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- In reprocessing qualifications are vital



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## Clinica Mobile's DRX-1 delivers high-speed care

Ace motorcyclists gain instant radiographic imaging from a flat panel system

Exuding the aroma of hi-octane fuel, the glamour of multi-coloured racing leathers, flashy sponsored brands and the glitz of the circuits, motorcycle racing can be an irresistible fast-action sport. Amid the roar of engines, the world's leading motorcycle aces, such as Marc Marquez, Valentino Rossi or Jonathan Rea, hit around 300kmh on tracks across the globe.

Interview: Daniela Zimmermann

High-speed duals thrill the crowds, but clearly the risk of accident and injury remain high, despite improvements over the last three decades in equipment, machines, safety features and medical facilities.

At the core of these is the renowned Clinica Mobile, a fully equipped medical and physiotherapy centre 'on wheels' to treat riders and the wider motorcycle racing entourage.

Since the 1970s, Clinica Mobile has grown from a group of caring and enthusiastic practitioners carrying medical boxes to race circuits into a mobile diagnostic and treatment facility with 50 employees attending Superbike World Championship and MotoGP races.

In 2015, for example, the facility performed 2,966 interventions for MotoGP alone, of which about 1,245



were for drivers and 1,721 for paddock staff. 'Very often it helps diagnose and treat minor injuries, but sometimes - 359 times in 2015 - an X-ray is required. All this must be carried out within our 65-metre square facility, which can treat up to eight patients simultaneously,' Medical Director Dr Michele Zasa explains. Circuits now have

Checking for minor fractures is important - they will race anyway, but they can relax knowing what the pain is

their own permanent medical facilities, but Clinica Mobile is still a critical resource for care and treatment. The unit constantly upgrades its equipment, the latest being an additional CARESTREAM DRX-1 flat panel from medical imaging systems and IT solution specialist Carestream Health. Installed at the back of the truck this produces

immediate radiographic images; the console captures images and a detector forwards exposures wirelessly to the console for processing and display, and then onward to printing and archiving systems.

The digital detector reduces exposure to X-rays compared to conventional systems and the light weight of the system makes this a versatile tool to conduct a range of traditional tests, e.g. general and trauma radiography and orthopaedics.

'Carestream's DRX-1 is a high-tech



Dr Michele Zasa is the Medical Director of the Clinica Mobile, a fully equipped medical and physiotherapy centre 'on wheels', and sometimes riders' refuge.

system, able to meet the diagnostic needs of the specialisms that we serve, allowing us to provide more timely and accurate support,' Zasa points out. 'It's a very important and extremely reliable tool, useful in case of falls and ascertained fractures. In diagnostics, you need to have good machines that produce excellent diagnostic images. I need to provide a good quality service to the top riders, so the quality of all our equipment is very important. In terms of diagnostics the Carestream DRX-1, is a very good system. For traumatology, we can diagnose more and more fractures and it's important to see, if the riders are in pain, whether there are minor fractures.

Continued on page 2



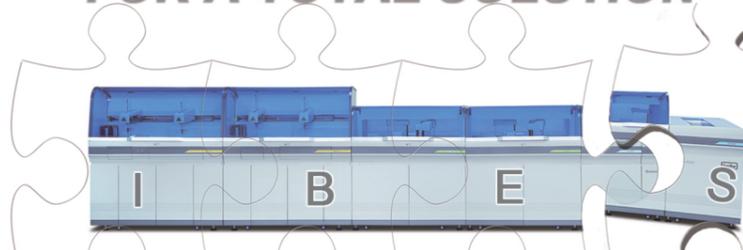
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## Clinica Mobile delivers high-speed care

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'It doesn't change much - they will race in any case, with the minor fractures, but for the psychology of riders it's important that they know when they feel pain that there is a small fracture, thanks to the machine seeing this. If they understand, they feel more comfortable and self-confident.'

The images are of such high quality that the riders are reassured and relaxed about their pain and raises confidence to return to the track.

Carestream has also benefited. 'Being on board the travelling medical centre during the races the DRX systems are tested to the full, both by the conditions and physical parameters,' explained Michele Ferrarese, the firm's Southern Europe Cluster Manager. 'This enabled us to demonstrate efficiency, consistent performance and ease of use.'

While life-threatening crashes have diminished in recent years, Clinica Mobile - which is privately funded by the organisers of the World Championship - has developed and evolved due to the inherent dangers.

Founded by Dr Claudio Costa in 1977, this mobile hospital is housed in a lorry, specifically equipped with physiotherapy beds, as well as X-ray and high intensity laser therapy and thermotherapy equipment used for inflammation and muscle relaxation.

Since 1977, Clinica Mobile staff have provided emergency treatments and saved many riders' lives, with the unit keeping pace with medical advances throughout the years. In 1988, this unit even received the blessing of Pope John Paul II. However, its role has altered with the building of permanent medical centres at each circuit to deal with life-threatening emergencies.

Nowadays, riders who crash on track are treated by local medical personnel in the circuit medical cen-

tre although, in less serious cases, they may still be transferred to Clinica Mobile for further treatment. Most of the mobile unit's work is to provide generic medical treatments, pain therapy, orthopaedic advice and imaging evaluation.

Attending each race are two doctors - an anaesthetist and orthopaedic specialist - as well as four physiotherapists and a radiology technologist.

The facility also treats many others who work at the track, for example managers, mechanics and journalists, any of whom might suffer a range of ailments. 'It's a mix of diagnostics, general medicine, traumatology consultation, and pain therapy to get riders back on the track as soon as possible,' explains Zasa who, having worked for Clinica Mobile since 2011, became the unit's Medical Director in 2014. 'You'll see plenty of riders on our beds, especially on Friday and Saturday afternoon, having physiotherapy treatments.'

The unit has also developed a family doctor approach for riders by offering GP-style services with blood checks and other tests.

'Clinica Mobile has seen a lot of drama, but it's also a second home for the riders. They come here for relaxing massages, or simply to chat and find a good environment. We cook outside and they come for a snack, or lunch, without having any pressure from their team, or journalists. This is very nice. They come not as top riders, but as normal boys having fun and enjoying life.'

Details: [www.clinicamobile.com](http://www.clinicamobile.com)  
[www.carestream.com/drx](http://www.carestream.com/drx)



Longer weaning

# These patients need

Research: Patients who experienced 'prolonged' weaning from mechanical ventilation show significantly higher mortality rates, Mark Nicholls reports

A study on weaning patients in intensive care units (ICUs) has compared those who underwent prolonged weaning off mechanical ventilation (MV) with patients classified as undergoing 'simple' or 'difficult' weaning.

Dr Xiu-Ming Xi from the Department of Critical Care Medicine, Fuxing Hospital, Capital Medical University, Beijing, lead researcher of the team in China, explained that the findings indicate that patients who experience prolonged weaning should receive closer attention.

Clinicians treating such patients should, he suggested, place greater emphasis on actively controlling the diseases initiated by MV, to improve cardiopulmonary function and nerve and mental state, and begin functional rehabilitation exercises as early as possible to reduce the mechanical ventilation time.

'In addition,' he said, 'tracheostomy should be considered earlier for patients who suffered from prolonged weaning because tracheostomy improved patients' comfort and communication, reduced sedative use, and may have contributed to earlier weaning.'

Prolonged weaning occurs in patients who fail at least three weaning attempts or require seven days of weaning after the first Spontaneous Breathing Trial (SBT) and those falling into this area were at greater risk of dying.

Researchers found that patients in the prolonged weaning group had a longer MV duration, with 18% of patients in the prolonged weaning group needing prolonged MV. In addition, incidences of re-intubation, ventilator-related pneumonia, and mortality were significantly increased.

The study also showed that the

patients with a low Glasgow Coma Scale score - a neurological scale giving a reliable and objective way



UK hospitals face funding black hole

# NHS takes radical steps to head off financial crisis

When two Spanish oncologists launched the first independent Spanish oncology forum this May in Madrid, European Hospital's correspondent spoke with Dr Javier Cortés, co-organiser of the event, to find out more about its expected impact in their field

Report: Mark Nicholls

Radical steps have been taken to address a growing financial crisis facing hospitals across England. Under new rulings, NHS England will allow the worst affected hospitals to relax critical performance indicators, such as waiting time targets, as the NHS financial crisis deepens.

The move is part of a package of measures taken by NHS bosses after hospitals exceeded their budgets by a record £2.45bn last year, triple the previous year's level.

Under the Strengthening Financial Performance and Accountability in 2016/17 report from NHS Improvement and NHS England, fines for missing targets for accident and emergency units, cancer and routine operations have been scrapped.

They will be replaced by a regime of "trust-specific incentives" being set up to help the worst-performing trusts tackle financial problems, with specialist senior managers drafted in to help some get out of trouble.

For the past few years, UK hospitals have been fined if they missed key targets - such as the four-hour A&E wait, the 62-day cancer treatment deadline and 18 week waits for routine operations.

With successive government placing great emphasis on targets to raise performance, the relaxing of them is seen as a radical step.

Hospitals will instead simply have to improve on current performance to access any extra money being invested in the NHS this year.

With nine out of ten hospitals in

financial difficulties, the new measures are designed to cut the £2.45bn overspend to £250m.

NHS England chief executive Simon Stevens said this was a make-or-break period with the pressures across the NHS "real and growing."

"We need to use this year both to stabilise finances and kick-start the wider changes everyone can see are needed," he added.

Meanwhile, it has also emerged the financial problems in hospitals almost meant the Department of Health failed to balance its budget overall.

Richard Murray, Director of Policy at The King's Fund - an independent charity working to improve health and care in England - described the overspend as "further evidence of the serious financial crisis engulfing the NHS."

He added: "The prospects for the current financial year are grim, with national leaders already admitting that the NHS will be in deficit again despite even more stringent controls on spending.

"The extension of the special measures regime, and other measures announced, could be an opportunity to provide support for the most financially challenged NHS organisations. But it still leaves large numbers of other NHS trusts struggling to balance the books and meet key performance targets."

The King's Fund has also stated that staffing levels within the NHS will have to be cut if the government wants to bring NHS finances under control.

"If the government is serious about restoring financial balance,



Richard Murray

Having previously worked at the Department of Health as an economic adviser and in a number of senior roles, Richard Murray moved to NHS England as Chief Analyst in 2013 before joining The King's Fund in January 2014 as Director of Policy.

it must review its priorities for the NHS and be honest with the public about what it can deliver with the money it has been allocated," he added.

Chris Hopson, chief executive of NHS Providers, which represents trusts, said: "We have to rapidly regain control of NHS finances, otherwise we risk lengthening waiting times for patients, limiting their access to wider services and other reductions in the quality of patient care."

In response to the Strengthening Financial Performance and Accountability in 2016/17 report, Stephen Dalton, chief executive of the NHS Confederation - which represents 85% of NHS providers and commissioners - said: "This is a serious moment for the NHS. Cuts to social care and public health as well as added pension costs are just some of the factors making it extraordinarily difficult for the NHS to bring down costs and demand this year.

"We recognise the importance of financial rigour, however it should be recognised that the service has

ing off mechanical ventilation raises mortality

# ed more attention

of recording the conscious state of a person for initial and subsequent assessment – at the start of weaning, were more likely to have prolonged weaning, meaning that the patient’s consciousness level and mental status affect the success of weaning.

‘Higher PaCO<sub>2</sub> levels at the initial SBT were independently related to prolonged weaning in our study,’ Xi pointed out, ‘Most patients undergoing weaning still have considerable gas exchange disturbances during the weaning process and may develop hypoxemia, hypercapnia, or both, during an SBT.’

‘Patients who experience failed weaning are frequently unable to increase their minute ventilation in response to a high PaCO<sub>2</sub> because of weakness of the respiratory muscles, altered respiratory mechanics, and other factors.’ The study follows a proposal at the International Consensus Conference to classify weaning of patients in intensive care units from mechanical

ventilation into ‘simple’, ‘difficult’, and ‘prolonged’ weaning, based on the difficulty and length of the weaning process.

For the prospective cohort study, the Beijing team examined the incidence and outcome of weaning according to the new categories.

