4D cardiac imaging: Strengthening case for MR

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Should TAVI be extended to lower risk patients?

The relatively new procedure for aortic valve replacement, namely Transcatheter Aortic Valve Implantation (TAVI), first performed in 2002, is considered to be an appropriate approach when conventional surgical aortic valve replacement (SAVR) for severe aortic stenosis is contraindicated because patients have left ventricular dysfunction or are very elderly with comorbidities. During the procedure a catheter with a balloon at its tip loaded with a new tissue valve is inserted into a femoral artery and is passed to the opening of the aortic valve where the inflation of the balloon allows the new valve to be positioned and expanded prior to the removal of the catheter and deflated balloon. Trials including two year follow ups comparing TAVI with conservative treatment in high risk, inoperable patients all show that the procedure is associated with higher survival time. However recent results also suggest that TAVI may be superior to SAVR in intermediate risk patients. So should TAVI be extended to intermediate and even low risk, younger patients or is this inadvisable? Earlier data have shown that significantly more patients suffered from stroke after TAVI compared with patients undergoing SAVR, as the former procedure tended to produce debris from the degenerated aortic valve and aorta. Paravalvular leaks have also been reported more frequently after TAVI, impacting on patient survival time. There is also a reported higher incidence in conduction abnormalities after the procedure, often occurring because of too deep implantation of the new valve; in such cases it becomes necessary to implant a pacemaker. Less common complications have included arterial dissection and perforation, myocardial ischemia and cardiogenic shock. However, during the decade since TAVI became the standard of care for inoperable patients with severe aortic stenosis, three major factors have contributed to the substantially lowered risk of complications following the procedure. Firstly preoperative assessment has benefitted from the many recent advances in cardiac diagnostic imaging. Secondly both valve delivery systems and valves have evolved, with the better controlled positioning of more compact, newer generation valves, preceded by pre-implantation site preparation, all allowing superior annular sealing and appropriate valve expansion without causing significant tissue trauma. Last but not least, surgical teams have now acquired a wealth of experience in performing the procedure. The results of randomized trials could well demonstrate that TAVI has even become a prudent therapy choice for younger patients with a low perioperative risk.

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The novelty of 4D
4D cardiac imaging is a recent technique. Its novelty is best illustrated by an editorial in ‘The Journal of the American College of Cardiology’. The editorial, published as recently as 2009, observed the role of “2- and 3-dimensional coronary mapping” in high-resolution digital imaging.

Major imaging vendors now offer real-time 3D/4D imaging products - across all modalities, PET/CT, MRI and ultrasound. However, the bulk of 4D applications so far have involved ultrasound - especially for cardiac imaging. This may be changing, with increased attention, above all, to MRI.

Ultrasounds’s longer legacy
One reason for ultrasound's pole position in 4D consists of a longer legacy. In the early 1980s, researchers from Duke University in the US reported that though MRI was faster, ultrasound offered the closest achievement of “3D real-time acquisition,” or what is now called 4D.

Technical standardization bodies also moved quickly to endorse and drive the take-up of 4D ultrasound. In 2008, the DICOM (Digital Imaging and Communications in Medicine) initiative approved Supplement 43 which addressed the exchange of real time 3D ultrasound datasets between different vendors. In 2011, IHE (Integrating the Health Enterprise) published a White Paper on 3D/4D imaging workflow.

Early adoption of 4D ultrasound by cardiologists
On their part, cardiologists were enthusiastic early adopters of 3D (and later 4D) ultrasound. The IHE’s White Paper mentioned above was written by its Cardiology Technical Committee. Another factor strongly favouring ultrasound was mobility, since small ultrasound devices could be transported to the patient. During this period, competing imaging modalities seemed to stand little chance as far as cardiology was concerned.

Computerized tomography (CT) was dismissed since it required cardiologists to use complex post-processing techniques in order to visualize the beating heart. Cardiac magnetic resonance imaging (MRI) was considered relatively expensive, with limited availability and requiring specialized training.

GE’s cSound: industry seizes the ultrasound opportunity
Industry was quick to seize the ultrasound opportunity. In 2015, healthcare technology giant GE released new software for its ultrasound machines called cSound. cSound-equipped machines intelligently process data being returned by an ultrasound signal, analysing almost 5 gigabytes of data every second, and then filtering it on a pixel-by-pixel basis via algorithms which produced real-time 4D views. This allowed cardiologists to observe how blood swirls around clots in arteries, measure blood leakage around the valves and assess damage. cSound reinforced GE’s presence at the cutting edge of ultrasound, reinforcing a technique patented by the company in the early 2000s and known as Spatial Temporal Image Correlation (STIC). STIC allowed for the quick capture of a full fetal heart cycle beating in real-time.

4D PET/CT and MRI turn to diagnostic oncology
Proponents of 4D PET (positron emission tomography)/CT and MRI were however not sitting by idly. Rather than cardiology, they turned their attention to other specialities, above all oncology where 4D offered huge potential in diagnostics.

4D PET, for example, seemed unmatched in characterizing solitary pulmonary nodules, while 4D CT offered a revolutionary approach in oncology - such as gating tumours and determining treatment margins. On its part, 4D MRI demonstrated a superiority to CT in soft-tissue imaging and in cases where radiation exposure was a concern.
From 4D to 5D imaging
As of now, the focus in diagnostics is to combine the anatomical with functional or molecular imaging, in order to make precise assessments of biological and metabolic pathways. Key modalities include PET with radio-labelled tracers for molecular imaging, and MRI using molecular markers for functional imaging. The molecular/functional enhancement is often referred to as 5D, and to its proponents, offers hope in increasing the specificity and sensibility of diagnostics.

At some stage in the future, it is inevitable that cardiologists will see the virtues of 5D imaging for diagnostics.

The challenge from multi-detector ultrasound scanners
Meanwhile, cardiac ultrasound faces competition in certain applications from other imaging modalities. In recent years, multi-detector CT scanners seem to offer considerable promise, particularly for non-invasive detection of coronary artery disease and higher flexibility for analysis and visualization of individual vessels. These images, nevertheless, continue to require special processing and rendering tools for assessment of segmental narrowing or occlusions.

The growing promise of 4D cardiac MRI
Rather than CT, cardiac (or cardiovascular) MRI in 4D seems to have rapidly become the principal technology paradigm challenger to ultrasound. Cardiac MRI scanners do not use ‘open’ magnets which face serious limitations in the case of moving objects - such as a beating heart. The magnet strengths most widely used for cardiac MRI are 1.5T and 3T - although the latter, in some conditions, require software to cancel artifacts. Higher strength magnets are, however, the technology of choice in studying conditions such as aortic constriction.

What is also a key advantage of cardiac MRI compared to CT is its lack of ionizing radiation, high spatial resolution and the ability to provide a functional cardiac assessment in one scan.

The technique of 4D cardiac MRI is closely based on traditional MRI. However, it is optimized for use in the cardiovascular system in real time, principally via ECG gating and rapid imaging sequences. This results in acquisition of images at each stage of a sequence of cardiac cycles, and functional assessment of the heart. Blood, in such sequences (technically known as balanced steady state free precession or bSSFP), appears bright due to contrast with blood flow. As a result, 4D cardiac MRI makes it possible to discriminate in a relatively easy fashion between the myocardium and blood.

With and without contrast agents
Cardiac MRI typically uses several approaches to make a comprehensive assessment of the heart and cardiovascular system. Some of the most promising applications include the ability to visualize heart muscle fat or scar in high resolution without the need for a contrast agent. This is based on a technique called ‘spin echo’, which shows blood as black, and identifies myocardium abnormalities through differences in intrinsic contrast.

On the other hand, contrast agents like gadolinium-DTPA can be used for applications such as infarct imaging - where healthy heart muscle appears dark, and infarction areas show in bright white. Contrast agents in cardiac MRI have also proven their worth for treatment of coronary artery narrowing, which starves the heart muscle of oxygen. The contrast agent reveals any transient perfusion defects from artery constriction. Knowing about the presence of such a defect assists in guiding interventional procedures.

Image quality, superior access to anatomical structures
Cardiac MRI provides images of superior quality, accuracy and versatility, alongside access to anatomical structures which are tough to achieve with ultrasound. Examples of these include congenital heart anomalies as well as anatomical changes after surgical interventions. The latest generation of MRI scanners allow for acquiring high-resolution isotropic data with detailed anatomical information and identical resolution in all three dimensions. Frontier areas of research for 4D MRI include qualitative and quantitative flow pattern analysis in mice with aortic constriction.

Detecting hemodynamic alterations with 4D MRI
At present, one of the most promising cardiac applications for 4D MRI consists of the detection of haemodynamic alterations. The incorporation of pharmacological stress procedures allows for enhanced detection of alterations in heart function during stress-induced ischemia.

In April 2014, a team at Northwestern University reported that 4D flow MRI would help better understand altered hemodynamics in patients with cardiovascular diseases and improve patient management and monitoring of therapeutic response. Their study, published in ‘Cardiovascular Diagnosis and
Therapy, noted that these hemodynamic insights could also lead to new risk stratification metrics in patients and impact upon individualized treatment decisions in order to optimize patient outcomes.

**Diagnostics and prognosis of heart events**

Cardiac MRI is also being seen as a diagnostic tool to predict heart events. In May 2016, a study led by John P. Greenwood from the University of Leeds in Britain noted that it was "a better prognosticator of risk for serious cardiovascular events than SPECT, regardless of a person’s risk factors, angiography results, or initial treatment, and that it would be a powerful tool for “the diagnosis and management of patients with suspected coronary heart disease.” The serious events, assessed over a 5-year period, included death, myocardial infarction/acute coronary syndrome, unscheduled coronary revascularization, or hospitalization for stroke, transient ischemic attack, heart failure, or arrhythmia.

The study was based on a multi-parametric cardiovascular MRI protocol, and performed on a 1.5T MRI scanner and published in the ’Annals of Internal Medicine’. It was formally known as the Clinical Evaluation of Magnetic Resonance Imaging in Coronary Heart Disease (CE-MARC), and billed as “the largest prospective comparison of cardiovascular MRI and nuclear myocardial perfusion imaging (MPI) with SPECT” with X-ray angiography used as the reference standard.

**Genotoxicity poses calls for caution**

There have, nevertheless, been some calls for caution due to the chance of genotoxic effects of cardiac MRI scanning. In October 2011, a study by researchers at Seoul National University in South Korea, assessed high-field intensity 3T clinical MRI scans in cultured human lymphocytes in vitro and “observed a significant increase in the frequency of single-strand DNA breaks following exposure to a 3T MRI.”

In June 2013, another study on cardiac MRI in ‘European Heart Journal’ reported similar conclusions, this time in vivo. The study, by researchers from University Hospital Zurich, prospectively enrolled 20 patients, and found a “significant increase in median numbers of DNA DSBs in lymphocytes induced by routine 1.5T” MR scanners. The study also made a recommendation, urging cardiac MRI to “be used with caution and that similar restrictions may apply as for X-ray-based and nuclear imaging techniques in order to avoid unnecessary damage of DNA integrity with potential carcinogenic effect.”

**Finns call for further studies**

Nevertheless, there has been no study so far on the genotoxic effects of MRI compared with those of CT scans. In addition, cardiac MRI risk research has been based entirely on cell level experiments with no conclusive and definitive evidence of actual cancer risk. This is in direct contrast to the link between ionizing radiation and cancer risk.

MRI is therefore still considered by its proponents as the safest alternative. Indeed, weeks after the University Hospital Zurich study, Finnish researchers published a riposte, again in the ‘European Heart Journal’, arguing that the “cellular mechanism of how cardiac MRI induced DNA damage was unknown "and may be different from that of radiation.” They concluded that it was “obvious that further larger studies are warranted before any restrictions” were imposed on the use of cardiac MRI.
Implantable cardioverter defibrillators - driven by MR compatibility, subcutaneous devices

In spite of a relatively short history, the use of implantable cardioverter defibrillators (ICDs) has been growing by leaps and bounds. For clinicians, an ICD offers a direct means to avoid sudden cardiac death. Other reasons for the popularity of ICDs include advances in technology, above all miniaturization. More recently, new implantation methodologies such as subcutaneous ICD promise a further boost to their use. The working of ICDs are also easy to explain to patients. There is, nevertheless, one major challenge which ICDs have to still address: limitations to battery life.

**Primary and secondary prevention**
The principle behind an ICD is relatively straightforward, and covers two broad types of prevention: primary and secondary.

Primary prevention, which accounts for the bulk of ICD implants, refers to patients who have not yet suffered life-threatening arrhythmia.

Secondary prevention concerns survivors of cardiac arrest secondary to ventricular fibrillation or sustained tachycardia (together known as a tachyarrhythmia). Although the user group is smaller, secondary prevention makes the strongest case for an ICD.

**Differentiating ventricular tachycardia and ventricular fibrillation**
After implantation, the ICD continuously monitors cardiac rhythm and detects abnormalities. ICDs are programmed to recognize and differentiate between ventricular tachycardia (VT) and ventricular fibrillation (VF), after which they deliver therapy in the form of a low- or high-energy electric shock or programmable overdrive pacing to restore sinus rhythm - in the case of ventricular tachycardia, to break the tachycardia before it progresses to fibrillation. Overdrive or anti-tachycardia pacing (ATP) is effective only against VT, not ventricular fibrillation.

**Defibrillation now almost 70 years old**
The first defibrillation of a human heart dates to 1947, when Claude Beck, an American surgeon at Western University in Ohio, sought to revive a 14-year-old boy whose pulse had stopped during wound closure, following cardiothoracic surgery. Cardiac massage was attempted for 45 minutes, but failed to restart the heart. Ventricular fibrillation was confirmed by ECG. Beck saw no other choice but to deliver a single electric shock. This did not work. However, along with intracardiac administration of procaine hydrochloride, a second shock restored sinus rhythm. Beck's success led to worldwide acceptance of defibrillation. However, his alternating current (AC) device (subsequently commercialised by RAND Development Corporation) was capable of defibrillating only exposed hearts.

**Merging defibrillation and cardioversion**
On its part, the pioneering of cardioversion (and the coining of this term) is credited to Bernard Lown, a physician at the Peter Bent Brigham Hospital in Boston. Lown merged defibrillation and cardioversion, and coupled these to portability. In 1959, he successfully applied transthoracic AC shock via a defibrillator to a patient with recurrent bouts of ventricular tachycardia (VT), who had failed to respond to intravenous procainamide. This was the first termination of an arrhythmia other than VF.

Two years later, Lown joined a young electrical engineer called Barough Berkovitz, who had been researching a relatively safer direct current (DC) defibrillator - based on earlier work in the Soviet Union and Czechoslovakia. Together, Lown and Berkovitz pioneered the concept of synchronizing delivery of an electric shock with the QRS complex sensed by ECG, and a monophasic waveform for shock delivery during a rhythm other than VF. Their work led to launch of the first DC cardioverter-defibrillator in patients.

