CVD: more attention required for women

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This was the theme for the 29th World AIDS Day on December 1st. Substantial progress has been made in developing and disseminating effective antiretroviral therapy (ART) for people diagnosed with HIV/AIDS. Indeed for the around 19 million people globally currently taking ART, the disease can be considered a chronic condition, albeit one that requires careful and continuous monitoring. Huge strides have also been made in reducing transmission of infection. Concerted efforts by national programmes and development partners have promoted safe sex and condom use (though not without some controversy and pontification about the value of celibacy) with studies showing that this reduces HIV transmission by 85%. Medical male circumcision, which reduces the risk of heterosexual men becoming infected by an estimated 60%, is also becoming acceptable in high risk countries where performance of this operation is not the cultural norm. The efficacy of pre-exposure prophylaxis (PrEP) for subjects at a high risk of becoming infected with HIV, such as those with infected sexual partners, has been demonstrated and is advocated in many countries. Vertical transmission, formerly accounting for up to 45% of babies acquiring the infection from their HIV positive mother, can now be prevented by prescribing ART to both mother and child during pregnancy, labour, delivery and breastfeeding. And programmes have been set up both to educate people who inject recreational drugs about the risks of HIV infection and to provide sterile injecting equipment to reduce the risk. However an enormous obstacle blocking the goal to end the AIDS epidemic by 2030 is that according to the WHO an estimated 14 million people (around 40% of all people with HIV) are unaware that they are infected with the virus. Not only are they not receiving ART, they are also unwittingly infecting others. Highly accurate rapid diagnostic tests or enzyme immunoassays are available, but many people are either geographically distant from such testing services or are too diffident to access them. So it is wonderful news that, according to WHO, twenty-three countries have so far approved policies for HIV self-testing, and many others are aiming to follow suit. Studies have shown that with such testing, performed in the privacy of one’s home with results available after 20 minutes, the number of people tested doubles. While there is great need to distribute kits to the most high risk areas, how many of us currently living in lower risk countries are celibate until we meet our life partner who has also been celibate prior to meeting us?

Frances Bushrod
Ph.D.

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Cardiovascular disease (CVD) is by far the leading cause of death in industrial countries. However, there are significant differences by continent/region, and even more so in terms of gender. There have also been some major recent changes in the evolution of CVD, compared to another major source of mortality - cancer. Once again here, there are some female-specific factors of interest.

The US and Europe
For Europe as a whole, latest figures from the World Health Organization (WHO) show CVD accounting for 45% of deaths, approximately the same level as the US, where the figure is 44%.
Cancer is the second largest cause of death in both the US and Europe. However, a significant margin separates its mortality impact from CVD.
There are also differences between the US and Europe in the relative impact of CVD versus cancer. In the former, cancer accounts for 32% of deaths (or almost three-fourths of that from CVD). In Europe, the share of cancer is less than half CVD deaths. The WHO data cover 52 countries in Europe, including all members of the European Union (EU).

A man’s illness?
Traditionally, heart disease was thought of as a 'man's' illness, although approximately the same number of women and men died each year of heart disease in the US and the EU.

Cardiovascular disease - more attention required for women

Cardiovascular disease (CVD) is by far the leading cause of death in industrial countries. However, there are significant differences by continent/region, and even more so in terms of gender. There have also been some major recent changes in the evolution of CVD, compared to another major source of mortality - cancer. Once again here, there are some female-specific factors of interest.

Indeed, gender issues in CVD deaths are significant, both in the US and Europe. Although a higher number of males die in the US from CVD as compared to females, the share of CVD as a cause of death is only slightly higher in American women (44.3% vs. 43.4%).
In Europe, the gap is far more dramatic, with CVD accounting for 51% of deaths among women and 42% among men.

Cancer replaces CVD as leading cause of death in northern/western Europe
There are nevertheless considerable divergences across European countries in CVD mortality as well as in recent changes in death rates due to CVD.
In ten advanced EU countries, more men now die from cancer than CVD. These countries are Belgium, Denmark, France, Italy, Luxembourg, the Netherlands, Portugal, Slovenia, Spain, and the UK. The case is the same for an EU non-member, Norway. Conversely, the highest numbers of deaths from CVD tend to be seen in Eastern European countries.

Raising awareness
One immediate priority for health professionals and policy makers is to raise awareness about CVD and women. Currently, ‘Red Day’, ‘Go Red for Women’ and ‘Women at Heart’ campaigns by professional societies and patient groups in the US and Europe have sought to boost awareness further, and do this faster.
The reasons for this are evident. In the US, just over half of women surveyed recognize heart disease as their Number 1 killer, according to a 12-year follow-up study published in 2010 in ‘Circulation: Cardiovascular Quality Outcomes’.
Nevertheless, the situation had improved significantly compared to the baseline year of 1997 when only 30 percent identified heart disease as their Number 1 killer, according to a 12-year follow-up study published in 2010 in ‘Circulation: Cardiovascular Quality Outcomes’.

CVD protection in younger women
The reasons for believing CVD was a ‘man’s’ disease (as mentioned above) were not simply hearsay. Women are protected by their hormones against CVD during their child-bearing years. However, this protection is lost as soon as they enter menopause. The net result is that women tend to get CVD at an age about 10 years more than men.
To complicate matters, CVD symptoms
in women are sometimes different from those in men. This adds to under-recognition of heart disease in women. For example, heart attack symptoms in women such as chest pain can be less profound than in men. Women may only feel an uncomfortable pressure in the chest centre which occurs sporadically or lasts a few minutes, or experience pain in one or both arms, their neck, back or stomach, along with shortness of breath and accompanied by a cold sweat, nausea, vertigo and weakness. Moreover, it has also been established that women have a higher prevalence of silent ischemia and of unrecognized myocardial infarction than men.

As a result, both women and physicians need to be trained to recognize female-specific symptoms.

**HRT and CVD risks**

One of the beliefs which has endured for several decades is that the estrogen drop during menopausal transition induces increased post-menopausal CVD risk in women, probably through harmful changes in CVD risk factors. One of the findings supporting this conclusion was that women who reached menopause before the age of 40 had a two-year lower life expectancy than women with a normal or late menopause.

Indeed, circulating estrogens do have a regulating effect on several metabolic factors, such as lipids, inflammatory markers, and the coagulation system. This was the reason for the popularity of Hormone Replacement Therapy (HRT), or exogenous estrogens. Until recently, HRT was recommended for use in post-menopausal women to limit CVD risk. The hypothesis was supported by several observational studies, but could not be conclusively proved in large randomized trials. Instead, HRT was shown to increase CVD event rate in older (>60 years) post-menopausal women. As a result, clinicians now recommend a careful evaluation of the risk/benefit of HRT replacement for preventing CVD, and the use of HRT has declined.

**Concurrent risk factors for women**

Other, concurrent risk factors include hypertension, hypercholesterolemia, hypertriglyceridermia and metabolic syndrome. These increase in women over the age of 45, or a few years before menopause. For example, systolic blood pressure rises steeply in older women compared with men. Hypertension is associated strongly with a higher prevalence of left ventricular hypertrophy and diastolic heart failure (HF). Studies have shown that even borderline hypertension (less than 14/9 cm Hg) causes more cardiovascular complications in females than in men.

At younger age, the prevalence of hypercholesterolemia is lower in women than men, but at over 65 years age, mean LDL-cholesterol levels are higher in women. Hypertriglyceridermia and low HDL-C levels are far more important risk factors for CVD in women than for men, as discussed below.

**Type 2 Diabetes**

Nevertheless, of the biggest areas of concern is Type 2 diabetes mellitus, which poses a much higher greater risk for cardiovascular complications in women than in men.

One meta-analysis of 37 prospective cohort studies published in the 'British Medical Journal' in December 2006 found mortality risk to be 50% higher in women with diabetes compared with men. In addition, it has been shown that Type 2 diabetes is a potent, independent risk factor for heart failure in women. However, this cannot be fully explained by coexisting cardiovascular risk factors or previous myocardial infarctions.

**Lifestyle factors**

Lifestyle changes also play a role. Obesity, for example, is a major CVD risk factor. It is more prevalent in men under the age of 45, but has begun to increase with advancing age in women, reducing the gap with time, and often reversing it in older women. This was one of the findings of a report called 'European Heart Health Strategy: Red Alert on Women's Hearts', published in 2009 by the EuroHeart Project, funded by the EU Commission and conducted jointly by the European Heart Network (EHN) and the European Society of Cardiology (ESC).

**Women and clinical trials**

The case of HRT, where findings from large randomized trials reversed those of observational studies, has brought another priority to the forefront, namely to increase the presence of women in CVD clinical trials.

The EU-funded EuroHeart project (see above) found women to be under-represented in many trials, even where important gender differences are present within most areas of heart disease. The proportion of women enrolled was 27–41%, even though the female prevalence of clinical conditions under study in the general population was similar for both men and women.

The case in the US is similar, in spite of a legal requirement that research funded by tax receipts must include women and minority groups. One study found that trials by the National Heart Lung and Blood Institute, attached to the National Institutes of Health (NIH), enrolled 38% women for the years 1965-1998. This fell further to 27% in 1997-2006. Furthermore, only 13 of 19 studies analysed gender differences.

Apart from the traditional belief that CVD was a ‘man’s’ disease, some experts believe that cost may also have been a consideration in under-recruitment of women, whose hormonal fluctuations tend to complicate pharmacokinetic and pharmacodynamic analysis.

Nevertheless, given the growing burden of CVD in middle-aged women relative to men, it is evident that greater gender-specific cardiovascular research is required to adapt existing guidelines for better cardiovascular health in women.

**Pregnancy as stress test for future CVD**

There is intriguing evidence that pregnancy might be a useful ‘stress-test’ for future CVD risk. Hypertensive disorders in pregnancy have been shown to be predictors for CVD events in later life. Impaired glucose tolerance and gestational diabetes in pregnancy are also female-specific risk factors for the development of diabetes and metabolic syndrome in young women. One of the conditions under close scrutiny is pre-eclampsia, which is characterized by high blood pressure and large amounts of protein in the urine. Although the etiology of pre-eclampsia has yet to be established with certainty, the hyperlipidemia of normal pregnancy (elevated total cholesterol and triglycerides) becomes more extreme in women developing the condition. The sharp growth in triglycerides leads to increased production of LDL (up to 3-4 times more than in a ‘normal’ pregnancy), along with reduced HDL-C. Together, this contributes to endothelial dysfunction.

One ongoing trial at Brigham and Women’s Hospital in Massachusetts seeks to demonstrate an association between pre-eclampsia during pregnancy and altered blood vessel function and abnormal hormone levels in later life. The trial, known as ‘Preeclampsia: A Marker for Future Cardiovascular Risk in Women’ commenced in 2012. Its results are expected to be published in the near future.
Microbotics (or micro-robotics) is a term that describes the emerging field of intelligent, miniaturized robotics. Biomedical microbotics offers a glimpse of a future where tiny, untethered devices (smaller than 1 mm in size) are inserted into patients via natural orifices or through extremely small incisions. Thereafter, they navigate autonomously through the bloodstream or inside fluids such as the vitreous humour in the eye cavity, targeting areas of interest with extreme precision.

Microbots aid medical professionals in earlier diagnosis and more effective treatment of diseases, delivering drugs to targets in the body, removing plaque deposits in the arteries or excising and repairing tissue at cellular levels – which are too small for direct manipulation. One of the most exciting possibilities offered by medical microbotics is to enable wholly new therapies which have yet to be conceived, simply because of the lack of small, precision-access equipment.

MEMS and MST
Biomedical microbotics seeks to combine established techniques of robotics such as motion control, path planning, remote operation and sensor fusion with new tools enabled by miniaturized MEMS (Micro-Electro-Mechanical-Systems) technology, as it was known in the US; the European equivalent was micro-systems technology (MST). Microbots are one outcome of the rapid growth in microcontroller capabilities in the 1990s, alongside the appearance of MEMS and development of high-efficiency Wi-Fi connections. MEMS, used for example in airbag sensors, opened the way for low-cost, low power consumption applications, while Wi-Fi allowed microbots to communicate and coordinate with other microbots.

Apart from coping with challenges on power and stretching the limits of material science, considerable research has also recently been focused on microbot communication. A good example of this is a 1,024 microbot ‘swarm’ at Harvard University which ‘spontaneously’ assembles itself into various shapes.

