BIÇAKCILAR
Touching Lives One Device at a Time

MARKETWATCH

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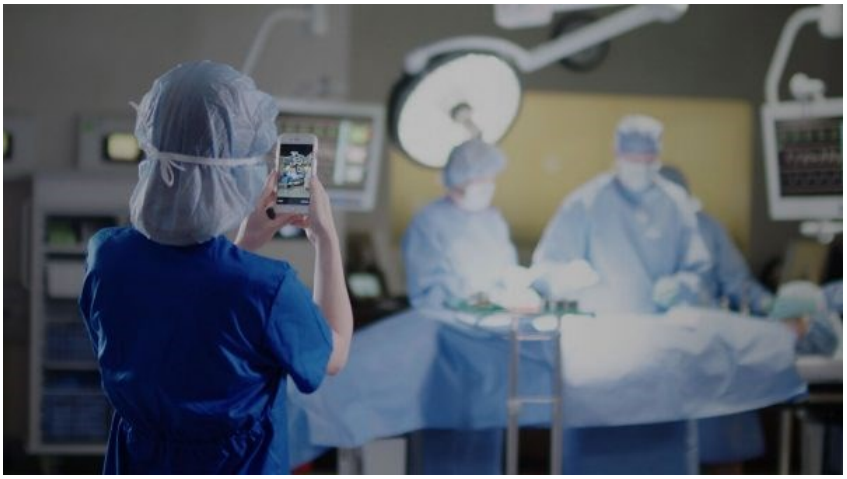
In this issue…First news is about surgery room...something unaccepted...

July 10, 2018

This Snapchat-like app lets patients' families get updates from the operating room

Called Electronic Access to Surgical Events, or EASE for short, the app helps hospitals keep patients' family members in the loop throughout the surgery process. Efforts to reduce any costs associated with diabetes is likely welcome news, and for device companies to take on risk in contracts bodes well for the future of value-based care.



When a patient undergoes surgery, his or her family members are often left in the dark throughout the majority of the process. Instead of keeping these family members feeling anxious and worried, hospitals are turning to a new app to better communicate with surgery patients' loved ones.

Called Electronic Access to Surgical Events, or EASE for short, the tool is akin to Snapchat. In a recent phone interview, Dr. Kevin de la Roza, a pediatric cardiac anesthesiologist and the co-creator of EASE, summed it up fairly simply: "EASE is a platform that allows us to securely and with HIPAA compliance communicate with these families."

Here's how EASE works: A patient can download the app for free and begin the registration process. Once signed up, the person can select others from their contact list who they want to receive updates on their progress. The patient then gets a QR code that the clinician scans to admit the individual to the EASE platform. Additionally, the provider scans the patient's medical bracelet.

After that, it's smooth sailing, and the medical team can send text, photo and video updates to the patient's family. The messages can be sent from the pre-op, surgery, PACU, NICU, ICU and medical floor settings. All received messages cannot be saved, and they disappear after 60 seconds.

EASE was originally developed in 2013 at Arnold Palmer Hospital for Children, which is part of Orlando Health. However, the tool has been implemented at a total of about 35 hospitals across the country. In a phone interview, Dr. Jose Perez, the corporate medical director of the NICU at Winnie Palmer Hospital for Women & Babies, discussed some of the perks of utilizing EASE. For doctors to be successful, they have to have positive patient outcomes and communicate with patients and families, he said.

"EASE allows us to do that communication piece," Perez said. "It really builds a trust relationship. I think it has far-reaching implications outside just a picture." In addition to assisting in day-to-day operations, the app has also come in handy in critical situations. De la Roza noted that Orlando Health utilized EASE during Hurricane Irma last year. The institution's NICU was on lockdown, and many families couldn't be with their babies. The staff was able to use EASE to keep parents in the loop and calm. Moving forward, de la Roza hopes to bring EASE to more institutions and keep improving the communication piece of the healthcare journey. "Hopefully it's a movement that's happening in healthcare," he said. "My vision is to keep growing this and expanding as best we can."