Three hundred and forty-three patients were included in the final analysis. The prevalence of simple, difficult, and prolonged weaning was 200 (58%), 99 (29%), and 44

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Dr Xiu-Ming Xi, from the Department of Critical Care Medicine, Fuxing Hospital, Capital Medical University, in Beijing, is one of China’s leading critical care practitioners and also President of Chinese Association of Critical Care Physicians.



**Stephen Dalton**

A nurse by background, Stephen Dalton has been a NHS provider services chief executive for 17 years, holding posts in Merseyside, Cheshire and Cumbria where, for nine years, he was CEO of Cumbria Partnership NHS Foundation Trust. He is also former chief executive of the Mental Health Network.

already made unprecedented savings in hugely challenging circumstances. The uncertainty following the Brexit vote is likely to compound financial concerns.

“Now is an important time for the Government and national bodies to assure NHS leaders that a focus on stability does not come at the expense of transformation.

“This is critical to improve care for patients at a local level and will ultimately deliver sustainability for the future.”

The Department of Health responded by saying the NHS is “performing well and delivering safer, more compassionate care.”

“We know some providers are under financial pressure caused by big rises in demand and our ageing population, but are investing an extra £10bn a year by 2020 to deliver the NHS’s own plan for the future,” said a spokesman.

However, the Patients Association rejected the plan to ease targets.

“This is the slippery slope back to the bad old days of never-ending waiting times and uncertainty - with patients left endlessly on A&E trolleys and waiting for life-changing operations,” said chief executive Katherine Murphy.

“We are calling on Government to urgently reconsider this decision and put the patients safety and wellbeing first. Patients should not be punished for years of financial waste in the NHS.”

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*Temperatures rise over labour division, cost increases and higher appreciation*

# Conflict at the 13th DKLM

With 800 professional participants and 400 industry partners, the German Congress of Laboratory Medicine (DKLM) (Mannheim, 28-30 September) is the largest in-vitro diagnostics professional event in German-speaking countries.

For the second time since 2014, the event is jointly organised with the umbrella association for German medical technologists and analysts (DVTa).

The congress theme 'Labor-mezizin verbindet' (lab medicine connects) reflects the fact that laboratory medicine is an interdisciplinary subject like no other and connects those who are involved in medicine across disciplines.

It works almost imperceptibly in the background, hardly noticed by patients. European Hospital spoke with this year's Congress President, Professor Berend Isermann, from University Hospital Magdeburg, about the key topics at the Congress and challenges the discipline faces.

During our talk, Professor Isermann outlined key topics chosen for the 13th DKLM. 'In addition to interdisciplinary POCT management the scientific presentations will focus on new inflammation mechanisms

and biomarkers, the improvement of basic care by means of innovative diagnostic technologies, the diagnostic challenge posed by metabolic pandemics, new diagnostic approaches of cellular reprogramming, and liquid profiling,' he said. 'Participants, however, will not only learn about the most recent research findings, they will also be offered numerous professional development and training events in the form of workshops and seminars.'

## Liquid biopsy or liquid profiling: will pathologists invade lab turf?

'Indeed, liquid biopsy and liquid profiling are different terms for the same procedure, which originates in oncology. Cell-free DNA or RNA, meaning cell-free nucleic acid, in blood allows the evaluation of tumour development. Tumour growth and tumour decrease can be shown quantitatively and new mutations can be detected.

'Laboratory medicine can use this procedure to detect many more changes, mostly epigenetic ones, such as damages to the beta cells at the onset of type 1 diabetes, or cell failure with type 2 diabetes. The potential is much wider and not at all limited to oncology. This is why we clearly prefer the term "liquid profiling". The term "liquid biopsy" misleadingly suggests that the technique is similar to tissue biopsy and thus an element of pathology. What

it really is, is liquid profiling – a procedure lab medicine has known and been doing for decades with the only difference being the fact that before we used blood proteins to establish a profile of a disease or a tumour. Cell-free nucleic acid is just another parameter.

'We are convinced that surveillance analysis is our job. There is a long-standing division of labour, which makes sense. This does not cut into the tasks of pathologists, quite the contrary: the two will complement each other very well. Histology will always be the first step: evaluating the lesion in situ and establishing the grade. This cannot be done using cell-free RNA/DNA – it will remain the pathologist's domain.

'Furthermore, the search for mutations in tissue will continue to be necessary as they are important tumour markers. However, generally speaking, a technology such as molecular diagnostic testing ought not be limited to a single group. We are not doing that and we expect others not to do that either.'

## POCT developments

'Point-of-care testing is becoming ever smaller and more compact. The current trend is called microfluidics, which means less volume and fewer reagents are required bedside to achieve accurate results. However, it is important to carefully evaluate where POCT is necessary, as it

is still an expensive procedure and less reliable than lab procedures in terms of specificity and sensitivity.

Obviously, there are situations and locations where POCT is indicated, be that emergency medicine or a remote doctor's office in the countryside. For the industry, POCT is a major growth segment. In view of these considerations, we expect POCT to be a controversial issue at the congress.'

## Assuring POCT quality

'No doubt, POCT is real technological progress and will become better and better. At the same time, correct pre-analytics has to be guaranteed – which is problematic because basically everybody works with the devices. Moreover, the quality of the results may well turn out to be a problem, since the people using the devices are not necessarily those who maintain them and ensure compliance with the law.

'Another issue is data management. It does not suffice to print the findings in a report and file it in the patient record. The data and results must be entered in the information system. At my institution, University Hospital Magdeburg, we have a POCT system and a working group that takes care of all issues and aspects involved in this technology. To support e-health, data that were generated at any location have to be input in the information system to make them available for everyone

who needs them.

'In my opinion it's clearly the task of the labs to ensure quality along the entire chain from pre-analytics through analytics down to post-analytics. In healthcare we have long been pioneers in terms of quality assurance and quality management – and we want to keep it that way.'

## Lab medicine challenges and major future changes

'That's a very complex question. One of our main concerns is – as in many other disciplines – to attract talent. We started a number of initiatives to promote junior professionals from graduate level programs to funding a chair. We offer train-the-trainer courses and established a junior academy together with the German Research Foundation. We put a lot of effort in these programmes and they do bear fruit: we could generate interest and the programmes are well accepted.

'Going forward rather than simply generating data, we have to focus on analysing and managing complex data sets to be able to cull more relevant information from these data. Systems diagnostics is a major change on the horizon and it's an issue in our junior academy. There will be more bio-informaticians in the labs – a development we welcome because the natural scientists in our discipline have always been very innovative.'

*German biobank develops standards for European Research Association*

# Frozen samples are scientists' gold

Our knowledge of causes and mechanisms of current and future diseases is on ice – not the perpetual ice of the polar caps but artificial ice. It is stored in biobanks at -80 to -160 °C. One of Europe's leading biobanks is the Interdisciplinary Bank of Biomaterials and Data Würzburg (ibdw), Germany. Since 2013, biomaterials culled at Würzburg University Hospital are stored centrally for research purposes in a state-of-the-art facility. Any discipline can make use of the quality-assured bank content. ibdw is one of the first biobanks to implement the concept of 'broad consent' and to almost fully automate its processes. Availability of biomaterials will allow research on issues and diseases that are not even known today.

## Broad consent

Since 2010, the German Federal Ministry of Education and Research (BMBF) has supported the establishment of centralised structures at five selected German locations to systematically collect liquid and solid human biomaterials. The University Hospitals in Aachen, Kiel, Heidelberg, Berlin und Würzburg were the first to implement centralised biobanks and the umbrella organisation 'German Biobank Nodes', founded in late 2013, will



With a medical degree from the University of Würzburg, Professor Roland Jahns became a CEA Fellow in Sophia Antipolis (France) and DFG Fellow at the Institute of Pharmacology and Toxicology in Würzburg. He specialised in cardiology in 2002 and received the GoBio Award of the German Federal Ministry of Education and Research (BMBF) in 2006. In that year he also became chair of the Working Group at Rudolf Virchow Centre for Experimental Biomedicine. He became a professor in 2008 and, since 2011, has been in charge of implementing the University Hospital Würzburg central biobank, becoming its director in 2013.

continue to develop the concept.

The purpose of a biobank is storage of patient tissue, blood and DNA samples donated for research. Prior to participating in a study,

a patient signs a detailed consent form describing the research and the future use of the donated samples. 'This broad consent is unique,' says Professor R Jahns MD, cardiologist and director of the Interdisciplinary Bank of Biomaterials. 'Drawing on our experience, a working group of the German Ethics Commission drafted a text template for non-specified storage and use of donor material for medical research purposes, since we don't know today what research might be necessary 20 years down the road. The consent survives the death of the donor.'

Ethically and legally this is a balancing act that requires numerous accompanying measures. For example, the donor can withdraw consent at any time, research results must be presented to the donor and the public in a transparent and comprehensible way and, prior to the release of material that is not tied to a specific purpose, an Ethics Committee must approve the research project for which the material was requested.

## Automation makes reproducibility

A further unique feature of the Würzburg biobank is the high degree of automation. It facilitates quality assurance and makes processes and

results reproducible and comparable across locations. The OECD standard that defines handling of human biomaterials requires end-to-end documentation of the sample path, from sample taking to storage. 'We document each and every step with a timestamp,' Jahns explains. 'On average we have ten to twelve timestamps per sample – completely automated. We are pioneering this process in Germany.'

The lack of reproducibility of research results prompted the Federal Ministry to intensify funding of centralised biobanks. Healthcare facilities have long been collecting blood and tissue samples in refrigerators. Any graduate student can take a frozen sample, thaw it, remove whatever he or she needs and refreeze it. In a modern biobank, a blood sample is separated into smaller 300 ml units prior to storage. These subsamples are usually sufficient to perform a triple assay that conforms to academic standards. 'Such a smaller sample will usually allow serial triplets. Thus one blood sample will generate 10 subsamples. When a researcher requests a sample, only one subsample will be removed, the others remain at -80°C. It is a basic principle of a biobank to turn one large sample into several smaller ones.'



## Keen protection

Currently, close to 200,000 liquid samples and 3,500 tissue samples are stored in Würzburg, allowing 1.2 million aliquots and 16,000 tissue sub-samples. Each sample tube is identified by an engraved unique barcode. 96 tubes fit on a rack, which is scanned prior to storage. The data are transmitted to the lab information system, which records the location of each tube.

Every piece of information is double-coded which means only the system itself knows where a certain sample is. 'We can request a sample by entering a code. A virtual server and a double firewall make unauthorised access from outside pretty much impossible. The biobank is close to 100 percent safe.'

## Biomarkers and molecular signature



After receiving his doctoral degree at the University of Würzburg, Germany, **Professor Berend Isermann** was Research Fellow at the Blood Research Institute in Milwaukee, Wisconsin, USA. Subsequently, he then joined the Department of Internal Medicine at the University of Heidelberg where in 2008 he obtained his qualification for university professorship. One year later he was appointed Director of Clinical Chemistry at the institution's Department of Internal Medicine. Since 2011 he has been heading the Institute of Clinical Chemistry and Pathobiochemistry at Otto von Guericke University, Magdeburg, Germany. Professor Isermann focuses his research on coagulation proteases, chronic vascular diseases, diabetic nephropathy and sterile inflammation.

**New analytical methods**

'There will be new analytical methods such as proteomics. High-resolution protein analysis has not yet arrived in lab routine, but it will do so because it yields a lot more information. It not only shows that something is docking onto the antibody but also shows the protein fragment itself – its modifications and much more. It creates information on an entirely new level.'

**Cooperation with medical colleagues and patients**

'It's very important for us to stay in touch with our medical colleagues, because this is the only way to ensure we have an uninterrupted flow of information. In the future, we will be playing an increasingly important role as consultants. The added value we create in medicine is often under-appreciated. We are sitting in the backseat, without direct contact with patients. Nevertheless, 70 percent of all diagnoses can be correctly made based on lab results.'

This is an extremely high level of performance – at a mere three percent of healthcare spend.

'Diagnostic imaging is much more time consuming and expensive than lab diagnostics. Lab medicine has become so efficient and so quiet that it's now not noticed and taken for granted. Our contribution to the diagnostic process should not be underestimated and maybe even be more appreciated. Laboratory medicine connects! In the future we will be open to organise our congress jointly with other disciplines.'