First endoscopic capsules date to mid-1990s
One of the first medical applications of microbot technology was in the gastro-intestinal (GI) tract. The microbotic intervention in the mid-1990s, by an Italian team, was published in the book ‘Sensors and Microsystems’ (World Scientific Publishing Co, Singapore, 1996) and consisted of endoscopic capsules which were simply swallowed by the patient. They captured video images as they moved naturally through the GI tract using in-built imaging and illumination systems.

In 2012, the U.S Food and Drug Administration (FDA) authorized a much smaller swallowable technology, namely a single-square-millimeter silicon circuit embedded inside a pharmaceutical pill, and produced by Proteus Digital Health. Other researchers have proposed robotic systems with autonomous locomotion and biopsy capabilities. Some are tested, with models already on the market.

Sequel to MIS
In many senses, medical microbotics is a natural sequel to minimally invasive surgery (MIS), which has, since the 1980s, represented one of the key developments in medical technology. MIS resulted in a leap in patient recovery time and a sharp reduction in trauma. Microbotics is expected to go even further, into what seems eerily close to the realms of science fiction.

From microgrippers to artificial bacteria
For example, researchers at Johns Hopkins University in Baltimore have developed microgrippers. The ‘arms’ of these star-shaped devices, less than a millimeter in size from one tip to another, are temperature-sensitive grippers and react when exposed to body heat.

In sufficient numbers, they provide a less-invasive way to screen for colon cancer than a colonoscopy – which currently requires taking dozens of samples with forceps.

Moreover, when required, the arms can be closed around tissue, thereby performing what is effectively an automated biopsy.

One of the most dramatic demonstrations of microbotic miniaturization is at the Swiss Federal Institute of Technology in Zurich (ETH Zurich), where artificial bacterial flagella (ABF), about half as long as the thickness of a human hair, have been developed (See also page 23). In initial experiments, ETH Zurich researchers have already made the ABFs transport polystyrene micro-spheres.

3D printing converges with miniaturization
New 3D printing technologies are now converging with miniaturization to open other frontiers for microbots. For example, the Nanoengineering Department at the University of California, San Diego (UCSD) have created 3D printed microbots in the form of a small fish (microfish), for sensing and detoxifying toxins. The microfish, with dimensions of just 120 x 30 microns, are designed for testing in applications such as directed drug delivery and microbot-assisted surgery.

UCSD researchers added a polymer nanoparticle (polydiacetylene) to capture pore-forming toxins, such as those found in the venoms of sea anemones, honeybees and
spiders, in order to establish that the microfi sh could be both detoxification systems and toxin sensors. When the nanoparticles bound with toxin molecules, they became fluorescent and emitted red-coloured light, whose intensity correlated to their detoxification abilities.

**Key design and engineering challenges**

Technologically, key challenges faced by microbotics include design issues for in-vivo applications. The microbots need to be small and reliable, and equipped with all necessary tools and sub-systems on board. They must be inserted into, steered and removed from the target area of a patient’s body, non-invasively. All this means a high degree of integration. MEMS devices were traditionally designed as components for insertion into larger electro-mechanical systems, along with physical interfacing for power supply and data input-output. In contrast, sub-millimetre sized medical microrobots must be manufactured in their final, operational and deployable form.

One emerging technology which seeks to address such challenges is known as Hybrid MEMS. It seeks to combine individual MEMS components through a robotic micro-assembly process, which brings together different manufacturing technologies such as lithography, nanosystems LIGA, Micro-Opto-Electro-Mechanical Systems (MOEMS) and 3D printing.

**Materials and power**

Apart from these kind of structural and miniaturization issues, other challenges of a robotic operation at microscopic scale consists of biocompatibility and power. The former has sought to be addressed with new generation MIS and implantable systems. However, few could underestimate the constraints of working in the human body – not only in terms of tracking precisely where a microbot is (especially in the vicinity of vital organs), but also making sure that it is neither toxic nor poses a threat of injuring tissue, while ensuring that it degrades safely or exits the body after completing its mission.

A key condition for effectiveness, therefore, is that microbots must have similar ‘softness’ as biological tissues. This is where the difference with traditional robots is most stark. Rather than cogwheels and cranes, pistons and levers, designers of microrobots are inspired by the tentacles of an octopus.

The provision of power for moving the microbot, gathering/transferring useful information and taking interventional action when necessary, is even more challenging. Microbots can use a small lightweight battery source or scavenge power from the surrounding environment in the form of vibration or light energy.

The Proteus ingestible pill authorized by the FDA in 2012 contains two electrode materials
which become electrically connected when the circuitry comes into contact with the stomach’s gastric juice. For 5 or 10 minutes, the chip has enough power to modulate a current, transmitting a unique identifier code that can be picked up by an external skin patch.

An alternative to an on-board battery is to power the robots using externally induced power. Examples include the use of ex-vivo electromagnetic fields, ultrasound and light to activate and control micro robots. Researchers are now also focusing efforts on wireless power transfer, such as using radio waves from outside the body to generate electricity. However, this approach too faces limitations at small scales. To be effective, a microbot would need an antenna, which needs to be large enough to collect a meaningful amount of energy and also stay fairly close to the source.

**Magnetic actuation**

Magnetic actuation technology has been applied in biological systems for several years, in areas such as targeted drug delivery where magnetized carrier particles coated with chemical agents are concentrated on specific target regions of the body using external magnetic fields. Magnetic beads of a few microns diameter have also been successfully steered inside cells to manipulate individual DNA molecules.

At the UC San Diego 3D printed microbots project referred to above, the microfish are powered by nanoparticles with hydrogen peroxide being the power source, while magnets provide steering.

**Molecular motors**

Some experiments have focused on using molecular motors for microbots. These molecular motors are the sensing and actuation systems ubiquitous in biological systems. They have been adapted over millions of years and play vital roles in processes such as cell motility, organelle movement, virus transport.

From a practical viewpoint, interest in such molecular machines for the next generation of hybrid biomotor sensing and actuation systems will be driven by biomedicine as well as related applications such as microfluidics (e.g. for nano-propellors) and chemical sensing.

Nevertheless, despite some signs of progress, the use of molecular motors in hybrid living-synthetic engineered systems remains several years away.

**Artificial bacterial flagella (ABF)**

The bulk of research into biological motors as power sources are focused on F1-ATPase and artificial bacterial flagella (ABF). ABF, which look like E. Coli, are 25 to 60 μm in length, about half the thickness of a human hair and the smallest artificial bacteria created to date. They can also swim at a speed of up to one body length per second, close to their natural counterparts, by virtue of external actuation of their whip-like tails (flagella). Crucially, they do not have moving parts nor do they require their own energy to swim.

ABFs are manufactured through a Hybrid MEMS process by vapour-depositing several ultra-thin layers of indium, gallium, arsenic and chromium onto a substrate, followed by ribbon patterning using lithography and etching. The ribbons curl into a spiral once they are detached from the substrate, due to differences in the molecular lattice structures of the various layers.

The size of the spiral, and the scrolling direction of the ribbon, can be determined in advance. The latter is due to the presence of nickel in the ‘head’ of the microbot. Nickel is soft-magnetic, in contrast to the other (non-magnetic) materials used, and enables the spiral-shaped ABF to move forward/backward as well as upward/downward within a rotating magnetic field generated by several coils, towards which the head constantly tries to orientate itself and in whose direction it moves. Steering the ABF to a specific target is achieved by adjusting the strength and direction of the rotating magnetic field.

Nevertheless, the precise placement of microbots is crucial in order to avoid a clinician’s nightmare – to place something solid in the blood, and trigger clots. Even ultra-sophisticated microbots which can follow a change in temperature, may not be able to fight the powerful currents in the bloodstream.

Europe is playing a major role in microbotics, with ETH Zurich considered a world leader in the field. One of its first biomedical microbots aims at ophthalmic operations on the retina. Drugs to treat the retina can now be injected into the eye, where they diffuse. However, only a fraction of the dose reaches its target. Microbots could potentially deliver drugs in a more targeted manner, reducing doses as well as side effects.
Top 10 health technology hazards for 2017

The safe use of health technology—from basic infusion pumps to large, complex imaging systems—requires identifying possible sources of danger or difficulty with those technologies and taking steps to minimize the likelihood that adverse events will occur. This list will help healthcare facilities do that.

Produced each year by ECRI Institute’s Health Devices Group, the Top 10 Health Technology Hazards list identifies the potential sources of danger that it believes warrant the greatest attention for the coming year. The list does not enumerate the most frequently reported problems or the ones associated with the most severe consequences—although such information is certainly considered in the analysis. Rather, the list reflects the Health Devices Group’s judgment about which risks should receive priority now.

All the items on the list represent problems that can be avoided or risks that can be minimized through the careful management of technologies. Additional content provided with the full article, which is available separately to members of certain ECRI Institute programmes, provides guidance to help manage the risks. In this way, the list serves as a tool that healthcare facilities can use to prioritize their patient safety efforts.

International Hospital presents here the abridged version of ECRI Institute’s 2017 Top 10 list of health technology hazards which is available as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems.

1. Infusion errors can be deadly if simple safety steps are overlooked

Most large-volume infusion pumps incorporate safety mechanisms for reducing the risks of potentially deadly intravenous (IV) infusion errors. These mechanisms have greatly improved infusion safety, but can’t eliminate all potential errors. And the mechanisms themselves have been known to fail. ECRI Institute continues to learn about and investigate incidents of infusion errors involving pump or administration set failures, staff unknowingly defeating a safety mechanism, or incorrect infusion programming. Such errors—particularly those that result in the uncontrolled flow of medication to the patient, known as “IV free flow”—can lead to patient harm and even death.

In many of these incidents, harm could have been averted if staff had:
- Noticed signs of physical damage to infusion pump components
- Made appropriate use of the roller clamp on the IV tubing
- Checked the drip chamber beneath the medication reservoir for unexpected flow

Once commonplace, these simple practices are now often overlooked—perhaps because staff implicitly trust the pump’s advanced safety features.

2. Inadequate cleaning of complex reusable instruments can lead to infections

The use of contaminated medical instruments can lead to disabling or deadly patient infections or instrument malfunctions. Outbreaks associated with the use of contaminated duodenoscopes—such as those that caused headlines in recent years—illustrate the severity of this issue. But duodenoscopes are not the only devices that warrant attention. ECRI Institute has received reports involving a variety of contaminated medical instruments that have been used, or almost used, on patients.

Complex, reusable instruments—such as endoscopes, cannulated drills, and arthroscopic shavers—are of particular concern. They can be difficult to clean and then disinfect or sterilize (i.e., reprocess) between uses, and the presence of any lingering contamination on, or in, the instrument can be difficult to detect.

Often, we find that inattention to the cleaning steps within the reprocessing protocol is a contributing factor. Healthcare facilities should verify that comprehensive reprocessing instructions are available to staff and that all steps are consistently followed, including precleaning of the device at the point of use.

3. Missed ventilator alarms can lead to patient harm

Ventilator alarm management challenges complicate efforts to prevent patient harm resulting from missed alarms. Ventilators deliver life-sustaining therapy, and a missed alarm could be deadly. Concerns include:
PATIENT SAFETY

• Alarm fatigue—in which staff become overwhelmed by, distracted by, or desensitized to the number of alarms that activate.
• Alarm notification failures—in which alarms are not effectively communicated to staff.

These concerns, and the ways to manage them, are similar to those that exist with physiologic monitoring systems, which we have addressed in previous Top 10 Health Technology Hazards lists. Ventilators, however, pose some unique challenges. For example: Collecting and analysing ventilator alarm data can be difficult, making it harder for hospitals to identify where their vulnerabilities lie. And the options for supplementing a ventilator’s alarms—so that the alarm can be noticed outside the patient’s room, for example—are limited.

As a result, ventilators will require different methods for studying the problem and different strategies for addressing it.

4. Undetected opioid-induced respiratory depression

Patients receiving opioids—such as morphine, hydromorphone, or fentanyl—are at risk for drug-induced respiratory depression. If not detected, this condition can quickly lead to anoxic brain injury or death. Thus, spot checks every few hours of a patient’s oxygenation and ventilation are inadequate.

Drug-induced respiratory depression is of particular concern for patients receiving parenteral and neuraxial opioids in medical-surgical and general care areas. However, it is also of concern for hospital or ambulatory surgery/endoscopy facility patients receiving opioids during procedural sedation and while in the postanesthesia care unit (PACU).

Even if they are otherwise healthy, such patients can be at risk if, for example:

• They are receiving another drug that also has a sedating effect
• They have diagnosed or undiagnosed sleep apnea or other conditions that predispose them to respiratory compromise
• They receive more medication than intended—for example, because of a medication error

ECRI Institute recommends that healthcare facilities implement measures to continuously monitor the adequacy of ventilation of these patients and has recently tested and rated monitoring devices for this application.