**The implantable ICD device: parallel pathways**
The Lown-Berkovitz effort was confined to external devices. The concept of an implantable, automated cardiac defibrillator dates to work by Michel Mirowski at Israel's Tel Hashomer Hospital in the mid-1960s. Mirowski moved to the US in 1968, where he joined forces with Morton Mower, a cardiologist at Sinai Hospital in Baltimore. The two tested a prototype automated defibrillator on dogs.

As often happens in science, another researcher had also been approaching the challenge on a parallel path. In 1970, Dr. John Schuder from the University of Missouri successfully tested an implanted cardiac defibrillator, again in a dog. Schuder also developed the low-energy, high voltage, biphasic waveforms which paved the way for current ICD therapy.

The first human ICD, however, was credited to Mirowski and Mower, along with Dr. Stephen Heiman, owner of a medical technology business called Medrac. In 1980, a defibrillator based on their design was implanted in a patient at Johns Hopkins University, followed shortly afterwards by a model incorporating a cardioverter. The ICD obtained approval from the US Food and Drug Administration (FDA) in 1985.

**From thoracotomy to transvenous implantation**
The first generation of ICDs were implanted via a thoracotomy, using defi-
brillator patches applied to the pericardium or epicardium, and connected by transvenous and subcutaneous leads to the device, which was contained in a pocket in the abdominal wall.

ICDs have since become smaller and lighter (thicknesses below 13 mm and weights of 70-75 grams). They are typically implanted transvenously with the device placed, like a pacemaker, in the left pectoral region. Defibrillation is achieved via intravascular coil or spring electrodes.

ICDs versus pharmacotherapy
Over the past two decades, clinical trials have demonstrated the benefits of ICDs compared to antiarrhythmic drugs (AADs). Three randomized trials, known as AVID (Antiarrhythmic versus Implantable Devices), the Canadian Implantable Defibrillator (CIDS) study, and Cardiac Arrest Study Hamburg (CASH), were initiated between the late 1980s and early 1990s in the US, Canada and Europe, respectively. In 2000, a meta-analysis of the three studies was published in 'European Heart Journal.' This found that ICDs reduced the relative risk of recurrent sudden cardiac death by 50% and death from any cause by 28%.

Use after myocardial infarction, quality of life issues
Follow-on initiatives looked at other issues. The Multicenter Automatic Defibrillator Implantation Trial (MADIT) found that ICD benefited patients with reduced left ventricular function after myocardial infarction (MI). In 2005, the Sudden Cardiac Death in Heart Failure trial (SCD-HeFT) established that ICD reduced all-cause death risk in heart failure patients who have LVEF ≤30%, have ischemic heart disease, are in sinus rhythm, and have a left bundle branch block (LBBB) with a QRS duration ≥150 ms. There is no similar recommendation in the European Society of Cardiology document.

The European Society of Cardiology recommendations include patients with QRS duration <120 ms. The US does not recommend CRT for any functional class or ejection fraction with QRS durations <120 ms.

ICD and magnetic resonance
The biggest driver of ICD use in recent years, however, may consist of compatibility with magnetic resonance (MR) imaging. Like other metallic objects, ICDs have been contraindicated for MR. This is however set to change, after the first MR-compatible ICD (Medtronic’s Evera SureScan) received FDA approval in September 2016. The relevance of MR was researched in significant depth by a team at Pittsburgh’s Allegheny General Hospital, led by Dr. Robert Biederman, medical director of its Cardiovascular MRI Center. The study covered patients in three implantable cardiac device case groups, namely cardiovascular, musculoskeletal and neurology. The findings were conclusive. In 92-100% of cardiac and musculoskeletal and 88% of neurology cases, MR exam provided value for the final diagnosis. In 18% of neurology cases, the MR exam altered the diagnosis entirely. In the bulk of cases, said Dr. Biederman, the information could not be obtained with cardiac catheterization, echo or nuclear. In addition, patients were saved from a biopsy of the heart muscle, with all its attendant risks.

The launch of leadless, subcutaneous ICDs
Meanwhile, other factors too are driving development of ICDs. One of the biggest shortcomings of ICDs is the need to run an electric lead through blood vessels. These are susceptible to breakages. In 2012, Boston Scientific received FDA approval for the world’s first leadless, subcutaneous ICD (S-ICD). Rather than leads, the device uses a pulse generator and electrode beneath the skin with a shocking coil implanted under the left arm. A second-generation S-ICD system, branded Emblem, was approved in 2015.

Nevertheless, S-ICDs have drawbacks. Lacking a lead in sufficient contact with the heart, they cannot pace patients out of bad heart rhythms. S-ICDs are also not MR compatible.

The challenge of battery life
Many experts believe that the principal challenge facing ICDs is battery life. According to the Mayo Clinic, batteries in an ICD “can last up to seven years.” It recommends monitoring battery status every 3–6 months during routine checkups, and states when the battery is “nearly out of power,” the old shock generator needs to be “replaced with a new one during a minor outpatient procedure.” Nevertheless, there has recently been some attention about the risk of the latter. In 2014, a research team led by Daniel B. Kramer of Harvard Medical School studied 111,826 patients in the US National Cardiovascular Data Registry (NCDR) who had end-of-battery life ICD generator replacements. They found more than 40% of patients died within five years of ICD generator replacement, and almost 10% within a year. The authors, however, emphasized that atrial fibrillation, heart failure, and left ventricular ejection fraction were independently associated with poorer survival as well as noncardiac comorbidities (chronic lung disease, cerebrovascular disease, diabetes and kidney conditions). What was needed, they concluded, would be a non-ICD control group.

A recent article in the ‘British Medical Journal’ (BMJ) suggests that battery life needs to be extended to 25 years or more to avoid the risks associated with replacement. The author, Dr. John Dean, a cardiologist at Royal Devon and Exeter Hospital in the UK, points out that 1-5% of battery replacements also carry infection risk for patients.

The future: patient needs and superior waveforms
Ultimately, it is patient needs which will drive the next wave in ICD development. While the medical devices industry has focused on device miniaturization, longer battery life is also clearly a priority. Indeed, a 2004 study in ‘Pacing and Clinical Electrophysiology’ found 90% of ICD patients saying they would trade off smaller ICDs for longer-lasting models.

ICD manufacturers are also looking at developing more sophisticated cardioversion/defibrillation waveforms in order to reduce the threshold of defibrillation, and thereby reduce pain and discomfort.
Imaging assessment of prosthetic heart valves

The novel document was produced by the European Association of Cardiovascular Imaging (EACVI), a registered branch of the European Society of Cardiology (ESC). They are endorsed by the Chinese Society of Echocardiography, the Inter-American Society of Echocardiography, and the Brazilian Department of Cardiovascular Imaging.

“Prosthetic heart valves are the best treatment for the majority of patients with severe symptomatic valvular heart disease,” said first author Professor Patrizio Lancelotti. “Heart valve disease is one of the most common types of cardiovascular disease and affects around 3-6% of the population over 65 years.”

Heart valve replacement is performed using mechanical or biological prostheses. It is estimated that by 2050, some 850 000 prosthetic heart valves will be implanted every year in western countries.

Dysfunction of prosthetic heart valves is rare but can be life threatening. When it does occur, it is crucial to determine the cause as this will define what treatment is required. The paper published provides the first recommendations on how to use multimodality imaging to detect and diagnose prosthetic heart valve complications.

When prosthetic heart valve complications are suspected, the authors recommend: First-line imaging with 2D transthoracic echocardiography (TTE); 2D and 3D TTE and transesophageal echocardiography (TOE) for complete evaluation; Cinefluoroscopy to evaluate disc mobility and valve ring structure; Cardiac computed tomography (CT) to visualize calcification, degeneration, pannus, thrombus; Cardiac magnetic resonance imaging (CMR) to assess cardiac and valvular function; Nuclear imaging, especially when infective endocarditis is suspected.

“In this paper we have underlined the incremental value of all imaging modalities to evaluate prosthetic heart valves,” said Professor Lancelotti. “Echocardiography should be used in the first instance to detect any dysfunction. Non-echo imaging modalities can be performed afterwards if more information is needed to establish the cause and extent of complications.”

He concluded: “We have introduced new algorithms to help clinicians diagnose and quantify prosthetic heart valve dysfunction. They are easy to use and we hope will improve assessment and subsequent management of patients so that when complications do occur, better outcomes can be achieved.”

European Society of Cardiology
http://tinyurl.com/go9gwqg

Combining two imaging technologies may better identify dangerous coronary plaques

Combining optical coherence tomography (OCT) with another advanced imaging technology may more accurately identify coronary artery plaques that are most likely to rupture and cause a heart attack. In a report, investigators from the Wellman Center for Photomedicine at Massachusetts General Hospital (MGH) describe the first use in patients of a catheter-based device utilizing both OCT and near-infrared autofluorescence (NIRAF) imaging.

“OCT provides images of tissue microstructure but not of its chemical and molecular composition,” says Gary Tearney, MD, PhD, of the Wellman Center and the MGH Pathology Department, coSenior author of the paper. “Since both of those characteristics are needed to fully understand coronary artery disease, the combination of OCT with NIRAF could provide a more powerful tool for investigating coronary pathology.”

The detailed images provided by OCT are created by bouncing near-infrared light off the internal surfaces of blood vessels and can identify plaques that have the appearance of rupture-prone “vulnerable” plaques with the potential to cause a heart attack or sudden cardiac death. Fluorescence imaging techniques like NIRAF illuminate an artery with a specific wavelength of light to excite certain molecules, which respond by emitting different wavelengths. Since only certain molecules respond, the resulting signal provides information on the molecular composition of analysed tissue.

Tearney’s team has been investigating whether the additional data provided by NIRAF could identify rupture-prone sites within arterial plaques – particularly fibroatheromas, advanced lesions consisting of a core of dead cells covered by an often-thin fibrous cap, which are particularly prone to rupture. In a previous study using coronary artery segments from cadavers, the investigators showed that the NIRAF signal was elevated in fibroatheromas and highest in those with thin fibrous caps. The current study is the first to investigate the use of NIRAF in living patients.

“Performing OCT-NIRAF imaging is just like conducting standalone coronary OCT imaging, and we are now able to obtain near-infrared fluorescence biological plaque information seamlessly integrated with OCT anatomical images, with no additional time required,” Jaffer says. “The clinical success of OCT-NIRAF should further pave the way forward for targeted near-infrared fluorescence molecular imaging using injectable molecular- or cellular-specific agents.”

The primary results of the study were confirmation that the procedure was as safe and as feasible to perform as conventional OCT. The OCT-NIRAF images revealed that the NIRAF signal was elevated in areas in which OCT results suggested the presence of a fibroatheroma, and even higher in lesions with thin caps or at sites of plaque rupture and clot formation. Several aspects of the NIRAF signal were different from the patterns produced by other coronary vascular imaging modalities, and more investigation is needed to determine the molecular underpinnings and clinical significance of NIRAF signal results. NIRAF was also elevated in sites showing evidence of inflammation, another potential biomarker of plaques likely to rupture.

Massachusetts General Hospital
http://tinyurl.com/jy33au9

First patient-based cardiac MRI study using 7T MRI

In a world-first, researchers from Charité – Universitätsmedizin Berlin and the Max Delbrück Centre for Molecular Medicine (MDC) have performed cardiac MRI imaging using a 7T MRI scanner in a patient-based study; 7T MRI imaging is a powerful new technology that allows high resolution images of the beating heart, and has the capability to provide valuable information of the myocardial (heart muscle) tissue structures. Results of the study show that the technology allows the visualizing of very subtle changes of the myocardial tissue structure in patients with abnormal thickening of the heart muscle.

http://tinyurl.com/go9gwqg
For more than four decades, SCHILLER has been committed to the fight against sudden cardiac death. While the most established manufacturers still sold heavy and bulky emergency devices, SCHILLER launched a handy emergency electrocardioscope that was ten times lighter. In one stroke the company not only made a name for itself, but also set new standards. Two years later, the smallest emergency ECG device with integrated printer followed. A built-in microcomputer allows the automatic measurement and interpretation of the ECG. This in turn enables the early detection of heart disorders. Thanks to suitable therapies and rehabilitation measures, physicians can thus protect people of all age groups from sudden cardiac death. Thanks to suitable therapies and rehabilitation measures, physicians can thus protect people of all age groups from sudden cardiac death. As success grew, so did the product portfolio: devices such as blood-pressure monitors and spirometers came to complete the offer, while complete diagnostic stations and monitoring devices are now being produced for clinics and medical practices.

SCHILLER has developed unique products, such as FRED easyport®, the world’s smallest defibrillator, or the "Fire of Life®" software, which analyses the autonomic nervous system. The HRV (heart rate variability) is analysed and the patient’s condition is displayed in the “Fire of Life®” graphics. This graphics shows how well the patient can cope with stress and how he reacts to rest. This opens up completely new diagnostic possibilities, allowing for example to reduce the risk of a burnout. However, resting on its laurels is not an option for SCHILLER because innovation is a priority for this Swiss company. One of the latest developments, for example, is the DIAGNOSTIC STATION DS20.

SCHILLER’s DS20 simplifies the daily work:

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www.schiller.ch
Cardiovascular magnetic resonance imaging (CMR) is turning into a key technology in the diagnosis of myocardial disorders. The method is constantly evolving, and is becoming capable of visualizing both healthy and diseased tissue in increasingly minute detail, even in a heart with normal function. It gives new insights in the heart muscle and assess myocardial damage, including in patients with hypertrophic cardiomyopathy (HCM), a genetically determined abnormal thickening of the heart muscle. 7T MRI imaging is expected to be powerful at visualizing tissue structure at the microscopic scale, including pathological changes and minute depressions. The full capabilities are under evaluation.

In clinical practice, cardiac imaging is performed using 1.5T and 3T MRI scanners. 7T MRI scanners, which constitute a further refinement of the technology, operate at a higher field strength, offering significantly improved resolution as a result. Most of these new scanners remain to be certified for routine clinical use, meaning that their use is limited to research applications; there are currently only five centres in the world capable of visualizing the beating heart using the 7T MRI technology. The biggest challenge of CMR imaging is the heart’s constant movement.