**These patients need more attention**

Continued from page 3

(13%) patients, respectively.

'Patients who experienced prolonged weaning had a significant increase in both 60-day and hospital mortality compared with patients who experienced either simple or difficult weaning,' said Xi.

'We found that a lower Glasgow score, and hypercapnia at the beginning of the weaning process, were independent risk factors for prolonged weaning.' In the prolonged weaning group, patients were more likely to be

from the medical ward and to have pneumonia as the cause for initiation of MV; they were also older and had a higher APACHE II score (Acute Physiology and Chronic Health Evaluation II) - one of several ICU scoring systems to assess ICU patients - on admission to the ICU.

The study was performed at medical-surgical ICUs of 13 municipal hospitals in Beijing and all patients who had been intubated and mechanically ventilated for more than 24 hours were screened.

# It's Time to Embrace the Future of Diagnostic Accuracy

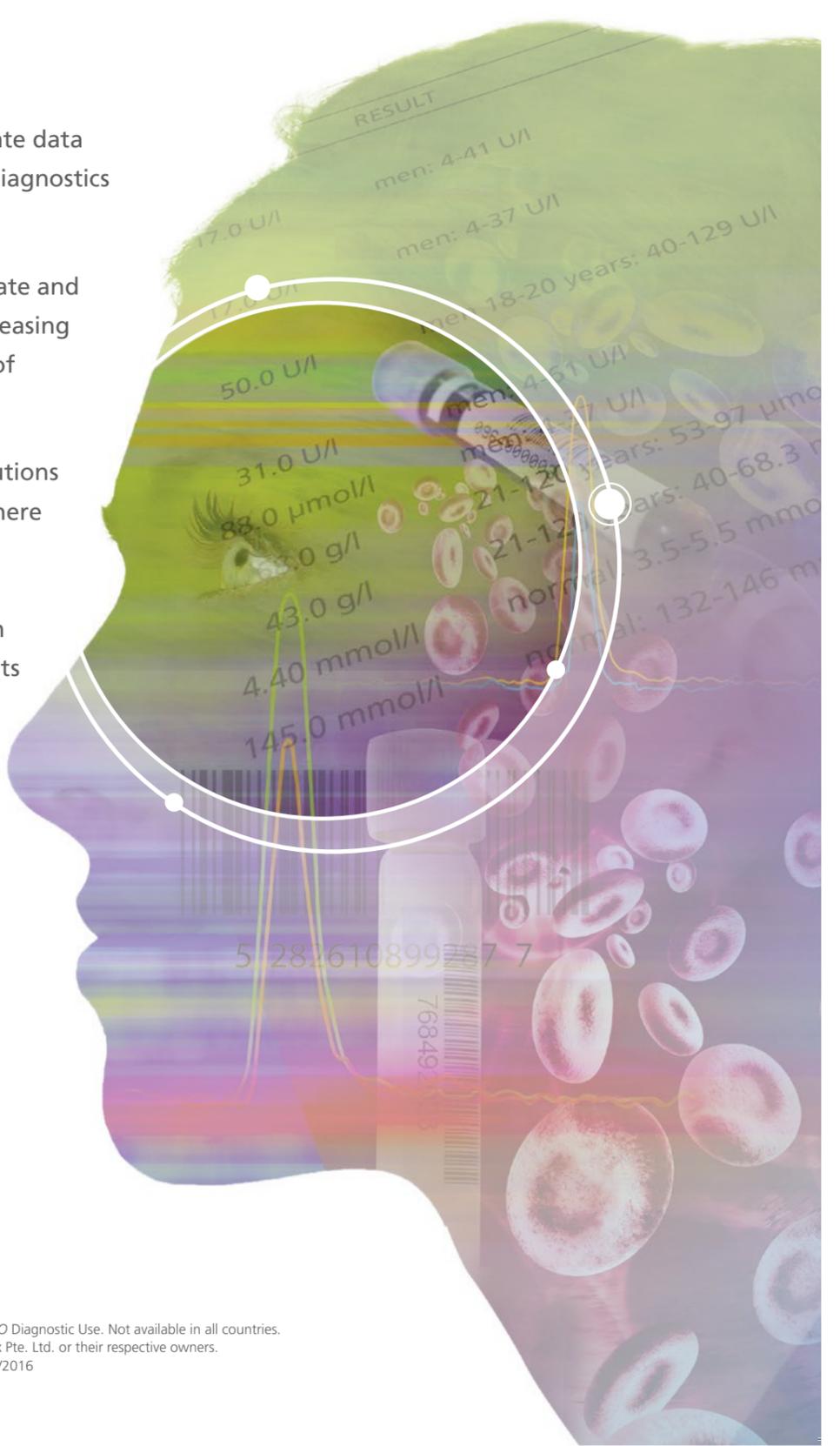
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**ibdW's Bio II Lab for automated processing of liquid biosamples**

The Würzburg biobank aims to support the research projects of the university's medical school. Therefore, it collects a broad range of samples for oncology, cardio-vascular diseases and endocrinology.

Samples from cancer patients usually encompass tumour core tissue, tumour margin tissue and non-tumour tissue. These samples are the basis for personalised therapies, since they allow examination of different tumour-specific molecular changes on the genetic level and molecular tumour signatures may be decoded.

Today, different mutations can be treated in a highly specific manner. Certain tumour DNA can be

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Surfaces impregnated with zinc molybdate self-disinfect for years

# The sustainable pathogen killer

Professor Peter Guggenbichler is only too aware of infection prevention and control issues in hospitals. Prior to his retirement in 2013, from the Children's Hospital at Erlangen University Hospital, in Germany, he led the Infectiology and Preventive Medicine Department, for 25 years. 'After countless nights on the intensive care ward I realised that the staff does not adhere to infection prevention and control guidelines because, realistically, these cannot be adhered to,' Guggenbichler explains.

According to the guidelines, nurses and doctors are supposed to disinfect their hands between 50 to 80 times during just one shift. After each fifth to sixth application of a disinfection agent they should also wash their hands because otherwise the hand disinfection agent merely spreads the dirt. According to the infection specialist this is not achievable: 'Staff would spend more than an hour per shift on hand disinfection, and in case of emergencies there is no time for this, anyway. This prompted me to think about alternatives and to precisely analyse the workflows in the hospital and on the intensive care ward.'

Every year around 5% of inpatients in Europe develop hospital acquired infections (HAIs). Of the 1.75 million patients affected, at least 10%, i.e. around 175,000 people, do not survive this (source: [www.ESCMID](http://www.ESCMID) 2015). The risk of nosocomial infections is therefore higher than the risk of being involved in a road traffic accident.

The staff's hands are contaminated but so are hospital surfaces, and pathogens and multi-resistant organisms are transmitted with

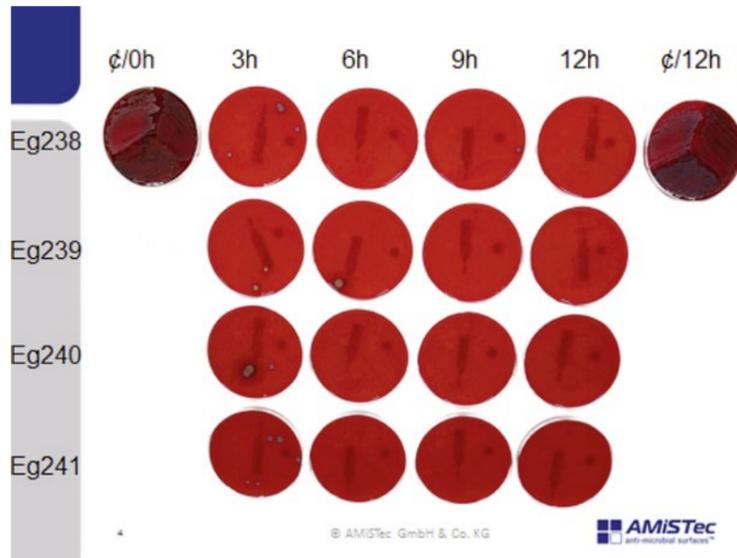


Figure 1: Results of effectiveness testing of *Staphylococcus aureus* (Sa), *Escherichia coli* (Ec) and *Pseudomonas aeruginosa* on hospital furniture with different additives and concentrations. The method used in the study was droplet application: application of  $10^8$  CFU/ml in 100  $\mu$ l. 238: zinc molybdate one percent, 239: molybdenum trioxide one percent, 240: zinc molybdate 0.5 %, 241: molybdenum trioxide 0.5 %. All microorganisms were destroyed within three hours.

every touch. Be it hospital furniture, touchpads, control knobs, cables, floors, computer keyboards or telephone receivers – as soon as something is touched it is no longer germfree, even if previously disinfected. Surfaces that can kill pathogens would therefore be ideal – and this is exactly what Guggenbichler has worked on for years, initially with antibiotics and disinfection agents and, since the 1990s, also silver.

'In 1999 we developed an outstanding silver technology, which is still effective for external ventricle drainages for intracranial pressure,

and is therefore still successful on the market. However, the most silver technologies do not work for the impregnation of surfaces because the pathogen-killing silver ions are used up after 3-5 weeks. As with disinfection agents and antibiotics, silver ions are incorporated into the metabolism of microorganisms, so they must be dissolved out of a hydrophilic surface and are then lost. This means that a number of silver technologies on sale is basically ineffective, and this is not being questioned enough.'

Guggenbichler and his team have now developed a technology which, with the help of various transition metal acids (mostly zinc molybdate in situ, i.e. the polymer itself), can generate  $H_3O^+$  ions, reactive oxygen species and photocatalytic activity from tiny amounts of water, and this has a strong antibacterial effect

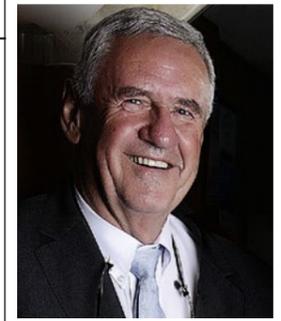
on the surface. 'The basic assumption about the effective mode of action is that hydrating oxonium ions ( $H_3O^+$ )(OH<sub>2</sub>)<sub>n</sub> (n=1.3) in contact with micro-organisms initially remove the hydration water and finally also the remaining water molecule. The now naked protons can attack the cell walls of bacteria in an unspecific way by permanently denaturing their protein shells and fimbriae. Additionally, the protons can block the effect of essential enzyme systems inside the cell. The entire process is known as proteolysis (coagulation necrosis),' the scientist explains.

The result is a slightly acidic surface, similar to the acid mantle of the skin, which, with a pH value of 4.2 – 4.5, quickly kills germs. Additionally, there is the positive zeta potential, i.e. a positively charged surface that attracts negatively charged microorganisms, so that overall there is a synergistic effect. Zinc molybdate is neither water nor alcohol soluble, so cannot be removed by disinfectants. It is thermally stable and non-toxic. Both elements, molybdate and zinc, are essential trace elements in the body, which even if they should become dissolved, remain below the permitted threshold level for 24 hours by factor 250.

'Obviously nurses will have to continue washing and disinfecting their hands, but if they forget to do so once in a while the consequences will be less dramatic. The new technology is a kind of safety valve: instead of disinfecting hands 60 times a day it can be done every 20-30 minutes instead, because the surfaces will remain self-disinfecting for many years.' To achieve this, there is no need to refurbish the entire hospital because the zinc molybdate can be applied retrospectively as a transparent film to telephone receivers, furniture and fittings etc. like any normal lacquer.

Guggenbichler already discovered this mode of action around ten years

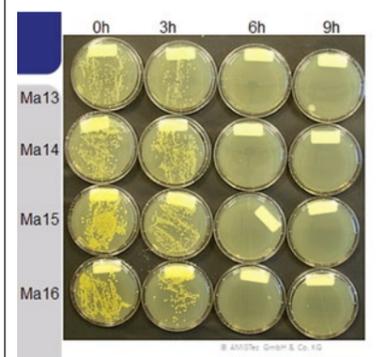
ago. But his discoveries really gathered pace since his retirement from the hospital and the foundation of the start-up company AMISTec, and patients will soon benefit from this. Paints and lacquers for large medical devices are now ready for use. However, the possibilities go way beyond this; airline seats, car air conditioning systems, shower trays and even underwater power cables will soon be self-disinfecting. We can only hope that hospitals will not miss the boat. With the rapid increase of multi-resistant pathogens and talk of the post-antibiotic era, there is an urgent need for action in the prevention of infection.