5. Infection risks with heater-cooler devices used in cardiothoracic surgery

Heater-cooler systems have been identified as a potential source of nontuberculous mycobacteria (NTM) infections in heart surgery. The likelihood of infection during surgery is not fully understood. However, these infections can be life-threatening and have resulted in patient deaths.

Heater-cooler systems are used in cardiothoracic surgeries to warm or cool the patient by extracorporeal heat exchange with the patient’s blood during heart-lung bypass procedures. These devices circulate warm or cold water through a closed circuit. Water in the circuit is not intended to come into direct contact with the patient or the patient’s circulating blood. However, aerosolized water carried by air from the exhaust vents of contaminated heater-coolers has been suggested as a cause of NTM infections.

Initial reports focused on one specific model of heater-cooler, but models from other suppliers could likewise become contaminated under certain circumstances and if appropriate precautions are not taken.

The U.S. Food and Drug Administration has issued recommendations for all heater-cooler devices; they are intended to help prevent and manage device contamination risks and to minimize patient exposure to heater-cooler exhaust air, which may contain aerosolized contaminated water.

6. Software management gaps put patients, and patient data, at risk

Inadequate medical device software management can delay a facility’s responses to safety alerts, allow cybersecurity vulnerabilities to be exploited, and impact patient safety.

Maintaining a central repository of up-to-date and easily retrievable information about the software versions used in a healthcare facility’s medical devices is challenging. But failure to do so leaves the facility ill-prepared to effectively manage software updates and alerts.

Mismanagement of software updates and alerts can adversely affect patient care or
impact patient/staff safety— for example, by:
- Causing downtime or otherwise affecting the performance of medical devices or interconnected systems
- Delaying identification and implementation of key software updates, including those that address safety concerns
- Allowing cybersecurity vulnerabilities to persist, possibly leading to lost, stolen, or inaccessible data

To address the hazard, a healthcare facility should verify that its computerized maintenance management system (CMMS) provides the capabilities needed to effectively track software versions for its medical devices and systems. In addition, the facility should establish practices for keeping the software version information in the CMMS current and complete.

7. Occupational radiation hazards in hybrid ORs

Clinicians working in hybrid ORs—operating suites that include built-in x-ray imaging systems—are at risk of unnecessary occupational exposures to ionizing radiation if appropriate precautions are not consistently followed. Particular concern exists in this environment because hybrid OR staff may be less knowledgeable than radiology and interventional radiology staff about the risks of radiation exposure, and they may be less experienced at taking appropriate precautions. In addition, with the increasing reliance on X-ray imaging systems during complex OR procedures, an increasing number of specialists and staff members who previously would have had little exposure to ionizing radiation during surgeries are now participating in these procedures. Because long-term exposure to radiation increases the risk of cancer, it is imperative that hybrid OR staff obtain OR-specific radiation protection training, that they put this training into action, and that available tools and methods be used to minimize radiation exposures.

8. Automated dispensing cabinet setup and use errors may cause medication mishaps

Poor choices made when setting up automated dispensing cabinets (ADCs), as well as mistakes made during use, can lead to harmful medication errors. Medication errors and near misses associated with ADCs have been traced to insufficient planning when setting up medication drawers, as well as errors made when stocking them. Incidents reported to ECRI Institute include: the presence of the wrong drug or dose in an ADC pocket, the availability of high-alert drugs in unsecured areas of the cabinet, and the unavailability of needed drugs. Problems such as these have resulted in delays in patient care and the administration of incorrect drugs or drug concentrations, leading in some cases to severe patient injury.

Careful planning is required to determine:
- Which medications should be available in a particular care area
- Where in the drawer a medication should be placed (e.g., to reduce the chances that one drug will be mistaken for another)
- Whether locked pockets or other control mechanisms should be used to further restrict access to certain medications
9. Surgical stapler misuse and malfunctions

Problems associated with the use and functioning of surgical staplers can lead to intraoperative hemorrhaging, tissue damage, unexpected postoperative bleeding, failed anastomoses, and other forms of patient harm.

Surgical staplers require meticulous technique to operate, and problems during use are not uncommon. The U.S. Food and Drug Administration receives thousands of adverse event reports related to surgical staplers each year, and ECRI Institute likewise consistently receives reports of surgical stapler problems. Although severe injuries are infrequent, they do occur. We have investigated fatalities and other cases of serious patient harm.

Commonly reported problems include: misfiring or difficulty in firing, misapplied staples, unusual sounds during firing (which can indicate a damaged or malfunctioning mechanism), and tissue becoming “jammed” in the mechanism.

To prevent patient harm, users must be familiar with device operation, they must carefully select the appropriate staple size for the patient and tissue type, and they must be alert to the signs that the stapler may not be functioning as intended.

10. Device failures caused by cleaning products and practices

The use of cleaning agents or cleaning practices that are incompatible with the materials used in a medical device’s construction, or that are otherwise inappropriate for the device’s design, can cause the device to malfunction or to fail prematurely, possibly affecting patient care. Specifically:

- Repeated use of incompatible cleaning agents can damage seals, degrade lubricants, and cause fluid intrusion. This can result in damage to electronics, power supplies, and motors.

Because there is no single cleaner or cleaning process that will work with all devices, hospitals must stock and use multiple cleaning products and familiarize staff with device-specific cleaning methods—tasks that pose a significant burden. Nevertheless, failure to do so can lead to ineffective cleaning (a potentially deadly circumstance), as well as excessive component breakage and premature equipment failures (which can affect patient care and be a significant financial burden).

For nearly 50 years, ECRI Institute, a nonprofit organization, has been dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes are best, all to enable providers to improve patient care.

More than 5,000 hospitals, health systems, public and private payers, ministries of health, associations, and accrediting agencies worldwide rely on ECRI Institute to deliver trusted medical information. Globally, ECRI helps organizations improve patient safety, and reduce healthcare costs through independent, evidence-based research and informed judgment.

To contact ECRI and be connected with your regional office, please email info@ecri.org.uk.
Sustainability Roadmap and Its Implication for the World
Walt Vernon, United States

One of the keynotes of the Affordable Care Act is the focus on population health, and incentives for healthcare organizations to keep their community members healthy and OUT of the health intervention system.

Healthcare organizations are beginning to recognize the connections between the health of their environment, the health of the communities, and their own fiscal health. At the same time, these same organizations are under intense pressure to reduce costs, which inevitably means minimizing the consumption of costly resources and the degree to which such resources go unused, and cost money to be hauled away.

This presentation taught how the AHA Sustainability Roadmap, a community-inspired set of tools, continues to grow and meet the goals of community health improvement.

Specifically, it presented how waste contracting holds vendors accountable to ongoing key performance metrics and if you are not taking advantage of waste contract specifications with minimization, training and education, and performance improvement in mind, what are your risks? For starters, 1) you are likely spending too much money; 2) you may not be taking advantage of services like training and education; 3) you may not be getting regular waste generation reports; 4) you probably are not hitting minimization and recycling goals!

This talk explored tools and opportunities available through this program and discussed new developments in other areas of sustainability as well as strategies for implementation.

Electronic Death Certificate (EDC) – A Decisive Step towards Electronic Health Record
Huma Saeed, Pakistan

Death certificate (DC) is crucial document of patient's medical record and considering this fact, electronic death certificate (EDC) was introduced. The objective was to assess the use of EDC system. Salient features favoring the concept were: no data loss due to fading of handwritten death certificates, eliminating chances of errors, time saving practice, and establishment of a digitized format for long term record keeping. In April 2013, the idea was shared with stakeholders who endorsed it and ensured full participation. Modifications were made in the certificate and test server designed to capture demographics and other necessary information from the registration system. Manual entry related to only two fields i.e. “cause of death” and “other significant condition.” Spellcheck option was provided. On October 22, 2013 a demo was given at HIMS committee meeting, a forum comprising of representation from all clinical services.

Following extensive discussions and adjustments, training sessions were conducted in April 2014 to familiarize users. EDC was formally launched in August 2014. Feedback was elicited from users via a questionnaire, especially with regard to comparison with the old format. Responses were as follows: 79.35% respondents observed that electronic version had enhanced the quality of death certificate, 77.33% stated it was a time saving step, 70.32% appreciated it as a user friendly process and significant number of respondents (85.16%) recommended the electronic version. DC has immense legal value and is required for many medico-legal purposes. Changing to electronic format has enhanced its quality, efficiency and also saved user's time.

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Mutua Terrassa (MT) is a non-profit health and social care organization serving a population of around 900,000 inhabitants in Catalonia (Barcelona, Spain), and was founded in 1900 as a Mutual Insurance Company for occupational accidents. The Entity has been gradually adapting to the needs of the community and strives to serve and offer a wider range of services, all related to health, well-being and personal autonomy. Currently, MutuaTerrassa activities involve: healthcare (University Hospital and a network of community care services), social healthcare, insurance, healthcare logistics and healthcare research and teaching.

The real strength of MT are people and their knowledge, a large team of nearly 4,000 qualified people, with more than 150 disciplines within the health and social care sector, but also in administrative functions, technical, logistic and management. But we would not be who we are disregarding the 1,500 trainees we embrace and help in their training career.

This is a challenging period for health and social care sector. As a global organization, MT is an active structure in constant change and adaptation. We have the aim at managing the complexity and the multiple interactions between the protagonists of the organization and among healthcare (acute care, primary care, sub-acute care, and social care).

The strategy of the MT knowledge management is to focus on the multi-disciplinary approach of achieving an organizational objective by making the best use of knowledge. “Always focusing all efforts on providing the best care”

Strategic directions:
1. Creating an Effective environment for the use of knowledge: MT Health University Campus.
2. Sharing and reapplying experimental knowledge within the organization and with our stakeholders.
3. Establishing mechanisms to facilitate the improving access to health and social care information.
4. Translating knowledge to effective actions.

Finally, the key point of the KM MutuaTerrassa strategy is to manage people and its variability. Managing people means to place each professional where there can be more useful in order to get the most professional goals with the highest satisfaction in terms of professional and organizational goals.

Mutua Terrassa University Campus
Health: Key figures (2015)

4000 qualified people
1460 trainees
263 postgraduate training
157 high specializations (doctors, psychologists, pharmacists, midwives, nurse’s mental health)
44,119 hours of continuing education
Typically, initiatives implemented to enhance operational efficiency are viewed as mutually exclusive of initiatives designed to promote patient-centered care and enhance safety. But, in reality, most contemporary health care efficiency initiatives actually promote patient-centered care and improve safety. Also, if carefully analyzed, these initiatives would not be found to increase healthcare costs. This presentation summarized efficiency strategies focused on care delivery, technology and facilities and will highlight how these strategies improve efficiency and enhance patient-centered care and safety without increasing costs. The presenters used examples from recent projects in Southeast Asia, the Middle East and Africa to illustrate these concepts. This discussed efficiency initiatives focused on care delivery which include:

- Developing an strategic and operating plan
- Implementing alternatives to inpatient care
- Designing a sustainable staffing strategies that address growth, development and retention

Efficiency strategies related to technology that include:
- Selecting the right level of medical equipment to match patient needs
- Integrating an electronic medical record that engages and serves patients
- Planning for future technology

The facility strategies explained in the presentation were:
- Minimizing space to maximize patient comfort and convenience
- Using facilities to improve patient safety
- Maximizing staff efficiency and future flexibility through facility design

The presentation concluded with data and specific examples of why safety is always the most cost effective approach and should, therefore, be the number one priority.

Pay for Performance and improving hospital quality within the ACA: lessons for other countries
Maureen Lewis, USA

The US Affordable Care Act (ACA) encompasses expanding access, and improving quality and efficiency. Pay for performance (P4P) measures are targeted at the latter objectives. P4P has historically delivered disappointing results, but with a good deal of prior work and systematic roll out, the implementation of the ACA has demonstrated the potential impact of rewarding good and penalizing poor performance in raising quality and controlling costs.

The presentation outlined the process, indicators and performance of US hospitals under Medicare’s P4P initiatives. In addition, examples from successful Affordable Care Organizations shed light on efforts to engage and reward primary and integrated care networks. Together these provided insights into P4P as a tool and why it has been successful this time around.
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Medical tourism refers to people who travel overseas for obtaining treatment. In the past, it referred to (wealthy/privileged) patients from developing countries who visited medical centres in industrialized countries to get treatment not available at home.