The research group led by Prof. Dr. Jeanette Schulz-Menger, Head of the Experimental and Clinical Research Centre’s (ECRC) Cardiac Outpatient Department, “Our aim was to test the potential of 7T MRI scanning in patients with hypertrophic cardiomyopathy, and to test whether the technology is capable of visualizing even the smallest morphological changes,” explains the cardiologist who specializes in CMR. The researchers succeeded in detecting ‘myocardial crypts’ – minute clefts or fissures which have so far been impossible to visualize in clinical practice in this location. Their success was made possible as a result of close cooperation with a research group at the MDC’s Berlin Ultrahigh Field Facility (B.U.F.F.), which was led by Prof. Thoralf Niendorf. Together, the researchers compared data obtained from patients with abnormal thickening of the heart muscle who had undergone scanning using both a 7T MRI scanner with 2D CINE imaging and a 3T MRI scanner. The researchers also studied images obtained from healthy volunteers, and using the new generation of MRI scanners. Following analysis, the researchers concluded that the use of 7T MRI gives new information in patients with hypertrophic cardiomyopathy. “In seven out of 13 patients, we were able to adequately visualize minute depressions in the myocardial tissue of the left ventricle,” says the study’s first author, Dr. Marcel Prothmann. “The technology’s high spatial resolution constitutes a massive leap forwards in terms of imaging quality. It allows the precise visualization of structural changes within areas of extensive thickening,” says Dr. Prothmann. High-resolution imaging may allow us to make more informed diagnoses when faced with a case of heart failure or another type of heart disease.

**How to identify high risk heart disease patients**

A new study shows that magnetic resonance imaging (MRI) scans are the safest and most effective way to identify high risk patients with cardiac chest pain.

The research, funded by the British Heart Foundation (BHF), showed that cardiac MRI was better overall at predicting serious events, such as death or heart attack, following chest pain suspected to be angina. The researchers from the University of Leeds carried out a five-year follow-up study in 750 people, to find out the best way of separating patients based on whether they were at high- or low-risk of serious heart events. They compared MRI scans, a non-invasive test which does not use potentially dangerous radiation, with SPECT, a procedure which uses ionizing radiation and is commonly used in the diagnosis of coronary heart disease.

Coronary heart disease (CHD), the world’s biggest killer, is responsible for nearly 70,000 deaths in the UK each year, an average of 190 people each day, or one death around every eight minutes.

Most deaths from CHD are caused by a heart attack. CHD occurs when the vital arteries which serve the heart are narrowed or blocked by a build-up of fatty tissues. This can cause chest pain, or angina, which can lead to a heart attack if left untreated. When a person has suspected angina, they are most likely to be tested with either an X-ray angiogram, an invasive procedure which uses a type of radio-opaque dye to image the inside of the arteries, or SPECT, a non-invasive procedure which also involves ionizing radiation. Ionizing radiation is damaging to living cells. In contrast, MRI scans use strong magnetic fields and radio waves to produce a detailed image of the inside of the body, and are already widely used to help diagnose other medical conditions.

The paper resulted from a large five year follow-up study and follows a series of papers from the original CE-MARC (Clinical Evaluation of MAgnetc Resonance imaging in Coronary heart disease) study. These papers have contributed to the growing body of evidence that cardiac MRI is the best option for the diagnosis and management of patients with coronary heart disease. Earlier evidence from this BHF-funded study also showed that MRI is more cost-effective than SPECT in the diagnosis of coronary heart disease.

This research is expected to inform future clinical guidelines for the investigation of stable coronary heart disease. In doing so it could ease pressure on the NHS as only one hospital appointment is required for MRI, compared with two for SPECT. Professor John Greenwood from the School of Medicine, who led the research, said: “Although SPECT is currently more widely available than MRI, the use of MRI across a wide spectrum of diseases means that it will be much more readily available for heart disease investigation in coming years.”

University of Leeds
http://tinyurl.com/a7cc2ny

**New ultrasound method creates a better picture of cardiovascular health**

Researchers at Lund University in Sweden have discovered a new and more accurate way to distinguish between harmful and harmless plaque in the blood vessels by using ultrasound. This can help healthcare providers determine the risk of strokes and heart attacks – which means avoiding unnecessary surgery for many patients.

In many parts of the world, atherosclerosis is one of the diseases responsible for a large number of cases of premature death. Six years ago, a handful of researchers at Lund University in Sweden started taking an interest in how to make it easier to recognize unstable plaques that in worst case scenarios rupture and cause heart attacks or strokes.

When Tobias Erlöv, who at the time was a doctoral student in biomedical engineering
at the Lund Faculty of Engineering, discovered that there is a fairly simple mathematical calculation that can be used to interpret ultrasound signals and thereby figure out whether the plaque in the carotid artery is harmful or not, the researchers were somewhat surprised.

Vascular surgery is currently only performed if there is excessive blockage to the blood flow, due to too large plaques. However, determining whether or not the plaque is unstable cannot be done by simply studying flow rates and plaque sizes – knowing the type of cell concerned is more important.

Simply put, harmless plaques consist of connective tissue and smooth muscle cells. Harmful plaques consist of fat (lipids) and macrophages. Unstable plaques can also involve bleeding.

“We have shown that there is a strong correlation between changes in the centre frequency and the size of the reflecting particles. The more harmful substances, the greater the so-called centre frequency shift”, says Tobias Erlöv, who is currently continuing his research at the Department of Biomedical Engineering.

The method can become useful to identify patients at risk of developing acute cardiovascular diseases, but also to follow up after surgery where plaque has already been removed.

In the future, ultrasound scans of the carotid artery will lead to the ability to perform surgery at an earlier stage in some cases, and the ability to avoid surgery completely in others.

People with cardiovascular diseases, and diabetics who risk developing them, can benefit from this new and accurate method.

“Ultrasound enables you to screen a larger population, and that in turn means that life-threatening cardiovascular diseases can be detected at an earlier stage”, says Magnus Cinthio, senior lecturer in biomedical engineering and one of the researchers leading the work.

“Another advantage is that the method is inexpensive and completely harmless to patients”, says Tobias Erlöv.

Lund University
http://tinyurl.com/jp8fbbz

Novel approach improves symptoms of hazardous lymph blockage

Paediatric researchers have devised an innovative, safe and minimally invasive procedure that helps relieve rare but potentially life-threatening airway blockages occurring in children who had surgery for congenital heart defects.

The physician-researchers developed new imaging tools and used minimally invasive catheterization techniques to treat plastic bronchitis, a condition in which abnormal circulation causes lymphatic fluid to dry into solid casts that clog a child’s airways.

The study, which describes the pathophysiological mechanism of plastic bronchitis and a treatment approach, arose from collaboration between Maxim Itkin, MD, an associate professor of Radiology in the Perelman School of Medicine at the University of Pennsylvania, and Yoav Dori, MD, a pediatric cardiologist in the Cardiac Center at The Children's Hospital of Philadelphia (CHOP). They co-lead a specialized team dedicated to the care of lymphatic disorders as part of the Center for Lymphatic Imaging and Interventions at The Children's Hospital of Philadelphia and the Hospital of the University of Pennsylvania.

“This is a new treatment option for children with plastic bronchitis and has the potential to offer long-term improvement of this condition,” said Dori. “This procedure may even provide cure and avoid the need for a heart transplant.”

The current study builds on the team’s 2014 article in Pediatrics, the first case report of the successful use of their technique in a patient with plastic bronchitis. “We have expanded on that study to report short-term outcomes in a larger group and to share insights into the development of plastic bronchitis, which has been poorly understood,” said Itkin. In addition to heart patients, children and adults with idiopathic plastic bronchitis, in which the cause is unknown, have also been treated successfully using these techniques.

Itkin and Dori discovered that the primary cause of plastic bronchitis is a lymphatic flow disorder, due to abnormal lymphatic flow into lung tissue. Because physical examinations and conventional imaging may not provide specific findings, lymphatic flow disorders often go undiagnosed.

Over the past several years, Itkin and Dori developed a customized form of magnetic resonance imaging (MRI), called dynamic contrast enhanced MR lymphangiogram, to visualize the anatomy and flow pattern of a patient’s lymphatic system. This technique allows clinicians to locate the site at which lymph leaks into the airways.

http://tinyurl.com/gp8fbbz

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September 2016
www.ihe-online.com & search 47050
Plastic bronchitis may occur in children as a rare complication of early-childhood heart surgeries used for single-ventricle disease, in which one of the heart’s pumping chambers is severely underdeveloped. Approximately 5 percent of children surviving this surgery experience plastic bronchitis because the surgery alters venous and lymphatic pressure. The authors argue that this altered pressure may interact with pre-existing anatomical differences in the patients’ lymphatic vessels. The abnormal circulation causes lymph to ooze backward into a child’s airways, drying into a caulk-like cast formation that takes the shape of the airways. The first sign of plastic bronchitis may be when a child coughs out the cast. However, if unable to cough it up, a child may suffer fatal asphyxiation.

After identifying the leakage site in a lymphatic vessel, the lymphatic team intervenes, using a technique called lymphatic embolization. Through small catheters, the team blocks the abnormal flow with a variety of tools: coils, iodized oil, and covered stents, based on an individual patient’s needs. In the current report, the team was able to perform lymphatic embolization in 17 of their 18 patients, ranging from age 2 to age 15 (median age 8.6 years). Fifteen of those 17 patients had significant improvements in cast formation, in some cases being cast-free longer than two years. Patients had transient side effects of abdominal pain and hypotension (low blood pressure), but the authors reported the procedure appeared safe in their patient group.

Safer, faster heart scans in view

A team of Oxford University researchers has developed a technique that could improve heart scans for patients, giving more information about the heart than traditional scans and without any injections, making them safer and faster.

The group of medical, physics and engineering researchers are based at the Oxford Centre for Clinical Magnetic Resonance Research (OCMR). They are using a property of hydrogen atoms to create a pixel-by-pixel map of the heart, called a T1-map, which allows examination of healthy and diseased heart tissue in greater detail than before. Currently, stress scans of the heart using magnetic resonance imaging (MRI) require patients to be injected with two substances. Adenosine is a medication injected into the patient that causes effects similar to exercise during the scan. Gadolinium - a rare earth heavy metal - is injected as a contrast agent to highlight areas of the heart suffering from decreased blood flow under exercise conditions.

Patients with severe kidney failure – who are usually at higher risk for heart disease – cannot clear Gadolinium and often are unable to benefit from a full MRI scan of the heart. T1-maps can potentially solve this problem in the future. Dr Alexander Liu, who leads the research with the guidance of his supervisors – Dr. Vanessa Ferreira, Dr. Stefan Piechnik and Professor Neubauer (the centre director), explained: "We wanted to see if using T1 mapping can give clearer, more clinically-useful results compared to traditional MRI scans that require injections of contrast agents. On traditional MRI scans, doctors are judging relative shades of light and dark on a scan, and even the most experienced specialists can disagree on what the image is showing them. T1 maps provide an objective number, which can be coded in colours, and may be less subjective. Additionally, patients with severe kidney failure – who are usually at higher risk for heart disease – cannot clear Gadolinium and often are unable to benefit from a full MRI scan of the heart. T1-maps can potentially solve this problem in the future.

In physics, T1 is the time constant that describes how quickly atoms return to normal thermodynamic state after being affected by radio waves and strong magnetic fields. Just like measuring body temperature in Celsius or Fahrenheit, the numbers themselves may not mean much, but any deviation from established normal ranges can suggest disease. In the case of T1 mapping, long T1 times indicate the presence of more water, something found in a number of heart conditions, including areas of the heart suffering from lack of blood supply due to blocked arteries. A T1-map just helps to visualize T1 values across the heart and find the precise location of the problem. It takes around three minutes to map the whole heart, and the values it measures are turned into a colour map, giving doctors an image which is potentially quicker to understand with less subjective interpretation.

Dr Stefan Piechnik developed the specific T1 mapping technique at Oxford, named ShMOLLi. He said: ‘T1 mapping allows us to look in finer detail at the heart in a non-invasive way, which has not been possible before. We can now get results without Gadolinium, meaning we have a technique that is safer and quicker and can be used with more people. The results are also less dependent on interpreting the images – medics have something based on hard numbers.’

Oxford University
http://tinyurl.com/h4ruhca

Transfusion with stored blood safe in heart surgery

A large registry study led from Sweden’s Karolinska Institutet sheds new light on the much debated issue of transfusions with stored blood. The study shows that the use of stored blood units does not influence patient outcomes after heart surgery.

In Sweden and most other western countries, blood units can be stored for as long as 6 weeks before being transfused. However, a high-profile publication in 2008, which claimed that storage for a mere 14 days or more was unsafe for heart surgery, has caused confusion and anxiety at hospital clinics worldwide.

“There have literally been hundreds of studies conducted on this topic the past five or six years, none of which have been able to provide a definitive answer”, says senior author Gustaf Edgren, MD, Associate Professor at the Department of Medical Epidemiology and Biostatistics.

To tackle the problem at its roots, Dr. Gustaf Edgren and his research team performed a large-scale study of almost 50,000 patients in Sweden over a 16-year period. The study was made possible by linking a number of high-quality health registries, which allowed researchers to include all heart surgery patients in Sweden during the study period, with complete information about all blood transfusions administered together with clinical details about the patients. The cohort included patients receiving transfusions with blood that had been stored between 14 and 42 days.

“This study is by far the largest investigation focusing on the issue of blood storage in this very sensitive patient group, and we find absolutely no hint of negative health effects associated with stored blood”, says lead study-author Ulrik Sartipy, a cardiac surgeon and associate professor at the Department of Molecular Medicine and Surgery.

“Thanks to these unique health registers we have been able to provide very firm reassurance that the current blood storage practices are safe,” says Gustaf Edgren.

Karolinska Institutet
http://tinyurl.com/zudvdff

http://tinyurl.com/zudvdff
Hospitals straddle a unique crossroads in terms of cybersecurity, crime and potentially, terror. In spite of a rapid shift to computerized prescriptions and electronic records, the hospital business is inherently complex, marked by privacy constraints as well as legacy IT infrastructure. In an era of cost cuts, hospital managers have also been tempted more by imaging scanners and surgical robots, rather than (invisible) firewalls and encryption systems.

### UCLA 2014: six years after Britney Spears, access still unhindered

As recently as 2014, after a massive hack, one of the world's most prestigious hospitals, at the University of California Los Angeles (UCLA), acknowledged that its patient data was not encrypted. At stake was data on 4.5 million patients, some dating to 1990. Six years previously, UCLA had paid out $865,000 (€778,000) after an employee stole medical data on celebrities including singer Britney Spears and actress Farah Fawcett, and put them up for sale.

### Situation challenging in both US and Europe

Many hospitals are accepting they have a serious cybersecurity problem on their hands. This follows mounting public concern - especially in the US - about growth in hospital data theft. Although American politicians have called for emulating some of Europe’s medical data security practices, the European situation hardly justifies complacency, as we shall see.

### Data on 80 million patients hacked, 9.3 million offered for sale

In the broadest terms, healthcare lags other economic sectors in terms of information security. In the US, healthcare accounted for three of the top seven security breaches in 2015. During the year, just one hacking incident at insurer Anthem Inc. potentially compromised medical data on 80 million Americans.