Josef-Peter Guggenbichler studied medicine at the University of Innsbruck and qualified as a paediatrician at the Mayo Clinic, Rochester, Minnesota, USA. After his return to Austria he became a professor at the University of Innsbruck (1980-'90) and then he worked as an extraordinary professor at the Department for Infectiology and Preventative Medicine at the Children's Hospital, University Hospital Erlangen, Germany (1990- 2009). Guggenbichler holds more than 30 patents for the antimicrobial impregnation of surfaces and is cofounder and managing director of the start-up company AMISTec ([www.amistec.at](http://www.amistec.at)) founded in 2011.

Details: <http://www.krankenhaushygiene.de/informationen/hygiene-tipp/hygienetipp2015/557>

Figure 2: Results of effectiveness testing of lacquer sample with zinc molybdate 0.25 % using different technologies (Ma13 – Ma 15), contact plate method. Application of  $10^7$  CFU/ml in 10  $\mu$ l. Determination of bioburden with Rodac plates after 0, 3, 6, 9 hours. All microorganisms were destroyed within three hours.



## Equipment for Histo-Pathology Labs

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## Frozen samples are scientist' gold

Continued from page 5

detected very early in blood – via a liquid biopsy – which can act as biomarker. 'Biomarkers are also interesting for cardiologists. We take different samples over time from a patient with poor cardiac pump function and compare them looking for biomarkers that tell us how the heart will recover after a myocardial infarction.

'The interesting point is that we collect prospectively but do the research retrospectively and still obtain valid results. Thus the samples are the scientists' gold,' Jahns explains.

Going forward, the number of biobanks to be funded in the context of the German Biobank Alliance will be doubled. The aim is for Germany to improve integration on the European level in the Biobanking and BioMolecular Resources Research Infrastructure



(BBMRI) to be able to contribute significantly to research on rare and widespread diseases such as diabetes, hypertension or cancer.

The robotic cryostore at ibdw (holding 600,000 biosamples)

# CARDIOLOGY 2016

NEWS AND TECHNOLOGY UPDATES FOR CARDIAC CARE

ROME • ITALY 27 AUG - 31 AUG 2016

## The virtual-heart arrhythmia risk predictor

Researchers have developed a personalised 3-D virtual heart that can help predict the risk of sudden cardiac death. Mark Nicholls reports

Research by a team at John Hopkins University (JHU) in Baltimore, USA highlights the patients who are most likely to face lethal arrhythmias.

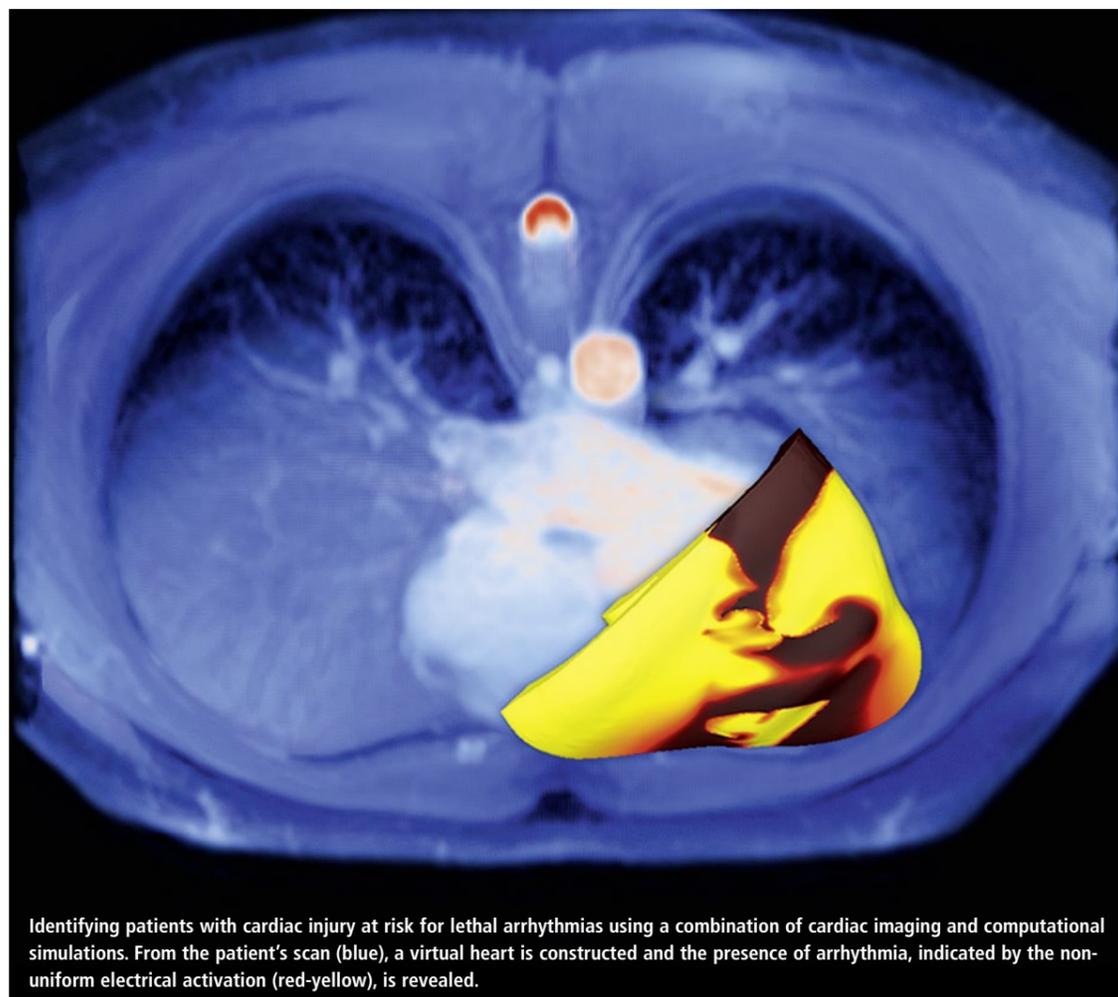
When patients suffer arrhythmia, cardiologists often respond by fitting a small defibrillator implant to sense the onset of arrhythmia and jolt the heart back to a normal rhythm. However, the question remains over how they decide which patients need the implant and the invasive surgery needed to fit it.

Aiming to address this, a team from the Department of Biomedical Engineering and Institute for Computational Medicine at JHU has developed a non-invasive 3-D virtual heart assessment tool to help doctors determine which patients face the highest risk of a life-threatening arrhythmia and would benefit most from a defibrillator implant.

Early evidence suggests the new digital approach yielded more accurate predictions than the current blood pumping measurement used by most physicians.

'Our virtual heart test significantly outperformed several existing clinical metrics in predicting future arrhythmic events,' Professor Natalia Trayanova, the university's inaugural Murray B. Sachs Professor of Biomedical Engineering, said. 'This non-invasive and personalised virtual heart-risk assessment could help prevent sudden cardiac deaths and allow patients who are not at risk to avoid unnecessary defibrillator implantations.'

A pioneer in developing personalised imaging-based computer models of the heart, she has worked on the project with cardiologist Katherine C Wu, associate professor in the Johns Hopkins School



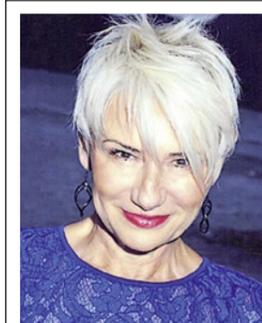
Identifying patients with cardiac injury at risk for lethal arrhythmias using a combination of cardiac imaging and computational simulations. From the patient's scan (blue), a virtual heart is constructed and the presence of arrhythmia, indicated by the non-uniform electrical activation (red-yellow), is revealed.

of Medicine, whose research has focused on MR resonance imaging approaches to improving cardiovascular risk prediction.

For the study, Trayanova's team formed its predictions by using the distinctive magnetic resonance imaging (MRI) records of patients who had survived a heart attack

but were left with damaged cardiac tissue that predisposes the heart to deadly arrhythmias. The study involved data from 41 patients who had survived a heart attack and had an ejection fraction – a measure of how much blood is being pumped out of the heart – of less than thirty-five percent.

Patients in this range are usually recommended implantable defibrillators, however, with the JHU team concerned about this measuring score system, they invented an alternative to these scores by using pre-implant MRI scans of the recipients' hearts to build patient-specific digital replicas of the organs.



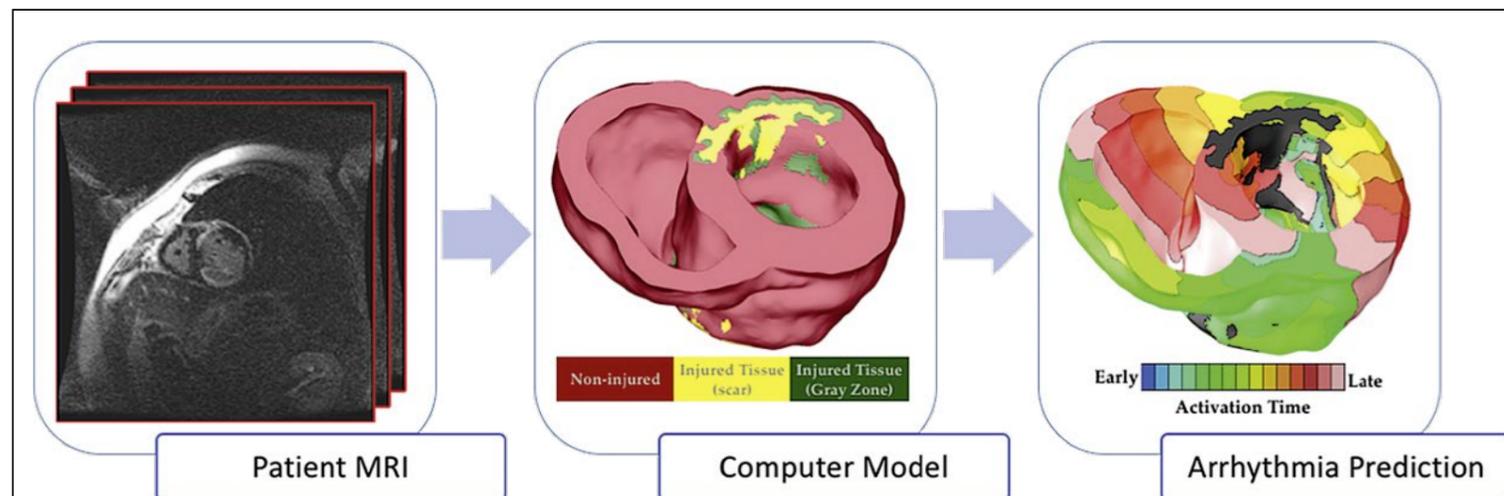
Natalia Trayanova PhD is the John Hopkins University's inaugural Murray B. Sachs Professor of Biomedical Engineering in the Department of Biomedical Engineering and Institute for Computational Medicine. She received her doctorate at the Bulgarian Academy of Sciences in Sofia (1986) and post-doctoral training in biomedical engineering at Duke University. Her research focuses on understanding the normal and pathological electrophysiological and electromechanical behaviour of the heart.

Using computer-modelling techniques developed in Trayanova's lab, the geometrical replica of each patient's heart was brought to life by incorporating representations of the electrical processes in the cardiac cells and the communication among cells. In some cases, the virtual heart developed an arrhythmia, and in others it did not.

The new non-invasive way to gauge the risk of sudden cardiac death due to arrhythmia has been named the VARP (virtual-heart arrhythmia risk predictor). Subsequent tests showed that patients who tested positive for arrhythmia risk by VARP were four times more likely to develop arrhythmia than those who tested negative. VARP predicted arrhythmia occurrence in patients four-to-five times better than the ejection fraction and other, invasive and non-invasive, existing clinical risk predictors. 'We demonstrated that VARP is better than any other arrhythmia prediction method out there,' Trayanova confirmed. 'By accurately predicting which patients are at risk of sudden cardiac death, the VARP approach will provide the doctors with a tool to identify those patients who truly need the costly implantable device, and those for whom the device would not provide any life-saving benefits.' Wu said that the early results indicate the more nuanced VARP technique could be a useful alternative to the one-size-fits-all ejection fraction score.

