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Touching Lives One Device at a Time

MARKETWATCH

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Human + machine: Accenture on the future of digital healthcare- By Susanne Hauner

At the recent Medidata NEXT conference in New York, Accenture's global lead for connected health Ronan Wisdom discussed new forms of human-machine collaboration and their potential impact on healthcare and clinical development.

"We're entering an age of human empowerment, where technology will augment humanity and fundamentally improve the way we live and work," Wisdom told delegates at the conference.

His keynote was titled 'Human + Machine'. The plus symbol, he pointed out, was significant in describing emerging applications of artificial intelligence (AI), which Accenture believes will appear in the form of collaboration between humans and intelligent machines.

He identified three key trends that are driving innovation in human-machine collaboration: "The first is the growth of smart devices and smart products," he said. "The second is new forms of interaction with those devices and the third is new forms of AI that are underpinning everything. And we think the combination of those three advances are going to change the opportunities for research across industries – healthcare included."

Smarter devices create new healthcare applications

Connected health devices are moving beyond wrist-worn trackers and becoming clinically relevant and medically accurate. This allows for new forms of health monitoring – for example, tracking disease progression by monitoring behaviour and cognitive function with smart clothing. Other recent examples include digital pills and injectable nano devices designed to function as biomarkers.

But beyond that, everyday objects are also becoming smarter and more connected, which Wisdom argues, gives them new potential for healthcare applications.

"I'm not talking about a smartphone, or a connected health wearable, or a regulator device," he explained. "I'm talking about everyday objects that we interact with – smart cameras, household appliances, cars and so on. Those objects are getting really, really smart and we think they're going to play an increasing role in our healthcare.

Fluorescent marker may enable safer brain cancer surgery

University of Bristol researchers have demonstrated in a clinical study that the use of a fluorescent marker would allow surgeons to more accurately spot and remove brain cancer.

The research, conducted in people with suspected glioma, was intended to investigate the use of 5-aminolevulinic acid or 5-ALA. The chemical glows pink in the presence of light.

According to the team, a fluorescent marker helps in differentiating the most aggressive cancer cells from other brain tissue. This is expected to enhance patient survival.

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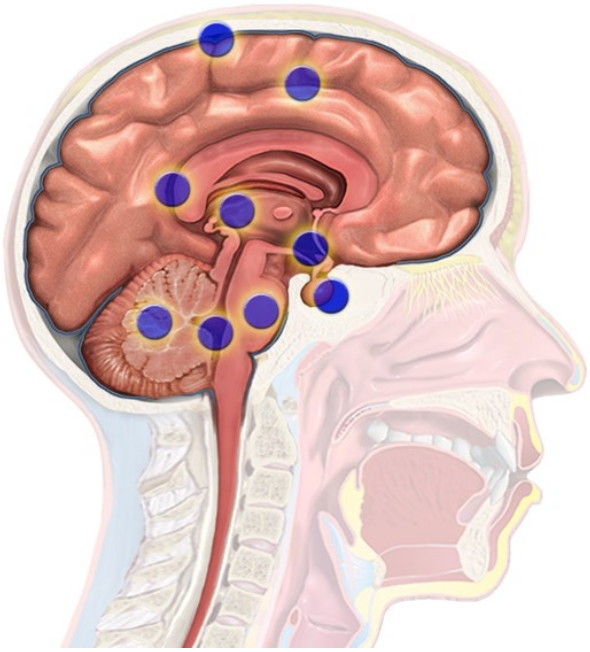


University of Bristol associate professor Kathreena Kurian said: “Many patients are treated with surgery and the aim is to safely remove as much of the cancer as possible.

“We wanted to see if using a fluorescent marker could help surgeons objectively identify high-grade tumour cells during surgery, allowing them to remove as much cancer as possible while leaving normal brain tissue intact.”

During the study, 99 patients with suspected high-grade gliomas were given a 5-ALA-containing drink for consumption before undergoing surgery. Prior studies showed that 5-ALA accumulates in fast-growing cancer cells.