However, the situation has since reversed, in certain cases dramatically. Medical tourism now typically refers to patients from industrialized countries who travel to poorer countries for lower priced, or more quickly available (and in some cases, superior) treatment. Top medical tourist destinations in this respect include India and Thailand as well as Costa Rica, Mexico and the Gulf.

India leads in higher-end procedures
Conversely, at the other end, if only surgical procedures for overseas patients are included, India leads the global medical tourism market. Consultants McKinsey estimated 180,000 medical tourists were treated at Indian facilities in 2004 (up from 10,000 just five years earlier). Arrivals have since been rising sharply and are estimated to have reached 250,000 in 2012, contributing 3 billion USD in revenues. This is effectively about 30% of the global market, estimated for the year at 10.5 billion USD by Transparency Market Research.

India has proven to be a preferred destination for US and UK patients, in particular, because of the use of English in most professional interactions, as well as the fact that both countries have a large number of Indian-origin physicians. Indeed, the US government’s top medic, the Surgeon General, is Vivek Hallegere Murthy, a 40-year old Indian.

India stands out as an interesting destination in another respect. Its massive generic drugs industry provides post-operative medicinal treatment at prices well below the West.

Market drivers: cost, waiting times, accreditation
Key factors driving medical tourism from the West to developing countries include the high cost of healthcare and increasing waiting times for certain procedures. Insurance in several countries often does not cover 100% of the costs of common age-related requirements such as a knee or hip replacement, or limits the choice of the prosthetics, or the surgeon and facility.

Accreditation of top hospitals in medical tourism destinations has also fuelled demand. The oldest international accrediting body is Accreditation Canada, which has accredited hospitals in about a dozen countries.

The best known accreditation group, however, is Joint Commission International (JCI) in the US. JCI was set up in 1994 to provide international clients education and consulting services, and several international hospitals now see accreditation as a way to attract American patients. JCI is an independent private, not-for-profit organization that seeks to develop nationally and internationally recognized procedures to help improve patient care and safety. It advises hospitals to meet standards for patient care and then accredits hospitals meeting the standards.

A British scheme, QHA Trent Accreditation, is an active independent holistic accreditation scheme. Another is GCR.org, which monitors success metrics and standards of almost 500,000 medical clinics worldwide.

These schemes vary in quality, size and cost to hospitals making use of them. Increasingly, hospitals are looking towards dual international accreditation, perhaps
having both JCI to cover potential US clientele, and Accreditation Canada or QHA Trent for Canadian and British patients.

### Indian price advantage boosted by quality, innovations

Practically all surgery procedures performed in medical tourism destinations cost a fraction of what they do in industrialized countries. For example, while a liver transplant in the US costs about 300,000 USD (€280,000), the figure in India is 50,000 USD (€47,000). Open heart surgery in India costs between 3,000 (€2,800) and 10,000 USD (€9,400), compared to 70,000 USD (€65,500) in the UK and 150,000 USD (€140,000) in the US. Such figures acquire added value when one reviews the conclusions of a Harvard Business School (HBS) study in November 2013, comparing data on angioplasty in the US versus India. The study found that one in 200 US angioplasty patients required emergency surgery, with half of them dying, while only two of 40,000 angioplasty patients at India’s CARE Hospitals required emergency surgery, with just one death in the OR since the hospital’s inception in 1997. The HBS study also studied other Indian hospitals and interventions, finding them to be on par or better than their US counterparts – for example, Apollo Hospitals with knee, coronary and prostate surgery as well as for infections related to the operating theatre and catheters, Narayana for coronary artery bypass procedures, Deccan for peritoneal dialysis and Aravind for ophthalmology. The HBS review noted India was not simply an innovator, but an innovator too, for example Indian doctors pioneered the beating-heart method of surgery, where they operate without shutting patients’ hearts down via a heart-lung machine, leading to fewer complications, shorter hospital stays and quicker recovery.

#### New segment of intra-Third World medical tourism

While much attention remains on Western medical tourists, one of the fastest growing market segments consists of patients within the Third World, who travel to more advanced developing countries. India again is at the top of the list. In early Dec 2016 / Jan 2017, for instance, it was announced that Iman Abdulati, a 36-year old woman weighing half a tonne, was to be flown to India from her home in Egypt for bariatric surgery. Such cases have drawn considerable attention for other, political reasons.

Pakistan patients with severe conditions requiring top-notch treatment are a routine media fixture in India. For example, in September 2016, Pakistan’s ‘Express Tribune’ featured the case of Abdul Basit, an 11-year old boy who had been suffering from the rare condition known as Crigler–Najjar syndrome and went for a liver transplant to India. Two years previously, after complications, the wife of former Afghan President Hamid Karzai gave birth to a girl at Fortis Hospital in New Delhi. In August 2016, ‘The Diplomat’ reported India had emerged as one of the fastest growing global healthcare destinations, particularly for patients from conflict countries like Afghanistan, Iraq, Yemen, Sudan, the Democratic Republic of Congo (DRC), and Somalia, attracting close to 400,000 foreign patients a year, half from war-ravaged countries.

The selection of India as preferred medical tourism destination is being officially sanctioned. In 2004, ‘BBC News’ reported that “India was chosen as the place” for sending sick patients from Tanzania unable to be treated at home, after the Tanzanian government “did a comparative analysis of health facilities in South Africa, India and western European countries.” In 2007, Companion Global Healthcare teamed up with hospitals in India (as well as Thailand and Singapore).
China lags India due to egalitarian healthcare model

Due to a variety of reasons, the other Asian behemoth, China, has a much less mature medical tourism sector. WHO figures show hospital bed densities far lower in India, at just 9 per 10,000 people (making a total of roughly 1 million beds) compared to 42 in China (about 5 million). However, the higher share of private beds in India (40% against 6.5% in China) means that India has slightly more private beds – about 400,000, against China’s 325,000.

More than anything, India’s lead over China in medical tourism symbolises its top-down approach to healthcare, in contrast to China’s bottom-up one which first aims at providing top-quality healthcare to local Chinese. As a result, China does not provide good healthcare for its middle and upper class. For Britain’s ‘Guardian’, poor rural Chinese were ‘curiously’ better off ‘than their city cousins.’ The ‘Guardian’ contrasted this with India, where “many city-based healthcare facilities are excellent....” This higher-end focus provides India with more medical tourists than China.

Hospital budgets: the sky’s the limit

There are now at least a dozen major private hospital groups in India. Leading groups (with 20-50 facilities, and 2,500-8,000 beds) include Apollo, Max Healthcare, Fortis, Escorts Healthcare, Wockhardt and the Manipal Group. Many of the above (as well as newcomers from cash-rich Indian conglomerates such as Reliance, the Hindujas, Sahara and ITC) are also pursuing the new concept of Medicities, involving suburban developments dedicated wholly to integrated hospital facilities.

The procurement budget of such groups is not insignificant. Apollo’s annual spending on medical equipment, for example, has been close to 200 million USD in recent years. Such budgets allow cash-rich Indian hospitals to procure state-of-the-art equipment - from Da Vinci robots and stereotactic laser surgery to wide-bore 3T Silent Scan MRIs.

Nevertheless, as far as spending is concerned, Indian hospital groups face several challenges in the coming years, especially from the cash-flush Gulf.

US hospitals lead Gulf partnerships

US hospitals are at the forefront of partnerships in the Gulf. One of the key reasons was the difficulty for medical tourists from the region to obtain US visas after 9/11, according to the American Hospital Association.

Key US partners of Gulf hospitals include Johns Hopkins Medicine, which has an agreement since 2006 to partner the General Health Authority for Health Services in the UAE. It also manages the 400-plus bed Tawam Hospital in Abu Dhabi and an affiliated centre offering state-of-the-art molecular imaging services. Johns Hopkins also has alliances with King Khaled Eye Specialist Hospital in Saudi Arabia.

Another example is the Cleveland Clinic, which is affiliated with the International Medical Centre in Jeddah, Saudi Arabia, and is a strategic partner at the 360-bed, multi-specialty Cleveland Clinic Abu Dhabi Hospital in the UAE.

Elsewhere in the UAE, Methodist International manages the operations of Burj Dubai Medical Centre as well as clinics in Dubai, while Partners Harvard Medical International is a key strategic collaborator with Dubai Healthcare City (which explicitly seeks to attract foreign medical tourists).

Education and training focus in Gulf

Many of these alliances are increasing their focus on education and training. For example, the Partners-Dubai Healthcare City has added a high profile unit called Harvard Medical School Dubai Center Institute for Postgraduate Education and Research, while in 2014 Johns Hopkins signed a partnership with oil major Aramco to provide medical education and training in Saudi Arabia.

Qatar, too, has sought US partners. The Weill Cornell Medical College was in fact one of the earliest ventures, established in 2001 as a partnership between Cornell University and the Qatar Foundation for Education, Science and Community Development. It aims to provide medical education and cutting-edge research.

Ironically, the focus on training might hit a traditional source of physicians in the Gulf especially hard, namely Indians who would be replaced by skilled locals.
Light combined with time-based data sees more deeply inside the body

New light-based technologies that facilitate a “look inside” the human body using light — and without cutting into the tissue — promise to enable both compact, wearable devices for point-of-care diagnostics as well as powerful new systems that provide even more information and from even deeper under the skin.

Recent work and visionary future directions are detailed in a new open-access article by Antonio Pifferi and colleagues at the Politecnico di Milano and Istituto di Fotonica e Nanotecnologie CNR. The article is part of a special section on Clinical Near-Infrared Spectroscopy and Imaging under Guest Editors Marco Ferrari (Università degli Studi dell’Aquila), Joseph Culver (Washington University School of Medicine in St. Louis), Yoko Hoshi (Hamamatsu University School of Medicine), and Heidrun Wabnitz (Physikalisch-Technische Bundesanstalt).

The desirability of noninvasively probing human tissues and their functions has sparked new physical concepts, theoretical models, instruments, measurement approaches, and applications, note the authors in “New frontiers in time-domain diffuse optics.”

We are at the dawn of the next generation of time-domain systems, with a breakthrough in performance, size, cost, and flexibility that has the potential for great impact on new and widespread applications, the authors assert. This breakthrough is enabled by impressive advancements in single-photon detection boosted by high-energy physics and positron-emission tomography systems.

In diffuse optical imaging, light is injected into the surface of a medium, such as the body. The light signal is re-emitted elsewhere on the surface and analyzed as to how it has changed. The analysis yields information about the chemical composition of the tissues, their densities, and other aspects.

The simplest methods compare continuous-wave properties of the original signal and the re-emitted light. Systems that also analyze frequency or time changes in the light signal provide additional data. Current state-of-the-art methods use technologies that enable time-to-digital conversion of the signal, providing even more detail.

Wearable time-domain devices already have been developed for continuous-wave systems, enabling studies in breast cancer detection, brain mapping, muscle monitoring, and non-invasive assessment of lipids, bone, and collagen. Time-domain techniques have also been used in non-destructive characterization of food, wood, pharmaceuticals, and semiconductor powers.

Over the next 20 years researchers envision that such systems will become smaller, making feasible their integration into wearable devices, and smarter, increasing their overall accuracy in detecting and identifying tissue components.

Future devices could be used in brain monitors or muscle oximeters, even for in vivo detection of the brain function during motor or cognitive tasks.

“What makes the future technology unique is its potential to probe noninvasively and in greater depth into human functions and chemical composition, yet with simple personal appliances usable at home and compatible with normal life,” Pifferi said. Currently unreachable organs and functions would be accessible, including the heart.

Quite surprisingly, Pifferi noted, after the thermometer and the blood pressure meter, not many other diagnostic devices for personal healthcare have been brought into the home.

“The new smart sensors, interacting in the ambient environment and transmitting hidden internal information over the cloud, will populate the Internet of Things to the benefit of clinical, industrial, and consumer-level applications,” he said.

SPIE
http://tinyurl.com/j3v43kn

Rapid test identifies disease pathogens

Researchers at the Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB in Stuttgart are developing a test which rapidly and cost-effectively identifies bacteria, fungi or viruses. It can be carried out directly in situ without laboratory equipment and specialist knowledge. “The ImmuStick can even detect pathogens outside the body — on medical devices or in hospital rooms for example. However, the technology would certainly also be of interest for testing human blood for germs or allergies”, says Dr. Anke Burger-Kentischer.

