long bones of the leg, **Dan Strauch**, chief marketing officer of GE Healthcare's surgery business

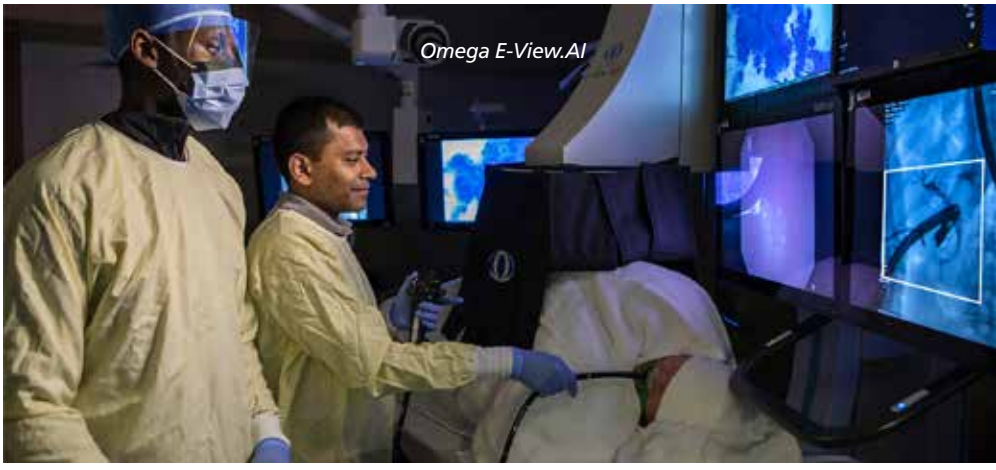
The company also introduced a new touchscreen user interface for the OEC Elite platform, which now has a separate roll stand for surgeons who want more control at the tableside.

"It allows you to really move around control of the system inside the OR, where you really need it," Strauch said.

The company's biggest introduction last year was of the OEC 3D, which was presented at RSNA in 2019 as a work in progress. This premium offering is currently 510(k) pending.

"We've really taken a lot of effort to develop a system that can be used as a 2D system, but when needed, they can get the 3D images for confirmation and to use navigation systems," Strauch said. "We really wanted to focus on a product that you can use during any surgery but that you can use as a 3D system as well. I think we're going to see 3D become a bigger part of the C-arm market in the next five years."

GE OEC 3D



Omega E-View.AI

Omega Medical Imaging

Over the last year, Omega Medical Imaging has been marketing its technology that utilizes AI to automatically collimate to the region of interest during interventional cases, reducing radiation exposure by up to 84 percent, according to the company.

This technology is used across Omega's line of interventional systems, but most specifically on its E-View.AI, a fixed C-arm designed for endoscopic procedures such as endoscopic retrograde cholangiopancreatography (ERCP).

The AI technology automatically detects the physician's region of interest while simultaneously reducing radiation exposure to patients, physicians and staff, said **Dan Alred**, marketing manager of Omega Medical Imaging.

The new imaging modality takes all the existing best practices to lower radiation exposure in interventional labs and further reduces dose by up to 84 percent, without changing existing workflow or sacrificing image quality, according to Alred.

The company's target market is hospitals and medical centers that perform interventional procedures and are looking to protect their patients and staff.

"If you're working in these labs every day, incorporating lifesaving technologies such as this to lower your radiation exposure is a no brainer," Alred said.

Philips

In the third quarter of last year, Philips launched the next generation of its Azurion image-guided therapy platform, first released in 2017. It includes tableside control with a single touch screen for the system and all applications.

In the same quarter, the company released the Azurion Lung Edition, a tailored version of the platform that includes visualization and workflow tools to treat early-stage lung cancer with bronchial microwave ablation.

"The treatment involves navigation through the airways without an incision and Azurion provides a better platform for imaging," said **Nicole Hermkens**, marketing leader for image-guided therapy systems at Philips.

The company also launched a new app called SmartCT, which provides guidance for users on how to do 3D imaging.

Siemens Healthineers

At the beginning of 2021, Siemens Healthineers received FDA clearance for its Cios Flow mobile C-arm.

Philips Azurion image-guided therapy

Siemens Cios Flow

Cios Flow has a tablet-like user interface that is consistent across the monitor cart, C-arm and from the sterile field. The remote user interface can be attached to the side of the OR table or to a separate mobile roll stand.

A new feature, SpotAdapt, was designed to visualize challenging areas more easily.

"SpotAdapt lets you specify a region of interest simply by pointing to the specific anatomical area on the large preview image," said **Allison Sutter**, marketing manager of the Advanced Therapies business at Siemens Healthineers. "With a single touch you can automatically optimize relevant imaging and post-processing parameters such as brightness and contrast."

The Cios Flow utilizes a Windows 10 operating system, with integrated security functions to help minimize cyberattacks on system and patient data. It comes with user management features to prevent unauthorized access, track changes made to the system, disable use of restricted applications and secure sensitive patient data with BitLocker encryption. The system meets the security standard that is required by the Department of Defense (DOD), according to Sutter.

The system is designed for use across multiple clinical specialties and is ideal for orthopedic trauma surgery, Sutter said.

Siemens Healthineers has also partnered with Radlink through the Siemens Healthineers Digital Marketplace to provide integrated access to Radlink HIP and Radlink TRAUMA software. In addition to patented image stitching technology, Radlink can be used preoperatively, intraoperatively and postoperatively to evaluate surgical alignment and verify optimal implant placement through noninvasive, real-time guidance. Radlink HIP and TRAUMA software will also be made available on the Cios Alpha and Cios Spin mobile C-arms.

STILLE

Responding to an increased focus on 3D imaging, STILLE recently launched a 3D extension that attaches to its imagiQ2 table to add 12 inches of unobstructed 3D imaging in certain procedures where reducing artifacts is key to providing clear imaging. The tabletop and the extension are made with a .4mm carbon fiber material with high translucency to help accommodate the 3D sweep and rotation of the C-arm and reduce radiation dose.

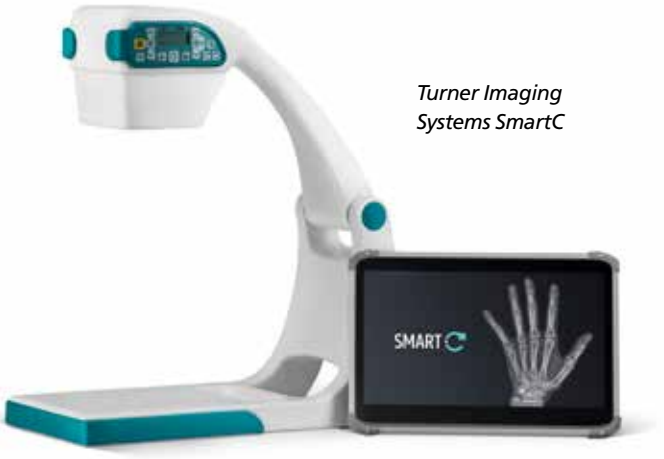
This year, the company released its Medstone5 CV mobile vascular table in the U.S. The table offers five movements — elevation, Trendelenburg, tilt, longitude and lateral — and a maximum imaging field, while also accommodating mobile CT scanners with a slim tabletop design.

"STILLE has been focused on increasing the clinical impact and flexibility that is a requirement in traditional OR settings as well as in the growing outpatient surgery center market," said **Susan Neese**, vice president of sales at STILLE. "With the addition of the Medstone5 CV, we are providing a versatile and flexible solution for multiple applications and complementing various fixed and mobile X-ray equipment."