The situation has since worsened. In June 2016, Baltimore-based privacy monitor Protenus reported a staggering 11 million patient records stolen in 29 incidents (24 at hospitals).

During the month, one hacker made two back-to-back online sale offers - for 655,000 medical records, followed a few weeks later by 9.3 million records. The numbers are of course impressive. However, as the hacker underlined to DarkNet news aggregator DeepDotWeb, this was only a start. “A lot more,” he said, was still “to come.”

### Identity theft - from drugs, explosives and insurance claims to duplicated you-and-me

One of the biggest risks is identity theft. Data on patients, including names, birth dates, social security and insurance policy numbers, diagnostic, treatment and credit card information, can be misused in several ways. Criminals also have an easy choice. If a target refuses to pay ransom, hackers can still sell the data.

Stolen IDs are used to buy drugs and equipment for resale, or to make insurance claims. Certain prescription medicines can be converted into synthetic addictive drugs, or especially potent explosives. A basic identify kit sells for $1,500 (€1,350), though certain medical data can raise the price dramatically. This compares to the couple of dollars sought for basic credit card information. Identity kit data can be used to professionally forge follow-on credentials such as new credit cards and lines of credit, insurance and social security subscriptions, driving licenses, marriage certificates (for illegal immigrants) and passports.

### A fast-growing and expensive problem

A February 2015 study by Ponemon Institute, a think-tank on data protection, shows US identity theft rising annually at about 20% since 2012. An estimated 2.3 million adults were affected by medical identity theft in 2014, up from 1.4 million in 2009.

The cost to patients is substantial. Ponemon found medical identity theft costing an average of $13,500 (€12,150) in out-of-pocket legal expenses and financial losses.

### Endangering patients

Beyond costs lie other dangers. These are often exacerbated by delays in hospitals informing patients about medical
data theft. As we shall see, such a lapse is hardly rare, and victims can end up with a thief’s health data incorporated into their own. A patient record may show a diabetic as being diabetes free, with other misinformation about allergies or blood type being potentially fatal. Reversing this is not always straightforward.

In summer 2015, the ‘Wall Street Journal’ reported an identity theft at Centerpoint Medical in Independence, Missouri, leading to erroneous billing about a non-existent injury. Although the error was pointed out to the hospital in January 2014, the hospital and a collections agency remained in hot pursuit until the year end for payments - and interest. The intervention by the influential US newspaper led to Centerpoint dropping the bills and charges. However, when the (real) patient’s record was found to contain wrong information about an allergy, a review was not permitted, in order to protect the thief’s health information - covered by the privacy provisions of HIPAA (Health Insurance Portability and Accountability Act).

**USBs, laptops - physical theft remains a major problem**

In spite of such growing threat awareness, the risk management spectrum remains immature. Most hospitals lack protocols to prevent data transfer to small, high-capacity USB sticks and CD-ROMs, or control access for laptops. Indeed, Department of Health and Human Services (HHS) data show that over 40% of US medical data breaches involve portable media devices. One good example is Chicago’s Advocate Medical Group where a laptop theft from an ‘unmonitored’ room in 2013 led to the loss of data, including social security numbers, on 4 million people. Advocate Medical took one month to notify patients, although many faced a clear risk of identity theft.

**No encryption, not even passwords**

One year previously, Howard University Hospital notified 35,000 patients that their medical data had been compromised, after a contractor at the hospital downloaded files onto a personal laptop, which was then stolen. The data, included names, addresses, Social Security numbers and medical information. It was password-protected but unencrypted. Several non-technical hospital staff, unfortunately, remain unaware about this crucial difference.

For example, at the end of 2013, Kaiser Permanente’s Anaheim Medical Center reported a breach of 49,000 records from an unencrypted, missing USB drive. A similar situation occurred again in May 2016 after 29,000 emergency room patient records were compromised at Indiana University’s Arnett Hospital, after being ‘accidentally’ downloaded to a USB drive. This time the data was neither encrypted nor password protected.

**Europe has similar problems as US**

The situation in Europe, too, is hardly encouraging. As far back as 2007, Britain’s Nottingham University Hospitals Trust faced the theft of a USB stick with patient data from a doctor. The theft came to light after a whistle-blower wrote to the ‘British Medical Journal’ and noted that it was common for doctors to carry patient data around on USB sticks in order to permit patient hand-overs. Although the Trust’s policy required confidential data storage on USB sticks to be limited to 128-bit encryption and be used solely on hospital computers, only the naive (continue to) believe that enforcing such a policy is possible.

One year later, a manager at Colchester Hospital in Essex was sacked after his laptop containing medical data was stolen by thieves who broke into his car while he holidayed in Edinburgh. At the time, the hospital’s CEO said the sacking was a clear endorsement about “how seriously” he took “security and patient confidentiality.” However, there was no explanation about why private medical data was present, and then too in an unencrypted form, on the laptop of a holidaying executive, when it could well have been accessed via a secure online network.

**Theft of laptop with 8.3 million (unencrypted) UK records**

The quantity of physical data theft from UK hospitals also continues to grow, even as security practices remain stuck. In 2011, an (unencrypted) laptop was stolen from an (unlocked) office in the headquarters of Central London NHS (National Health Service). The laptop contained hospital records of 8.3 million identifiable patients. Overall, according to an investigation by ‘Pulse’ magazine, 55 UK hospitals have reported breaches, including records dumped in public places, or provided to the wrong patients. The lack of a risk management policy was demonstrated emphatically in April 2014. In spite of claims that the (massive) UK national records database “has never been compromised,” Freedom of Information disclosures showed four serious medical data security breaches since 2009.

**French hospitals: laconic about cybercrime**

France, too, is in a similar quandary. It is implementing a single national medical database with information on 66 million residents. This complements an electronic medical record (known as DMP 2) with open architecture to make it easier for sharing data among hospitals and healthcare professionals.

In May 2016, the journal ‘Le Nouvel Observateur’ noted though several French hospitals had been targeted by cybercriminals, there was a deafening silence about the issue. In addition, it said, there was little clarity about whether patients would be informed in case of a data breach. What was especially alarming was that only 50 experts were responsible for computer security at 1,000 French hospitals.

**US Senate tightens the screws at end of 2012**

In the US, meanwhile, although the privacy of medical health data is codified by HIPAA and reporting rules from 2009 require hospitals to notify both the authorities and the media if a data breach affects 500 or more patients, there are no requirements for criminal prosecution. Until November 2012, in spite of more than 22,000 complaints about HIPAA privacy violations, the US government imposed just one fine. During that month, after a particularly feverish spell of attacks, the US Senate took HHS to task in a public hearing. By June 2013, HHS had made fines of over $1.5 million (€1.35 million).

**Howard University hospital attacked twice in 2012**

2012, the year of the Senate hearings, was clearly a turning point in US attention to medical data safety. In May, prosecutors charged Laurie Napper, a technician at Howard University Hospital for using her position at the hospital to gain access to patients’ names, addresses and Medicare numbers and selling this information. This was barely a few months after the same hospital had notified 35,000 patients about their medical data being compromised.
US military medical records compromised
In November 2012, TRICARE, the health insurer for the US military, announced the theft of backup computer tapes with 5 million names, Social Security numbers, and, in some cases, clinical notes and lab test results. The fact that these records also contained the home addresses of military personnel added another category of security risk to the theft.

Whether due to larger fines for medical privacy violations and/or a fast-growing number of cybercriminals, Ponemon Institute found that 40% of US healthcare organizations reported a criminal cyber attack in 2013, twice the level of 20% in 2009.

After Chinese attack, FBI heightens attention to hospital cybersecurity
One key development has been the FBI’s entry in 2014 into hospital cybersecurity. One of the trigger events was a theft by Chinese hackers of data on 4.5 million patients held by one of the US’ largest hospital operators, Community Health Systems Inc.

Soon after, as noted previously, US health insurance giant Anthem Inc. reported what may be the biggest medical record hack in the world. Anthem holds data on 80 million Americans, including names, dates of birth, Social Security numbers, Medicare and health plan identification numbers as well as diagnostic and medical/surgical procedural data. Ironically, only a few weeks before, Anthem’s CEO announced that his company and the health insurance industry ranked at the end of the list in customer service.

The risk of attacks by hostile foreign interests was, however, not new. Indeed, in the tipping point year of 2012, Utah’s Department of Health reported that hackers from eastern Europe had stolen medical information on 800,000 people, or almost 25% of the State’s residents.

Shutting down a hospital: the problem of ransomware
Beyond medical identity theft lies ransomware, which may be the fastest growing security risk. Rather than stealing data, ransomware locks down systems and encrypts files. Typically, a pop-up screen then demands ransom in exchange for a key to decrypt files and return access to a user.

Ransomware offers one of the best risk-reward portfolios for criminals who target hospitals. The technology is relatively unsophisticated and versatile, and hackers can make money quickly via extortion rather than seeking to sell data on the black market.

In February 2016, Hollywood Presbyterian Medical Center called in the FBI after ransomware forced its IT systems offline. Physicians could not access electronic records or communicate via email. Some emergency patients were diverted to other hospitals while outpatients missed treatments. Although reports about a $3.6 million (€3.24 million) ransom payment were reduced to $17,000 (€15,300), the fact that ransom money was paid is likely to increase the risk of copycat cybercriminals. The FBI recommends organizations do not pay ransom.

At the end of March, MedStar Health, a ten-hospital group in Maryland with over 100 outpatient facilities and 30,000 staff, became the largest medical entity to be successfully attacked by ransomware. Though MedStar stated there was “no evidence of compromised information,” the bulk of its electronic operations was shut down. This time too, the FBI, was called in.

By June 2016, at least a dozen US hospitals had been targeted by ransomware. The number is likely to grow.

Ransomware forces German hospital to use pen and paper, postpone surgeries
The threat of ransomware is also serious in Europe.

In February 2016, the respected German publication ‘Deutsche Welle’ (DW) reported that a number of hospitals in the country had fallen prey to ransomware, disrupting core healthcare services and internal systems. DW named several leading hospitals, including the Lukas Hospital in Neuss and the Klinikum Arnsberg hospital in North Rhine-Westphalia.

The Lukas Hospital was forced to revert to phone calls, fax and pen-and-paper records for several weeks, with high-risk surgeries postponed until handwritten notes had been filed.

On the other hand, Klinikum Arnsberg fared far better. A quick response saved it after the ransomware, entering via email, was detected on one server. All other servers, some 200 in total, were switched off to prevent contagion.

From IP to terror: other cyber-risks associated with healthcare
The healthcare threat spectrum extends beyond hospitals.

In October 2013, the US Food and Drug Administration (FDA) reported an alarming security breach at its Center for Biologics Evaluation and Research. The hack compromised 14,000 accounts, including proprietary pharmaceutical company data.

Issues of intellectual property (drug formulae, manufacturing processes etc.) and trade secrets are of evident interest, to competitors, both at home and abroad. This is not a trifling matter, given the billions of dollars spent in developing and marketing a drug, and the billions more expected from its sale.

The interest in biologics in particular, shown by the hack at the FDA, has been of concern since several biologic products have recently begun to come off patent, while many more are expected to do so in the future.

Last but not least, biological products include vaccines - with all their attendant implications for terrorist attacks. At the end of May, one of France’s biggest hospitals, the Pitié-Salpêtrière at Paris, was subject to a break-in at a laboratory storing bacteria. In November 2015, just after the Paris terrorist attacks, another city hospital, Necker, had reported the theft of Hazmat suits - which can be used to protect against bacteria/biowarfare agents. Whether there is a connection between the two is something one can only speculate about.

There will no doubt be other risks. For example, we know of one case of theft of a hospital’s fire safety plans. These identified storage areas for radioactive substances and hazardous waste. Here again, the authorities seem to be at a loose end.

Until hospitals and other actors in the healthcare industry develop and implement security best practices, the threat of disruptions, caused by petty criminals and ranging through to foreign corporate spies and terrorists, will clearly persist.

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Introduction of the development of the mobile smartphone application, “PWH easyGo” to help patients and visitors to navigate different departments and facilities on the hospital premises with ease

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**ABSTRACT:** “PWH easyGo” is a mobile smartphone application (app) designed to help patients and visitors to look for different departments and facilities on the hospital premises. Posters with QR code are displayed at various hospital entrances. Users with the app installed can scan the QR codes printed on posters on site or manually select their current locations and destinations in the app, and the system will display the relevant routes with photos. It is the first such app developed by the Hong Kong Hospital Authority and is available for download at Apple Store (iOS version) and Play Store (Android version). A video file demonstrating the use of “PWH easyGo” can be found at URL: http://www3.ha.org.hk/pwh/film/pwheasygo20150608_eng.mp4

An approach to improve patient safety and quality beyond accreditation

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**ABSTRACT:** Patient safety improvements demand a complex system-wide effort, involving a wide range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice and safe environment of care. Healthcare accreditation is one of the major steps towards improving quality and patient safety. Amongst the several accrediting agencies across the world, the Joint Commission International (JCI) stands out as the gold standard in healthcare accreditation. The patient safety journey for hospitals like the Apollo Group, formally started with Apollo Hospitals, Delhi becoming the first JCI accredited Hospital in India, in 2005. In the years to come, eight hospitals of the Group also became JCI accredited; taking the number of hospitals accredited by JCI to twenty-three in the country. The National Accreditation Board for Hospitals and Healthcare providers (NABH) was formed thereafter and today nearly three hundred hospitals are accredited by NABH across the country. There is more to patient safety and healthcare quality beyond just accreditation. With a view to further improve patient safety; Apollo Hospitals have taken several initiatives.
Perception of Healthcare Providers Regarding Hospital Bed Utilization: A prerequisite for quality improvement initiatives in Healthcare institutions

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ABSTRACT: Hospital bed utilization is influenced by various factors which can be divided into patient, physician and administration related. These factors should be seen from the eyes of healthcare providers so that any improvement initiative taken by the administration is matched with the health worker’s perception which ultimately affect the hospital efficiency and quality of care.

Aim and Objective: To ascertain the factors influencing hospital bed utilization from the perspective of healthcare providers.

Methods: This cross sectional study was conducted in an apex tertiary care public institution in northern region of India. All the resident doctors and nurses in the 18 wards of 7 specialties and 7 super specialties were interviewed using a structured validated self-administered questionnaire.

Results: A total of 279 participants (117 doctors and 162 nurses) were enrolled in the study. The factors significantly influencing bed utilization with regard to doctors are patients (2.34, 0.36), physician (2.47, 0.32), administrative (2.61, 0.29) and with regard to nurses are patient (1.97, 0.40), physician (1.97, 0.46), administrative (2.39, 0.40). Conclusion: Changing healthcare trends in the recent past (innovations in policy decisions, technological advances, business sustainability aspect, quality initiatives etc.) gave an insight to policy makers (administrators) to consider the perception of healthcare providers (human resource) regarding bed utilization as an important component of healthcare delivery system.