The method works as simply as a pregnancy test. The ImmuStick is a test strip onto which a few drops of fluid are applied. If the fluid contains pyrogens, fragments of pathogens, this is shown by a coloured strip in a viewing window. First of all, human immune receptors sensitive to certain pyrogens are applied to the surface of the stick. These are laboratory-produced immune receptors which are synthesized on the basis of the biological model. During production, at the docking point of the immune receptors to which the pyrogens normally bind, a type of placeholder is mounted which is marked with a dye. When drops of a fluid containing pyrogens are then applied to the test strip, the pyrogens rush to the docking point on the immune receptor. The placeholders marked with the dye migrate with the fluid through the test strip until they are visible in the viewing window. The colour signal thus indicates that pyrogens that have docked on the immune receptors are present.

The ImmuStick project was financed with money from the Discover programme. In this way the Fraunhofer-Gesellschaft is supporting projects for the duration of one year in order to demonstrate the feasibility of a technology. The ImmuStick has passed this test. “We were able to show that it works very well for the bacterial pyrogen LPS. Together with industrial partners, we now want to develop it into a product”, says project manager Burger-Kentischer. “We are currently testing further immune receptors that are specific for other pyrogens.”

Currently envisaged are applications in the food and pharmaceuticals sector or in medical technology, as a complete absence of germs or pyrogens is required there. In principle, the ImmuStick would also be of interest for blood analysis. Pyrogens in the blood often lead to blood poisoning, sepsis, from which many people still die today, especially weakened intensive care patients. “However, blood is a special challenge as it is complex and contains many constituent parts. But in the medium term we are aiming at blood analysis”, says Burger-Kentischer.

As pyrogens also include certain allergy trigger factors, an application here would also be conceivable. In the food and pharmaceutical industries, for example, it is important that products are free of allergens. With the ImmuStick these could be detected quickly, cost-effectively and simply. Costly and laborious laboratory tests would therefore no longer be needed or
could be supplemented. At present the IGB researchers are seeking cooperation partners who want to further develop the ImmuStick to make it ready for the market.

Pyrogens become a problem when hygiene is of particular importance — in the food and pharmaceutical industries for example, or on intensive care wards in hospitals. Especially people with weakened immune systems can become severely ill. For this reason, tests are frequently carried out and the surfaces of machines or medical devices are tested for pyrogens using swabs. However, to date these tests have been costly and laborious as pyrogens can only be detected with laboratory equipment. A widely used standard test is the detection of LPS, a structure that is present in the membrane of certain bacteria. At present this test takes up around two hours. Other pyrogens can even only be detected in animal experiment.

Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB
http://tinyurl.com/jyrlqct

New remote-controlled microrobots for medical operations

Scientists at EPFL and ETHZ have developed a new method for building microrobots that could be used in the body to deliver drugs and perform other medical operations.

For the past few years, scientists around the world have been studying ways to use miniature robots to better treat a variety of diseases. The robots are designed to enter the human body, where they can deliver drugs at specific locations or perform precise operations like clearing clogged-up arteries. By replacing invasive, often complicated surgery, they could optimize medicine.

EPFL scientist Selman Sakar teamed up with Hen-Wei Huang and Bradley Nelson at ETHZ to develop a simple and versatile method for building such bio-inspired robots and equipping them with advanced features. They also created a platform for testing several robot designs and studying different modes of locomotion. Their work produced complex reconfigurable microrobots that can be manufactured with high throughput. They built an integrated manipulation platform that can remotely control the robots’ mobility with electromagnetic fields, and cause them to shape-shift using heat.

Unlike conventional robots, these microrobots are soft, flexible, and motor-less. They are made of a biocompatible hydrogel and magnetic nanoparticles. These nanoparticles have two functions. They give the microrobots their shape during the manufacturing process, and make them move and swim when an electromagnetic field is applied.

Building one of these microrobots involves several steps. First, the nanoparticles are placed inside layers of a biocompatible hydrogel. Then an electromagnetic field is applied to orientate the nanoparticles at different parts of the robot, followed by a polymerization step to “solidify” the hydrogel. After this, the robot is placed in water where it folds in specific ways depending on the orientation of the nanoparticles inside the gel, to form the final overall 3D architecture of the microrobot.

Once the final shape is achieved, an electromagnetic field is used to make the robot swim. Then, when heated, the robot changes shape and “unfolds”. This fabrication approach allowed the researchers to build microrobots that mimic the bacterium that causes African trypanosomiasis, otherwise known as sleeping sickness. This particular bacterium uses a flagellum for propulsion, but hides it away once inside a person’s bloodstream as a survival mechanism.

The researchers tested different microrobot designs to come up with one that imitates this behaviour. The prototype robot presented in this work has a bacterium-like flagellum that enables it to swim. When heated with a laser, the flagellum wraps around the robot’s body and is “hidden”.

“We show that both a bacterium’s body and its flagellum play an important role in its movement,” said Sakar. “Our new production method lets us test an array of shapes and combinations to obtain the best motion capability for a given task. Our research also provides valuable insight into how bacteria move inside the human body and adapt to changes in their microenvironment.”

For now, the microrobots are still in development. “There are many factors we have to take into account,” says Sakar. “For instance, we have to make sure that the microrobots won’t cause any side-effects in patients.”

EPFL
http://tinyurl.com/zg3rsf
International trial evaluates focused ultrasound for essential tremor

A study offers the most in-depth assessment yet of the safety and effectiveness of a high-tech alternative to brain surgery to treat the uncontrollable shaking caused by the most common movement disorder. The paper outlines the results of an international clinical trial, led by Jeff Elias, MD, of the UVA Health System, that evaluated the scalpel-free approach called focused ultrasound for the treatment of essential tremor (ET), a condition that afflicts an estimated 10 million Americans. Not only did the researchers determine that the procedure was safe and effective, they found that it offered a lasting benefit, reducing shaking for trial participants throughout the 12-month study period. “This study represents a major advance for neurosurgery, treatment of brain disease and specifically the treatment of ET,” Elias said. “For the first time in a randomized controlled trial, we have shown that ultrasound can be precisely delivered through the intact human skull to treat a difficult neurological disease.”

The multi-site clinical trial included 76 participants with moderate to severe essential tremor, a condition that often robs people of their ability to write, feed themselves and carry out their normal daily activities. The trial participants all had tried existing medications, without success. The mean age was 71, and most had suffered with their tremor for many years. Seventy-five percent of participants received the experimental treatment using focused ultrasound guided by magnetic resonance imagining. The remaining 25 percent underwent a sham procedure, to act as the control group. (They were later given the opportunity to undergo the real procedure.)

Participants who received the treatment showed dramatic improvement, with the beneficial effects continuing throughout the study period. The researchers employed a 32-point scale to assess tremor severity, and they found that mean tremor scores improved by 47 percent at three months and 40 percent at 12 months. Participants reported major improvements in their quality of life. People who couldn’t feed themselves soup or cereal could again do so.

Participants who received the sham procedure, on the other hand, showed no significant improvements. “The degree of tremor control was very good overall in the study, but the most important aspects were the significant gains in disabilities and quality of life – that’s what patients really care about,” Elias said. The most commonly reported side effects were gait disturbances and numbness in the hand or face; in most instances, these side effects were temporary but some were permanent.

Based on the clinical trial led by Elias, the federal Food and Drug Administration has approved the focused ultrasound device for the treatment of essential tremor.

University of Virginia Health System
http://tinyurl.com/z4pv5ss

Increased BMI during adolescence predicts fatal cardiovascular events in adulthood

Overweight and obesity in adolescents have increased substantially in recent decades, and currently affect a third of the adolescent population in some developed countries. This is an important public health concern because obesity early in life is considered to be a risk factor for death from cardiovascular disease and from all causes in adulthood. Some studies suggest that an elevated body-mass index is associated with an increased risk of death from cardiovascular causes. However, a determination of the BMI threshold that is associated with increased risk of fatality remains uncertain. (BMI is a calculation of a person’s weight in kilograms divided by the square of their height in meters, to quantify body mass and enable categorization as underweight, normal weight, overweight, or obese.)

In light of the worldwide increase in childhood obesity, Prof. Jeremy Kark from the Hebrew University-Hadassah Braun School of Public Health and Community Medicine, in the Hebrew University of Jerusalem’s Faculty of Medicine, together with Dr. Gilad Twig of Sheba Medical Center, and Dr. Hagai Levine also of the Braun School of Public Health and other colleagues in Israel, set out to determine the association between body-mass index (BMI) in late adolescence and death from cardiovascular causes in adulthood.

Their study was based on a national database of 2.3 million Israeli 17-year olds in whom height and weight were measured between 1967 and 2010. The researchers assessed the association between BMI in late adolescence and death from coronary heart disease, stroke, and sudden death in adulthood by mid-2011. During 42,297,007 person-years of follow-up, 2918 of 32,127 deaths (9.1%) were from cardiovascular causes, including 1497 from coronary heart disease, 528 from stroke, and 893 from sudden death.

The results showed an increase in the risk of cardiovascular death in the group that was considered within the “accepted normal” range of BMI, in the 50th to 74th percentiles, and of death from coronary heart disease at BMI values above 20. The researchers concluded that even BMI considered “normal” during adolescence was associated with a graded increase in cardiovascular and all-cause mortality during the 40 years of follow-up. This included increased rates of death from coronary heart disease, stroke, and total cardiovascular causes among participants. As BMI scores increased into the 75th to 84th percentiles, adolescent obesity was associated with elevated risk of death from coronary heart disease, stroke, sudden death from unknown causes, and death from total cardiovascular causes, as well as death from non-cardiovascular causes and death from all causes. Participants also had an increased risk of sudden death.

The rates of death per person-year were generally lowest in the group that had BMI values during adolescence in the 25th to 49th percentiles, although higher rates were observed among those below the 5th percentile.

How might adolescent BMI influence cardiovascular outcomes in adulthood? The researchers considered two possible pathways. First, obesity may be harmful during adolescence, since it has been associated with unfavourable metabolic abnormalities through risk factors such as unfavourable plasma lipid or lipoprotein levels, increased blood pressure, impaired glucose metabolism, insulin resistance, and formation of coronary and aortic atherosclerotic plaques. Furthermore, the timing of exposure to obesity during a person’s lifetime may play an important role. Second, BMI tends to “track” along the life course so that overweight adolescents tend to become overweight or obese adults, and overweight or obesity in adulthood affects the risk of cardiovascular disease.
“Our findings appear to provide a link between the trends in adolescent overweight during the past decades and coronary mortality in midlife,” said the paper’s senior author, Prof. Jeremy Kark. “The continuing increase in adolescent BMI, and the rising prevalence of overweight and obesity among adolescents, may account for a substantial and growing future burden of cardiovascular disease, particularly coronary heart disease.”

The Hebrew University of Jerusalem
http://tinyurl.com/zwt4n4d

One-third of patients with low flow aortic stenosis do not improve with transcatheter aortic valve replacement

Aortic stenosis (AS), the narrowing of the aortic valve in the heart which causes restricted blood flow, is one of the most common and serious valve disease problems. For patients with one type of AS – low flow – transcatheter aortic valve replacement (TAVR), a minimally invasive procedure which corrects the damaged aortic valve, is often the best option for restoring the heart’s normal pumping function. However, approximately one-third of low flow AS patients treated with TAVR continue to suffer persistent low flow AS even after the procedure, ultimately increasing their risk of death. Now, researchers from the Perelman School of Medicine at the University of Pennsylvania have examined this high-risk patient population to determine the cause of this persistent low flow AS and to evaluate their risk of dying during the year following the procedure.

“There has been a lot of interest in these patients with low flow AS, as their surgical mortality is higher than other patients. TAVR is often a good option, but not all of them will be able to normalize flow following the procedure and these persistently low flow patients have a 60 percent higher risk of mortality at one year,” said Howard C. Herrmann, MD, FACC, MSCAI, John W. Bryfogle Professor of Cardiovascular Medicine and Surgery, and director of Penn Medicine’s Interventional Cardiology Program. “Low flow before TAVR is one of the most important predictors of mortality following TAVR, but it is one of the harder qualities to measure. This presents a challenge to properly treating patients with low flow AS, and can leave some patients at higher risk.”

To better understand the potential benefits of TAVR for low flow AS, researchers conducted an analysis of 984 patients with low flow AS from the PARTNER trial and continued access registry from April 2014 through January 2016. A baseline and follow-up echocardiogram, evaluation of post-TAVR hemodynamics – blood flow – and one year outcomes were assessed.

Through this analysis, researchers identified the large subgroup of patients who, following TAVR, failed to regain normal flow despite a successful procedure. In the first six months following TAVR, flow improved in roughly 66 percent of the patients evaluated. However, those with severe low flow AS had the highest mortality rate – 26 percent – at one year, as compared to approximately 20 percent for those with moderate low flow and even less for those with normal flow.