STILLE also added a new ergonomic Pan Handle Control Module for the imagiQ2 that gives surgeons full access to all the motions of the table, including STILLE's patented Free Float and Iso-Roll designs, with sightless contact. Buttons are identified by touch and it eliminates a need for a technologist to control the table.

"Giving the surgeon full control during challenging clinical procedures will enhance the surgeon's ability to operate the table with a level of unmatched precision and help reduce OR time by

STILLE panhandle control



Turner Imaging Systems SmartC

eliminating the need to have a technologist reposition the patient and reduce the need to recapture an image," Neese said.

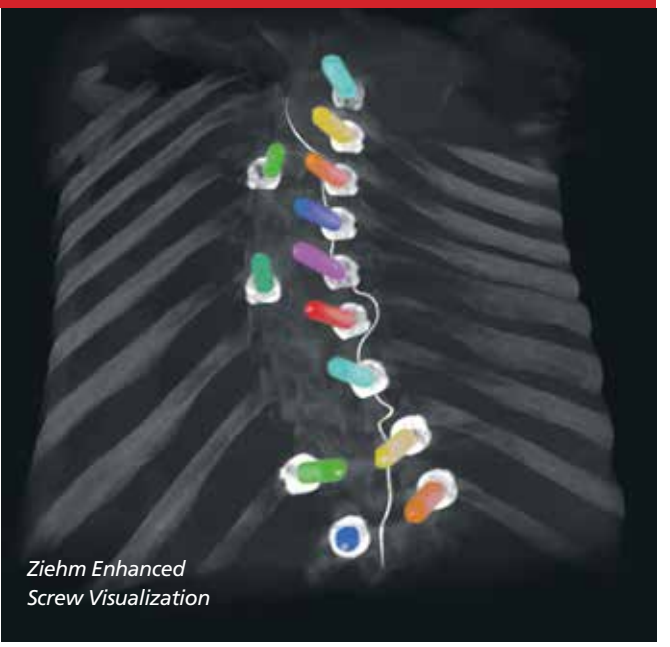
Turner Imaging Systems

Since last year, Turner Imaging Systems made several updates to its Smart-C mini C-arm software, including modification to the C-arm sleep feature.

"Before, there was a fixed time of five minutes," said **Mike Orthner**, a Turner Imaging product manager. "We found that in certain surgeries, it takes that long for specific tasks, so we listened to our customer and let them adjust it."

The company also made overall image quality Improvements and has been promoting the capability of its C-arms to allow pushing images over Wi-Fi or cellular. The feature has been used by the NFL to consult with surgeons located elsewhere before putting players back in the game.

Turner also introduced a novel sterile drape for the C-arm tablet that allows the surgeon or OR staff to use the tablet in the sterile field.



Ziehm Enhanced Screw Visualization

Ziehm Imaging

At this year's ECR, Ziehm Imaging is releasing a new C-arm variant with a larger 30-kilowatt generator. The system is designed to enable a mobile catch lab for cardiovascular procedures.

The company is the first to have a system with a 30-kilowatt generator on the market, versus its 2.4-kilowatt generator class, said **Martin Ringholz**, director of global marketing for Ziehm Imaging.

"Typically there's a lot of pressure on an existing OR," Ringholz said. "If you have a lack of square footage, it's easy to fit in. They can shift it to another existing OR and increase the caseload without having construction work."

In July of last year, Ziehm Imaging acquired French-based imaging software developer Therenva. The merger will allow more seamless integration of the software company's preoperative CT data fusion system with Ziehm's C-arms.

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Interventional and surgical X-ray equipment markets plummeted in 2020

By Bhvita Jani

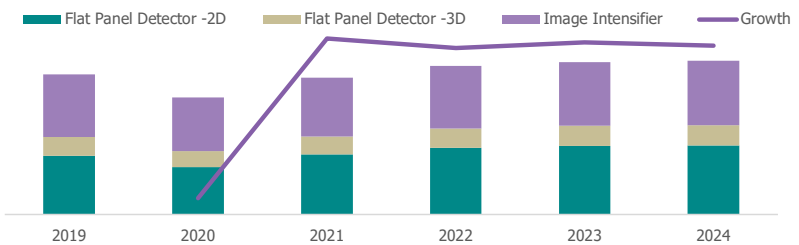
The world market for Interventional and Surgical X-ray equipment is forecast to reach almost $3.9 billion by 2024, according to a new report from Signify Research. The World Markets for Interventional X-ray and Surgical X-ray are Estimated to Have Declined by 17.4% and 16.3% Respectively in 2020. Growth in this market is predicted to return from 2021 onwards as the negative impact of the pandemic is expected to subside. Recovery is forecast to be gradual rather than "V shaped", with the steady return of elective procedures and as healthcare expenditure is restored following the diversion to COVID-related equipment.

Product trends

In the Surgical X-ray market, Flat Panel Detector (FPD) 2D Mobile C-arms are forecast to have the fastest growth through to 2024, with a CAGR of 3.4%. In 2020, there was a shift toward low-end to mid-range FPD 2D systems as a result of stretched capital expenditure budgets. Demand for image intensifier systems is slowing down, with the key markets now the emerging regions. However, in developed markets, such as the United States, usage of imaging intensifier systems is still high in pain management clinics. 3D mobile C-arms are primarily used for imaging the joints, spinal fusion and fractures and the market is expected to start seeing signs of recovery from 2021 onwards, following the return of elective spinal procedures to pre-pandemic levels. Countries with the highest adoption of 3D Surgical X-ray imaging include China, Western Europe and the United States.

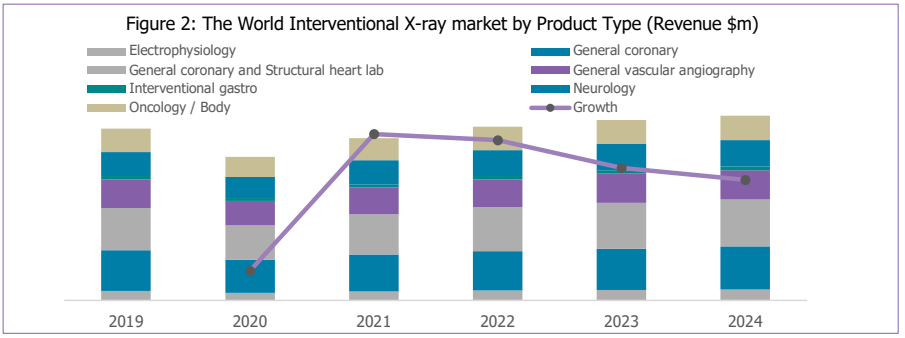
Within the Interventional X-ray market, the Interventional Cardiology (IC) market was more negatively impacted by COVID-19 than Interventional Radiology (IR) due to heavier reliance on elective procedures. An increase in the number of structural heart procedures performed, in particular percutaneous coronary intervention (PCI), continues to be a factor maintaining clinical demand for the IC market. The IR market has experienced a continued expansion of clinical procedures being performed. An increased incidence of peripheral vascular disease is driving demand for general vascular angiography. Despite an estimated 26% drop in the hybrid operating room segment in 2020, fastest growth is predicted for this product category through to 2024.