Highlighting Service Excellence in Lorma

Dr. Rufino L. Macagba, Jr., MD, MPH
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Executive Director, Human Resource Lorma Medical Center

Mr. Enrique Fernandez
Training and Organizational Effectiveness Officer Lorma Medical Center

ABSTRACT: Service Excellence Training is an important continuing priority in Lorma Medical Center. Its design and contents are modified as needed to respond to patients’ comments on the quality of service by Lorma staff. Noted inadequacies in customer satisfaction were based in the Patient Surveys of Lorma in 2013. Floating of Satisfaction Assessments is done monthly by the Patient Relations Office and summaries of the same are submitted by the Executive Secretary to the Department Heads concerned for immediate action, monitoring and reporting on improvements made. The premise is that process improvements should be based on data (1).

Pre-operative Verification, Site Marking and Time Out - Spreading Patient Safety Culture from Major Operating Theatre to Day Surgery

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ABSTRACT: In this article, we describe how we spread safety culture of correct site surgery from Major Operating Theatre to Day Surgery. We discuss how we integrated the High 5s Project Correct Site Surgery protocol into the Day Surgery Operating Theatre (DSOT) workflow and monitored compliance through audit and feedback. We also reflect on how human factors analysis (HFACS) helps in bridging the gaps by providing a tool for recognizing possible causes of non-compliance.
National University Health System (NUHS) Transitional Care Program

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ABSTRACT: Frail elderly patients require a longer time to recuperate after hospitalization, and are often discharged home from the hospital with little support despite their needs for complex care. They are particularly vulnerable to hazards of hospitalization and fragmented care if not appropriately managed. Geriatrician-led transitional care program called NUH-to-Hone (NUZH) was started in March 2014 to provide high-quality person-centered interdisciplinary care for older adults who were discharged from the National University Hospital (NUH) Singapore. It aims to enhance the quality and safety of post-discharge care at home, leading to an eventual reduction in readmissions and prolonged hospital stay. In the first year of implementation, there was a 67%, 68% and 75% reduction in readmissions, emergency room visits and length of hospital stay respectively.

Using online and scenario-based learning to improve nurse-patient interaction and enhance patient experience

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ABSTRACT: In this article, we describe our project to initiate an online learning course, using real-world scenarios to help nurses enhance their communication skills with patients so as to improve the patient experience. The philosophy behind our project is 'a complaint is a gift'. We discuss how patients' complaints are incorporated into our curriculum and the use of HEART language to provide patients a better hospital experience. The 'HEART' acronym refers to five attributes which we believe all nurses should embody: Be HUMBLE, be EMPATHETIC, use APPEALING statements, be RESPONSIBLE and TELL the facts when interacting with patients. The communication modules are hosted online as an alternative to classroom teaching, as this offers increased learning flexibility.

MAA Medicare – Crossing Borders

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CEO, MAA MEDICARE CHARITABLE FOUNDATION

ABSTRACT: This article describes the activities of MAA Medicare Charitable Foundation, which provides support for two charitable arms- the MAA Medicare Kidney Charity Fund and the MAA Medicare Heart Charity Fund. Author describes how such charitable organizations can play a vital role in supporting the care of patients with kidney disease in cases where such care is not available through the public programs offered by the government. Public employees and government retirees who need dialysis can receive care from private dialysis centers, through government subsidies. But many low-income patients who cannot afford the high price of dialysis would be deprived of care without the MAA Medicare and other non-profit programs for dialysis. The article highlights how a public-private partnership between NGOs that finance such a program, can play an important role in strengthening the health system and accessing effective and affordable care in a setting where such care would not otherwise be available to vulnerable segments of the population.

Emerging Grandeur Niche in Chinese Wellness Tourism at Phuket Island

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ABSTRACT: China’s biggest population size is the foremost intriguing factor in the country’s wellness tourism opportunity. Preventative medicine and health prevention is one of the most growing healthcare sectors due to state-of-the-art advanced medical diagnostics and technology. However, wellness tourism in China is still in its infancy, it offers massively new opportunities for the outbound wellness tourism industry. Several reports reveal that environmental assets, including fresh air, clean water and natural
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Ibuprofen patch - delivering pain relief directly through skin

Researchers at the University of Warwick have worked with Coventry-based Medherant, a Warwick spinout company, to produce and patent the world’s first ever ibuprofen patch delivering the drug directly through skin to exactly where it is needed at a consistent dose rate.

They have invented a transparent adhesive patch that can consistently deliver a prolonged high dose of the painkiller ibuprofen directly through the skin. The University of Warwick researchers and Medherant have found a way to incorporate significant amounts of the drug (up to 30% weight) into the polymer matrix that sticks the patch to the patient’s skin with the drug then being delivered at a steady rate over up to 12 hours. This opens the way for the development of a range of novel long-acting over-the-counter pain relief products which can be used to treat common painful conditions like chronic back pain, neuralgia and arthritis without the need to take potentially damaging doses of the drug orally. Although there are a number of popular ibuprofen gels available these make it difficult to control dosage and are inconvenient to apply.

This novel patch incorporates polymer technology developed by the global adhesive company Bostik and exclusively licensed for transdermal use to Medherant.

The key features of Medherant’s new patch technology are:

- The patch remains highly tacky and thus adheres well to skin even when the drug load reaches levels as high as 30% of the weight/volume of the patch. The drug load made possible by this new technology can be 5-10 times than that found in some currently used medical patches and gels.
- High drug load and a consistent drug release profile means the Medherant patches out-perform other patches and gels in their ability to deliver a consistent and significant dose of drug over a prolonged time from a small patch.
- It is a cosmetically pleasing transparent design with stronger adhesion than other commercial products – remaining stuck over its time of action but easy and comfortable to remove.

University of Warwick research chemist Professor David Haddleton said:

“Many commercial patches surprisingly don’t contain any pain relief agents at all, they simply soothe the body by a warming effect. Our technology now means that we can for the first time produce patches that contain effective doses of active ingredients such as ibuprofen for which no patches currently exist. Also, we can improve the drug loading and stickiness of patches containing other active ingredients to improve patient comfort and outcome.”

University of Warwick
http://tinyurl.com/k9jaayh

Advances in cancer diagnosis

Researchers at the University of Warwick and Medherant have found a way to incorporate significant amounts of the drug (up to 30% weight) into the polymer matrix that sticks the patch to the patient’s skin with the drug then being delivered at a steady rate over up to 12 hours. This opens the way for the development of a range of novel long-acting over-the-counter pain relief products which can be used to treat common painful conditions like chronic back pain, neuralgia and arthritis without the need to take potentially damaging doses of the drug orally. Although there are a number of popular ibuprofen gels available these make it difficult to control dosage and are inconvenient to apply.

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University of Warwick
http://tinyurl.com/k9jaayh

Researchers use gene therapy to extend estrogen’s protective effects on memory

The hormone oestrogen helps protect memory and promote a healthy brain, but this effect wanes as women age, and even estrogen replacement therapy stops working in humans after age 65. Now researchers at University of Florida Health have used gene therapy in a rat model to show that the expression of a particular receptor can reinstate lost memory function.

The scientists included Thomas C. Foster, Ph.D., a professor of neuroscience and the Evelyn F. McKnight chair for research on cognitive aging, and Linda A. Bean, Ph.D.

“A window of time, starting around menopause, when initiation of hormone replacement therapy with estrogen helps protect the brain against injury and Alzheimer’s disease. However, this window seems to end around age 65,” Foster said. “We wanted to find out what is regulating this window.”

The researchers used gene therapy to overexpress two different estrogen receptors found in the hippocampus, a part of the brain essential to memory regulation. They found that an abundance of one of these receptors, called alpha, reinstated memory in aging rats when paired with estrogen.

Estrogen helps to do this by increasing the brain’s “plasticity,” which is the ability to form and maintain connections between brain cells as things are learned. As plasticity declines, so do the number of connections in the brain, and certain types of memories begin to fade. Without the protective effect of estrogen, women may lose brain plasticity and start forgetting things more often. The loss of estrogen’s protective effects may explain why women are more likely than men to develop...
dysfunctional memory problems such as Alzheimer’s disease.
The researchers looked at the effects on memory in six groups, which received gene therapy for expression of the alpha receptor, the beta receptor or a control gene. The three different gene therapy groups then received estrogen or a placebo for the next several weeks, until memory testing and examination of brain plasticity. The project involved 72 animals. Only the group with gene therapy for the alpha receptor plus estrogen showed any beneficial effects on memory and increased brain plasticity markers.

“In the short term, this finding helps us understand how estrogen rescues memory and keeps the brain young and plastic,” Foster said. “In the long term, this finding may eventually allow us to bypass estrogen and target the receptor or brain plasticity mechanisms directly.”

University of Florida Health
http://tinyurl.com/qbkrmz9

Low blood flow in back of brain increases risk of recurrent stroke

Patients who have had a stroke in the back of the brain are at greater risk of having another within two years if blood flow to the region is diminished, according to results of a multi-centre study led by researchers at the University of Illinois at Chicago. These stroke patients are the most likely to benefit from risky intervention to unblock arteries, and they can be identified using a new MRI-based technology developed at UIC.

The vertebrobasilar region in the back of the brain is responsible for locomotion and balance. Vertebrobasilar strokes can be devastating, causing partial or total paralysis. They account for 30 percent to 40 percent of all strokes, or about 200,000 cases per year in the U.S.

Stroke patients found to have narrowing of the blood vessels in the back of the brain caused by atherosclerosis can have angioplasty, a procedure to open blocked arteries, but the procedure carries its own risks. And because blockages don’t always correlate to locally reduced blood flow – thought to be the real culprit in raising stroke risk – researchers wanted to better understand the relationship between arterial blockages, blood flow, and recurrent strokes.

“Having a blockage present in a blood vessel doesn’t always correlate to low blood flow,” says Dr. Sepideh Amin-Hanjani, professor of neurological surgery at the UIC College of Medicine and principal investigator on the study. “There can be a blockage and flow can be normal, if other nearby blood vessels are able to compensate.”

She and her colleagues wanted to try to identify which stroke patients are at highest risk for further strokes and so might benefit from angioplasty despite the risks of the procedure.

They followed 72 adult patients who had a stroke or temporary symptoms of a stroke, known as a transient ischemic attack, in the back of the brain and who also had at least 50 percent blockage of the arteries in that part of the brain. The patients were followed for an average of 22 months at five academic medical centres as they continued receiving standard care for their condition from their neurologists.

Participants were evaluated for reduced blood flow in the back of the brain using NOVA, or Noninvasive Optimal Vessel Analysis, a software program that can quantify the volume, velocity, and direction of blood flowing through any major vessel in the brain using standard MRI equipment. The NOVA software was developed at UIC by Dr. Fady Charbel, professor and head of neurological surgery, who is a co-author of the new study.

One-fourth of the study participants were found to have diminished blood flow in the back of the brain, which turned out to be a significant predictor of subsequent stroke. These patients had 12- and 24-month stroke-free survival rates of 78 percent and 70 percent, respectively, compared to 96 percent and 87 percent for patients with normal blood flow.

“At one year, the risk for patients with low blood flow was about five times as high as risk for patients without low flow in the back of the brain,” Hanjani said. For these patients, the benefits of angioplasty probably outweigh the risks.

“About three-quarters of patients didn’t have low blood flow in the vertebrobasilar region – other arteries are doing the job of ensuring that proper blood flow is reaching that area – and these patients would not benefit from treatments aimed at opening the vessels, such as angioplasty – in fact, the procedure would put these patients at unnecessary risk,” Hanjani said.

University of Illinois at Chicago
http://tinyurl.com/jxl37yo

New method of diagnosing deadly fungal lung infection in leukemia patients discovered

A team of researchers have discovered a new way for early detection of a potentially deadly fungal infection in patients with suppressed immune systems such as those being treated for leukemia or who have had an organ transplant.

A multidisciplinary research group led by Allan Brasier of The University of Texas Medical Branch at Galveston.

Patients receiving leukemia chemotherapy treatments, bone marrow stem cell transplants or lung transplants are some of those at risk for serious infection by the disease-causing Aspergillus fungus, a common mould in the environment that easily becomes airborne. When inhaled, the mould colonizes the respiratory tract. In patients with immune suppression from their chemotherapy treatment, the mould invades into the bloodstream where it spreads and infects several organs including the liver, lungs and brain. People with normal immune systems are able to destroy the inhaled mould without becoming infected.

Despite close monitoring for infection and aggressive anti-fungal therapy in vulnerable people, the fatality rates are as high as 50 to 90 percentdepending on a patient’s underlying disease and site of infection. While early diagnosis can improve the patient’s outcome, timely detection of the infection is difficult.

Currently, the infection is diagnosed with X-rays and tests that measure levels of fungal molecules that produce an immune reaction in a patient’s blood. These tests are not very accurate and often can lead to a wrong diagnosis.

The study describes how the team studied patients undergoing chemotherapy for leukemia, bone marrow transplants and lung transplants from several of the collaborating institutions and identified, confirmed and evaluated a new method of detecting the infectious mould in patients with leukemia. Similar people with no health conditions participated in the study as a comparison group.

The test results for the mould were different for each group of patients, so future commercial diagnostic tests using this
Taking antidepressants during pregnancy increases risk of autism by 87%  

Using antidepressants during pregnancy greatly increases the risk of autism, Professor Anick Bérard of the University of Montreal and its affiliated CHU Sainte-Justine children’s hospital revealed. Prof. Bérard, an internationally renowned expert in the fields of pharmaceutical safety during pregnancy, came to her conclusions after reviewing data covering 145,456 pregnancies. “The variety of causes of autism remain unclear, but studies have shown that both genetics and environment can play a role,” she explained. “Our study has established that taking antidepressants during the second or third trimester of pregnancy almost doubles the risk that the child will be diagnosed with autism by age 7, especially if the mother takes selective serotonin reuptake inhibitors, often known by its acronym SSRIs.”

Bérard and her colleagues worked with data from the Québec Pregnancy Cohort and studied 145,456 children between the time of their conception up to age ten. In addition to information about the mother’s use of antidepressants and the child’s eventual diagnosis of autism, the data included a wealth of details that enabled the team to tease out the specific impact of the antidepressant drugs. For example, some people are genetically predisposed to autism (i.e., a family history of it.) Maternal age, and depression are known to be associated with the development of autism, as are certain socio-economic factors such as being exposed to poverty, and the team was able to take all of these into consideration.