“Unfortunately, many centres do not routinely measure flow, but rather focus more on a patient’s pressure gradient or valve area when evaluating aortic stenosis pre-and post-TAVR,” said Herrmann. “While low flow is more challenging to monitor, this measurement can better inform the patient’s risk of mortality, and in turn lead to better treatment.”

The researchers noted that the identification of remedial, or treatable, causes of persistent low flow following TAVR, such as severe mitral regurgitation and atrial fibrillation, may represent an opportunity to improve the outcomes of these patients.

Penn Medicine
http://tinyurl.com/htz5gvj

Study identifies aortic valve gradient as key to TAVR outcomes

Patients with a combination of left ventricular dysfunction and low aortic valve gradient, or reduced force of blood flow through the aortic valve, have higher mortality rates and a greater risk of recurrent heart failure after transcatheter aortic valve replacement (TAVR), with low aortic valve gradient the driving force behind their poor outcomes.

Patients with this profile, however, should still be considered for TAVR, especially since research on similar patients who had surgical valve replacement found that they could withstand the procedure, Suzanne J. Baron, M.D., M.Sc., the study’s lead author, said.

Low aortic valve gradient is a result of aortic stenosis, a narrowing of the opening of the aortic valve. This condition results in restricted blood flow from the left ventricle to the aorta. Stenosis

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can also lead to impaired left ventricular ejection fraction, meaning that the heart pumps an inadequate amount of blood with each beat.

To treat aortic stenosis, physicians typically replace the aortic valve, either through open heart surgery or through TAVR. During TAVR, a new valve is delivered to the heart through arteries in the leg or chest. For patients at high risk of surgical complications, TAVR has been shown to be at least as effective as open heart surgery.

Previous studies of valve replacement through surgery have shown that patients with impaired left ventricular ejection fraction and low aortic valve gradient do not do as well as those with better cardiac function and blood flow. In this study, researchers set out to determine the role that left ventricular dysfunction and low aortic valve gradient play in rates of death and recurrent heart failure following this less invasive procedure. Since left ventricular dysfunction and low aortic valve gradient are often seen together, researchers aimed to determine which of these factors was the driving force behind the poor clinical outcomes. After adjusting for several clinical factors, including age, sex, previous cardiovascular bypass grafting, and previous angioplasty, only the presence of a low aortic valve gradient was associated with higher mortality rates and recurrent heart failure. The effect of left ventricular ejection fraction was no longer significant.

Baron, a cardiologist at Saint Luke’s Mid America Heart Institute, University of Missouri-Kansas City, in Kansas City, Missouri, said the finding that left ventricular dysfunction was not independently associated with long-term mortality after adjusting for clinical factors “provides important reassurance regarding the benefits of TAVR, even in patients with severe left ventricular dysfunction.” The study results also suggest that patients with a low aortic valve gradient may be a subset of aortic stenosis patients who have less long-term benefit from this procedure, although the majority of these patients who were still alive one year after the procedure had improved quality of life. Baron concludes that “neither severe left ventricular dysfunction nor low aortic valve gradient alone or in combination provide sufficient prognostic discrimination to preclude treatment with TAVR in the absence of other adverse prognostic factors.”

Visualizing muscle disease

Researchers at ETH Zurich have developed a new marker substance for positron emission tomography (PET) that will allow them to monitor the progression of the degenerative muscle disease amyotrophic lateral sclerosis (ALS) in a patient’s brain. Many people will remember the Ice Bucket Challenge back in the summer of 2014. This social media campaign helped patient support groups to promote public awareness of the rare, but debilitating and incurable muscle disease, amyotrophic lateral sclerosis (ALS). The challenge involved one person nominating three others through social media, creating a snowball effect, to make a financial donation to an ALS support group, or – as a forfeit – to pour a bucket of ice-cold water over their heads. This action was supposed to give participants a brief insight into one of the symptoms experienced by someone suffering from degenerative muscle disease. ALS induces progressive degeneration of the motor neurons that control the muscles. The patient suffers from muscular atrophy and paralysis, accompanied by symptoms such as difficulty walking, speaking and swallowing. At best, drugs can delay the progression of the disease, but often life expectancy is only a few years after the initial diagnosis. Very little is known about the causes of the disease.

A new marker substance developed by ETH researchers in collaboration with specialists at St. Gallen Cantonal Hospital and University Hospital Zurich could potentially make a vital contribution to ALS research. The new substance could perhaps make it possible to monitor the progression of ALS in patients using positron emission tomography (PET). The PET imaging technique renders specific molecules on the cell surface visible within the body tissue. The scan uses marker substances, known as PET ligands, that adhere to these molecules via the lock-and-key principle. The radiation emitted by the radioactive markers is very short lived, with a half-life between several minutes and a few hours. This radiation is measured during the PET scan.

The newly developed PET ligand binds to a receptor molecule in the body’s neurotransmitter system for cannabis-based substances, known as the cannabinoid receptor 2 (CNR2). This is very common in inflamed nerve tissue, and is also found in the central nervous system of patients suffering from ALS.

“The big challenge we faced was to develop a PET ligand that only binds to CNR2, but not to the related cannabinoid receptor 1 (CNR1),” explains Simon Ametamey, a professor at the Institute of Pharmaceutical Sciences at ETH Zurich. CNR1 occurs naturally in the human brain, where it elicits the pain-relieving and intoxicating effect of cannabis. The researchers in Professor Ametamey’s group synthesized a series of molecules and performed an in vitro study to measure their ability to bind to the receptors CNR2 and CNR1. The team went on to successfully test the molecule with the most obvious preference for CNR2 in rats and mice with inflamed nerve tissue. The scientists have filed a patent for this molecule. The next step will be to perform clinical trials in humans.

“The new PET ligand could help us to research ALS more effectively and to understand how the disease progresses,” says Professor Ametamey. It could also improve the early diagnosis of the disease. It might also be potentially interesting for research and diagnosis of other neurological disorders such as Alzheimer’s, Parkinson’s or multiple sclerosis.

ETHZ

http://tinyurl.com/gvnvsy5

Titanium-gold alloy that is four times harder than most steels

Titanium is the leading material for artificial knee and hip joints because it’s strong, wear-resistant and nontoxic, but an unexpected discovery by Rice University physicists shows that the gold standard for artificial joints can be improved with the addition of some actual gold.

“It is about 3-4 times harder than most steels,” said Emilia Morosan, the lead scientist on a new study in Science Advances that describes the properties of a 3-to-1 mixture of titanium and gold with a specific atomic structure that imparts hardness. “It’s four times harder than pure titanium, which is what’s currently being used in most dental implants and replacement joints.” Morosan, a physicist who specializes in the design and synthesis of compounds with exotic electronic and magnetic properties, said the new study is “a first for me in a number of ways. This compound is not difficult to make, and it’s not a new material.”
In fact, the atomic structure of the material — its atoms are tightly packed in a “cubic” crystalline structure that’s often associated with hardness — was previously known. It’s not even clear that Morosan and former graduate student Eteri Svanidze, the study’s lead co-author, were the first to make a pure sample of the ultra-hard “beta” form of the compound. But due to a couple of lucky breaks, they and their co-authors are the first to document the material’s remarkable properties.

“This began from my core research,” said Morosan, professor of physics and astronomy, of chemistry and of materials science and nano-engineering at Rice. “We published a study not long ago on titanium-gold, a 1-to-1 ratio compound that was a magnetic material made from nonmagnetic elements. One of the things that we do when we make a new compound is try to grind it into powder for X-ray purposes. This helps with identifying the composition, the purity, the crystal structure and other structural properties.

“When we tried to grind up titanium-gold, we couldn’t,” she recalled. “I even bought a diamond (coated) mortar and pestle, and we still couldn’t grind it up.”

What the team didn’t know at the time was that making titanium-3-gold at relatively high temperature produces an almost pure crystalline form of the beta version of the alloy — the crystal structure that’s four times harder than titanium. At lower temperatures, the atoms tend to arrange in another cubic structure — the alpha form of titanium-3-gold. The alpha structure is about as hard as regular titanium. It appears that labs that had previously measured the hardness of titanium-3-gold had measured samples that largely consisted of the alpha arrangement of atoms. The team measured the hardness of the beta form of the crystal in conjunction with colleagues at Texas A&M University’s Turbomachinery Laboratory and at the National High Magnetic Field Laboratory at Florida State University; Morosan and Svanidze also performed other comparisons with titanium. For biomaterials, for example, two key measures are biocompatibility and wear resistance. Because titanium and gold by themselves are among the most biocompatible metals and are often used in medical implants, the team believed titanium-3-gold would be comparable. In fact, tests by colleagues at the University of Texas MD Anderson Cancer Center in Houston determined that the new alloy was even more biocompatible than pure titanium. The story proved much the same for wear resistance: Titanium-3-gold also outperformed pure titanium.

Rice University
http://tinyurl.com/jto5exc

Common heart complication after lung transplantation

Cardiac arrhythmia is a common complication following lung transplantation, and one that has a significant negative impact on long-term patient survival, reports a team of UPMC researchers in the largest study of its kind to date. The results provide critical information that will hopefully lead to better care of transplant recipients.

Arrhythmia, a rapid and irregular heartbeat, can lead to chest pain, stroke and heart failure. In addition, the blood-thinning drugs often used to treat atrial fibrillation, the most common type of arrhythmia, carry risks of heavy bleeding.

“Arrhythmias present a lot of challenges for both physicians and patients. After noticing this complication in many of our lung transplant recipients, we decided to investigate how often and when it was happening, as well as any risk factors,” said lead researcher Jonathan D’Cunha, M.D., Ph.D., associate professor, Department of Cardiothoracic Surgery, University of Pittsburgh School of Medicine, and chief of Lung Transplantation, Department of Cardiothoracic Surgery, UPMC. “Now that we have a better understanding of these events, we can develop a standardized treatment plan, and better educate patients in advance.”

Performing 70 to 100 lung transplants per year, UPMC is one of the leaders for this procedure in the US. In the new study, researchers examined the medical records of 652 UPMC patients who underwent a single or double lung transplant between 2008 and 2013. They found that about 30 percent of patients developed arrhythmia, most often during the first week following surgery. Risk factors for a postoperative arrhythmia included being older and having had a previous heart surgery.

Researchers also found transplant recipients who developed an arrhythmia were 1.6 times more likely to die within 5 years than those who didn’t, a finding Dr. D’Cunha attributed more to the potential complications of treating arrhythmia than the abnormal heart beats themselves.

“Our study suggests that we may need to treat patients with blood thinners only for a short amount of time — until they are out of the window of highest risk — which will hopefully improve long-term outcomes,” Dr. D’Cunha explained.

In addition, because arrhythmia after lung transplant can be an anxiety-provoking experience for patients, the findings will allow surgeons to better prepare patients and families for what to expect.

University of Pittsburgh School of Medicine
http://tinyurl.com/h3cerpp
Anti-tumour antibodies could counter atherosclerosis

Investigators at the Stanford University School of Medicine have learned the signal that tumour cells display on their surfaces to protect themselves from being devoured by the immune system also plays a role in enabling atherosclerosis, the process underlying heart attacks and strokes. A biological drug capable of blocking this so-called "don't eat me" signal is now being tested in clinical trials in cancer patients. The same agent, the investigators found, was able to prevent the build-up of atherosclerotic plaque in several mouse models of cardiovascular disease. If this success is borne out in human studies, the drug could be used to combat cardiovascular disease — the world's No. 1 killer — and do so by targeting not mere risk factors such as high cholesterol or high blood pressure, but the actual lesions bearing direct responsibility for cardiovascular disease: atherosclerotic plaques.

"It seems that heart disease may be driven by our immune system's inability to 'take out the trash,'" said Nicholas Leeper, MD, associate professor of vascular surgery and of cardiovascular medicine.

Atherosclerosis is caused by the deposition of fatty substances along arterial walls. Over the years, these substances form plaques. It's now known that numerous dead and dying cells accumulate in atherosclerotic plaques, which inflammation renders brittle and vulnerable to rupture, the ultimate cause of heart attack and stroke.

Contributing to the pathology is malfeasance on the part of a class of immune cells that first arrive at the site with presumably benign intentions, said Leeper.

"Even a perfectly healthy body turns over more than 100 billion cells a day, every day," he said. "One of the several jobs performed by immune cells called macrophages is to come and gobble up those dead and dying cells, which might otherwise begin releasing substances that can foster inflammation."