Study surgeons then used operating microscopes to look for fluorescent tissue while removing the brain tumours. The removed tissue was tested for accuracy in a pathology lab.

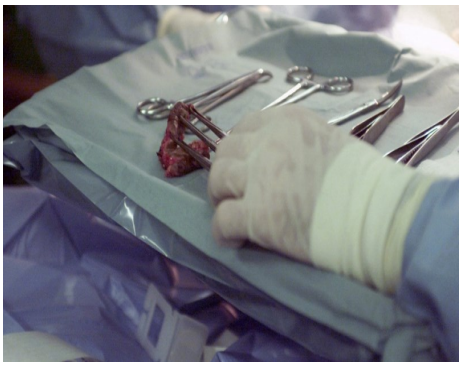
Data revealed that surgeons were able to see fluorescence in 85 patients, and 81 of these were confirmed by pathologists of having high-grade disease. One was observed to have low-grade disease and three could not be assessed.

Out of the 14 patients where surgeons did not see any fluorescence, seven tumours were subsequently analysed by pathology and all were found to have low-grade disease.

Findings from the study were presented at the 2018 National Cancer Research Institute (NCRI) Cancer Conference.

A larger study with more patients having low-grade disease is required to validate the fluorescent marker approach. The researchers intend to evaluate other types of markers for low-grade glioma cells.

Breaking point: should we be reusing more medical devices? By Elliot Gardner



A huge number of medical devices used by hospitals are labelled as ‘single-use’. As a cost-saving measure many hospitals rely upon ‘reprocessed’ single-use devices as a cheap yet safe alternative to buying expensive new equipment, but recent manufacturer efforts to halt reprocessing could lead to hiked hospital costs. Elliot Gardner finds out more. Since the 1980s, an increasing number of medical device products have been labelled ‘single-use’, designed to be used once, on one patient, and to then be discarded. The result was that products could be made more cheaply, and being used just once meant ensuring product sterilisation was no longer an issue. However, the practice has since become so widespread that some are asking whether single-use medical device manufacturing has become akin to planned obsolescence.

Planned – or built-in – obsolescence is the practice of designing a product with an artificially limited lifespan, so that it becomes obsolete after a certain amount of uses or a specific amount of time. The European Union (EU) has recently been cracking down on planned obsolescence in the consumer world, with Apple investigated in France over intentionally shortened iPhone lifespans. Single-use device (SUD) reprocessing for medical devices has become a widespread practice for non-invasive and minimally invasive devices, such as compression sleeves, tourniquet cuffs, scissors, forceps, scalpels and cardiac catheters, with dedicated companies cleaning, disinfecting and repurposing used SUDs. The process saves hospitals a significant amount of money, and is US Food and Drug Administration (FDA) approved when carried out correctly to specific guidelines. But, a growing amount of medical devices are now being designed with integrated technology, such as electronic chips, that inhibit reuse and reprocessing, eliminating any hospital cost-saving.

Reprocessing: a new lease of life

In reality, only a very small number of SUD devices are suitable for reprocessing. According to Thording it is an enormous engineering and regulatory challenge to receive FDA clearance, but while he comments that this is a good thing for patient safety, he says there is untapped potential in the medical device market. “There is still large potential for more single-used devices to be reprocessed, which can significantly add to the savings already achieved by hospitals,” he says. “However, for more single-use devices to be reprocessed there must be greater insistence on the part of the hospital that device costs need to come down and willingness in the reprocessing industry to make the investments.”

Reprocessing itself is a costly process, as a substantial amount of research and development needs to go into repurposing devices, but compared to investing in new technology, hospitals can save a significant amount of money by using reprocessed SUDs. Thording explains that “the investment in R&D and regulatory affairs associated with getting FDA clearance is substantial, and engineering teams often must work for three to four months to submit FDA clearance. “Yet it is still a lot less expensive than manufacturing the original device, which is why hospitals can realise substantial savings – some facilities more than $1m per year. Reprocessing is not a low-cost activity; however hospitals can still generate significant savings, as reprocessed devices cost 40%-60% less than a new device.”