Figure 1: The World Surgical X-ray market by Product Type (Revenue $m)



Key regional trends

- North America: The North American market has been significantly impacted due to postponement of non-critical surgeries, and as budgets for non-diagnostic X-ray equipment were diverted to COVID response. The North American market will be driven by replacements of existing equipment and increasing demand from outpatient clinics and facilities.
- Latin America: Brazil has been one of the worst impacted countries globally by COVID-19, resulting in a severe market retraction for both the interventional and surgical X-ray markets in 2020.
- Western Europe: The Western Europe market is forecast to experience pricing pressures from 2020 onwards, with the economy suffering as a result of high COVID-19 impact. Recovery is expected to be steady and gradual through to 2024 as economies struggle with the impact of the pandemic.
- Eastern Europe, Middle East and Africa: The Saudi Arabia-Russia oil price war and the COVID-19 pandemic have further set back the prospects of a recovery and the market is forecast to sharply decline in 2020 by 20.1%. Postponement of elective procedures contributed to the huge drop in demand in 2020.
- Asia Pacific: The Chinese market has had one of the quickest recoveries from the COVID-19 pandemic globally, with a forecast contraction of high single digits in 2020 for the Surgical X-ray market. Demand for hybrid operating rooms and 3D mobile C-arms is high in China, mainly in high-end hospitals.



COVID-19 impact (clinical impact)

From 2021 onward, there is expected to be pent-up demand for both Interventional and Surgical X-ray systems. With the postponement of non-essential elective surgeries and medical procedures to conserve medical resources for COVID-19 patients, cardiovascular procedures were severely impacted during 2020. However, the massive financial burden of COVID-19 on healthcare providers is expected to result in reduced capital expenditure budgets for imaging equipment, including Interventional X-ray and Mobile C-arm systems.

While PCI procedures are assumed to be critical in treating acute myocardial infarctions (MI), only a small amount of PCI procedures performed on patients were for these life-threatening conditions. The rest of the PCI procedures are considered as "elective procedures" and were deferred during the pandemic. Globally, hospitals saw a decline in cardiovascular procedures.

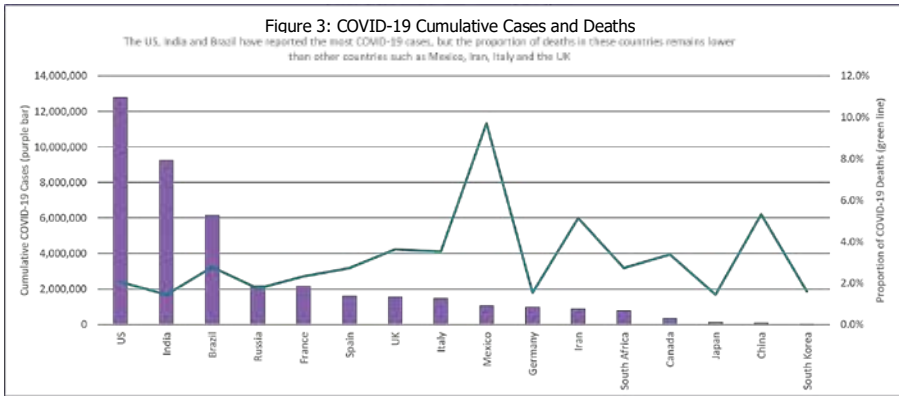
The pandemic is having a negative impact across all interventional markets (including IC and IR), due to a combination of reduced vendor sales activity (on-site demonstrations, new product launches, conferences) and plummeting elective procedure volumes during national lockdowns.

Demand for image intensifier mobile C-arms was less impacted than for FPD equivalents in 2020 due to COVID-19, as providers focused on cost-effective equipment due to reduced capital budgets.

Top trends and key takeaways

3D mobile C-arms are forecast to have the highest adoption in China, Western Europe and the United States. The Chinese market accepts the benefits of 3D mobile C-arms from a navigational and clinical perspective. In contrast, the United States market is a challenging market for 3D mobile C-arm system manufacturers to penetrate due to the extensive use of Medtronic's O-arms in minimally invasive spinal surgery, also offering navigational capabilities.

In India, local X-ray manufacturers were spearheading the uptake of both surgical and interventional X-ray systems pre-COVID. Within the mobile C-arm market, Kiran facilitated the uptake of low-end 2D FPD mobile C-arms from 2019 onward, offering more affordable FPD solutions than global vendors. As a result, the Indian market is gradually shifting from predominantly image intensifier systems to a higher presence of 2D FPD technology. In a similar manner, Involution Imaging is accelerating the uptake of cath labs in rural areas of India, making cardiovascular care more accessible and affordable to the wider part of society.



Flat Panel Detector 2D Mobile C-arms are forecast to have CAGR of 3.4% through to 2024.

Augmented reality is expected to be at the forefront of state-of-the-art hybrid operating rooms, in order to aid procedural navigation, reduce operating times, and radiation exposure. Real-time navigation data can be used to enhance patient outcomes using holographic images, as well as having full visibility of the operating room. Within image-guided therapy, 3D scan images, segmentations and measurements can be layered on top of the patient directly in the interventional suite for real-time clinical decision support, as well as preoperative planning.

The multidisciplinary use of hybrid operating rooms (HORs) is facilitating uptake through to 2024, as healthcare providers tightly monitor return on investment, and usage statistics to better inform purchasing decisions. Despite the initial higher associated cost compared to dedicated interventional X-ray systems, the increased profitability and the flexible utilization are fueling uptake in developed markets. Usage of HORs is predominantly in cardiac surgery, followed by vascular procedures, facilitating enhanced clinical precision and patient outcomes in more complex cases.

About the author: Bhvita Jani is a senior market analyst at Signify Research.

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Leading the way to increased growth, reduced costs, and improved patient care

By Dr. Raymond W. Liu and Dr. C. Matthew Hawkins

Interventional radiologists are projected to increase outpatient procedures by 23% over the next ten years, providing hospitals a tremendous growth opportunity.

The healthcare industry is at a tipping point. Patients personally engage in their care more than ever and seek treatment options that are less invasive and more promising. At the same time, the Biden administration has reinvigorated the push toward value-based care that prioritizes value over fee-for-service. These factors are forcing hospitals and healthcare systems to rethink their care delivery model in order to diversify their portfolios and provide high-quality patient care. What if one particular specialty could help the healthcare system meet these critical goals?

Interventional radiologists (IRs) are leading the way in the transformational shift toward value-based healthcare. Estimates predict the IR market to be valued at $29.2 billion by 2024 — a 6.1% compounded annual growth rate, creating opportunities for high-quality, cost-conscious treatments. As the field's advancements in research and cutting-edge technological treatments expand, so too has the role of the interventional radiologist in patient care. Leveraging the skills of IRs and giving them a larger role in the care team can help hospitals and health systems generate revenue, reduce costs, and improve both patient care and the patient experience.

Interventional radiologists generate revenue and drive growth

Interventional radiologists are projected to increase outpatient procedures by 23% over the next ten years, providing hospitals a tremendous growth opportunity. IRs perform highly efficient procedures with short recovery times, ideally suited for outpatient and lower cost free-standing centers. The specialty also has the capability to effectively manage outpatients after discharge, avoiding readmissions and potentially leading to additional cost savings. One model of a hypothetical IR clinic predicted $992,000 in annual charges and collected revenues of $298,000 as a result of robust outpatient IR care. IR is expected to lead in growth among some of the most lucrative specialties. By contributing

positively to the bottom line, IRs help administrators focus on growing their reach and generating new revenue streams.

From a competitive standpoint, IR provides cutting-edge care that uses its advanced technological reputation to influence patients' care decisions. Having robust IR capabilities in the inpatient setting could aid in attracting more patients. From an ambulatory perspective, one health system experienced a 722% increase in Evaluation and Management billing charges over three years as a result of their IR inpatient care, with work relative value units (wRVUs) increasing by 669%. As more patients look for innovative treatments that are less invasive and require a shorter recovery time, demand for IR treatments will most likely continue to grow.