In this issue… Hewlett Packard supercomputer built to advance understanding of the brain

Global technology company Hewlett Packard Enterprise (HPE) has been chosen by the Ecole Polytechnique Fédérale de Lausanne's (EPFL) Blue Brain Project, a Swiss brain research initiative to build a next-generation supercomputer for the modelling and simulating of the mammalian brain. The supercomputer, called Blue Brain 5, will be predominately used for simulation-based research, analysis and visualisation, with the aim of advancing the understanding of the brain.

The Blue Brain Project is pioneering the approach of reconstructing and simulating digital models of brains in an attempt to discover how different parts in the brain work together.

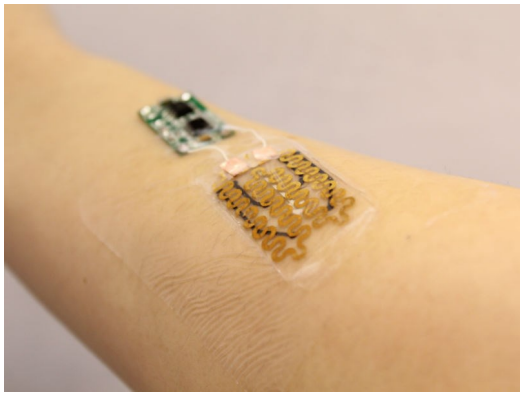
Overall costs of creating the supercomputing technology could reach CHF18m. HPE's design is based on the company's SGI 8600 System, which the company claims will provide tailored and scalable compute performance to enable the Blue Brain Project to pursue its goal of modelling entire mouse brain regions by 2020.

HPE president and CEO Antonio Neri said: "Our mission is to create technologies that improve our quality of life, including powering technologies for the healthcare industry to deliver targeted treatments and save lives. "Through our relationship with the Blue Brain Project, HPE is bringing advanced supercomputing and bespoke applications to empower new research that can have transformative benefits for the neuroscientific community and society at large."

The flexible architecture of the HPE SGI 8600 System is said to be integral for the Blue Brain Project's goals as it can host different sub systems that are designed for tasks, such as visualisation or deep learning, while being operated as a single system.

Blue Brain Project co-director Felix Schürmann said: "The Blue Brain Project's scientific mission is critically dependent on our supercomputing capabilities. Modelling an individual neuron at Blue Brain today leads to around 20,000 ordinary differential equations, when modelling entire brain regions, this quickly raises to 100 billion equations that have to be solved concurrently. HPE helps us to navigate the challenging technology landscape in supercomputing." The Blue Brain Project's HPE SGI 8600 supercomputer consists of 372 compute nodes delivering 1.06 petaflops of peak performance. The system has 94 terabytes of memory and runs Intel Xeon Gold 6140 and Intel Xeon Phi 7230 processors, as well as NVIDIA Tesla V100 graphic processors. The system uses single and dual-rail Mellanox InfiniBand high-performance networks and has four petabytes of high-performance storage from DataDirect Networks. The supercomputer also features a liquid cooling solution, designed to be energy efficient and not exhaust heated air into the surrounding working environment.

Smart bandage monitors and tailors treatment for chronic wounds



With the concept of being able to assist the natural healing process, the bandages were designed with heating elements and thermoresponsive drug carriers that deliver tailored treatments in response to embedded pH and temperature sensors that track signs of infection. A microprocessor reads the data from the sensors and releases drugs on demand from its carriers by heating the gel. The entire product is attached to a transparent medical tape, forming a flexible bandage that is less than 3mm thick. All the components keep the bandage low-cost and disposable, except for the microprocessor, which is reusable.

Blood flow in the heart revealed in a flash

Intracardiac flow at 4D CT: Comparison with 4D flow MRI

July 9, 2018

Researchers at Linköping University have for the first time been able to use information from computer tomography images to simulate the heart function of an individual patient. Some of the modelling methods they use have been developed in the motor industry.