But, because SUD reprocessing cuts into the profits of the associated original equipment manufacturers, some are implementing techniques to block advancements in the field. “[As an example,] sensor-enabled catheters in the cardiology space are extremely expensive, and manufacturers invest heavily in chipping and locking the devices so they can’t be reprocessed,” says Thording. “Thankfully some of the more advanced reprocessing companies are able to ‘break the locks’ and secure the hospital savings. Some of these catheters cost $2,000-$3,000 or more.”

There is no clinical rationale for such ‘locks’, and the result is simply more expensive devices that cost hospitals more money. And the problem isn’t set to dissipate – when new devices are developed, they are priced even higher than current technology, which will gradually be phased out, resulting in steadily rising prices and a monopolised market. But how can the problem be solved? According to Thording, rather than policymakers or manufacturers, the power lies with the hospitals themselves. “Hospitals are really in a position to make the biggest difference. When manufacturers push expensive devices to the hospitals, they have the ability to stand up and say ‘no’. “By refusing to purchase new products with few technical or clinical advancements and which are designed to prohibit reprocessing, hospitals can support this practice, thus reducing costs significantly.”

Tiny New Pacemaker Small Enough for Infants

Researchers at Children's National Health System, working with engineers from Medtronic, have created a pacemaker appropriately tiny enough to implant into infants. Measuring only one cubic centimeter, about the size of a large pill, it allows the device to be implanted inside the child in a minimally invasive fashion.

Currently, because of their size, pacemakers implanted into very small children either remain outside the body or require open surgery with large incision. The new pacemaker is so small that a one centimeter incision is all that's necessary to place it under the ribcage. The incision is used not only for the pacemaker, but through which the electronic lead is delivered through and attached to the pericardium. The procedure is much faster, less invasive, and results in less pain and quicker recovery for the children. Of course, the overall costs of the procedure and follow up treatment should be reduced as well.

"As cardiologists and pediatric surgeons, our goal is to put a child's health and comfort first," said Rohan Kumthekar, M.D., one of the docs at Children's National that worked on the new device and ways to implant it. "Advancements in surgical fields are tending toward procedures that are less and less invasive. There are many laparoscopic surgeries in adults and children that used to be open surgeries, such as appendix and gall bladder removals. However, placing pacemaker leads on infants' hearts has always been an open surgery. We are trying to bring those surgical advances into our field of pediatric cardiology to benefit our patients."

The research, so far, has been performed on infant models, but work is moving toward clinical trials that may end up revolutionizing how infant cardiac arrhythmias are treated.

Barco's New 27" 4K Surgical Monitor

Barco is releasing a new 4K surgical monitor that's designed to give clinicians a high fidelity live image during interventional procedures. The Barco MDSC-8427 has a 27" screen, providing a new, larger size over common 24″ and 26″ monitors.

The display features the company's smart image processing technology optimized to improve how live video comes through. A wide color gamut and built-in color calibration help to reproduce the surgical scene accurately. A wide viewing angle gives everyone around the operating room a clear picture with minimal distortion.

The MDSC-8427 can be mounted on a cart alone or in a dual-display configuration on a surgical boom.

It has a bunch of connectivity options, including DP, HDMI, 12G-SDI, Quad-SDI, and IP, so all kinds of devices like endoscopic cameras, computers, and such, can be connected to it.

"The new MDSC-8427 is a first in our next generation of 4K displays for the operating room," said Johan Stockman, Barco's VP surgical imaging, in a statement. "Careful consideration went into the new design. We wanted to create a display that combines surgical aesthetics with surgical precision. This new paradigm of display design shows how fine form can meet function in the operating room".