A prime example of this successful model is Mount Sinai Hospital in New York, where the IR department moved from having 65% of IR treatments conducted as inpatient procedures to 65% of them conducted as outpatient procedures, which led to substantial growth. Mount Sinai Interventional Radiology started with one hospital with five IR rooms and five staff members and grew to six hospitals with 13 IR rooms and 10 IR staff within 10 years. As a result, they increased their revenue tenfold.

Containing costs

When patients are treated by an IR, the benefits extend well beyond the patient experience to the overall quality and cost of care. IR treatments can lower the costs for hospitals and insurers — without sacrificing high-quality outcomes. This also aligns with risk-based payment models, making IR services well positioned for the shift to value-based care.

IR treatments often result in fewer interventions and complications, along with shorter length of stay, particularly as part of a broader patient care team. For example, Brigham Health in Boston embraced the technical skills of IRs, assigning them a leadership role in efforts to prevent central line-associated bloodstream infections (CLASBI). As key members of the Vascular Access Team, IRs were empowered to object to inappropriate central lines often being left inside patients "just in case." This innovation, which leveraged IRs' skill sets and abilities to assess optimal quality-care standards, led to a decrease in CLASBI from 106 to 80 per year, saving potentially $1.2 million in direct Agency for Healthcare Research and Quality (AHRQ) costs and approximately $500,000 in new admissions.

These positive impacts are strongly felt in rural settings. Here, homebound patients and those in assisted-living facilities often face daunting logistical and financial challenges in finding specialty hospital care. But IRs have the skill set and technology that allows them to reach this patient population outside the hospital. In Highland, Indiana, for example, a group of primary care physicians saw many patients struggling to reliably access care because they lacked transportation, faced care-coordination challenges, and did not receive adequate case management. The team engaged an interventional radiologist to provide critical treatments outside the hospital, such as ultrasound-guided needle biopsy, gastrostomy tube management, paracentesis and thoracentesis, wound care, and drug infusions. Within 12 months, the practice treated more than 1,000 patients, reduced emergency department usage by 77%, and cut hospital readmissions by 50%. Patient satisfaction scores increased from 17% to 84%.

If hospitals and health systems embrace this outpatient model, they could potentially cut costs by avoiding unnecessary admissions and providing patients the care they need. An IR can help make this happen. And, as evidenced by the Indiana case, they can also improve patient outcomes at the same time.

Delivering quality care

IRs harness the power of advanced imaging to see inside patients' bodies and treat complex conditions less invasively and more precisely. As skilled collaborators and problem-solvers, IRs add their expertise to improve outcomes of multiple procedures to make care safer. Patients have a positive experience and go home with an improved quality of life.

Patients further benefit by decreased time away from work and family and reduced out-of-pocket expenses for deductibles and travel. Having IR services available on the weekends can reduce hospital length of stay and even progress patients toward an early discharge. Decreasing length of stay also benefits the hospital's bottom line. Analysis shows that speeding up some procedures saves 200 to 500 patient days, producing savings of $5-$10 million or more.

IRs have tremendous impact for disease management, such as postpartum hemorrhaging, a serious condition resulting in loss of fertility and possible death. Hysterectomy, a very common treatment, often leads to longer hospital stays, loss of fertility, and higher hospital charges than the alternative IR treatment, known as uterine artery embolization (UAE). When IRs are included in the care team, they perform UAE to control bleeding, allowing new mothers to benefit from a safer, less invasive procedure that may preserve their ability to have children.

Interventional radiology has emerged as a valuable new specialty that can be a dynamic force in patient care teams. By working across specialties and throughout the whole body, IRs have a uniquely valuable perspective. As patients demand innovative approaches with less down time, hospitals and health systems should look to IRs to grow their business, provide cost-effective care for complex conditions, and enhance the overall patient experience.

About the authors: Raymond W. Liu, M.D., FSIR, (pictured left) is an interventional radiologist at Massachusetts General Hospital and the Society of Interventional Radiology's Health Policy and Economics Division Councilor. C. Matthew Hawkins, M.D., FSIR, is an interventional radiologist at Children's Healthcare of Atlanta and chair of SIR's Economics Committee.

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12 months in cardiology

FDA lifts injunction on Philips defibrillators

Last April the FDA gave Philips the green light for its Emergency Care and Resuscitation business to resume development and distribution of defibrillators in the U.S., following a two-and-a-half-year injunction.

The injunction was issued through a consent decree in November 2017 after the FDA accused the company of violating current good manufacturing requirements mandated by the Federal Food, Drug and Cosmetic Act (FD&C Act) and of being noncompliant with quality system regulations in its manufacturing of AEDs and Q-CPR Meters.

"The injunction lift is an important milestone for Philips, as we have enhanced the regulatory compliance processes in our ECR business and throughout the company," said Frans van Houten, CEO of Royal Philips, in a statement. "Providing our customers with safe and reliable products and solutions remains our highest priority, and I am proud that our AEDs save lives daily, with their very high reliability record."

The injunction required the Dutch healthcare giant to stop manufacturing defibrillators at two U.S. facilities until the FDA could inspect and certify that the sites complied with Quality System Regulations.

Philips subsequently restructured its quality control function and appointed new leadership, retrained personnel and introduced culture change initiatives to become compliant with the necessary regulations.

Robotic PCI exposes patients to 20% less radiation, says new study

Applying robotic percutaneous coronary intervention exposes patients to 20% less exposure compared to manual PCI, according to a study in May by Corindus, a Siemens Healthineers company. The investigators found that using a robotic PCI solution like Corindus' CorPath GRX System cuts the amount of exposure for patients without increasing fluoroscopy time or contrast utilization.

"CorPath GRX is designed to remove the physician from the radiation field during the procedure," Corindus CEO Mark Toland told HCB News. "They control the robot while watching a high-definition monitor from behind a protective shield or inside a control room adjacent to the lab. This reduces physician radiation exposure by over 95%."

Fluoroscopy systems expose interventional cardiology patients to more radiation than any other medical specialty, putting them at increased risk for cancer, cataracts, and other radiation-related illnesses. The authors note that raising the table, and hence, the patient, away from the radiation source is associated with minimized dose exposure. Robotics can perform this maneuver without limiting the operator's ability to work, as the devices are being held and driven inside the robot.

In addition to reducing radiation exposure, the positioning of CorPath GRX provides the operating physician with greater visualization of the case than they would have if using manual PCI, due to closer proximity to the angiographic images.

AI software for cardiac echo could help in COVID-19 fight

A U.K. company with software that uses AI to predict the likelihood of a patient developing coronary artery disease entered into a clinical research agreement with Mayo Clinic in late May to further develop the product.

The partnership will also explore using AI analysis of echocardiograms to potentially help triage COVID-19 patients, as heart disease is associated with worse outcomes.

Ultromics, which spun out of research at Oxford University, markets the EchoGo Core and EchoGo Pro, which apply AI to echocardiograms to better diagnose heart disease.

The EchoGo Core product, which is FDA cleared, provides automated scores for ejection fraction and Global Longitudinal Strain. Without the device, the scores are only 76% accurate and highly variable based on which clinician performs the calculations, said Ross Upton, Ultromics' chief executive officer.

The company's EchoGo Pro product, which is CE marked but has not yet been submitted for FDA clearance, predicts whether a patient is at risk of a heart attack and requires intervention.

The partnership will allow Ultromics to use Mayo Clinic's extensive cardiac data sets to help develop the company's image analysis product suite. Mayo Clinic will use EchoGo Core to analyze echocardiograms of COVID-19 patients, to better understand how the virus affects the cardiovascular system.

Ziehm Imaging acquires French-based imaging software developer Therenva

With the acquisition of Therenva in late July, Ziehm Imaging is aiming to leverage its distribution network of mobile C-arms to market the French-based software developer's imaging software portfolio globally.