Computer tomography systems, also known as CT scanners, are found in most Swedish hospitals. They can be used for a simple investigation to rapidly determine whether a patient has cardiovascular disease -- problems with calcification of the blood vessels that supply the heart with oxygen. The investigation is quick, and the patient can go home immediately after.

"The next step, if it is suspected that something is wrong, is a significantly longer and more complicated investigation, where the patient must spend the night in hospital. We have developed a method where we instead use all of the information that we already have from the first investigation. Our method may have major clinical significance," says Anders Persson, professor in medical imaging and director of the Center for Medical Image Science and Visualization (CMIV).

One person who has played a key role is Jonas Lantz, researcher at the Division of Cardiovascular Medicine and CMIV. He presented his doctoral degree in applied thermodynamics and fluid mechanics at LiU. He has imposing knowledge of the methods used to simulate flowing fluids and turbulence in the aeronautical and motor industries, and their application for flow through human blood vessels. He has used these modelling methods to simulate the blood flow in a patient's heart, with the aid of the high-resolution images that are produced from the CT scanner. He has used the huge computing power available from the supercomputers at the National Supercomputer Centre (NSC) at LiU.

"This is the first time we have shown that we can simulate the function of the heart in a particular patient. In the future, we won't need to use supercomputers: the calculations can be done at the CT scanner," says Matts Karlsson, director of NSC and professor in applied thermodynamics and fluid mechanics.

In order to be certain that the images, which -- it must be remembered -- are calculated in a computer, agree accurately with reality, the researchers asked a dozen patients whether they were willing to remain for a short time after the CT investigation and undergo a further investigation using magnetic resonance imaging.

"Most of them agreed to the further investigation, and this means that we have been able to compare the calculated images with reality. The images are nearly identical," says Anders Persson.

Even though only twelve patients took part in the study, the results are so remarkable that an article is being published in the scientific journal Radiology.

Tino Ebbers, professor of cardiovascular medicine, is convinced that the technology will be useful.

"Magnetic resonance cameras are effective, but they are not available everywhere. The investigation is expensive, patients should not have any metal like pacemakers in their body, and the investigation takes quite some time. Since CT scanning is quick and easy, we can reach completely new patient groups. We can now simulate how the heart is functioning in individual patients," he says.

"We can study the motion of the heart muscle, its physiological condition and its function, while the patient is comfortable at home," Anders Persson emphasises.

It is no coincidence that LiU researchers present results that require deep knowledge within not only flow patterns and turbulence but also medicine and image processing, using methods that require supercomputers.

"This is a good example of how we manage the infrastructure we have at LiU, with magnetic resonance cameras, computer tomographs and supercomputers. We don't sit in our own isolated rooms: it's easy to carry out cross-disciplinary research at LiU. However, at the same time it does need people with a foot in both camps, such as Jonas Lantz, since our methods have been taken from medical research, image processing and applied fluid mechanics," says Matts Karlsson.

CardioFocus launches HeartLight in Japan

The launch follows reimbursement approval the Marlborough, Mass.-based company won under Japan's National Health Insurance this month, after having won regulatory approval with the Japanese Ministry of Health, Labour and Welfare last July.

The HeartLight system is designed to allow electrophysiologists to control the delivery of laser energy through direct visual guidance to isolate pulmonary veins with a high procedural flexibility. The device includes a compliant balloon to accommodate diverse PV anatomies and has a short learning curve to allow for quick adoption of the tech, the company said.

CardioFocus said that its distribution partner JLL will sell the HeartLight system to hospitals through its electrophysiology division.

"We established our partnership with JLL in 2014 and have been systematically planning for this commercial rollout ever since. We are pleased to now offer our innovative technology to the Japanese market and look forward to achieving substantial growth over the coming years," exec chair Paul LaViolette said in a press release.