Trayanova is hopeful the new risk prediction methodology could also be applied to patients who had prior heart damage, but whose ejection fraction score did not target them for therapy under current clinical recommendations.

The next step is to conduct further tests involving larger groups of heart patients.



The virtual heart arrhythmia risk predictor. Patient-specific heart models are constructed from clinical imaging data. A virtual-heart model is then used to predict the patient risk of lethal arrhythmias.

Cardiac MRI adds crucial data on acute in-patient diagnoses

# CMR should complement echocardiography

MRI increasingly helps to diagnose cardiac disease, yet its role in clinical decision-making of acutely hospitalised patients has hardly been explored. ESC delegates will have a glimpse at how cardiac MRI (CMR) can add information, and sometimes change diagnosis in patients with acute conditions requiring hospitalisation, when Estefania De Garate presents the results of a study that could potentially impact on future cardiac clinical practice.

Report: Mélisande Rouger

In the study, one of the first to observe the role of CMR in this setting, De Garate and Dastidar (Figure) compared the value of echocardiography and CMR in a cohort of 231 acutely hospitalised patients. They found that CMR confirmed the echo diagnosis in 11% of these patients, but interestingly added significant new information in 41% and changed the diagnosis made on echo in 30% of the cases.

'CMR is increasingly used in out-patients and our results now show the promising role of this technique in sicker hospitalised patients in whose diagnosis and management can be changed by having a CMR,' Chiara Bucciarelli-Ducci, who directed the study, told European Hospital.

The study also compared the level of agreement between echocardiography and CMR in the assessment of left ventricular (LV) function. 'We found that the level of agreement in patients with severe dysfunction was very good but in patients with mild and moderate dysfunction the agreement was only fair.'

'If the heart works normally or really badly the two techniques appear to perform equally well, but when there are mild-moderate abnormalities, CMR has the advantage of higher spatial resolution and can distinguish subtler abnormali-



Estefania De Garate and Amardeer Ghosh Dastidar, the first co-author of the paper

ties', De Garate explained.

In a paper currently in submission, they explain in depth the potential use of CMR in the acute setting. The session is likely to attract a lot of interest and, as the abstract was among the top scored, it will be presented in the 'Cardiac MRI-Advances in Science' session at the ESC 2016 congress.

'We believe our results could be of interest to a wider cardiac audience. This work shows how CMR has an increasing role in cardiology and clinical practice, and can be a really useful tool for clinicians to guide management and decision-making in hospitalised patients.'

Echocardiography continues to be the first line imaging test and our study does not want to suggest that it should be replaced by CMR. Quite the opposite, that CMR should be considered and used as an additional test to complement echocardiography when necessary' Bucciarelli-Ducci said.

The Bristol Heart Institute at the University Hospitals Bristol NHS Trust is a tertiary centre in the SouthWest of England. The CMR Unit performs around 3,000 CMRs a year, an impressive number – as Bucciarelli-Ducci said: 'The UK is the leading country worldwide where the highest number of CMR

scans are performed clinically by a community that is also very active scientifically.'

In the rest of Europe, Italy, Switzerland, the Netherlands, Germany and Spain are significantly active communities with an increasing number of clinical CMR activity per year.

Few factors can limit the use of CMR in clinical cardiology include a significant training in image interpretation. Access to equipment and elevated costs remain as major drawbacks to wider distribution. Examination time usually takes about an hour, but it can be shortened depending on the needs of the patient, and on the information required by the physician. 'We can tailor the CMR protocol according to the clinical question,' she said, 'and give you an answer in 10 minutes when needed.'

De Garate and Bucciarelli-Ducci hope the results of the study will contribute to clarify the role and the use of CMR in daily practice even in sicker patients. 'The mandate of the scientific CMR community is to generate and diffuse the evidence on the clinical use of CMR in daily practice.'

'This piece of work hopefully will contribute to incentivise colleagues,' said Bucciarelli-Ducci, adding that it will also get the attention of healthcare policy makers and scientific societies to consider CMR in the guidelines.

# Algorithm for prosthetic heart valves

Cardiologists have highlighted the importance of echocardiography and cardiac CT – to evaluate the condition of prosthetic heart valves and to evaluate the need for recommendations.

Report: Mark Nicholls

With prosthetic heart valves recognised as the best treatment for the majority of patients with severe symptomatic valvular cardiac disease, the new algorithms will help clinicians diagnose and quantify prosthetic heart valve dysfunction.

Latest figures suggest that heart valve disease affects up to 6% of over 65-year-olds, with about 850,000 prosthetic heart valves expected to be implanted annually in western countries by 2050.

As the number of prosthetic valve implants continues to rise, the European Society of Cardiology (ESC) felt it was important to establish recommendations for assessing the condition of the implants using multimodality imaging.

Professor Patrisio Lancellotti, head of the intensive care cardiology unit at the Liège University Hospital Centre and Professor of Clinical Medicine at Liège University, led the ESC initiative. 'The guidelines are designed to underline the incremental value of all imaging modalities to evaluate prosthetic heart valves.'

The ESC recommendations include first-line imaging with 2-D transthoracic echocardiography; 2-D and 3-D TTE and trans-oesophageal echocardiography for complete evaluation; cinefluoroscopy to evaluate disc mobility and valve ring structure; cardiac CT to visualise calcification, degeneration, pannus, thrombus; cardiac MRI to assess cardiac and valvular function.

Weekend admissions of AF patients raises future death risk

# Cardiac records highlight an emerging trend

Two new studies have focused on the impact of weekend care and discharge on heart patients within the NHS in England. In one, patients suffering atrial fibrillation (AF) who were admitted to a National Health Service (NHS) hospital over the weekend faced a higher risk of dying within five years than patients admitted during normal hours.

In a second study, researchers found that HF patients discharged from hospitals in some parts of England at weekends were at an increased risk of dying than those sent home during regular weekday hours.

The new AF research on patients was led by Dr Rahul Potluri, founder of the Algorithm for Comorbidities, Associations, Length of Stay and Mortality (ACALM) study unit at Aston University's Medical School, in Birmingham, and focusing on 42,687 patients with one of the most common forms of abnormal heart rhythm.

The study found that atrial fibrillation patients admitted outside normal operating hours (9am-5pm, Monday-Friday) had a ten percent

increased risk of dying within the next five years.

The research was adjusted to account for external factors that



Rahul Potluri PhD is founder of the ACALM (Algorithm for Comorbidities, Associations, Length of stay and Mortality) study unit at Aston University in Birmingham. His clinical epidemiology research identified a link between high cholesterol and breast cancer and other prominent studies include health service research evaluating differences in death rates from weekend admission and discharge from UK hospitals, ethnic variations and the interplay between cardiovascular disease and mental health.

could influence death rates, such as age, gender, ethnic group, and the most common causes of mortality in the UK.

It is believed that AF affects about a million people in the UK, though many more may be undiagnosed and are unaware that they have the condition. In a separate study, the researchers looked at 31,760 atrial fibrillation patients discharged from hospitals in the north of England at weekends, finding a thirty-two percent increased chance of dying over the next five years compared to those sent home during regular weekday hours.

Across the UK there are more than 500,000 people diagnosed with HF. 'This study shows that the weekend effect is very much a reality for those suffering two of the most prevalent heart conditions in the UK,' Potluri pointed out. 'These patients are, quite simply, more likely to die if admitted or discharged outside regular hours, and that trend is particularly noticeable at the weekend.'

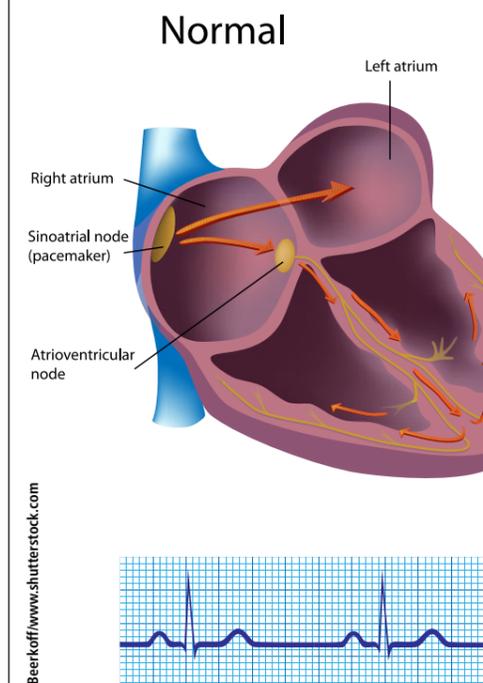
The researchers said they were not in a position to comment on

the underlying reasons for this from their study but did say it suggested that the level of support provided at weekends, from all teams involved in healthcare – in the hospital and in the community – should be addressed.

'What this research shows is that the weekend effect is not a universal phenomenon,' Potluri added. 'Across the two conditions we studied, its impact was varied, suggesting it can't be tackled effectively by blanket improvements to care.'

'Our findings suggest that the weekend effect is very complex and further research is urgently needed to assess what the implications of the weekend effect are for individual conditions, before any costly changes to services are implemented.'

\* The research involved the records of 929,552 patients (42,687 admitted with atrial fibrillation and 31,760 discharged following heart failure) between the first of January 2000 and 31 March 2013 across a number of North of England hospitals. Data was analysed according to the ACALM study protocol.



AF-patients who were admitted to an NHS hospital over the weekend had a ten percent increased risk of dying within the next five years than others.

Multimodality imaging assessment

# Algorithms define Prosthetic valve dysfunction

Integration of all imaging modalities – including CT – to define and quantify prosthetic heart valves in a new series



**Patrizio Lancellotti** is head of the intensive care cardiology unit at the University of Liège Hospital Centre and Professor of Clinical Medicine at the University of Liège. A pioneer in cardiac imaging techniques, his research has led to significant progress in the care of patients suffering functional mitral insufficiency. A former president of the European Association of Cardiovascular Imaging (EACVI) and the author of 330 peer-reviewed publications, he was also co-chair of the Task Force that drafted the ESC Guidelines for endocarditis, promoting the need for an approach based on a multimodal imaging.

‘Nuclear imaging currently has very limited application in the evaluation of PHV, other than in the setting of suspected infective endocarditis,’ Lancellotti explained.