Building on a two-year market cooperation in Europe, the combined companies will focus on the cardiovascular image fusion and 3D navigation solutions. Further down the line, the combined companies are poised to develop new solutions for pre- and intraoperative image-based decision support in cardiovascular, and potentially other clinical areas.

"We are really excited to extend our partnership and work even closer together with the committed team at Therenva," Klaus Hörndler, CEO at Ziehm Imaging, said in a statement. "The Therenva portfolio is the perfect addition to our leading C-arm portfolio, and we look very much forward to further driving the OR integration in the future together."

Therenva has designed advanced and user-friendly imaging software tool sets for cardiovascular procedures since 2007. According to a statement, the company's EndoNaut endovascular navigation solution is ideal for connection with the Ziehm Vision RFD Hybrid Edition mobile C-arm.

Philips to acquire Intact Vascular with upfront cash offer of $275 million

In August, Philips announced it was set to acquire Intact Vascular for an upfront cash consideration of $275 million (€234 million) — a move that expands its image-guided therapy portfolio.

A U.S. developer of medical devices for minimally invasive peripheral vascular procedures, Intact Vascular will integrate its specialized implantable device, Tack Endovascular System, for treating Peripheral Artery Disease (PAD) with Philips' interventional imaging platform and diagnostic and therapeutic devices.

"Through the integration of our interventional imaging systems and diagnostic and therapeutic devices, we will be able to provide clinicians with a complete procedural solution to optimize the treatment of patients with this disease," said Chris Landon, senior vice president and general manager of image-guided therapy devices at Philips.

PAD affects more than 200 million people worldwide, with plaque building up in the arteries and reducing blood flow to the limbs, most commonly the legs. This can lead to recurrent fatigue, leg pain, foot or leg wounds, and critical limb ischemia (CLI).

The Tack Endovascular System enables patients to receive standard and drug-coated balloon PAD treatment results. The minimal-metal, dissection repair device precisely treats peripheral artery dissections following balloon angioplasty in above-the-knee and below-the-knee therapeutic interventions. The implant leaves less metal behind compared to stents, preserves future treatment options and preserves limbs. It also repairs dissections and optimizes post-angioplasty outcomes in the challenging CLI patient population.

Stroke admissions drop by nearly a third in early pandemic months

Hospitals saw almost a third as many cases of stroke and mini-stroke (TIA) patients in March and April of 2020 as they did during the same time last year.

That's what a team of U.S. researchers found in September after reviewing patterns of stroke and mini-stroke admissions, as well as ED stroke alerts, from 2020 and 2019. Many patients are believed to have avoided going to the hospital for care out of fear of COVID-19. This can put them at risk for some neurological deficit associated with that, as well as post-stroke complications, including fatigue, depression, anxiety, and cognitive impairment.

"I think one of the bigger concerns is that with strokes and mini-stroke, the highest risk of recurrence is in the first couple of weeks or months after that initial event," Dr. Malveeka Sharma, vascular neurologist at the University of Washington, told HCB News. "Our goal in treating someone during that first event is to get them rehabilitated but then also do our best to prevent another event from happening."

Declines coincided with U.S. stay-at-home recommendations in late March, with the greatest fall in stroke and TIA admissions occurring between March 23 and April 19, 2020. During this period, there were 281 admissions, compared to 410 in the same period in 2019, a 31% drop.

Henry Ford Allegiance Health opens advanced hybrid operating room

Henry Ford Allegiance Health opened an advanced hybrid operating room in October combining imaging equipment found in a cardiac catheterization lab and specialized features native to an operating room designated for open-heart surgery.

The combination of these resources is expected to create an environment that offers real-time guidance during procedures and enables clinicians to switch from a minimally invasive cardiac operation to open-heart surgery without having to transport the patient to another room.

"The hybrid operating room includes low-dose X-ray imaging, CT abilities, advanced ultrasound modalities, Fractional Flow Reserve, and multidisciplinary interfaces to allow for the seamless integration of future technology," Susan Wilkinson, a communications specialist for Henry Ford Allegiance Health, told HCB News. "The advanced technology will provide higher quality and safety by bringing all aspects and back-up scenarios of a patient's care into one place for greater efficiency and expediency."

Patients needing a conversion from a minimally invasive cardiac procedure to open-heart surgery had to be transported in the past to an operating room. The elimination of transport can be lifesaving according to the hospital.

To prepare for development of the room, Henry Ford Allegiance Health interventional cardiologists studied with experts from Henry Ford's Center for Structural Heart Disease for nearly two years.

Kentucky hospital first in US to implant Bluetooth-enabled cardiac device in patient

In October, St. Elizabeth Edgewood became the first U.S. hospital to implant a Bluetooth-enabled biventricular cardiac defibrillator, the Abbott Gallant, within a patient.

"This next-generation device communicates wirelessly to the patient's physician and also lets patients access information about the device using an app on a smartphone," said Dr. Mohamad Sinno, a cardiac electrophysiologist with the St. Elizabeth Heart and Vascular Institute, in a statement.

Research shows that better patient engagement and compliance with monitoring reduces hospitalizations, ensures better clinical outcomes and improves survival. The smartphone connectivity is expected to achieve these objectives by improving patient remote monitoring rates and patient engagement in remote monitoring.

The solution pairs with Abbott's myMerlinPulse, an iOS- and Android-compatible mobile smartphone app that streamlines communication between doctors and patients. With the app, patients can access their data, device performance and transmission history. Physicians can use the app to monitor patients remotely and identify asymptomatic episodes and patient-triggered transmissions. This enables early intervention and reduces clinical burden.

It also is MR compatible and offers more flexibility than traditional bedside monitors, and enables easy transmission of data mutually. Access to device status such as battery longevity is done in a cybersecure mode with enabled two-way authentication.

New evidence that MR scanning possible with non-MR-compatible cardiac implants

Patients with non-MR-compatible devices for cardiac trouble can safely undergo MR exams, according to a group of researchers who published findings in late October.

While prior research has demonstrated the safety of performing MR procedures on patients with non-MR-conditional devices, not all groups have been accounted for. This includes pacemaker-dependent ICD patients, those with abandoned or fractured leads, patients whose hearts won't function if their defibrillator is removed or stops working, and those undergoing chest and cardiac MR exams.

"The findings of this study should decrease the level of concern regarding performing MRs in patients with implanted cardiac devices," study lead author Dr. Sanjaya Gupta, of Saint Luke's Mid America Heart Institute in Kansas City, Missouri, told HCB News. "Essentially, this study shows that virtually all patients with an implanted cardiac electronic device can undergo MR scans safely, regardless if their device is labeled as MR-conditional by the FDA. As we collectively gain more experience with protocols like the one featured in our study, more and more hospitals will offer MR scans to their patients with non-MR-conditional devices."

While all implants today are MR compatible, millions of people worldwide, including young people, have older devices that are not considered compatible.

The findings were published in Radiology: Cardiothoracic Imaging.

Fujifilm makes entry into surgical and fluoroscopy markets

FUJIFILM Medical Systems U.S.A. entered the surgical and fluoroscopy markets in November with the release of its Persona C Surgical C-Arm and Persona RF Premium System.

"As a longtime leader in diagnostic imaging, entering the radiographic fluoroscopy market with the innovative Persona C Surgical C-Arm and Persona RF PREMIUM System is a natural extension to our company and for our customers," said Hidetoshi Izawa, vice president of modality solutions and clinical affairs at FUJIFILM Medical Systems U.S.A. Inc., in a statement.