“We defined exposure to antidepressants as the mother having had one or more prescription for antidepressants filled during the second or third trimester of the pregnancy. This period was chosen as the infant’s critical brain development occurs during this time,” Prof. Bérard said. “Amongst all the children in the study, we then identified which children had been diagnosed with a form of autism by looking at hospital records indicating diagnosed childhood autism, atypical autism, Asperger’s syndrome, or a pervasive developmental disorder. Finally, we looked for a statistical association between the two groups, and found a very significant one: an 87% increased risk.” The results remained unchanged when only considering children who had been diagnosed by specialists such as psychiatrists and neurologists. The findings are hugely important as six percent of pregnant women are currently being treated for depression with antidepressants.

University of Montreal  
http://tinyurl.com/zglp3h

Medical diagnosis: brain palpation soon possible?  

If there is a technical exploration of the human body that the physician practice in any medical examination to diagnose or prescribe additional tests, it is palpation. The brain, however, has the distinction of being not possible to feel without a very invasive procedure (opening of the skull) reserved for rare cases. Drawing on seismology, researchers from Inserm led by Stéfan Catheline (Inserm Unit 1032 “Applications of Ultrasound therapy”) have developed a non-invasive method of imaging of the brain by MRI which gives the same indications as physical palpation. A term may be used for early diagnosis of brain tumours or of Alzheimer’s disease. The Inserm researchers have managed, via MRI to detect natural brain shear waves using computational techniques borrowed from seismologists and known as “noise correlation.” They were able to draw of brain elasticity image.

“If this method can be developed in the clinic, it would be both a comfort for the patient and the doctor because today vibrating the brain is painful enough. Of course, this method will be complementary to the existing ones and the future is a multimodal medical diagnosis,” says Stefan Catheline, Senior Research Director Inserm author of this work.

“Alzheimer’s disease, epilepsy, multiple sclerosis, hydrocephalus involve changes in the hardness of brain tissue. This new technique could detect those changes and be used to prevent brain biopsies.”

This method of brain palpation could have other application areas such as the analysis of the development of neurodegenerative processes, the impact of a traumatic injury or tumour, or the response to treatment.

INSERM  
http://tinyurl.com/zyyj9x

Using ultrasound to improve drug delivery  

New approach could aid in treatment of inflammatory bowel disease. Using ultrasound waves, researchers from MIT and Massachusetts General Hospital (MGH) have found a way to enable ultra-rapid delivery of drugs to the gastrointestinal (GI) tract. This approach could make it easier to deliver drugs to patients suffering from GI disorders such as inflammatory bowel disease, ulcerative colitis, and Crohn’s disease, the researchers say. Currently, such diseases are usually treated with drugs administered as an enema, which must be maintained in the colon for hours while the drug is absorbed. However, this can be difficult for patients who are suffering from diarrhea and incontinence. To overcome that, the researchers sought a way to stimulate more rapid drug absorption.

“We’re not changing how you administer the drug. What we are changing is the amount of time that the formulation needs to be there, because we’re accelerating how the drug enters the tissue,” says Giovanni Traverso, a research affiliate at MIT’s Koch Institute for Integrative Cancer Research, a gastroenterologist at MGH, and one of the senior authors of a paper describing the technique in the Oct. 21 issue of Science Translational Medicine.

“With additional research, our technology could prove invaluable in both clinical and research settings, enabling improved therapies and expansion of research techniques applied to the GI tract. It demonstrates for the first time the active administration of drugs, including biologics, through the GI tract,” says Daniel Blankshtein, the
New recommendations to reduce radiation risk from digital screening mammography

Radiation-induced breast cancer risk from digital mammography is low for the majority of women, but risk is higher in women with large breasts, who received 2.3 times more radiation and required more views per examination to image as much of the breast as possible compared to those with small or average-sized breasts.

The study also found that screening every two years instead of annually, and beginning at age 50 instead of 40 or 45, lowers the likelihood of radiation-induced breast cancer in all women. The findings from a team of researchers include Rebecca Hubbard, PhD, an associate professor of Biostatistics in Biostatistics and Epidemiology in the Perelman School of Medicine at the University of Pennsylvania.

In eight screening strategies estimated using two models, the group simulated the lifetime risk of women developing radiation-induced breast cancer from digital screening mammography and dying from the disease compared to the number of deaths averted through early detection.

The group found that screening 100,000 women, ages 50 to 74, every two years, prevented 627 deaths. The radiation exposure from these screening exams, and any subsequent diagnostic work-ups, caused 27 breast cancer cases and 4 breast cancer deaths. Although screening 100,000 women annually from 40 to 74 years prevented 968 deaths, it also raised cancer risk five-fold, causing 100 additional radiation-induced breast cancers and 12 additional breast cancer deaths compared with screening every two years from age 50 to 74.

Recommendations released recently by the U.S. Preventive Services Task Force, an independent panel appointed by the federal government, echo the study’s finding that women between the ages of 50 and 74 should be screened once every two years for breast cancer.

“Choosing a screening schedule that reduces harms while maintaining the benefits of more frequent screening makes screening mammography safer for all women,” Hubbard, who is also senior author on the study, said. “As our understanding of the effects of individual characteristics on harms and benefits of mammography grows, we can more effectively tailor screening strategies to minimize harms and save more lives.”

While not explicitly reviewed in the research, the findings suggest risk is also higher in those with breast implants, which require twice as many views during mammography, and/or denser breasts which require additional evaluations resulting in more radiation exposure.

The study also noted that obtaining fewer mammograms would also result in fewer false positives, which can prevent radiation exposure from possibly unneeded follow-up diagnostic mammograms.

Perelman School of Medicine
http://tinyurl.com/qjlej6z

Eye-tracking device helps accurately identify stroke

While researchers and physicians have been using the approach for years to diagnose balance issues, it has never been used for stroke.

Studies show that $1 billion is wasted each year on unnecessary tests and hospital admissions for people with dizziness who are suspected of having a stroke but who actually have benign inner ear problems. On the other hand, about 40,000 to 70,000 patients have strokes each year that are initially missed when they come to the emergency room presenting dizziness.

To differentiate stroke from other conditions that cause dizziness, neurologist David Newman-Toker devised a technique that looks for minute differences in eye movements.

A 2009 study showed that the test can outperform more standard clinical tests for stroke, including an MRI or CT scan, but they come with a drawback. “Learning to administer these tests correctly requires months to years of mentorship and can be extremely difficult, even for specialists,” he says.

To automate the process, Newman-Toker turned to video-oculography. While researchers and physicians have been using the approach for years to diagnose balance issues, it has never been used for stroke.

He is now testing the capability of a pair of computerized eye goggles to administer this exam. The technology resembles a pair of swim goggles and uses a video camera connected to a computer to examine eye movements. In patients with severe dizziness, if the goggles find the eyes stay stable when the head is rotated, eye jerking changes direction or either eye is higher, the patient has a stroke; otherwise, it is a benign postviral ear condition known as vestibular neuritis.

Newman-Toker is working to demonstrate the device’s accuracy and utility in emergency room clinical practice and says the technology could be in use in about five years.

John Hopkins Hospital
http://tinyurl.com/pgftpgj
Higher staffing levels linked to reduced risk of inpatient death

A study led by King’s College London and the University of Southampton has shown that a higher registered nurse to patient ratio is linked to a reduced risk of inpatient death.

The study of staffing levels in NHS hospitals found that in trusts where registered nurses had six or fewer patients to care for, the death rate for patients with medical conditions was 20 per cent lower than in those where they had more than 10. Hospitals with more doctors per bed also had lower death rates but hospitals with more unregistered nursing support workers may have had higher death rates.

The study, by researchers from King’s College London, the University of Southampton, Karolinska Institutet, Stockholm and the New York School of Medicine, analysed two measures over two years (2009-11): the number of beds per registered nurse, doctor, and healthcare support worker in 137 acute care trusts; and the number of patients per ward nurse, drawn from a survey of just under 3000 registered nurses in a nationally representative sample of 31 of these trusts (46 hospitals and 401 wards).

They also calculated the predicted number of deaths for medical and surgical inpatients, taking account of influential factors, such as age, other underlying conditions, and number of emergency admissions during the previous 12 months.

Among patients admitted to medical, wards, higher death rates were associated with higher numbers of occupied beds for each registered nurse and for each doctor employed by the trust. By contrast, higher numbers of healthcare support workers were associated with higher rates of inpatient death.

When all staff groups were included in the statistical analysis of all 137 trusts, the associations remained significant only for doctors and healthcare support workers.

But analysis focussing on nurses actually working on wards of the subsidiary group of 31 trusts showed that the death rate was 20 per cent lower in those where each registered nurse cared for an average of six or fewer medical inpatients than in trusts were each registered nurse cared for 10 or more. These associations remained significant after further statistical analysis.

The results on surgical wards were similar, with higher registered nurse to patient ratios associated with a 17 per cent lower inpatient death rate.

The registered nurse headcount varied by as much as a factor of four between those at the top and bottom of the staffing scale. Even after taking account of all nursing staff, this variation only dropped to a threefold difference between those with the highest and lowest nurse headcounts.

Kings College London
http://tinyurl.com/hujs9hc

Sharp images of moving tumours

By cleverly combining two medical imaging techniques, A*STAR scientists have found a way to produce high-resolution images of the lungs that is both high resolution and accounts for lung movement due to breathing. The method is expected to greatly assist clinicians when they target tumours in the lungs during radiotherapy.

Cancerous tumours in the lungs are often treated by irradiating them with high-energy X-rays, but this therapy is complicated by the fact that tumours are moving targets, due to the expansion and contraction of the lungs as the patient breathes.

Currently, two biomedical imaging techniques are used to help clinicians locate tumours in the lungs, both of which have their advantages and disadvantages. Three-dimensional computed tomography (3D-CT) provides high-resolution images, but it can only provide snapshots in time and there are safety concerns surrounding exposure to X-rays. In contrast, four-dimensional magnetic resonance imaging (4D-MRI) does not employ ionizing radiation and allows continuous tracking of the lung motion, but its low spatial resolution yields blurred images.

Now, Soo Kng Teo and co-workers at the A*STAR Institute of High Performance Computing in Singapore have combined these two techniques to realize the best of both approaches — a high-resolution imaging method that accurately accounts for lung movement.

The researchers used 3D-CT to obtain a sharp static image of the lungs. They mathematically combined this static image with the four-dimensional (the three spatial dimensions plus time) information extracted from images obtained using 4D-MRI. This enabled them to achieve a high spatial resolution to realize excellent clarity and show movement of a lung tumour over several breathing cycles.

They tested their imaging technique on six lung-cancer patients and obtained impressive results: the average error was less than two millimetres.

As with all medical innovations, adoption of the technique in hospitals depends on obtaining the backing of medical equipment companies and meeting the many regulatory requirements. “The biggest hurdle will be convincing equipment manufacturers to adopt the imaging method,” says Teo.

A*STAR
http://tinyurl.com/hucafzb

Team develops wireless, dissolvable sensors to monitor brain

Wireless brain sensors developed by researchers at Washington University School of Medicine in St. Louis and the University of Illinois at Urbana-Champaign are smaller than a pencil tip and can monitor intracranial pressure and temperature before being absorbed by the body, negating the need for surgery to remove the devices.

Such implants potentially could be used to monitor patients with traumatic brain injuries, but the researchers believe they can build similar absorbable sensors to monitor activity in organ systems throughout the body.

“Electronic devices and their biomedical applications are advancing rapidly,” said co-first author Rory K. J. Murphy, MD, a neurosurgery resident at Washington University School of Medicine and Barnes-Jewish Hospital in St. Louis. “But a major hurdle has been that implants placed in the body often trigger an immune response, which can be problematic for patients. The benefit of these new devices is that they dissolve over time, so you don't have something in the body for a long time period, increasing the risk of infection, chronic inflammation and even erosion through the skin or the organ in which it's placed. Plus, using resorbable devices negates the need for surgery to retrieve them, which further lessens the risk of infection and further complications.”

Murphy is most interested in monitoring pressure and temperature in the brains of patients with traumatic brain injury.

About 50,000 people die of such injuries annually in the United States. When patients with such injuries arrive in the hospital, doctors must be able to accurately measure intracranial pressure in the brain and inside the skull because an increase in pressure can
Bone marrow lesions can help predict rapidly progressing joint disease

A new study from the Medical Research Council Life-course Epidemiology Unit, University of Southampton, shows lesions, which can best be seen on MRI scans, could help identify individuals who are more likely to suffer from more rapidly progressing osteoarthritis. The SEKOIA study, a major international osteoarthritis disease-modifying trial, carried out MRI scanning on the knees of 176 men and women over 50 years old. They were then followed up for an average of three years with repeated knee X-rays. Individuals with abnormalities on their MRI scans at the first appointment were compared to those without to examine the effect on disease progression. Individuals with bone marrow lesions (BMLs) on their MRI scan were found to have osteoarthritis that progressed more rapidly than those that did not. On average, the space within the joint is lost at a rate of 0.15mm per year however the Southampton study shows that, overall, individuals with BMLs had a loss rate that was 0.10mm per year faster than those without BMLs. This may lead to earlier need for joint replacement or other intervention. BMLs show up on MRI as regions of bone beneath the cartilage with ill-defined high signal and represent areas of bone marrow edema, fibrosis, and necrosis. The Southampton researchers believe that therapies to target these abnormalities may slow the progression of this disabling joint disease, but further work is required to examine this.

University of Southampton
http://tinyurl.com/zgoujbx

New health sensing tool measures lung function over a phone call, from anywhere in the world

SpiroCall enables patients to measure lung function over a phone call. It is designed to work with any type of phone around the world, not just smartphones. Most people in the developing world who have asthma, cystic fibrosis or other chronic lung diseases have no way to measure how well their lungs are functioning outside of a clinic or doctor visit. But many do have access to a phone, though it may be a 10-year-old flip phone or a communal village landline instead of the latest app-driven smartphone. That’s why University of Washington computer science and engineering and electrical engineering researchers have developed SpiroCall, a new health sensing tool that can accurately measure lung function over a simple phone call. A paper to be presented shows that SpiroCall’s results came within 6.2 percent of results from clinical spirometers used in hospitals and doctor’s offices, meaning it meets the medical community’s standards for accuracy.

“We wanted to be able to measure lung function on any type of phone you might encounter around the world — smartphones, dumb phones, landlines, pay phones,” said Shwetak Patel, Washington University of computer science & engineering and electrical engineering at the UW. “With SpiroCall, you can call a 1-800 number, blow into the phone and use the telephone network to test your lung function.” In 2012, researchers from the UW’s Ubicomp Lab introduced SpiroSmart — which lets people monitor their lung function by blowing into their smartphones. The patients take a deep breath in and exhale as hard and fast as they can until they can’t exhale any more. The phone’s microphone senses sound and pressure from that exhalation and sends the data to a central server, which uses machine learning algorithms to convert the data into standard measurements of lung function.