Many cells in the human body feature a "don't eat me" signal on their surface: a protein called CD47. The protein tells the immune system that a cell is alive, still going strong and part of a person's healthy tissue.

Normally, as a cell approaches death, its CD47 surface proteins start disappearing, exposing the cell to macrophages' garbage-disposal service. But atherosclerotic plaques are filled with dead and dying cells that should have been cleared by macrophages, yet weren't. In fact, many of the cells piling up in these lesions are dead macrophages and other vascular cells that should have been cleared long ago.

In the new study, Leeper, Kojima and their colleagues performed genetic analyses of hundreds of human coronary and carotid artery tissue samples collected at Stanford and at Sweden's Karolinska Institute. They found that CD47 is extremely abundant in atherosclerotic tissue compared with normal vascular tissue, and correlated with risk for adverse clinical outcomes such as stroke.

Alerted to the Leeper lab's discovery, Weissman, a co-author of the new study, provided anti-CD47 antibodies so Leeper's group could test their efficacy in battling atherosclerosis.

In a laboratory dish, anti-CD47 antibodies induced the clearance of diseased, dying and dead smooth muscle cells and macrophages incubated in conditions designed to simulate the atherosclerotic environment. And in several different mouse models of atherosclerosis, blocking CD47 with anti-CD47 antibodies dramatically countered the build-up of arterial plaque and made it less vulnerable to rupture.

Many mice even experienced regression of their plaques — a phenomenon rarely observed in mouse models of cardiovascular disease.

Looking at data from other genetic research, the scientists learned that surplus CD47 in atherosclerotic plaques strongly correlates with elevated levels, in these plaques, of a well-known inflammation-promoting substance called TNF-alpha.

Further experiments showed that TNF-alpha activity prevents what would otherwise be a progressive decrease of CD47 on dying cells. Hence, those cells are less susceptible to being eaten by macrophages, especially in an atherosclerosis-promoting environment.

"The problem could be an endless loop," said Leeper, "in which TNF-alpha-driven CD47 overexpression prevents macrophages from clearing dying cells in the lesion. Those cells release substances that promote the production of even more TNF-alpha in nearby cells." Leeper and Weissman said they hope to find out, in clinical trials of human patients, whether CD47-blocking antibodies will prove effective in breaking that vicious circle.

Stanford Medicine
http://tinyurl.com/zt8ws4

Scientists apply new imaging tool to common brain disorders

A Yale-led team of researchers developed a new approach to scanning the brain for changes in synapses that are associated with common brain disorders. The technique may provide insights into the diagnosis and treatment of a broad range of disorders, including epilepsy, Alzheimer's disease, schizophrenia, depression and Parkinson's disease.

Certain changes in synapses — the junctions between nerve cells in the brain — have been linked with brain disorders. But researchers have only been able to evaluate synaptic changes during autopsies. For their study, the research team set out to develop a method for measuring the number of synapses, or synaptic density, in the living brain.

To quantify synapses throughout the brain, professor of radiology and biomedical imaging Richard Carson and his co-authors combined PET scanning technology with biochemistry. They developed a radioactive tracer that, when injected into the body, binds with a key protein that is present in all synapses across the brain. They observed the tracer through PET imaging and then applied mathematical tools to quantify synaptic density. The researchers used the imaging technique in both baboons and humans. They confirmed that the new method did serve as a marker for synaptic density. It also revealed synaptic loss in three patients with epilepsy compared to healthy individuals.

"This is the first time we have synaptic density measurement in live human beings," said Carson, who is senior author on the study. "Up to now any measurement of synaptic density was post-mortem."

The finding has several potential applications. With this non-invasive method, researchers may be able to follow the progression of many brain disorders, including epilepsy and Alzheimer's disease, by measuring changes in synaptic density over time. Another application may be in assessing how pharmaceuticals slow the loss of neurons. "This opens the door to follow the natural evolution of synaptic density with normal aging and follow how drugs can alter synapses or synapse formation."

Yale University
http://tinyurl.com/hnrz9y8
How to reduce hospital noise at neonatal units

Hospital noise is an issue for babies born prematurely who are at high risk when it comes to external influences such as noise. Their systems are underdeveloped and they need as much sleep and rest as possible to recuperate. This is one of the reasons why the Neonatal Unit at the highly specialized Rigshospitalet hospital in Denmark, began cooperating with the noise measurement company SoundEar this year.

Not all sound is noise
Staff at the Neonatal Unit stress that there is a difference between what they call ‘good sound’ and noise. The point being that not all sound is noise, and not all sound should be eliminated. It is important for the development of the newborns that they hear sound such as their parents and siblings talking and singing to them. It is also important that staff can communicate audibly in critical situations, and it is inevitable that some medical equipment, such as respirators, are noisy. What they do want to reduce is unnecessary sound stemming from alarms, furniture, work flow and talk.

Keeping parents in the loop
An important part of the project is to keep parents informed about why the noise meters are installed and not only focus on reducing noise, but also inform them that they should still talk to their newborns in all rooms. Half of the noise meters are anonymous white boxes which solely measure and collect noise levels. The other half of the noise meters also have a display with an ear, that lights up green, yellow or red, indicating the current level of noise in the room.

Reduction in noise levels at the NICU is expected to be achieved through different layers of nudging:

- The noise meters with displays should help staff and families become aware of their own noise levels and change their noisy behaviour.
- The software helps staff become aware of when and where noise levels are critical and something should be done differently.
- The software sends out noise reports on a weekly basis via email to key staff members who use these reports as a basis for further discussion about noise at staff meetings.

Changing routines
After having the SoundEar devices hanging in the NICU for a few months, staff was asked to fill out a questionnaire about the perceived hospital noise levels, and whether the SoundEar devices seemed to have changed anything. 14 staff members, primarily nurses, answered the questionnaire and 78.6% reported that the SoundEar devices had made them more attentive to noise levels. The same amount reported to have changed some of their behaviour because of the SoundEar devices. The change that most staff members reported to have made, was to unpack syringes and other types of medical equipment outside of patient rooms, because they had noticed that the ripping of plastic made an unnecessary amount of noise around the children. Others reported lowering their voices and lowering the noise level of alarms as changes they had made after the installation of the SoundEar devices.

Several staff members also reported to have seen an increase in parents’ attention to noise levels, and that they commented on noise to other visitors and siblings, thereby spreading the attention to noise.

Custom-made software
All the noise meters transfer noise measurement data wirelessly to a central computer, where it is accessible to staff through a piece of software, developed specifically for hospital use by SoundEar in cooperation with staff at the NICU.

Jointly creating a noise measurement system
An important part of the project was to create a system that would help reduce hospital noise and become part of the daily routine at hospitals. For SoundEar, this meant focusing on what staff needed and what their everyday work life looked like and adjusting to that. In the early days of the project, SoundEar viewed the software platform as the main component of the system and something that staff should be able to interact with daily. They should monitor noise levels just as they were used to monitoring the health levels of the newborns.

To make the software as useful as possible, SoundEar conducted several interviews with staff members. Very soon, it became clear that even though nurses viewed reducing hospital noise as important, their focus was on the critical medical care for the newborns and keeping them alive and well. Their time was limited and they would not be able to prioritize time from their busy schedules to consult a piece of software that did not have immediate medical importance for the children.

Instead, they suggested that a few members of the staff should be responsible for driving the hospital noise reduction, checking the software and gathering insights for the rest of the staff to discuss at weekly meetings. Along the way, the procedure evolved into auto-generated noise reports being sent to key staff members to be discussed at staff meetings on a weekly basis.

www.soundear.dk
2016 Durban Congress highlights patient-centred care and safety

“How addressing the challenge of patient-centred care and safety” was the theme addressed in the International Hospital Federation (IHF) 40th World Hospital Congress held in Durban, South Africa, 31 October to 3 November 2016, attended by national and international healthcare leaders and organizations from 50 countries.

Discussions on the challenges being encountered by different countries when it comes to making patients the centre of quality and affordable healthcare services and management, as well as the solutions on how to improve hospitals’ delivery of quality care and the healthcare status of each country were tackled.

Quality of Care, Capacity Building in Leadership and Management, Governance and Accountability, Ethics and Medical Legal Issues, Financing and Universal Health Coverage, Health Technology, and Service Delivery were some of the tracks explored during the Congress.

Dr. Aaron Motsoaledi, the Honourable Minister of Health of the host country, Republic of South Africa, mentioned in his welcome message the two objectives of the South African National Development Plan that are needed to be comprehended not only by African healthcare leaders and personnel, but by all healthcare leaders internationally: “(1) The quality of services in the public health system must be improved (2) The relative cost of private healthcare must be reduced.”

These two important points were emphasized and tackled in detail in the three-day congress through member, free paper and special sessions as well as the pre-congress meetings, which included the African Regional meeting, hosted by the National Department of Health of South Africa.

Erik Normann, IHF President, in his opening remarks, expressed his delight at the fact that the Durban Congress was the first to be hosted by IHF on the African continent since the creation of the IHF in 1929.

Apart from addressing the challenges and delivering interesting and trending healthcare topics, the congress has also made sure that all the events and activities held would make a difference in patient-centred care by featuring cutting-edge delivery approaches and inventive management practices.

Aligned with those innovative healthcare management practices, IHF members and delegates had unique opportunities to exhibit and share their accomplishments and practices in hospital leadership to the global healthcare community through expositions. The IHF CEO Circle, the exclusive professional network for senior healthcare executives was also highlighted in the congress through meetings.

IHF 2016 International Awards

The IHF 2016 International Awards attracted many excellence entries from 19 countries. The Awards, given to hospitals, not individuals, because healthcare is acknowledged as a team endeavour, recognize achievements in several areas, such as quality and patient safety, corporate social responsibility, innovations in service delivery at affordable costs, and healthcare leadership and management practices.

In the last day of the event, the delegates were also given the chance to visit and tour some of the distinguished hospitals and healthcare facilities in Durban, South Africa which included: KZN Children’s Hospital, Ethekwini Hospital and Heart Centre, Inkosi Albert Luthuli Central Hospital, King Dinuzulu Hospital, and Prince Mahiyeni Memorial Hospital.

All the mentioned activities and events of this year’s World Hospital Congress show its key unique features on how it can contribute and respond to the needs in the global healthcare nowadays.

Delegates were already looking forward to attending next year’s congress, the IHF 41st World Hospital Congress, which will take place 7-9 November 2017 in Taipei, Taiwan, with the theme “Patient-friendly and Smarter Healthcare.”

All the mentioned activities and events of this year’s World Hospital Congress show its key unique features on how it can contribute and respond to the needs in the global healthcare nowadays.

A selection of Congress presentations appears on pages 15-17 of this issue of International Hospital.

www.ihf-int.org

MEDICA 2016

A powerful incentive for the international medical technology business

MEDICA 2016 peaked again this year in what was a great event for the medical technology industry. In the trade fair halls, all of which were fully booked, the atmosphere was definitely positive and for the first time ever, there were more than 5,000 exhibitors from around 70 countries, who provided tailored solutions for outpatient and inpatient care. From current trends to spectacular innovations right up to solutions which will shape the future – the portfolio of the biggest medical trade fair in the world was unique, and this market of possibilities, which is constantly changing, was a place for a highly qualified audience from all over the world to come together:

More than 80 percent of the 127,800 visiting trade experts had significant decision-making authority.

In terms of innovations, the current market is characterized by a special dynamic resulting from the unstoppable digitalization of healthcare and implicating all sectors, both outpatient and clinical, as well as physicians and patients.

A top-class supporting programme, consisting of conferences, meetings and forums, provided a thematic and target group appropriate immersion of highly specialized contents. For this reason, MEDICA distinguished itself again as a strongly frequented platform for the transfer of knowledge and further education.

www.medica.de
EIZO Corporation acquires endoscopy monitor business from Panasonic Healthcare

Two major players in the monitor sector have joined forces. The medical monitors business of Panasonic Healthcare Co., Ltd. (“Panasonic Healthcare”) became part of the EIZO Corporation in August 2016. The business transfer allows EIZO to combine the expertise of the two leading monitor solution manufacturers, especially for applications in medical imaging. The acquisition allows Karlsruhe-based EIZO GmbH to offer the entire product range of medical monitors for minimally invasive surgery, including 2D, 3D and 4K models.

EIZO had already announced the planned expansion of its business in the healthcare market with a particular focus on the field of operating rooms in a mid-term business plan in 2015. “Uncompromising quality and innovative products are EIZO’s strengths,” said Peter Ziegler, Managing Director of EIZO GmbH in Karlsruhe. “Acquiring monitor solutions from Panasonic Healthcare lets us extend this offer into endoscopic image display.”