The Persona C Surgical C-Arm allows for fast, precise positioning and advanced image quality for different diagnostic imaging and minimally invasive surgical procedures. The mobile C-arm system offers 21x21 cm or 30x30 cm amorphous silicon flat panel detection options for ultra-low-dose fluoroscopy and vascular imaging. It also has a removable grid with 81 cm of free space, and dedicated radiography mode for high-quality still imaging.

The Persona RF Premium System images skeletal, digestive, urinary, respiratory and reproductive systems in real time, as well as specific organs such as the heart, lungs and kidneys. It has a 17x17 DR detector and can be configured with an optional overhead tube crane and upright radiography Bucky.

Both solutions were shown at the 2020 virtual RSNA meeting.

SCCT issues new guidance on cardiovascular CT training

In November the Society of Cardiovascular Computed Tomography published a new guideline for both cardiology and radiology trainees in cardiovascular CT.

The guidance instructs program directors in the design of a training curriculum that is meant to equip independent practitioners and advanced practitioners with the same level of competence.

"The rapid growth and established benefit of a CCT approach in multiple clinical domains require programs to adopt a comprehensive training curriculum to meet the growing need for well-trained independent and advanced practitioners in both cardiology

and radiology," said Dr. Andrew Choi, co-chair and lead author of the guideline, in a statement. "This guideline allows cardiovascular medicine to expand high-quality CCT in the United States and around the world."

Curricula created under the guideline will provide users with the same technical understanding and overall case volumes in coronary imaging, structural heart disease and congenital heart disease. The recommended case volumes will serve as a minimum basis to evaluate competency, particularly among independent practitioner graduates who are diverse in their training backgrounds, local volume and supervisor expertise.

The guideline was published in the *Journal of Cardiovascular Computed Tomography* and co-published in *Radiology: Cardiothoracic Imaging and JACC: Cardiovascular Imaging*.

Over 80% drop in SPECT-MPI had no impact on rate of abnormal findings

The University of Alabama Medical Center performed over 80% less SPECT myocardial perfusion imaging at the peak of the pandemic.

A retrospective study, however, performed by researchers at the University of Alabama at Birmingham found that the decrease did not create any shift in the rate of abnormal SPECT-MPI findings.

"We hypothesized that due to the highly restricted availability of testing, only high-yield patients will undergo SPECT-MPI, while those expected to be normal would be delayed," the authors wrote in January. "However, we did not find any statistically or clinically significant increase in the rate of abnormal SPECT-MPI or that of myocardial ischemia during this period."

Exams like SPECT-MPI were postponed in accordance with guidelines issued by both the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging during the pandemic, leading to significant restrictions.

Comparing the results of 210 patients who underwent SPECT-MPI in March and April 2020 to those of 1,106 who underwent the exam around the same time in 2019, the researchers found SPECT-MPI volumes at the hospital fell from 553 per month to 105, a decrease of 81%. The proportion of abnormal results, however, only dipped from 31% at the baseline to 27% at the peak.

Deep learning system could save time in scoring coronary calcium

Quantifying and scoring coronary calcium may soon be simplified with a deep learning system developed by researchers at Brigham and Women's Hospital and Massachusetts General Hospital.

While detectable on CT scans, coronary calcium requires radiological expertise, time and specialized equipment to calculate the amount of plaque present. Clinicians often must look at the CT slice by slice for "bright specks" of calcium in the coronary arteries and circle each one. All the specks are then added up by the software they work with to calculate the coronary artery calcium score.

The automated calcium scores correlated closely with manual, human-made calcium scores and independently predicted who would have a major adverse cardiovascular event. In addition, the inclusion of three National Heart, Lung, and Blood Institute-funded trials in its training further supports the generalizability of these findings to clinical settings, according to the authors.

"The most important next step is the prospective implementation and evaluation of the system in opportunistic and organized screening settings to identify unknown high-risk individuals for cardiovascular disease (CVD), and include these individuals into CVD prevention programs. This can lead to an increase of population health," said Dr. Hugo Aerts, director of the Artificial Intelligence in Medicine (AIM) Program at Brigham and Women's Hospital & Associate Professor at Harvard Medical School.

Apple iPhone 12 magnet may pose risk to cardiac implants

The Apple iPhone 12 series includes a new feature that can accidentally deactivate or interfere with the functioning of cardiac implants.

Researchers at Henry Ford Heart and Vascular Institute discovered a strong magnet in the phone can turn off a defibrillator or deliver electrical pulses to a pacemaker that cause the heart to beat out of sync when the phone is placed near a patient's chest. This can result in a potentially lethal condition called ventricular fibrillation, a condition in which ventricles of the heart quiver instead of pumping normally due to disorganized electrical activity.

"Obviously, we can't perform surgery every time we need to control one of these devices, which is why they are engineered to allow us to use strong magnets over the chest to control their function," said cardiologist and lead investigator Dr. Gurjit Singh in a statement. "So, we began to wonder if the magnet in the iPhone 12 would affect the safe operation of these devices."

The researchers immediately drafted a manuscript of their findings that caught the attention of the FDA and the Association for the Advancement of Medical Instrumentation (AAMI) upon being published. It also was seen by Apple, which published a warning on its website in late January.

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Eight ransomware prevention strategies for healthcare providers

By Shridar Subramanian

While cybercriminals promised to stop ransomware attacks on healthcare organizations during the pandemic, it never really happened. According to Health IT Security, the U.S. healthcare sector was the most targeted globally in Q3 2020, with attacks doubling year-over-year. And the costs are measured in millions of dollars and increased risks to priceless patient privacy (and your reputation).

With cyberattacks continuing to evolve and proliferate, healthcare providers need to look at how they can prevent their organization from suffering the damages that result from ransomware. The following are some ransomware prevention strategies that healthcare providers should consider to keep both company and patient data safe.

1. Filter inbound emails There are lots of choices for email filtering solutions that can serve as your first line of defense. Healthcare providers should look for software or filtering services that proactively scan and block spam, virus, and other threats in real time before they can wreak havoc. Some use artificial intelligence (AI) to keep up with new threats and adapt defenses, while others use a Bayesian filter to detect and block personalized spam emails. It's also worth choosing a solution that is easy to manage via a web browser, with customizable settings.

2. Keep firmware up to date Software patches are frequently driven by newly discovered vulnerabilities. Healthcare organizations need to establish a regular assessment plan to confirm that all their critical applications, databases, and servers run the latest firmware. And immediately patch any that aren't.

3. Evaluate security systems and firewalls With more and more remotely connected devices — including IoT devices that present new potential vulnerabilities — healthcare organizations need to ensure that their endpoint security systems and firewalls work as expected. They also need to make sure that these protections are sufficient to keep their data secure, compliant, and available at all times. For organizations with remote workers, it's more important than ever that these users connect to your network via a secure virtual private network (VPN). Along the same lines, they need to ensure all patient records and patient processing systems are protected by encrypting all their data — both at rest and in transit.

4. Train people Cybersecurity education should be a core element of an overall data protection strategy. Team members must be trained so they can spot suspicious emails, attachments, or SMS attacks. They need to be educated and tested on social engineering attacks to understand that they should never click on a link or download an attachment unless they are 100% sure it is from a known sender. And they should have a general understanding of best practices for protecting devices and data.

5. Take regular backups The best way to mitigate the fallout from a ransomware attack is to be prepared. That means backing up data frequently and replicating copies both to an offsite location and the cloud. Organizations will need to establish their recovery point objective (RPO) and recovery time objective (RTO) and ensure their backup solution can meet them. They should also look for a backup solution that takes regular, immutable snapshots that can't be deleted or altered, preventing crypto-ransomware encryption. That way, organizations know their backed-up data is always safe, accessible, and recoverable.