University of Washington
http://tinyurl.com/hpgmr2u

Researchers identify process that causes chronic neonatal lung disease

Pediatric researchers at UT Southwestern Medical Center have identified a key component of the pathogenesis of bronchopulmonary dysplasia (BPD), a devastating and sometimes fatal lung disease that affects premature infants. Their findings clarify what prompts the inflammatory response that results in BPD, which previously had been unclear. The study determined how the NLRP3 inflammasome activates the protein Interleukin 1 beta, which in turn triggers inflammation and development of BPD. In an animal model of BPD, researchers also tested two FDA-approved drugs that either block the effect of or decrease the production of Interleukin 1 beta and found that these treatments allowed more normal lung development.

Bronchopulmonary dysplasia, a common chronic lung disease in premature infants, develops as a result of the ventilation and oxygen necessary for these infants to survive. Infants born before 30 weeks gestation have immature lungs that lack surfactant, a substance comprised of phospholipids and proteins that is needed for lungs to properly function. This causes premature infants to develop respiratory distress syndrome, requiring the aid of mechanical ventilation. The infants’ exposure to elevated oxygen levels during ventilation activates the process of inflammation that leads to BPD.

“The same ventilation that ultimately saves their lives, damages their lungs,” said Dr. Rashmin Savani, Professor and Chief of Neonatal-Perinatal Medicine. “Our findings suggest that if we target premature infants born at less than 28 weeks gestation from three to 10 days after birth with this therapy, we might be able to drastically reduce or even eliminate the development of BPD.” Dr. Savani also holds the William Buchanan Chair in Pediatrics. Next steps include testing the therapeutic intervention strategies outlined in this study in larger animal models, potentially followed by a Phase 1 clinical trial.

UT Southwestern Medical Center
http://tinyurl.com/12jytztz
Agfa HealthCare collaborates with IBM and Watson to advance cognitive imaging

Agfa HealthCare has joined the Watson Health medical imaging collaborative, a global initiative comprised of more than fifteen leading health systems, academic medical centres, ambulatory radiology providers and imaging technology companies. The collaborative aims to bring cognitive imaging into daily practice to help doctors address breast, lung, and other cancers; diabetes; eye health; brain disease; and heart disease and related conditions, such as stroke.

Members of the collaborative plan to put Watson to work to extract insights from previously ‘invisible’ unstructured imaging data and combine that with a broad variety of data from other sources. In doing so, the efforts may help physicians make personalized care decisions relevant to a specific patient while building a body of knowledge to benefit broader patient populations. This information may include data from electronic health records, radiology and pathology reports, lab results, doctors’ progress notes, medical journals, clinical care guidelines and published outcomes studies.

Initial plans include training Watson and evaluating potential new offerings in a variety of patient care environments ranging from stand-alone ambulatory settings to integrated health delivery networks. The aim in doing so is to gather data based on diverse real-world experience and to share findings to inform how the medical community might reduce operational and financial inefficiencies, improve physician workflows, and adopt a patient-focused approach to improving patient care and outcomes.

“With an ability to draw insights from massive volumes of integrated structured and unstructured data sources, cognitive computing could transform how clinicians diagnose, treat and monitor patients,” said Anne Le Grand, vice president of Imaging for Watson Health. “Through IBMs medical imaging collaborative, Watson may create opportunities for radiologists to extract greater insights and value from imaging data while better managing costs.”

James Jay, Vice President Imaging IT and Integrated Care Solutions businesses at Agfa HealthCare, elaborates: “We are very excited about the opportunity to collaborate with IBM and Watson. Healthcare systems are under enormous pressure to improve productivity; our combined expertise has the capability to harness the untapped power of technology to deliver the gains that have so far only been achieved in isolated use cases. Together we will look for ways to advance our customers’ ability to leverage the analytics power of Watson united with our own Enterprise Imaging platform, to assure that the right knowledge is available, at the right time, to help diagnose and treat their patients. We will be diving into specific use cases to turn the power of big data into real, tangible applications focused on specific improvements in either speed or accuracy of decisions.”

Watson is the first commercially available cognitive computing capability representing a new era in computing. The system, delivered through the cloud, analyses high volumes of data, understands complex questions posed in natural language, and proposes evidence-based answers. Watson continuously learns, gaining in value and knowledge over time, from previous interactions. In April 2015, the company launched IBM Watson Health and the Watson Health Cloud platform. The new unit will help improve the ability of doctors, researchers and insurers to innovate by surfacing insights from the massive amount of personal health data being created and shared daily. The Watson Health Cloud allows this information to be de-identified, shared and combined with a dynamic and constantly growing aggregated view of clinical, research and social health data.

http://tinyurl.com/homrlhs

Varian Medical Systems announces company name for imaging components business

Varian Medical Systems announced in July that Varex Imaging Corporation will be the name for its imaging components business upon the completion of the planned spin-off of that business as a new, stand-alone public company via a tax-free distribution to Varian stockholders in a transaction anticipated to be completed by the end of calendar year 2016.

The Varex Imaging name will draw from the 65-plus years of technology leadership and strong industry brand recognition of Varian and its reputation in X-ray imaging technology. As an independent company, Varex Imaging will pursue new growth strategies by leveraging its position as a global leader in components, software and services for expanded imaging applications and markets.

Varian Imaging Components president Sunny Sanyal, who will assume the role of CEO of Varex Imaging upon completion of the spin-off, stated, “As a trusted imaging components partner, we have a laser focus on providing our customers with high-quality and cost effective products that enable them to develop and deliver new next-generation imaging systems. Excellence in imaging is a top priority and this is evident in the new company name.”

Varian Imaging Components is a leading global supplier of components, software and engineering services for imaging equipment manufacturers and system integrators in the medical diagnostics, dentistry, veterinary care, security and industrial inspection industries. It manufactures X-ray tubes, high energy X-ray sources, flat panel image detectors, connectors, collimators and image processing software; all key components of X-ray imaging systems. The planned spin-off of Varian Imaging Components is subject to numerous conditions, including final approval by the Varian Board of Directors, effectiveness of a Registration Statement on Form 10 to be filed with the Securities and Exchange Commission, and receipt of an opinion of counsel regarding the federal income tax treatment of the spin-off.

www.varian.com

Healing little hearts with the aid of Sonosite point-of-care ultrasound

Surgical teams from the UK-based charity Healing Little Hearts are using the NanoMaxx point-of-care ultrasound to help accelerate recoveries and improve outcomes for pediatric patients with congenital heart defects. Healing Little Hearts provides life-saving heart operations to babies and children across India who would not otherwise have access to treatment, as well as helping to develop local pediatric surgical programmes. Dr Sanaulla Syed, a pediatric cardiac anesthetist with the charity, commented: “Obtaining vascular access in small children can be difficult, and the availability of point of care ultrasound systems has revolutionized this practice. As the technology has improved, this has led to other applications, and we now use ultrasound for a range of diagnostic applications before, during and after cardiac surgery. Ultrasound-guided regional anesthesia – specifically bilateral paravertebral blocks – can also significantly reduce the amount of opiates required for surgery, considerably shortening post-operative recovery times and offering improved analgesia.”

www.sonosite.com
Anesthesiology and ultrasound today

Since the last decade, ultrasonography (US) has become an essential clinical tool in anesthesiology, intensive care and emergency medicine, improving both safety and patient comfort. US indeed allows an extremely wide use for both bedside examination and technical procedures in a way that was previously not possible. For example, this technology is useful for regional anesthesia [1], but also for placing central venous access with a reduced risk of complications, for assessment of gastric emptiness [2], or for an early assessment of severe trauma patients [3]. Recent reports even suggest that US may be interesting in airway assessment and in predicting difficult airways [4], or to assess lung function and conditions such as pneumothorax, pulmonary edema [5] etc. It is no longer possible to work as an anesthesiologist without having immediate access to bedside high quality ultrasonography.

Among various techniques of regional anesthesia, peripheral nerve blocks (PNBs) consist in anesthetizing only a single limb or a specific anatomical area. A huge body of scientific evidence demonstrates that PNBs provide major interests during perioperative patient care in many surgical specialties. As a matter of fact, PNBs are even frequently superior to general anesthesia. However, PNB techniques require expertise and technical skills, since it is necessary to administer the local anesthetic in close vicinity of nerve trunks or nerve roots in order to interrupt the nerve impulses. To summarize, the overall safety in regional anesthesia requires the ability to avoid injecting local anesthetic intraneurally as well as intravascularly, and to reduce the injected doses. This is where US plays a role.

Ultrasound-guided regional anesthesia has allowed increasing safety standards and reducing complications as never before [6]. When using US guidance the anesthesiologist is able to identify the various anatomical structures and adapt the procedure to inter-individual anatomy. Furthermore, US guidance allows real-time needle guidance and assessment of local anesthetic spread around neural structures, which was not allowed by previous PNB techniques that were using nerve stimulation [7]. Visualizing the spread of local anesthetic also enables early diagnosis of intravascular or intraneural injection. Furthermore, there is now scientific evidence that US guidance decreases the number of vascular punctures as well as reduces the injected volumes of local anesthetics while increasing the overall success rate of PNBs. Moreover, USGRA improves patient comfort [8].

If ultrasound devices designed for the operating theatre must provide high quality images, all usual imaging modes and at least two probes of compact size enabling the ultrasound systems to be mobile, the recently released EXAPAD, manufactured by the French ECM company, opens a brand new concept of mobile US devices that are designed no longer for the radiologist or cardiologist, but for anesthesiologists and emergency physicians. It features many unique and original tools that make this device really innovative and exceptionally adapted to the operating room or intensive care environment. The EXAPAD comes with a nice and sober look, as a “big” 15” tablet. It is as easy to use as a smartphone allowing the user to swipe from one menu to another. It is indeed, the first US device having been specially designed for use in intensive care, operating room or in emergency situations where the physician frequently works in a narrow space, surrounded by many devices and under sterile conditions. Therefore, the size and mobility of the EXAPAD are of tremendous importance. For example, the EXAPAD may be orientated either vertically or horizontally according to preference by simply rotating the screen.

The EXAPAD’s new features, such as the IPAD remote control and the voice control of all major settings (i.e. gain, depth, frequency, focus) allow the physician to change the settings without the need to touch the screen. This is highly interesting during sterile procedures (i.e. PNBs or central venous access placement). Another advantage is the fact that the central unit is totally waterproof and its screen can be cleaned.

The IPAD remote control also displays the US image. At the bedside, this tool is not a gadget, but on the contrary offers a real improvement in comfort for the anesthesiologist, since the EXAPAD central unit may be located ahead of the patient, providing full performance of the system on the IPAD while enabling the user to change the settings and view the image on the IPAD screen. The EXAPAD also offers the possibility, via the Internet or a local network, to share US images in real time for teaching purposes or for remote use of the system.

References


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Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM-2): a population-based prospective study


Background
Breast tomosynthesis (pseudo-3D mammography) improves breast cancer detection when added to 2D mammography. In this study, we examined whether integrating 3D mammography with either standard 2D mammography acquisitions or with synthetic 2D images (reconstructed from 3D mammography) would detect more cases of breast cancer than 2D mammography alone, to potentially reduce the radiation burden from the combination of 2D plus 3D acquisitions.

Findings
Between May 31, 2013, and May 29, 2015, 10,255 women were invited to participate, of whom 9,672 agreed to participate and were screened. In these 9,672 participants (median age 58 years [IQR 53–63]), screening detected 90 cases of breast cancer, including 74 invasive breast cancers, in 85 women (five women had bilateral breast cancer). To account for these bilateral cancers in cancer detection rate estimates, the number of screens used for analysis was 9,677. Both 2D–3D mammography (cancer detection rate 8.5 per 1000 screens [82 cancers detected in 9,677 screens]; 95% CI 6.7–10.5) and 2D synthetic–3D mammography (8.8 per 1000 [85 in 9,677]; 7.0–10.8) had significantly higher rates of breast cancer detection than 2D mammography alone (6.3 per 1000 [61 in 9,677], 4.8–8.1; p<0.0001 for both comparisons). The cancer detection rate did not differ significantly between 2D–3D mammography and 2D synthetic–3D mammography (p=0.58). Compared with 2D mammography alone, the incremental cancer detection rate from 2D–3D mammography was 2.2 per 1000 screens (95% CI 1.2–3.3) and that from 2D synthetic–3D mammography was 2.5 per 1000 (1.4–3.8). Compared with the proportion of false-positive recalls from 2D mammography alone (328 of 9,587 participants not found to have cancer at assessment) (3.42%; 95% CI 3.07–3.80), false-positive recall was significantly higher for 2D–3D mammography (381 of 9,587 [3.97%; 3.59–4.38], p=0.00063) and for 2D synthetic–3D mammography (427 of 9,587 [4.45%; 4.05–4.89], p<0.0001).

Interpretation
Integration of 3D mammography (2D–3D or 2D synthetic–3D) detected more cases of breast cancer than 2D mammography alone, but increased the percentage of false-positive recalls in sequential screening. These results should be considered in the context of the trade-off between benefits and harms inherent in population breast cancer screening, including that significantly increased breast cancer detection from integrating 3D mammography into screening has the potential to augment screening benefit and also possibly contribute to overdiagnosis.
Bi-directional digital Doppler

The DMX Digital Vascular Doppler is the first handheld Doppler that combines high performance in probe sensitivity with audio clarity and a visual representation of waveforms that have previously only been available with large and expensive desktop laboratory systems. The new Dopplex DMX is rechargeable using USB and utilizes Bluetooth communication for transfer of electronic records to computer systems, allowing reports to be easily created. Measurements can also be stored on the SD card for review or transfer to a computer. Bi-directional waveforms are uniquely generated from the digital Doppler spectrum and are presented on a high resolution display with wide viewing angle. This gives the clinician objective evidence to assist in the diagnosis of vascular disease that other Dopplers may find difficult or impossible to achieve. Audio clarity is further enhanced with the innovative Dynamic Digital Noise Reduction (DDNR) system, eliminating background hiss and crackle noise when moving the transducer while searching for blood vessels. This facilitates the assessment of small and diseased vessels.