Last month, CardioFocus said it landed a $21 million debt investment from GPB Capital, with plans to use the proceeds to back the commercial launch of its HeartLight catheter for treating atrial fibrillation.

Medline buys Canadian stroke rehab device maker NeuroGym

Medline has acquired physical therapy and rehabilitation equipment maker NeuroGym Technologies of Ottawa.

NeuroGym's equipment is designed for people who have had a stroke or other traumatic brain injury, spinal cord injury, chronic neurological conditions such as multiple sclerosis, balance issues and/or the need for fall prevention therapy.

The equipment requires the patient to initiate movement, which the company says can help rewire the brain and speed recovery. It includes a sit-to-stand trainer, bungee mobility trainer to re-teach walking and improve balance, a pendulum stepper for lower extremity strength and range of motion, and the "TimTrainer," which integrates camera-capture technology and interactive gaming to improve motor control and coordination.

What is Happening in India?

More med devices may come under drug law

NEW DELHI: In a move to regulate quality of high-end medical devices and equipment such as implants, X-ray machines, MRI and CT scan equipment, and dialysis machines, the health ministry has proposed to expand the list of devices under the purview of drug law.

The Central Drugs Standard Control Organisation (CDSCO), the drug quality regulator under the ministry, has suggested to add eight new categories of medical devices under the definition of drug, which will be directly regulated under the Drugs and Cosmetics Act. At present, only 23 medical devices qualify as drugs and are monitored for quality by the Drugs Controller General of India (DCGI).

All other medical devices are sold without any quality checks or clinical trials. The latest proposal would mean companies will have to do trials in India, submit safety data and meet other such regulatory requirements to seek before seeking approval for selling such high-end critical products.

The list proposed by CDSCO includes implantable medical devices, MRI equipment, CT scan equipment, defibrillators, dialysis machines, PET equipment, X-ray machines and bone marrow cell separator. The regulator has proposed to notify these eight categories of medical devices as 'drugs,' under Section 3 of Drugs and Cosmetics Act.

"This will be notified in the official Gazette of India and it will come into force after a period of twelve months from the date of its publication," the regulator said in a public notice inviting comments from all stakeholders by mid-July. The move assumes significance as increasing number of such products are entering the market with several variants and brands.

Many of these products are life-saving devices, priced exorbitantly and used in critical care. Medical device market in India is pegged at around $7 billion, growing annually at 10-12%. Estimates show medical technology sector has the potential to touch $50 billion by 2025.

Currently, India imports around 80% of the medical devices.

Ramifications of rationalizing trade margins of medical devices from landed cost will have a catastrophic impact on Indian export

ew Delhi: Prominent public health experts and industry insiders are of the opinion, if India isn't cautious in the method of calculating trade margin rationalisation, it may face implications on its exports of medical devices.

India's Export-Import policy is constantly under the scanner of the south Asian countries and there have been far too many pieces of evidence. For instance, immediately after the price capping of stents by the Indian government, Pakistan, Sri Lanka and Bangladesh followed suit and got a similar line of price control. In February 2017, India slashed the price of coronary stents by 80%. Immediately, in the same month, Pakistan's senate committee on health directed the health ministry and the Drug Regulatory Authority of Pakistan to formulate a pricing policy on stents within a month.

Consequently, in April, Bangladesh too joined the bandwagon; the Directorate General of Drug Administration, contemplated bringing down the current price by half. 6-months later, Sri Lanka followed suit – the prices of the bare-metal stent and the drug-eluting stent was reduced at a similar rate.
This clearly proves that any Export-Import policy which GOI will try to implement is clearly pursued by the neighbour ring countries.
Albeit, India is considering trade margin rationalisation as an alternative mechanism to price control, the medical device industry is concerned whether the calculation will be balanced and agreeable. The neighbouring countries may again take a page out of India's book and implement similar margins by including only the landed cost. If these countries exporting Indian medical devices also demand a landing cost based selling price, it will be catastrophic for 16 billion USD worth Indian drugs/ device export of India.