6. Count on the cloud Cloud storage gives organizations fast access to offsite data and is one of the pillars of a sound backup strategy. Cloud storage can also be less expensive than on-premises storage while adding an additional layer of protection. And, while even cloud-based data can be infected with ransomware that's uploaded with a backup, sound backup practices — see #5 above — can overcome just about any attack.

7. Don't pay the ransom While an attack will cause major problems, we recommend that organizations never pay a ransom. Cybercriminals often don't give access even if companies do pay. It's worth considering getting ransomware insurance to help mitigate the damage.

8. Be proactive While all these strategies are important for protecting against ransomware, organizations may still fall victim to a successful attack. That's where planning makes the difference. With the right hardware, software, and best practices in place, they can recover quickly with minimal damage done. We suggest it's time for every healthcare organization to get a serious security-health check-up that ensures they have a healthy security posture that can withstand even the most sophisticated ransomware attacks.

About the author: Shridar Subramanian is the chief medical officer at StorageCraft.

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Three ways telehealth will get better in 2021

By Adnan Iqbal

During the Covid-19 pandemic, telehealth has gone from a nice-to-have to a must-have. Indeed, the crisis has spurred health providers to rethink the entire patient experience, as they've realized that patient care does not have to be face-to-face in every case. Physicians can deliver effective and complete care virtually — while providing greater convenience and comfort to their patients.

As telehealth benefits become clear, physicians and care teams are eagerly exploring more ways to expand at-home and remote care. Meanwhile, patients are clamoring for better, more convenient healthcare experiences on their end.

Until recently, video consultations with a doctor were available only to those patients with the means — a fancy smartphone, a high-speed connection, and an expensive concierge medical plan. And, pre-pandemic, only a small percentage of providers were equipped to operate telehealth services. But now, in the wake of COVID-19, we know that a large majority of providers in the U.S. are available via telehealth.

This increased ease of access has led to more regular and complete care for patients. Telehealth is also making life easier for practitioners, who themselves can now work from home. In a world where chronic conditions lead to increasing costs, telehealth is proving to be a great way for health systems to effectively do preventative care and reduce the number of people who arrive at the emergency room.

The past 12 months have shown us that telehealth can truly move the needle for both patients and physicians. But the reality is that telehealth is not always equitable and can further exacerbate the growing digital divide. While we make it easier for some patients to get in front of a physician, we must not make it harder for others.

Take, for example, Americans who are 65 and older. These are the patients who typically require chronic disease management. According to the Pew Research Center, only about 60% of these patients use smartphones or have broadband connections at home. Likewise, low-income Americans are another at-risk group, as only about half of these patients have basic digital literacy.

In the wake of COVID-19, we know that a large majority of providers in the U.S. are available via telehealth.

The *New England Journal of Medicine* found that while telehealth visits climbed from 3% to 80% in the pandemic's early days, the proportion of visits by patients 65 and older declined from 41% to 35%. And among patients with a non-English preference, video visits dipped from 14% to 7%.

But the situation should improve in the year ahead. How? Here are three predictions for telehealth in 2021:

1: Telehealth will be more accessible to everyone. Telehealth doesn't have to be video-only. For instance, healthcare providers can make it easier for everyone to stay connected by deploying a text-first communication strategy that enables them to reach all or most of their patients. Healthcare providers will also invest in systems that have built-in language tools to ensure that all patients, no matter their native tongue, can get the right care from the comfort of their homes. Designing a telehealth experience that works for everyone — not just the wealthy — providers can go a long way toward bridging the digital divide.

2: Telehealth will offer patients greater control. Video visits will soon be the bare minimum. Healthcare organizations will have to include value-add services as part of their telehealth offering to stay a step ahead in an increasingly competitive marketplace. These services might include online self-scheduling tools that make it easier for patients to book their appointments and interactive text messaging that guides patients to the right type of care with the right provider, based on their unique needs.

3: Telehealth will start to pay for itself. Telehealth will continue to deliver overall cost benefits to both providers and patients. For example, the technology can enable clinics to extend their hours of operation while helping to cut down on cancellations and no-show rates. It can also allow providers to focus on a higher level of care while reducing expensive and unnecessary visits to emergency rooms.

The bottom line is that telehealth is here to stay because its advantages are obvious. It helps providers improve care and cut costs, and it improves access for patients. Indeed, telehealth will radically redefine the way healthcare is delivered — and it will continue to do so for many years to come.

About the author: Adnan Iqbal is co-founder and CEO of Luma Health.

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Four ways to maximize value from your EHR and improve usability

By David Lareau

As a paper recently published in the Journal of the American Medical Informatics Association (JAMIA) notes, despite "basic federal requirements promoting a user-centered design approach to electronic health record (EHR) development and usability testing," EHR usability remains a major hurdle for healthcare organizations.

Another study published in the *Journal of Medical Internet Research* shows that 75% of clinician respondents "who reported burnout symptoms identified the EHR as a contributor. Lower satisfaction and higher frustration with the EHRs were significantly associated with perceptions of EHR contributing toward burnout."

Physician burnout creates a corrosive loop of clinician depression, depersonalization, inadequate care, low patient satisfaction, negative feedback, and unprofessional behaviors (up to and including substance abuse). The result is a dysfunctional healthcare system that is continually drained of clinical talent and fails to serve the needs of patients.

While authors of the study published in JAMIA say vendors are "beginning to address aspects of EHR implementation that play a critical role in shaping EHR usability," it is imperative that healthcare decision-makers prioritize initiatives to improve the EHR user experience. Specifically, stakeholders should maximize value from their existing EHRs by focusing on these four core areas:

1. Improving patient care

The last thing a clinician wants to do during a patient visit is tap away on the laptop while desperately trying to locate information. EHRs need streamlined workflows so clinicians can quickly find patient- and condition-specific information at the point of care. An effective EHR workflow for point-of-care use would include a comprehensive review of all data in the chart, real-time filtering of information, and highlighting of potentially relevant data point for the user.

Technology must enhance the ability of clinicians to provide quality care, not act as a barrier. Thus, it is essential that healthcare leaders provide tools that liberate clinicians from the drudgery of data entry and allow them to focus on patients. To improve patient care, leaders must implement tools that enable clinicians to serve patients and not act as data entry clerks. Technologies that automatically capture billing and coding details from a clinician's documentation allow clinicians to provide better care.

2. Increasing physician productivity

User-friendly EHR workflows can have a huge impact on physician productivity and satisfaction. If clinicians can easily access information when they need it, they can spend more time on patient care and they can see more patients because they've eliminated the time wasted finding and entering EHR data.

Workflows that support the automatic identification and interpretation of patient medical information from previous visits, lab reports, inpatient records and other sources can quickly provide clinicians with relevant information, saving them time and avoiding unnecessary frustration. And a more productive physician results in increased patient satisfaction, happier staff, greater efficiencies and ultimately, an improvement in the bottom line.

3. Managing operational expenses

Streamlined clinical and documentation workflows mean greater efficiency, which provides opportunities for healthcare organizations to reduce operating expenses. The need for transcriptions, for example, can be reduced if clinicians have the documentation tools necessary to quickly capture information about a patient visit at the point of care. The more that documentation requirements can fit into the natural clinical workflow without creating additional burden, the less work for clinical and administrative staff who can then focus on patient care and more revenue generating activities.

4. Ensuring accurate reimbursement

Providers can't get paid what they're supposed to if they don't submit accurate information to health insurers. Providers primarily have relied on retrospective, manual chart reviews to uncover possible documentation and coding gaps. If a gap is identified, patients may be asked to make a follow-up visit.

Clearly this is at best an inconvenience for the patient and clinician, and at worst a waste of valuable time and resources that is replicated thousands of times each day. To minimize data entry while ensuring the right information is captured for accurate reimbursement, EHRs need technologies in the background that can verify billing, coding, compliance, and quality measurement.