HUNTELEIGH
i www.ihe-online.com & search 47006

3D colonoscopy navigation system

The new SCOPEPILOT navigation control unit provides true 3D representation of an endoscope’s position when inside a patient’s bowel tract. It delivers a real-time representation of a colonoscope’s orientation for highly accurate insertion tracking and effective colonic loop management. This fully supports quality standards in colonoscopy and training, to ensure smooth and efficient colonoscopy navigation and improve patient comfort. The SCOPEPILOT system provides advanced orientation features to ensure the highest quality standards in colonoscopy and training. These include image rotation on both horizontal and vertical axis to improve differentiation of the insertion tube, as well as zoom functionality for improved evaluation and detection of looping. A true 3D image is generated by the endoscope’s built-in multidimensional sensors which are induced by a magnetic field generated outside of the patient. These sensors transmit to a control unit where data is processed and displayed in real-time during a procedure, enabling dynamic tracking and handling control of the endoscope. The SCOPEPILOT image responds coherently with the movement of the scope, providing smooth and stable image quality. The colour and contrast of the imagery ensures a high depth of view in order to more easily differentiate colonic loop configuration. SCOPEPILOT’s sensors are integrated into the colonoscope, thus keeping the scope’s working channel free for advanced therapeutic procedures. The system can be activated via the operation panel or remote control when needed at any time during a procedure. Pictures can be taken at the touch of a button and downloaded to a storage device via the USB port in the front panel.

PENTAX MEDICAL
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Fully-featured ICU ventilation for military patient transports

Specially modified for military compliance to meet the highest demands in the most challenging environments worldwide, Hamilton Medical’s transport ventilator is now available for use by armed forces to safely accompany...
Oncology workflow with advanced toolset for PET/CT

Carestream now offers an oncology reading workflow for PET/CT studies that equips clinicians with new native tools for its enterprise image management system that deliver both quantitative and qualitative information to help improve and expedite the reading process. The latest upgrade for the company’s enterprise image management platform incorporates advanced tools to aid in tumour detection and tracking. This can help radiologists deliver more meaningful reports while also enhancing collaboration with clinicians and patients. Traditional oncology features cannot adequately address the increased demand to be expected for long-term monitoring of oncology patients as the world’s population ages.

The new CT Perfusion and Subtraction modules contain interactive tools to ease the process of analysing and comparing three-dimensional (3D), CT perfusion (CTP) and digital subtraction angiography (DSA) images. This equips users to analyse CT brain perfusion scans for tissue perfusion and tissue blood volume, while X-ray angiography (XA) subtraction capabilities provide a DSA workflow for analysis of vessel blockages in areas with bony or dense soft tissue. Carestream also developed PET segmentation that allows users to examine tumour standardized uptake values (SUV) traces on the PET image without the need for a physical trace on a CT exam. This capability can play an important role in detection of early stage cancers. The company’s streamlined oncology reading workflow includes: automatic fusion of PET, SPECT, CT and MR images; automatic registration between volumetric datasets that provide efficient comparison of multiple time points; synchronized manipulations, colour maps, measurement tools and pre-defined layouts that aid in analysis; reproducible 2D and volumetric lesion segmentation and automated comparison to observe progression over time; threshold segmentation, spberoid region of interest (ROI), metabolic tumour volume (MTV) and total lesion glycolysis (TLG); bookmarks to catalogue lesions and speed future access and precise follow-up data for enhanced patient care.

An efficient reading workflow is supported by use of Carestream’s native Vue Reporting module that can present interactive hyperlinks to critical images and automatic inclusion of quantitative analysis in the form of easy-to-understand comparison tables and charts, which oncologists and referring physicians prefer. Vue Reporting also offers bookmarks and lesion management reporting in accordance with international standards such as response evaluation criteria in solid tumours (RECIST). Reports and images can be shared using Carestream’s Vue Motion universal viewer that supports viewing on FDA-approved mobile devices.

HAMILTON MEDICAL

Siemens Healthineers has launched a range of new MR applications to help hospitals reduce the time needed for MR imaging within neurology. It is estimated that 20 to 25 per cent of all MR examinations are neurological, with the number expected to grow in 2016. The applications have therefore been designed to help organizations increase patient throughput in order to maintain an efficient workflow. One of the applications, Simultaneous Multi-Slice (SMS) EPI, employs an innovative technique to acquire imaging slices simultaneously rather than sequentially, reducing 2D acquisition times with acceleration factors up to eight. Simultaneous Multi-Slice (SMS) EPI can bring DTI and BOLD into clinical routine. This can particularly benefit surgical neurology cases through surgical mapping, potentially helping to reduce post-surgical deficits, and ultimately leading to improved efficiency in the utilization of operating room resources. A further application, GOBrain, enables clinically validated brain examinations in just five minutes. Facilitated in part by Siemens’ high-channel density coils and DotGO software, clinically essential image orientations and all relevant contrasts can be acquired rapidly. In turn, this can improve patient throughput, and costs per scan can potentially be reduced. Shorter scan times can also be better tolerated by patients, and can help reduce the need of sedations and rescans, which can be time-consuming and costly. It is paramount that imaging techniques used to assess neurological conditions continue to advance at a fast pace, as diseases such as dementia are on the rise. There is an increase in demand for diagnostic imaging within neurology, and a priority is to ensure patients receive their tests within the recommended turnaround time. In addition to speed and quality, standardization across systems is also an important element for hospitals when it comes to meeting healthcare efficiency demands. The recently introduced syngo MR E11 software platform is a uniform application platform for the MAGNETOM family.
Automated lighting system for laminar flow operating theatres

New for the hospital market, the innovative, automated lighting system FlexInLight offers greater, real time lighting quality and precision, eliminates clutter and guarantees a greater level of asepsis in the operating zone. Telstar has developed a lighting system built into laminar flow ceilings for operating theatres which automatically orientates the light source to any point as controlled by the user, within the surgical working space in a precise manner. Under the brand FlexInLight, this new system provides stability and cleanliness of the air volume provided by the laminar flow system. It also facilitates operability within the surgical process by eliminating the physical obstacles typically encountered. Comprised of motorized spot lights embedded in the laminar flow ceiling, this system replaces conventional surgical lamps to provide an open space within the working area, removing obstructions in the laminar flow ventilation process, which is one of the main drawbacks caused by the presence of traditional lamps. In this manner, the new lighting system ensures the cleanliness and asepsis within the working area, offering the maximum degree of protection against possible post-surgical infections produced by microorganisms in the air inside the operating theatres, caused or generated by exposed instruments, equipment and lamps in the air flow. In addition, this innovative and versatile lighting system assures the two basic conditions for optimum lighting quality within the visual space of the surgeons during the operation: zenith lighting and shadow-free lighting. FlexInLight is composed of a total of six motorized lighting units embedded in a laminar flow ceiling, with the capability of orientating the lighting units towards any point within their working envelope. The system, which can be fully configured to the requirements of the technical/medical team, provides a light intensity exceeding 100,000 lux, the maximum output currently provided by conventional lamps. This enables FlexInLight to address and technically surpass the specifications of available alternative technologies. Also, an advanced automated control system enables the new system to control both the vertical angle of the light, to provide appropriate lighting level to the operating zone, and orientation of the light, to suppress shadows, thus providing an optimum lighting environment. The system as a whole offers greater precision and light projection positioning for each light unit with a resolution margin of error of ±1 cm. In turn, the number of light units and their distribution within the ceiling ensure both the light output and the air flow laminarity. At a user-level, the system relies on artificial vision. Using a pointing device as a remote control, the surgeon can decide and act directly to determine the exact position where the light beam must be projected at all times, in a process which is faster and more accurate than that available from conventional lighting systems. This sophisticated system is intended particularly for operating theatres that require a high level of bacteriological safety, such as major surgery operating theatres. Even so, its modular design and arrangement and simple installation make it suitable for other environments with fewer restrictions, such as examination rooms, or outpatient or interventional operating theatres where, even if a high level of asepsis is not required, larger free space facilitates the use of special devices such as imaging equipment.

TELSTAR

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Mid-range ultrasound scanner

E-CUBE 11, the newest addition to the E-CUBE product portfolio. Built around the latest imaging technologies, equipped with a rich set of high-end features, the mid-range system offers a newly designed interface combined with advanced imaging solutions for shared services including general imaging, obstetrics & gynecology and internal medicine. In order to effectively manage demanding caseloads, the E-CUBE 11 features a simplified way of scanning with more programmable keys and a new touch screen, leading to about 28% reduced exam time and faster workflow with 35% fewer keystrokes on average, compared with a conventional system. Powered by an intuitive interface of a capacitive touch screen (10.4”) with instant response, the system promotes streamlined exam flows to improve exam quality with less effort. Its new usability concept for UI/UX design also helps reduce repetitive movements and even a learning curve, providing a new level of user performance. Additional advantage of the enhanced CPU (Intel Core i7) and integrated SSD (Solid-State Drive) increases process efficiency and patient throughput by the E-CUBE 11 system. Based on Alpinion’s Crystal Signature Technology, the newly adaptive imaging algorithm and enhanced digital signal processing enable the E-CUBE 11 system to process more information and faster for diagnosis with exceptional detail, clearer border definition and the ability to assess subtle changes in tissue. The E-CUBE 11 system delivers a high level of image performance across a wide range of clinical applications and patient body types. Without compromise between frame rate and image quality, it improves temporal resolution with up to 200% higher frame rate and 150% better colour PRF. A newly adaptive post processing by each application delivers clearer image detail and contrast resolution by increased signal-to-noise ratio and a wider range of gray scales. The introduction of the HD Digital Beamforming enables consistently excellent image quality from near to far field zone across all clinical capabilities. Suitable for a shared service environment, the E-CUBE 11 has the power and application diversity to support a spectrum of specialties from general imaging to OB/GYN, cardiology and more.

ALPINION MEDICAL SYSTEMS

www.ihe-online.com & search 47043
Reed Sinopharm hosts world’s largest healthcare event - tHIS in Shanghai

The Health Industry Summit (tHIS) 2016 was held in Shanghai at the National Exhibition and Convention Centre from 17 to 20 April.

The organizer posted a record 380,000 entry scans, 216,784 professional visitors and more than 55,000 exhibiting staff to the venue over four days. In preparation of the large concentration of visitors, the city of Shanghai initiated its municipal level security mechanism and increased the frequency of the subway to divert the large crowds and dense traffic to the venue. Hotels were also fully booked in Shanghai during the event period. Only in its second edition, tHIS has already been firmly established as the world’s largest health industry event with over 330,000 square meters of exhibition space and 107 individual conferences.

Key events included China’s three top medical equipment and pharmaceutical exhibitions (CMEF, PHARMCHINA and API China) and the leading healthcare investment forum - Healthcare China 2016. This year’s investment forum was co-organized by Reed Sinopharm, JP Morgan Asset management, CICC and Sinopharm Capital and was attended by more than 700 selected investors and institutions.

The exhibition featured the entire industry value chain and presented some of the latest cutting edge technology including genetic diagnostics, rehabilitation robotics, wearable tech, 3D printing and more.

6,900 exhibiting companies from 30 countries were at the show presenting tens of thousands of products and services. Well-known healthcare equipment giants like GE, United Imaging, Siemens, Philips and Mindray as well as major pharmaceutical groups in China like Sinopharm, Shanghai Pharma and CR Pharmaceuticals were in attendance with major stand presence.

Natural Health and Nutrition Expo were among the fastest growing segments in the portfolio, helped by the expected population boom in light of the reversal of the single child policy as well as a growing health-conscious middle class in China.

With the start of China’s 13th Five-year plan in 2016, the “Health China 2020” programme focusing on the co-development of healthcare, pharmaceutical production and health insurance has put the health industry among the top priorities for development in China and part of the national strategy.

Companies in China not traditionally associated with healthcare have also shifted major investment and resources into the sector, many renaming their company in the process to reflect this focus in industry coverage.

International giants with the likes of Alibaba, Lenovo, Fosun and Wanda Group have all taken a foothold into key segments of the industry in anticipation of major opportunities in the future.

The Health Industry Summit is organized by Reed Sinopharm, a joint venture between the world’s leading event organizer Reed Exhibitions and China’s leading state-owned pharmaceutical group Sinopharm. Its next edition will be held in May 2017 in Shanghai.


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**CALENDAR OF EVENTS**

<table>
<thead>
<tr>
<th>August 27-31, 2016</th>
<th>ESC Congress 2016</th>
<th>Rome, Italy</th>
<th><a href="http://www.escardio.org">www.escardio.org</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>August 31-Sept 2, 2016</td>
<td>Medical Fair Asia</td>
<td>Singapore</td>
<td><a href="http://www.medicalfair-asia.com">www.medicalfair-asia.com</a></td>
</tr>
<tr>
<td>September 10-14, 2016</td>
<td>CIRSE</td>
<td>Barcelona, Spain</td>
<td><a href="http://www.cirse.org">www.cirse.org</a></td>
</tr>
<tr>
<td>September 20-22, 2016</td>
<td>12th Health Asia 2016 International Exhibition &amp; Conferences</td>
<td>Karachi, Pakistan</td>
<td><a href="http://www.health-asia.com">www.health-asia.com</a></td>
</tr>
<tr>
<td>September 22-23, 2016</td>
<td>4th Annual Africa Hospital Expansion Summit</td>
<td>Accra, Ghana</td>
<td><a href="http://www.africa.hospitalexpansionsummit.com">www.africa.hospitalexpansionsummit.com</a></td>
</tr>
<tr>
<td>October 1-5, 2016</td>
<td>ESI CM</td>
<td>Milan, Italy</td>
<td><a href="http://www.esicm.org">www.esicm.org</a></td>
</tr>
<tr>
<td>October 5-6, 2016</td>
<td>3rd Annual Turkey Hospital Expansion Summit</td>
<td>Ankara, Turkey</td>
<td><a href="http://www.turkey.hospitalexpansionsummit.com">www.turkey.hospitalexpansionsummit.com</a></td>
</tr>
<tr>
<td>October 30-November 3, 2016</td>
<td>IHF</td>
<td>40th World Hospital Congress</td>
<td>Durban, South Africa</td>
</tr>
<tr>
<td>November 14-17, 2016</td>
<td>MEDICA</td>
<td>Düsseldorf, Germany</td>
<td><a href="http://www.medica.de">www.medica.de</a></td>
</tr>
<tr>
<td>November 21-22, 2016</td>
<td>HIMSS Europe World of Health IT (WoHIT) Conference &amp; Exhibition</td>
<td>Barcelona, Spain</td>
<td><a href="http://www.worldofhealth.it">www.worldofhealth.it</a></td>
</tr>
<tr>
<td>November 27-December 2, 2016</td>
<td>RSNA</td>
<td>Chicago, USA</td>
<td><a href="http://www.rsna.org">www.rsna.org</a></td>
</tr>
<tr>
<td>January 23-26, 2017</td>
<td>MEDLAB at Arab Health</td>
<td>Dubai, UAE</td>
<td><a href="http://www.arabhealthonline.com">www.arabhealthonline.com</a></td>
</tr>
</tbody>
</table>

For more events see www.ihe-online.com/events/

Dates and descriptions of future events have been obtained from usually reliable official industrial sources. IHE cannot be held responsible for errors, changes or cancellations.
World of Health IT

Centro de Convenciones Internacional de Barcelona (CCIB)

21–22 November 2016
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