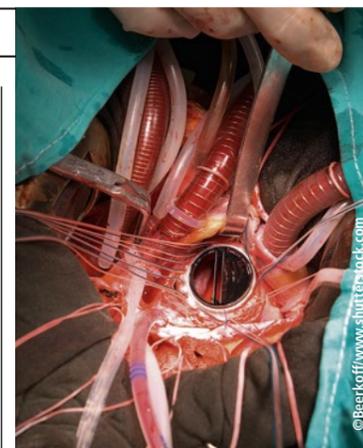
The Chinese Society of Echocardiography, the Inter-American Society of Echocardiography and the Brazilian Department of Cardiovascular Imaging have already endorsed the recommendations in

the document, which brings a series of tables providing parameters, criteria, and new algorithms. ‘Although relatively rare, valve dysfunction does occur with prosthetic heart

valves in the forms of structural valve deterioration or non-structural problems,’ he explained. ‘Though often challenging, establishing the exact cause of PHV dysfunction is

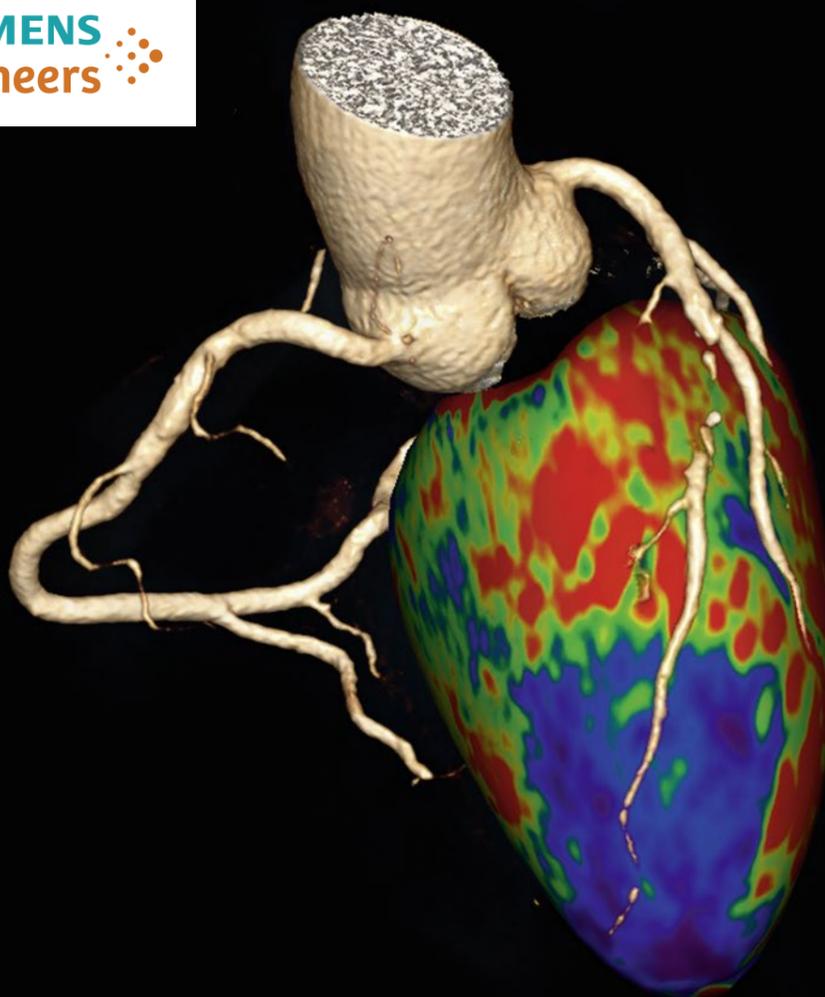
essential to determine the appropriate treatment strategy. The new algorithms to help clinicians diagnose and quantify prosthetic valve dysfunction are easy to use.’

‘In clinical practice, a comprehensive approach that integrates several parameters of valve morphology and function assessed with echocardiography is key to appropriately detect and quantitate PHV dysfunction. Other imaging modalities are complementary tools for the diagnosis and management of PHV complications.’



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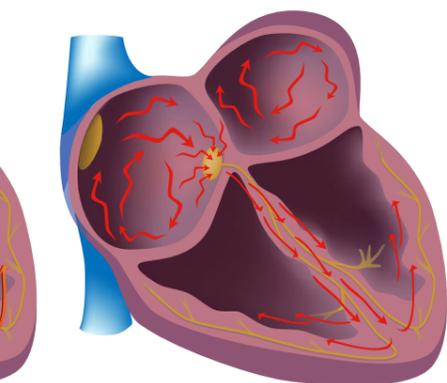
With its evaluation of dynamic myocardial perfusion, syngo.CT Myocardial Perfusion takes you to a new level in measuring the myocardial blood flow and allows you to use actual quantitative assessment for the hemodynamic relevance of intermediate stenoses of the coronaries.<sup>2</sup> This enables you to choose the right diagnostic approach for every patient.

<sup>1</sup> Optional application

<sup>2</sup> Rossi A, Pugliese F et al., Eur Heart J Cardiovasc Imaging. 2014 Jan;15(1):85-94.

# Migma

Atrial Fibrillation



Over the weekend faced a higher risk of dying over the

# A new technique for dilated

UK researchers are working on a more precise imaging technique for dilated cardiomyopathy that may lead to more effective treatments, Mark Nicholls reports

A study from the University of Oxford Centre for Clinical Magnetic Resonance Research (OCMR), part of the Division of Cardiovascular Medicine at the university, has demonstrated how the next generation of MRI scanners can work to measure heart conditions in dilated cardiomyopathy cases.

Oxford's new 7 tesla MRI scanner increased the phosphocreatine (PCr) signal-to-noise ratio by two-and-a-



Chris Rodgers is an Associate Professor of Biomedical Imaging in the Division of Cardiovascular Medicine at the University of Oxford and a Supernumerary Fellow and Stipendiary Lecturer in Physical Chemistry at Merton College, Oxford. His research – funded by his Sir Henry Dale Fellowship from the Wellcome Trust and the Royal Society – focuses on developing new methods for <sup>31</sup>P magnetic resonance spectroscopy and using Oxford's new 7-Tesla scanner and 3-T.

half times compared to values from a typical 3-Tesla MRI scanner. This means that 7-T scans provide a more precise reading of the energy supply in a patient's heart.

The study leader Chris Rodgers, Associate Professor of Biomedical Imaging at the University of Oxford, explained that the latest work builds on findings from Professor Stefan Neubauer, the head of the Division of Cardiovascular Medicine, who showed in the 1990s that dilated cardiomyopathy is associated with depleted energy reserves inside the muscle cells of the heart.

Neubauer measured this using phosphorus magnetic resonance spectroscopy on a 1.5-T MRI scanner.

More recently, the Oxford unit took delivery of an MRI scanner operating at a magnetic field-strength of 7-T – only the second 7-T system in the UK, and the only cardiac-capable 7-T system in the country – made by Siemens Healthineers. This was used in conjunction with a radiofrequency coil made by Rapid Biomedical GmbH.

'Our study was designed to show the feasibility of scanning cardiac patients in this new machine, and to show that we have much greater ability to monitor the phosphorus metabolites in the heart responsi-

ble for energy delivery,' Rodgers explained. 'This is part of a programme of work to deliver cutting-edge methods to monitor cardiac metabolism, primarily using the Oxford 7-T MRI scanner.'

'We intend to use these methods in forthcoming clinical studies of

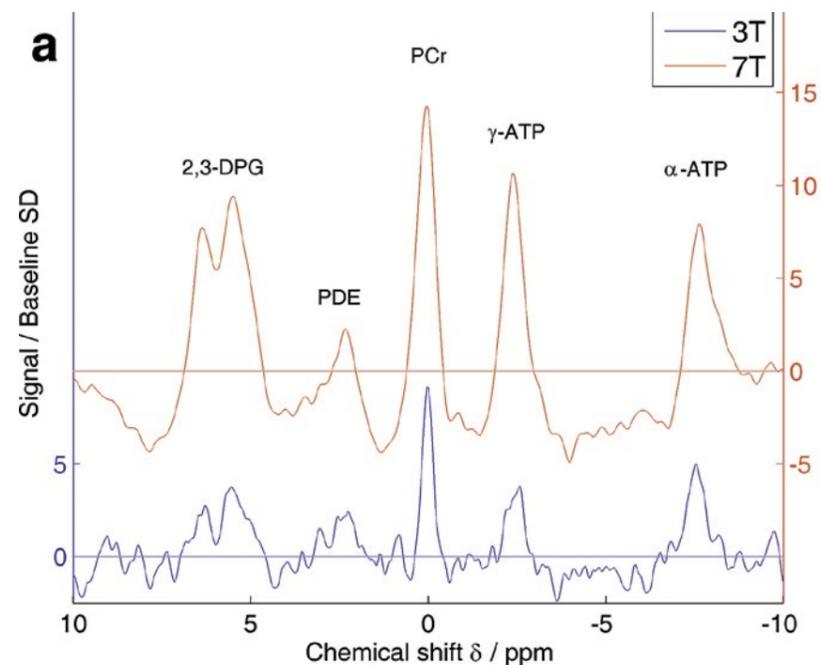
other cardiomyopathies, diabetes, and to monitor the effects of new drugs designed to treat heart failure.'

His team performed phosphorus magnetic resonance spectroscopy to record the concentrations and rates of generation/consumption of phosphate metabolites in ~60mL volumes at regular intervals across the chest.

Taking less than an hour in an MRI scanner equipped with special hardware for phosphorus measurements, the 7-T scans showed a marked improvement against 1.5-T and 3-T results, whose quality has previously prevented the wider uptake of phosphorus spectroscopy methods.

'We have seen a 2.6 times improvement in data quality at 7-T com-

Figure A, Graph shows comparison of spectra in a typical patient (57-year-old woman) at 3 T and 7 T. These spectra have had a matched filter applied and have been normalized to mean baseline noise, so the PCr peak height is, by definition, the PCr SNR. Increase in SNR at 7 T is readily apparent. B, Corresponding mid-short axis localizer image acquired at 7 T. C, Corresponding four-chamber localizer image acquired at 7 T. The spectroscopy matrix is overlaid in red, and the voxel plotted in A is highlighted. The yellow-shaded region denotes the regional saturation slab used to suppress signal from overlying skeletal muscle.



Changing research approaches as well as cardiac patient care

# Plumbing the depths of big data

Big Data has the potential to turn the approach to science and research on its head, according to leading expert Professor Viktor Mayer-Schönberger. In the future, he believes, researchers could adopt a position where they 'start with the data and then come up with the question.'

'They will be thinking about the hypothesis as the answer to the question,' he explained. 'That's because big data captures all the data from a scenario, often data that we did not expect it to scoop up. That has immense potential, particularly within the world of medicine and scientific research. With Big Data, we can ask questions of it that we did not think of when we collected the data.'

This is significant, he pointed out, because scientists traditionally start with a hypothesis and then collect the data to answer the questions they have posed.

Though as Professor of Internet Governance and Regulation at the Oxford Internet Institute, University of Oxford, he emphasised, 'this requires us to ask the right question.'

Speaking to cardiologists at the opening lecture of the recent British Cardiovascular Society conference

in Manchester, he posed the question 'Big Data: a big deal for cardiology?' outlining the role and impact big data can have in highlighting trends in disease and illness prediction and, consequently, how it may offer the opportunity to prevent it; he also warned that clinicians and researchers need to be responsible

and trustworthy in how they use it. Big Data, he suggested, first had an impact in the sphere of public health with the discovery of the H1N1 virus in 2009 as its spread alarmed health authorities across the world because of the lack of vaccine. The Centre for Disease Control and Prevention (CDC) sought to

constrain the spread and was able to monitor outbreaks but with a two-week delay.

However, by monitoring what people were searching for online from its five billion daily search requests, Google found a correlation to CDC data from what people were seeking.

'The remarkable element in how this gave a prediction was about time,' said Professor Mayer-Schönberger. 'Google could do that in real time. This is precisely what big data is all about – about understanding the world through data.'

He said the world is 'at the beginning of a wave of data', pointing to data having grown 100-fold from 1987-2007 and is now doubling every 18-20 months.

'In the year 2000, three-quarters of data was analogue, whereas today it is less than one percent,' he said. 'Within half a generation we have moved from the analogue world to the digital world.'

'The promise of big data is that we can take a quantity of data and, with new quality, gain new insights. It is a paradigmatic change.'

Professor Mayer-Schönberger said big data moves medicine 'beyond the average' and helps clinicians with improved decision making, particularly when data is re-used in terms of personalised medicine. 'Data re-use is key to the big data future, but there is a dark side,' he warned his audience of cardiologists. 'You have to understand that big data can only work if there is trust and responsibility among those who use data. Patients will only volunteer that valuable data to you if they can trust you.'

'In the future, big data is going to change the way you, as cardiologists, not only attend to your patients with individual diagnosis and suggestions for treatment, but how to discover and make those predictions.'

mn



r with 7-T magnetic field-strength

# cardiomyopathy

pared to 3-T,' the professor added. 'This translates into being able to acquire the same quality data in five minutes that previously took 30 minutes, or into being able to use a finer spatial resolution, or into being able to measure other metabolites, such as inorganic phosphate which occur at lower concentrations in the body and were not visible in our scans.'

In the healthy heart, the concentration ratio of phosphocreatine (PCr) – the primary energy buffer of heart muscle cells – to adenosine triphosphate is approximately 2:1.

'In the failing heart,' Rodgers added, 'the concentration ratio drops to around 1.5:1. We measured this change in our group at 3-T and

7-T. The more sensitive 7-T experiment, in theory allowed us to detect changes in less severe cases of dilated cardiomyopathy than in the cohort we studied.'