Panasonic Healthcare has been expanding its endoscopy monitor business since August 2010. Over the years, the company has built strong global partnerships with manufacturers in both endoscopy and OR integration. Panasonic Healthcare products are used in operating rooms around the world where they offer medical specialists outstanding colour settings and accurate colour reproduction. Michael Unger, formerly General Manager at Panasonic Biomedical Sales Europe B.V., sees the merger as a positive step for the future. "The many years of experience which EIZO and Panasonic Healthcare have accumulated in the area of imaging technology will provide surgeons with an entirely new level of quality and support in the operating room. As General Manager of Endoscopic Imaging for EIZO GmbH, I am delighted to continue supporting ongoing medical advances through the sale of our medical monitors.”

www.eizo.com
www.panasonic-healthcare.com/global/

Siemens Healthineers acquires Conworx Technology GmbH to deliver open connectivity for 100+ point-of-care instruments

Siemens Healthineers recently announced the company is expanding its informatics capabilities for point-of-care testing with the acquisition of Conworx Technology GmbH, the Berlin-based developer of point-of-care device interfaces and data management solutions. The addition of the Conworx suite - including UniPOC and POC-CELERATOR - complements the Siemens Healthineers award-winning RAPIDComm Data Management System and will elevate the informatics offerings for the point-of-care market by delivering open connectivity for more than 100 different instruments from all major manufacturers.

This acquisition is another proof point of the Siemens Healthineers strategic direction to enable healthcare providers around the world to meet their current and evolving challenges and to excel in their respective environments. Through products and solutions designed to increase efficiency and to reduce costs, Siemens Healthineers is setting new trends in healthcare together with its customers - working under the motto “Engineering Success. Pioneering Healthcare. Together.”

As the trend of consolidation and industrialization in healthcare continues and regulatory requirements for point-of-care testing intensify, the need for sophisticated informatics to communicate instrument and patient data at the point of care becomes increasingly important. Siemens Healthineers and Conworx will deliver open connectivity offerings that will enable seamless data integration from any manufacturer’s point-of-care analyser - managed by a single informatics solution to streamline operations and access to data, and improve risk management.

“As hospitals consolidate and acquire physician offices, there is a huge need by emerging healthcare networks for seamless integration of hundreds of decentralized devices that are spread across dozens of sites,” said Peter Koerte, President, Point of Care Diagnostics, Siemens Healthineers. “It is clear to us that to satisfy our customers’ needs, we must deliver solutions that ensure superb connectivity, no matter which analyser is being connected. We are determined to continue Conworx’s practice of working closely with every vendor to ensure that all connected analysers are working to the best of their ability.”

Now a wholly-owned subsidiary of Siemens Healthcare GmbH, Conworx’s team of 75 employees will merge with the Siemens Healthineers team to become Siemens Healthineers Point of Care Informatics. This new team of interface development, application development and data management specialists will be led by Roman Rosenkranz, the current CEO of Conworx Technology GmbH.

"By joining with Siemens Healthineers, we will get access to a global organization to even better support our joint customer base,” said Roman Rosenkranz, CEO of Conworx Technology GmbH. “Together we will be able to develop leading informatics products that help our customers to manage their growing point-of-care networks now and in the future.”

Conworx Technology GmbH was established in 1999. The deal was closed by Siemens Healthcare GmbH in late October 2016.

www.conworx.com/en/
www.siemens.com/healthineers

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Interventional oncology platform for tumour analysis and therapy

Philips’ next generation interventional oncology solution OncoSuite enables physicians to provide analysis and minimally invasive, targeted treatment of tumour lesions reducing the impact to healthy tissue. It offers clinicians a better view of the treatment targets for informed decision making, while performing the procedure. While OncoSuite can be used for a number of different cancers including bone, kidney and lung, the system and its specific tools have been optimized for the treatment of patients with liver cancer. Given the steady increase in the prevalence of non-alcoholic fatty liver disease and liver cancer, the development and availability of new technology is much needed to provide interventional oncologists with a breakthrough that allows best possible treatment for these patients. What matters most in these cases, is the ability to visualize the liver tumours, even small ones, during the procedure and to approach them in a very targeted way to maximize the therapeutic outcome, while avoiding the destruction of healthy liver tissue. OncoSuite is designed to help physicians see, reach and treat liver cancer in a better way. OncoSuite enhances tumour embolization and ablation procedures with Philips’ interventional X-ray systems. It is the only platform in the industry that supports both procedures, enabling physicians to target multiple tumour lesions simultaneously. OncoSuite comprises the company’s innovative product offerings for enhanced imaging (XperCT Dual), live 3D image guidance for tumour embolization (EmboGuide) and live 3D image guidance for tumour ablation (XperGuide). Minimally invasive, image-guided interventional oncology procedures are a highly effective option for patients who cannot be treated through conventional techniques such as surgery, chemotherapy or radiation therapy. Interventional oncology procedures are rapidly increasing and OncoSuite provides the first complete interventional oncology portfolio for interventional radiologists, enabling physicians to see the entire tumour and its feeder vessels to directly target treatment avoiding healthy tissue. The innovative Open Trajectory function within XperCT Dual enables better centering of the liver with significantly improved visualization during the procedure of peripheral hepatic tumours in a single sweep. This feature provides a more targeted field of view making it possible to effectively scan larger patients. Previously, with the traditional geometric movement of the C-arm of the interventional X-ray system, part of the liver image was truncated and larger patients required multiple scans to visualize tumours in the periphery of the liver. Embolization procedures involve blocking the arteries feeding a tumour with beads to deprive it of nutrients and oxygen. They require the insertion of a catheter, which must be guided to the tumour site with the aid of live image-guidance. BTG (Biacompatibles UK Ltd) and Philips have been working in close collaboration on the visualization benefits of radio-opaque beads in combination with image-guided therapy. Together the companies have calibrated LC Bead LUMI and Philips Live Image Guidance Software to help interventional radiologists and multi-disciplinary teams to visualize better treatment options for patients with liver cancer. As a result, the next generation OncoSuite also features the world’s first optimized imaging for LC Bead LUMI that provides real-time visible confirmation of bead location during embolization procedures. In addition, the new Wiper Movement functionality improves workflow with automatic dual phase imaging, helping physicians to acquire two 3D cone beam CT datasets at different times of the procedure in a single step.

PHILIPS

Arab Health Stand S2C10

www.ihe-online.com & search 47125

Patient dedicated in-line blood gas monitoring system

The next generation CE-marked Proxima bedside blood gas analyser (BGA) incorporates a new design and an extended analyte panel. Parameters now added to the new system include glucose and calculated parameters, such as P/F ratio and temperature corrected gases. The ability to monitor blood gases and measure blood glucose frequently and easily, directly by the patient, can enable earlier interventions and closer patient management, which is vital in fast changing critical situations. As a patient-dedicated system, Proxima is always connected to the patient via their arterial line and ready to go instantly. Since results are also delivered without the caregiver leaving the patient’s bedside, this significantly reduces time to result compared to conventional benchtop analysers. Its novel design means the system can travel with the patient on their pathway through the hospital. This is possible since the Proxima sensor contains an array of proven biosensor technology on a silicon chip, each a miniaturized version of the electrochemical sensors used in a traditional blood gas analyser. In addition to the sensor, the next generation Proxima system includes a medical grade tablet monitor with an intuitive touchscreen user interface. All results are reported to the monitor and seamlessly transferred directly into laboratory information systems and electronic patient records. This is a key requirement for the successful implementation of point-of-care (POC) testing.

As an ex-vivo analyser operating as a closed system, blood is drawn directly from the patient and over the Proxima sensor. Following analysis, all blood is returned to the patient, meaning that there is no blood loss and risk of iatrogenic anemia is reduced. Furthermore, infection risk to staff and patients is minimized as the arterial line remains closed throughout sampling. The design of Proxima also reduces pre-analytical errors due to the delivery of a high integrity blood sample direct to the sensor for immediate analysis with no mixing or anti-coagulant required. The addition of glucose to the new Proxima’s analyte panel is significant as glucose measurements play a key part in the care of critically ill patients. Both hyperglycaemia and hypoglycaemia are associated with increased morbidity and mortality in intensive care unit (ICU) patients. Keeping patients in normal glycemic range is difficult with current systems. The ability to regularly monitor arterial blood glucose using Proxima will support closer clinical management for improved glycemic control.

SPHERE MEDICAL

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Surgical displays

The new 31” and 55” 4K UHD displays and a 26” high-brightness, full-HD display complete Barco’s latest surgical display product line. By expanding its range of 4K, high-brightness and high-resolution displays, the company aims to offer a premium imaging experience in the OR. Enriched with brand-new features for surgical applications, all three surgical displays offer state-of-the-art image quality, wide colour gamut and visual accuracy. Both new 4K displays (MDSC-8231, MDSC-8255) now allow image mirroring and rotation to present images per the surgeon’s perspective. Screen cloning on DVI out is also possible, with resolution downscaled from 4K to FHD for easy recording.

The MDSC-8231 is the second generation of Barco’s near-patient 31” 4K surgical display, which now comes in a slimmer and lighter design while maintaining its high-quality image capabilities. Designed for 4K endoscopy imaging and the digital operating room, it offers highly realistic images. It is a high-brightness display capable of resolutions 4x greater than HD, presenting surgeons with rich detail and colour-correct images with excellent depth perception while enabling them to operate with confidence with MDSC-8231’s automated failover feature with backup signal. The 55” 4K MDSC-8255 is perfect for multi-imaging within the OR and can be integrated on or into walls. It can display the equivalent of the information shown on four 27” full HD monitors on a single screen. It is the large size, medical-grade referral display for showing 4K endoscopy camera output or a multi-source image composition to improve workflow during procedures.

Barco’s 26” Full HD MDSC-2326 display boasts the brightness and superior imaging needed for near-patient applications in conditions with high ambient light. Delivering up to 900 cd/m² luminance, it is also extremely durable, featuring guaranteed lifetime protection with easy-to-clean, high quality, scratch-resistant optical glass. The display combines full connectivity with a smart cable management system to minimize clutter, and is easily mounted on surgical booms and spring arms.

BARCO
Arab Health Stand S1F01
i www.ihe-online.com & search 47144
Disposable masks for non-invasive ventilation

Now available are the NEW EAGLE disposable masks for non-invasive ventilation (NIV) and administration of oxygen and other breathing gases. A new disposable interface concept allows one mask to stay with the patient from emergency accident site EMS to transport vent, emergency room vent, acute care, surgery, sub-acute care, to hospital room respiratory support NIV procedures. Features include 3 colour coded sizes (S,M,L), chin cup, low deadspace, light weight, built-in 22mm ID (female) port, clear view and simple headgear.

Integrated ports for scope and gases are also provided as well as 4 optional swivels for connection to respiratory devices.

HANS RUDOLPH
Arab Health Stand H1C10
i www.ihe-online.com & search 47143

Connectivity for point-of-care HbA1c analysers

A new connectivity package for EKF’s Quo-Test and Quo-Lab HbA1c analysers enables secure bi-directional communication between these POC analysers and a multitude of central data management systems. Using the industry recognized POCT1-A2 communication protocol, EKF’s connectivity solution unlocks a host of new features aimed at improving security and quality control (QC) for diabetic HbA1c testing. The new connectivity package includes a proprietary connector interface box, cables and a software upgrade. This enables EKF’s HbA1c analysers to automatically transmit patient data to the majority of Lab Information Management Systems (LIMS) or Hospital Information Systems (HIS). Traceability and results recall speed are improved by use of patient ID and increased demographic data (such as family name and date of birth). These can now be recorded through either selecting from a pre-approved list or via the barcode scanner and keyboard. Also ensuring the integrity of results generated at the POC, security and QC are enhanced on Quo-Lab and Quo-Test through user ID and QC lockout functions which are included in the connectivity package. By restricting access to trained users only, the lockout functions minimize the chances of user error and adhere to security protocols in many institutions. Furthermore, unauthorized users will be prevented from accessing patient information. Multiple user-defined QC lockout options are also available to POCT coordinators in order to enforce regular testing of QC materials and ensure compliance. In addition to ensuring the reliability of results, the new connectivity package also allows the clinician to add commentary to any test result, further enhancing the monitoring and management of diabetes in a point-of-care setting.

EKF DIAGNOSTICS
Arab Health Stand Z1H30
i www.ihe-online.com & search 47136

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