Instead of relying on inefficient and error-prone manual methods, physicians can immediately address any treatment, documentation, or coding gaps while patients are still in the exam room. More accurate documentation and coding ensures accurate reimbursement.

Long story short: An EHR that is difficult to use can lead to physician burnout and lower quality of patient care. By focusing on enhancing patient care, improving clinician productivity, ensuring accurate reimbursement, and reducing operating expenses, healthcare organizations can dramatically improve the usability of their existing EHRs.

About the author: David Lareau is the chief executive officer of Medicomp Systems, which provides physician-driven, point-of-care solutions that fix EHRs.

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Use pandemic lessons to re-engineer healthcare

By Dr. Margaret Ferguson

Physicians are on the front lines of healthcare every day. When they speak out about what the American healthcare system needs to function properly, we should listen.

Recently, physician leaders of America's top medical groups and health systems commented on how what they've learned from COVID-19 can chart the path for healthcare delivery in the future. Speaking as part of the Council of Accountable Physician Practices (CAPP), a coalition of more than 30 integrated medical groups and health systems encompassing more than 85,000 physicians, here are their ten recommendations.

1. Our fragmented care delivery system cannot support major healthcare crises or the effective management of care even in normal times. Medical groups that made investments in care delivery improvements — such as population health management, telehealth, robust health IT to support care teams — had the culture, leadership, and connectivity to quickly pivot during the pandemic.

2. Telehealth is now an established care delivery option that overcomes safety and access barriers, therefore it should be paid for at the same level as in-person care. Virtual visits are the house call of the present era. The waivers put in place to override restrictions on paying for both telephonic and video visits should be permanently adopted.

3. Care is moving home and should continue to do so. The need to care for patients who were especially vulnerable to COVID-19 furthered the use of home-monitoring devices, video visits, and in-home care. Even hospital-in-the-home is getting a boost as CMS relaxes regulations to care for these patients in alternative locations to make more room for inpatient COVID stays.

4. Population health systems and predictive analytics are the key to managing patients effectively. These tools, developed to manage the care for specific cohorts of patients, measure outcomes, and qualify for value-based programs, proved their worth in this crisis by providing valuable intelligence to make quick, accurate decisions. Integrated health systems were able to quickly identify vulnerable patients and see to their needs, as well as evaluate infection trends. Some providers deployed artificial intelligence to predict future outbreaks on a block-by-city-block basis.

5. The pandemic could sound the death knell for fee-for-service medicine. In this crisis, the financial downside of fee-for-service became clear, hitting some providers very hard. As patient visits dried up, pay-for-procedure medicine left many physician practices in a financial hole from which it will be hard to recover. In contrast, integrated groups that had primarily value-based and/or capitated contracts are expected to fare better.

6. Glaring disparities in access and health status must be addressed. The vulnerability of certain minority and low-income groups is forcing everyone to look at the reasons behind the statistics, and is creating momentum to address social determinants as well as employer-sponsored coverage. Public/private partnerships are needed to ensure that everyone has access to good care, coverage, and better opportunities to live healthy lives.

7. Physicians need to be connected to other medical providers, specialists and patient resources. Some larger medical groups already share resources with practices that are isolated or in rural areas to provide connected, coordinated care over a broader geography and/or network. This trend should continue to make sure no patient is left behind — and no doctor, either.

8. The well-being of medical providers must be a priority. During this crisis, stress, burnout and even trauma among healthcare providers also reached pandemic proportions. Health system leaders responded in numerous creative ways to help their frontline staff. This attention to mental and physical health of providers will also prove invaluable in the future and should be "baked" into the system.

9. Look at redesigning medical facilities. The anti-infection and safety precautions put in place during the pandemic will likely become permanent procedures in medical practice. Many employees who started working remotely may stay remote, and the use of telehealth and more in-home care will force us to rethink more strategically about what kinds of brick-and-mortar facilities are actually needed, and how they should be designed.

10. Finally, accountable medical leaders must be involved in designing the healthcare system of the future. Physicians, administrators and other providers who believe that they should be good stewards of every healthcare dollar and who have experience in value-based care have a wealth of knowledge to share. In redesigning the healthcare system of the future, they must have a seat at the table.

About the author: Dr. Margaret Ferguson is a board member for the Council of Accountable Physician Practices, and president and executive medical director for Colorado Permanente Medical Group.

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The rise of robotic angio

By David Pacitti

"Fear the robots." Those three words have long been the caveat and cornerstone of classic science fiction. But in the angiography suite, robotics has received a decidedly warmer reception since debuting more than a decade ago. Simply defined, robotic angiography involves any medical imaging device that leverages some form of robotics — a mechanical arm, for example, or a small, motorized vehicle — to aid with procedures that otherwise would fall to a human in the angiography suite.

Interest in robotic angiography is rising thanks to accelerated growth in minimally invasive procedures performed in the angiography suite. In interventional radiology (IR), these procedures are primarily tumor embolization and ablation. In the cardiovascular space, they include structural heart procedures for artificial valve replacement of the aortic and tricuspid valves as well as complex endovascular procedures such as abdominal aortic aneurysms. During these IR and cardiovascular procedures, robotic angiography helps improve physical access to patients, facilitate advanced imaging, and control infection.

Regarding patient access, robotic angiography allows for unmatched flexibility with head-to-toe coverage. Radial artery access is a rising trend within the interventional cardiology community, and robotic angiography allows clinicians to obtain images without sacrificing patient safety by rotating the patient table laterally to allow for easy access to the patient's wrists without compromising workflow. During a mitral valve procedure, a robotic angiography system permits the interventional cardiology team to work with ultrasound and anesthesia teams to provide critical information to guide the replacement valve or device — without interference from the movements of the angiography system. And in an endovascular abdominal aortic aneurysm, the wide C-arm of some robotic angiography units enables vascular surgeons to safely access larger patients while working with devices and instruments.

On the advanced imaging front, robotic angiography possesses unique capabilities in rotational angiography and fusion imaging. Allowing spins from multiple positions around the patient table, rotational angiography (aka 3D cone beam computed tomography) is increasingly used for real-time confirmation in IR oncology procedures such as liver tumor embolization. In structural heart procedures, robotic angiography systems provide new levels of integration and workflow, enabling simultaneous fusion of CT, ultrasound, and angiography. And in vascular procedures, CT fusion imaging enables physicians to treat patients with less radiation exposure and more efficiently (i.e., for complex fenestrated stent grafts).

In the infection control arena, some robotic angiography units allow for an operating room (OR) type of environment by avoiding contact with the angiography suite's ceiling and floor. This OR-like environment permits necessary laminar air flow over the patient while limiting contact with bodily fluids, cabling, and medical equipment.

Expect use of robotic angiography systems to expand in the coming years, in part because more surgical procedures will become minimally invasive. In the IR space, for example, more embolization and ablation procedures will be used to treat new conditions. These procedures will potentially include bariatric embolization, prostate artery embolization, and osteoarthritis embolization (aka geniculate embolization), or the embolization of blood vessels connected to nerves in the knees to prevent joint pain. In the structural heart realm, repair of mitral and tricuspid valvular disease eventually will be as commonplace as transcatheter aortic valve repair (TAVR), bringing relief to an underserved patient population that currently undergoes highly complex procedures at higher-acuity institutions.

As the integration of robotics in the angiography suite increases, we can expect this integration to enable increased access to care, improve quality of care, and drive the development of innovative telehealth solutions.

All of this means we have good reason to welcome robotics to the angiography suite.

David Pacitti is president and head of the Americas for Siemens Healthineers.

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