Whilst still at the basic research stage, Rodgers believes the primary impact on patient treatment is that these more sensitive measurements

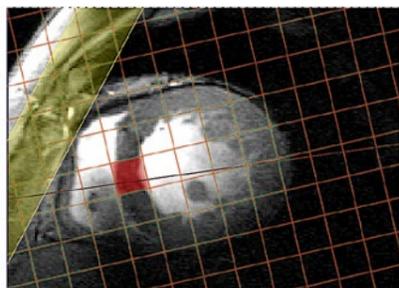
facilitate trials of new treatments such as new drugs, devices, or lifestyle modifications, because the imaging can detect smaller improvements or deteriorations in the heart's metabolic status than were previously visible.

'It ought to be possible to detect earlier improvement in response to treatment, and to quantify the relative merits of different treatments more accurately,' he said. 'We are also planning studies to understand the interplay between heart disease and disease in other organs, e.g.

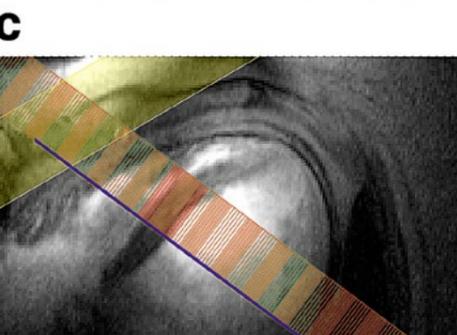
type II diabetes, or obesity.

'Having treatments that have been based on a more rigorous understanding of the heart's biochemistry will hopefully mean they will be more effective at treating heart disease.'

Research centres and teaching hospitals will also benefit, with the new approach helping improve understanding of the heart's metabolism in clinical studies.



© Rogers/Radiology



Austrian Viktor Mayer-Schönberger, Professor of Internet Governance and Regulation at the Oxford Internet Institute, University of Oxford, England, founded Ikarus Software in 1986, which focuses on data security. Given his interest in 'big data', he researches the role of information in a networked economy. He has authored numerous articles and seven books including 'Delete: The Virtue of Forgetting in the Digital Age'.



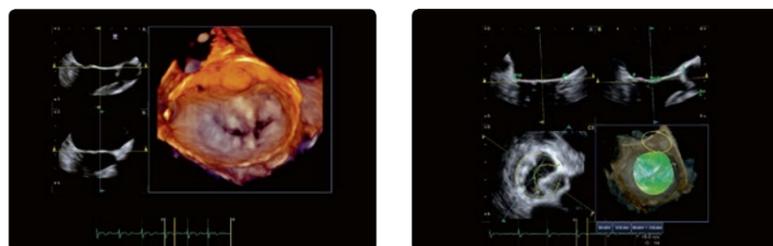
Big Data: A Revolution That Will Transform How We Live, Work, and Think by Viktor Mayer-Schönberger and Kenneth Cukier; Published by Hodder & Stoughton, UK 2013; Price 7,99 Euro. ISBN: 9781848547926

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The 2016 British Cardiovascular Society conference

# Prediction and prevention

**Big data, the genetic basis of coronary artery disease and sudden cardiac death in the young were among key subjects for British cardiologists at their 2016 annual conference, Mark Nicholls reports**

Within the theme 'Prediction and Prevention', the 2016 British Cardiovascular Society annual conference held in Manchester this June, featured innovative and interactive presentations, sessions, workshops, panel discussions, debate and a fas-

inating scientific programme.

The keynote speech, 'Big data: a big deal for cardiology?' delivered by Professor Viktor Mayer-Schoenberger, Professor of Internet Governance and Regulation at Oxford University's Internet Institute,

focused on the role of information in a networked economy.

The BCS Lecture 'Elucidating the genetic basis of coronary artery disease; implications for prediction, prevention and treatment' was delivered by Professor Sir Nilesh Samani, British Heart Foundation (BHF) Chair of Cardiology at Leicester University, who was knighted in 2015 for his services to medicine and medical research.

Professor Cliff Garratt, Chair of the Programme Committee and BCS Vice-President (Education & Research): 'Over the last few years, Professor Samani's group has led large-scale studies that have identified multiple genetic loci that affect risk of coronary artery disease. This presentation will present the current state of the discovery process, discuss what we have learned and illustrate the clinical translation potential of the findings.'

Prediction and prevention in acute coronary syndromes, the title of the BHF Bench-to-Bedside session - consisting of presentations (basic, translational or clinical) focused on a particular clinical condition - focused on the work of the BHF Centre for Cardiovascular Science at the University of Edinburgh.

'Over the last 30 years, this Edinburgh unit has led the way in describing new underlying causes of coronary heart disease, improving the identification of those at greatest risk, and ultimately demonstrating several innovative ways to treat coronary heart disease,' explained Professor Garratt.

The Sir Thomas Lewis Lecture saw Professor Michael Ackerman from the Mayo Clinic focus on prediction and prevention of sudden cardiac death in the young, while clinical anatomist, author and broadcaster Professor Alice Roberts discussed what embryology of the heart and other organs has taught us about our evolutionary origins.

In recent years, the BCS conference has gained recognition for offering 'something completely different' and, following on from the year's well-received presentation on Music and the Cardiovascular System, the focus for the popular Tuesday afternoon Auditorium session was Photography and the Heart. The conference also provided coverage of all the new developments in cardiology and cardiovascular science in training, a dedicated imaging track, arrhythmias with sessions on AF ablation and on first-line management of cardiac arrhythmias; intervention with sessions on acute coronary syndromes, myocardial infarction and percutaneous management of structural heart disease; heart failure; and adult congenital heart disease.

Sessions also included clinical science and translational research, basic science and hot topics, the Young Investigator's Prize, resuscitation, education for revalidation (E4R) and international sessions in association with the European Society of Cardiology and the American College of Cardiology.

An area for interactive education included 100+ Hot Topic sessions,



Cliff Garratt is Professor of Cardiology at the Institute of Cardiovascular Sciences, Professor of Cardiology at Manchester University and Hon. Consultant Cardiologist at Central Manchester University Foundation Trust. A clinical academic with an interest in arrhythmias and clinical cardiac electrophysiology, his research and clinical interests focus on the mechanisms and management of atrial fibrillation and familial sudden cardiac death syndromes.

poster sessions, simulator training, and an imaging Village with interactive, supervised CT, MRI, echo and nuclear imaging work-stations.

Garratt said the conference, again held with the British Heart Foundation, has attracted progressively increasing numbers of delegates over recent years. 'There is little doubt that there's an increasing - rather than decreasing - need for today's cardiologists to have a broad understanding of all the major subspecialist areas. The British Cardiovascular Society Annual Conference is uniquely positioned to facilitate this in one meeting.'

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*Smaller and more effective insertable cardiac monitors*

## Device sensitivity and versatility increase

**Remote monitoring through smaller, more effective, insertable cardiac monitors is playing a significant role in delivering care improvements for heart patients.**

**Greater sensitivity** and versatility of devices, as well as more patient-friendly implantation options, were issues outlined at the CardioStim 2016 EHRA Europace world congress on cardiac electrophysiology, held in Nice, France.

The 'Improving Patient Outcomes in Arrhythmia Management' scientific session focused on Biotronik Home Monitoring systems, during which experts from Australia, Switzerland and the USA discussed the latest research on how remote monitoring systems and insertable cardiac monitors (ICMs) can improve patient outcomes.

In highlighting the rising importance of using remote monitoring via ICMs to enable earlier diagnosis and prevention in patients who have arrhythmias (but are not yet indicated for a pacemaker or ICD), the senior cardiologists also outlined how home monitoring is reducing mortality, hospitalisation and healthcare costs.

During the congress, Berlin-based cardio and endovascular medical technology specialist Biotronik also unveiled findings of the first-in-human trials of its new BioMonitor 2 ICM device to delegates with

experts. Covering 30 patients, this pilot study revealed high R-wave amplitudes and a 93.8 percent success rate for daily home monitoring transmissions from a device that can be inserted in as little as two minutes.

'For ICMs to have a significant impact on early arrhythmia diagnosis, reliable detection including sensing, data quality and transmission

is critical,' lead investigator Dr Sze-Yuan Ooi, from Sydney, explained. 'This study shows promising results for BioMonitor 2 in all of these fields. The high transmission success rate is key because we need robust, high-integrity data for our patients to derive the maximum benefit.'

BioMonitor 2 has an extended sensing vector with the combination of the rigid (55mm long) and flexible (33mm) part allowing adjustment to the shape of the body.

Sensitive to changes in heart rhythm with the automated detection of atrial fibrillation, bradycardia, sudden rate drop or high ventricular rate, this device can make up to six ECG transmissions a day.

Ooi described the BioMonitor 2 as a 'big step forward' in terms of technology, design and implantation technique, compared to the first generation Biotronik Biomonitor device.

'The pilot study showed that the R-wave amplitude is greater than the original Biomonitor device, the implantation process was easy, straightforward and quick and the other important finding out of all this was the



More at risk patients will become candidates for LAA closure

# Device trial could benefit stroke patients

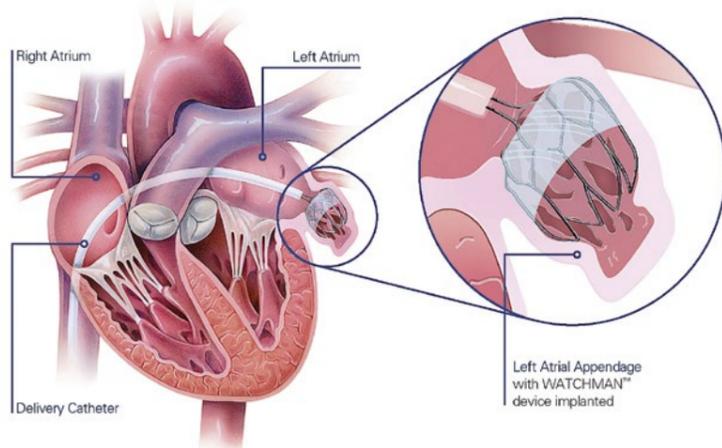
In the fast-evolving field of left atrial appendage closure a new study has delivered data that could benefit thousands of patients at risk of stroke. Led by Professor Martin Bergmann, head of Interventional Cardiology at Cardiologikum Hamburg in Germany, the EWOLUTION study was conducted to evaluate the Watchman Left Atrial Appendage (LAA) closure device from manufacturer Boston Scientific.

'The LAA field is evolving very quickly for stroke protection, mainly in the elderly,' Professor Bergmann explained. 'Anti-coagulants are a great step forward yet have left many patients with bleeding complications, so these drugs are not the solution for all patients.'

The LAA is believed to be the source of more than 90% of stroke-causing clots that come from the left atrium in people with non-valvular atrial fibrillation.

In recent years LAA closure has been seen as an alternative, though progress has been held back because of hesitancy among GPs, neurologists and non-interventional cardiologists to refer patients for the procedure because there was no clear data on success rates.

However, the recently published three-month results from the EWOLUTION registry found that LAA closure with the Boston Scientific Watchman device has a



LAA with WATCHMAN device

high success rate in complete LAA closure with low peri-procedural risk. 'We can now say that, irrespective of post procedural drug regimen, the risk of thrombus on the device is quite low, even in patients that have not received any oral anticoagulation because of their bleeding risk,' Bergmann confirmed.

The success of the trial, he added, will see more patients becoming candidates for LAA closure.

In Europe, two LAA closure devices are currently available - each with a different approach - but Bergmann said the Watchman device - which is anchored in the distal part of the LAA and closes LAA right at the entrance leaving the ridge to the pulmonary vein free - is the only one now underpinned by prospective data.

Watchman is a catheter-delivered heart implant designed to close the left atrial appendage to prevent the migration of blood clots from the

LAA, and thus, reduce the incidence of stroke and systemic embolism for higher risk patients with non-valvular AF.

Many patients are still being denied anticoagulation, he pointed out, because there are compliance issues, leaving them with a high stroke risk. However, he added: 'Ewolution should pave the way in Europe to solidly establish LAA closure in routine practice as one of the options that is available.'

Dual antiplatelet therapy (DAPT) following the implant also appears to be safe.