6 medical devices aiming to change the world in 2018- 2019

1. **EnduraGel-** It is estimated that approximately one in 50 people will have a brain aneurysm and, if left untreated, it will continue to grow and eventually burst, bleeding into the brain tissue and often causing disability or death. Given the seriousness of such a situation – and the lack of a treatment to prevent it – Dr Owen Clarkin and a team of researchers from Dublin City University developed something called EnduraGel. Made up of more than 80pc water, the technology is an injectable hydrogel for the treatment of aneurysms and is injected through very fine catheters – less than 1mm in diameter – into the affected area. With the inclusion of uniform amorphous microparticles – which have a very specific chemistry – microparticles predictably thicken the gel to allow controlled delivery of a highly biocompatible hydrogel into the aneurysm space. This should lead to a reduction in aneurysm recurrence and improved outcomes for patients.

2. CueStim- Those living with the central nervous system disorder called Parkinson's disease will be familiar with a number of daily challenges, among them being 'freezing of gait' (FOG), a feeling whereby their feet are stuck or glued to the floor, preventing them from moving forward. This is often triggered by cognitive factors such as distraction, anxiety or even passing through doorways or tight spaces. NUI Galway's medical device research centre, Cúram, has developed cueStim, a device worn across the patient's waist that electrically stimulates a change in the body, capable of triggering an exit from FOG or preventing an event occurring. The device is controllable through Bluetooth via a smartphone and will allow a person to get moving again.

3. Graphene biomaterial for heart health- Another amazing medtech breakthrough was achieved by a team of researchers at the Science Foundation Ireland-funded (SFI) AMBER Centre in Dublin, with a graphene-based biomaterial capable of regenerating diseased heart tissue. The material – comprising both protein collagen and the 'wonder material' graphene – becomes an electroconductive biohybrid, which enables it to enhance cell growth and, when electrical stimulation is applied, directs cardiac cells to respond and align in the direction of the electrical impulse. Because of the roughness of the material as a result of its graphene base, the biomaterial prevents infection by bursting the walls of bacteria, simultaneously allowing the heart cells to multiply and grow. For those with extensive nerve damage, current repairs are limited to a region only 2cm across, but this new biomaterial could be used across an entire affected area as it may be possible to transmit electrical signals across damaged tissue.

4. Electronic, disposable diagnostic chip- Dr Maria Daniela Angione of Trinity College Dublin has developed an electronic chip that has, as its active layer, a molecularly engineered biopolymeric material with tailored functionalities in a multi-array setting. The chip is integrated into a sensing platform and employed as a sensitive and disposable diagnostic tool. The need for such a device is paramount given that there is an urgent demand for availability of rapid, portable and accurate diagnostic techniques that can be used to control epidemics, among other things. Unlike other more expensive diagnostic kits, Angione's disposable chip is easy to manufacture rapidly, on top of being cheap to make. Right now, the chip is already at the clinical trials stage and, given that it has already attracted interest from world-leading pharmaceutical companies, it could be available on the market in the next three to five years.

5. Delphi: The brain damage detector powered by AI- The SFI-funded Irish Centre for Foetal and Neonatal Translational Research (INFANT) is one of the foremost leaders in infant care in Europe, and earlier this year received €570,000 to further develop its smart brain monitoring system. Called Delphi, the artificial intelligence (AI) technology will help to detect the severity of brain damage as soon as possible, enabling early intervention and appropriate therapies tailored to each individual baby. Brain injury at birth can have a devastating effect on a life, possibly leading to permanent disabilities such as cerebral palsy, epilepsy or learning difficulties. That is why early detection of neonatal brain injury can be vital to improve outcomes and reduce the impact of brain damage. While existing techniques track a baby's vital signs, this electrical monitoring system will analyse neonatal electrical brain patterns and combine this data with other vital sign information to provide an overall brain health index for the baby.

6. Prima bionic vision system- Having so far successfully restored central vision in three patients with age-related muscular degeneration, the tiny device is implanted beneath a person's retina. The generated electrical impulses are then sent back to the brain via the optic nerve, thereby restoring a substantial amount of vision.