Data from the prospective multi-centre registry show that the implant procedure was successful in 98.5% of cases; 99% of implanted devices presented no or minimal peri-device leakage at the first follow-up, assessed by peri-procedural trans oesophageal echocardiogram (TEE); device or procedure related serious adverse events (SAE) rates at

92 days were similar if patients were treated with warfarin or DAPT; rates for bleeding SAE were also similar if warfarin or DAPT was used post-implantation (4.8% vs. 3.6%, respectively).

Following Watchman implantation, Bergmann added, 6% of patients received no anticoagulation, 27% received oral anticoagulation (16% warfarin and 11% novel oral anticoagulants - NOACs), 60% received dual antiplatelet therapy (DAPT) and 7% of patients were on single antiplatelet therapy.

Stroke (0.4%) and bleeding (4.1%) rates were low overall and did not vary by post-implantation medication.

The study, the professor said, is a significant step forward in the treatment of such patients and in the field of stroke prevention. 'We especially see the procedure being adapted in rising numbers in the interventional field because we see a lot of patients who have no indication for pulmonary vein isolation but have a problem with stroke prevention based on atrial fibrillation.'

One factor to emerge from the trial was with the 11% of patients treated with NOACs, who post-procedurally had the best data.

'To be able to use NOACs for this therapy, which has the advantage of very short



An interventional cardiologist, Professor Martin Bergmann MD heads Interventional Cardiology at Cardiologikum Hamburg in Germany, a high volume PCI centre. His focus is on structural heart work including TAVI, mitral clip, LAA, PFO and ASD procedures. More than 1,000 patients are part of the EWOLUTION registry across 45 centres.

half-life,' Bergmann added, 'means that it may be even better than dual anti-platelet therapy, but this is something we will have to test in randomised trial or larger numbers.'



Device held by physician



Sze-Yuan Ooi MD is a coronary interventionalist and cardiac device implanter at the Eastern Heart Clinic and Prince of Wales Hospital in Sydney, Australia. His research interests include new coronary stents and implantable device technology, coronary inflammation, coronary physiology and pressure wire technology.

transmission success rate of 93.8pc, which is really exceptional.

'Biotronik has invested heavily over the years in its Home Monitoring System and that is borne out in this trial. The most important aspect with the devices is the ability to make a diagnosis, that comes first and foremost, as well as the implantation procedure being not too invasive,' Ooi pointed out.

Biotronik Home Monitoring transmits patient heart data automatically on a daily basis, rapidly detecting deterioration in a patient's clinical status.

Early detection of clinically relevant events, in particular paroxysmal and asymptomatic arrhythmias, such as atrial fibrillation, enables the physician to adapt patient therapy at a very early stage.

Continued on page 14

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The dedicated stroke session at ESC 2016

# Imaging in intra-arterial interventions

ESC session highlights the cardiologist's role in stroke treatment and how imaging techniques can help them to carry out catheter based IA interventions correctly.

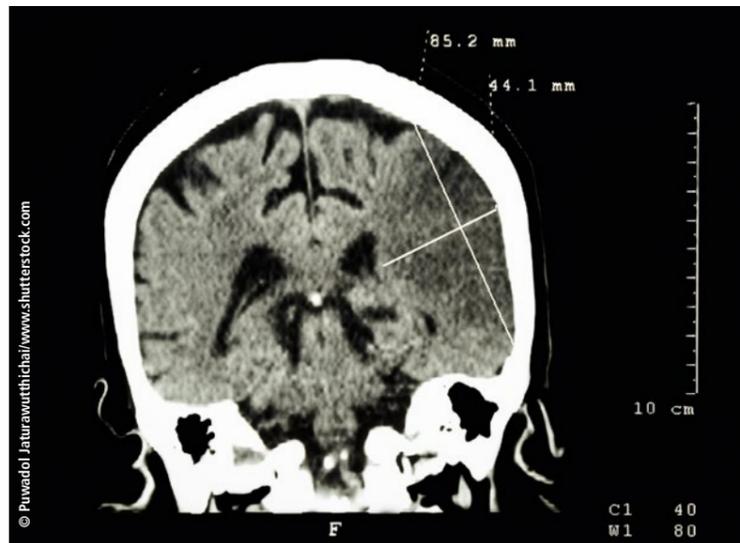
Report: Melisande Rouger

Stroke patients will first undergo a CT scan as they enter the hospital. Before any further imaging scan is carried out, the medical team must decide whether they need to intervene intra or extra cranially. 'Imaging enables you to see which pathology you are dealing with and helps you select patients for either recanalisation or revascularisation or, in some cases, occlusion by embolisation,' according to Dr Andreas Schwartz, Director of the Neurological Department of Hannover Hospital.

The cause of stroke can often be found in the vessel, intimal flaps, or inflammation of the endothelium – and atheroma or plaque intersection in the vessel wall can also trigger an event. Calcification, aneurysm or the presence of a tumour around the vessel could also lead to an arterio-embolic event.

Ultrasound is the best modality to detect defects in the vessel-lumen itself, in particular a moving intimal flap, according to Schwartz. 'You have to see moving pictures in this case, and US will help you better than any other modalities,' he believes. Alternatively, one can use digital angiography by injecting a contrast product in the catheter.

Endothelium inflammation is also best identified with ultrasound, because it enables measurement of the endothelium thickness. The alternatives are high-resolution 3-T MRI and cross sectional imaging. MRI and cross sectional imaging are also good to find out whether the problem is intramural, or if it is caused by the presence of atheroma in the vessel wall. 'If you just do conventional CTA you won't find all these pathologies,' Schwartz under-



Cerebral infarction at left hemisphere (CT-scan)

lines. 'Ultrasound is a prerequisite in stroke units all around Europe.'

Because ultrasound is easily movable around the hospital, all patients will undergo an ultrasound scan of the head and neck vessels within 24 hours of their arrival if CT shows no bleeding.

CTA or MRA will be preferred in plaque pathology imaging. To visualise plaque dissection, it is best to carry out a special type of MRI in a cross sectional mode. '3-D reconstruction doesn't tell you anything, you need cross sectional imaging to know what is in the vessel wall because you wouldn't see it in the angiography scan. You would fail in finding the dissection type,' he explained.

However an angiogram, CTA or MRA scan combined with 3-D reconstruction will help locate a tumour if it is compressing vessels.

For intracranial treatment, everything depends on whether one

looks at the anterior or posterior part of the circulation. 'If you are in the posterior part of the circulation of the brain vertebral artery, or basilar artery, you depend on the intra-arterial angiogram. CTA or MRA will not help, you will need to perform an angiogram by catheter, an invasive method. But in the anterior part of the circulation, you can use the angiogram with MRI or CT,' he explained.

Only a neuroradiologist will be able to conduct intracranial examinations, and it is recommended to have both a neurologist and an interventional neuroradiologist perform revascularisation, recanalisation and embolisation in a stroke unit. However, only large hospitals can afford such specialists and, at the moment, they are fairly rare across Europe. Germany has about 160 stroke units but not the same number of neuro interventionists, said Schwartz, who has worked on



Andreas Schwartz is Director of the Neurological Department of Hannover Hospital and Associate Professor of Neurology at Heidelberg University in Germany. His main research interests are cerebrovascular diseases, neuroradiology with special interest in MR and angiography, multiple sclerosis and Parkinson's disease. He has over 180 publications in international journals and is a full member of a number of national and international societies (ENS, AAN, RSNA, ANSR, ESNR) in the neurological field. Since 1996, he has also served as a regional representative of the German Stroke Foundation.

certifying stroke units in Europe as part of his long-term involvement with the German Society of Neuroradiology.

Cardiologists, who have performed thrombolysis in coronary heart disease since the 1970s, are the most suited professionals to carry out extra cranial investigations when no other specialist is available, he believes. 'There are not enough neuro interventionists around. That's why cardiologists have performed stenting and carotid endarterectomy for so many years. They can and should do it, but only in small hospitals, and they need imaging to do so,' he said.

Sending an interventional radiologist to stroke units when needed could be another solution, but equipment would remain a problem, because not every hospital has all the necessary machines and catheters. 'That would be a problem. I don't think it could work as a long-term solution,' he said.

Expertise should come first and before turf battles between medical disciplines. 'In the end it all comes down to this: You have to choose the professional with the most experience,' he concluded.

# Advancing cardiac dysfunction

Cardiologists have highlighted the importance of echocardiography and cardiac CT – to evaluate the impact of recommendations.

Report: Mark Nicholls

An innovative cardiac monitoring system that delivers continuous resynchronisation to patients, has shown a 35% risk reduction of hospitalisation for heart failure (HF) patients.

The finding comes from the RESPOND-CRT (cardiac resynchronisation therapy) clinical trial, which was designed to investigate the clinical efficacy and safety of device-based optimisation using the SonR cardiac contractility sensor in patients with advanced heart failure.

The proprietary SonR sensor from global medical technology and innovation company LivaNova delivers individualised therapy to heart patients by allowing for cardiac resynchronisation to be continuously adapted to the individual's needs.

The trial, led by renowned cardiologists Professor Josep Brugada and Dr Jagmeet Singh, compared optimisation with SonR to optimisation using echocardiography – widely considered to be the gold standard approach. Speaking at the CardioStim 2016 EHRA Europace world congress on cardiac electrophysiology, held in Nice, France, Professor Brugada said the overall positive response to CRT reached in



Dr Jagmeet Singh from Massachusetts General Hospital, Boston, is the Associate Chief of the Cardiology Division and Professor of Medicine at Harvard Medical School. He is the Founding Director of the Resynchronisation and Advanced Cardiac Therapeutics Programme.

Mobile digital X-ray units for hospitals and more...

# Wireless radiography on the move

With clients worldwide, the 20-year-old imaging and digital radiography solutions firm medical ECONET provides mobile radiography systems to hospitals, ambulance and mobile home care services, military clinics in conflict zones, as well as medical facilities on sea-going vessels.

With clients worldwide, the 20-year-old imaging and digital radiography solutions firm medical ECONET provides mobile radiography systems to hospitals, ambulance and mobile

home care services, military clinics in conflict zones, as well as medical facilities on sea-going vessels.

To that end, the firm's radiography solutions are equipped with a unique hybrid-powered technology.

The firm describes its mobile X-ray system POX-100BT as 'an ideological designed foldable device, which allows the user to work completely without any cables and without dependence to electricity due to its integrated high-performance Lithium-ion battery. With one full charge it is possible to make up to 1,000 images, which allows a complete unrestricted workflow in many different scenarios without any external power source.'

'The POX-100BT is highest mobility due to lightweight carrying bag for DR system

quickly installable and smooth to move, due to the big inflated wheels. The power output of 5 kW enables examinations of all human body parts without limitations.'

The firm's wireless Digital Radiography (DR) detector meX+1417WCC has an imaging size of 36 x 43cm, beneficial when mobile.

'Due to the wireless file transfer and automatic exposure detection (AED) of the detector, the user can work in a most comfortable way without any disturbing cables. With only 3kg weight, the flat panel is very easy to handle and provides brilliant image quality within few seconds after the exposure. The equipped meX+ Image Acquisition Software allows the optimisation and full diagnosis of images and external provision by patient CD, e-mail or teleradiography.'

The best image results are achieved by combining a UHD resolution notebook, the device manufacturer advises.

Device sensitivity an

Continued fr



Continuous cardiac resynchronisation reduces hospitalisation

# ng AF and renal ion care

nce of all imaging modalities – including  
ate prosthetic heart valves in a new series



**Professor Josep Brugada** is medical director of the Cardiovascular Institute, at Hospital Clinic, University of Barcelona, Spain, and a past president of the European Heart Rhythm Society. With his brothers, Pedro and Ramon, he identified Brugada Syndrome, a genetic disease characterised by abnormal electrocardiogram (ECG) findings and an increased risk of sudden cardiac death.

the group of patients treated with SonR was 75%, compared to 70.4% in the echo group. It also emerged that optimisation with SonR resulted in a significant improvement in clinical response for patients with atrial fibrillation and renal dysfunction.

Professor Brugada from the Cardiovascular Institute, Hospital Clinic, University of Barcelona, said: 'In order to deliver the very best CRT treatment to our heart failure patients, there has been a real need for an optimisation solution that is both automatic and efficient.'

'The results of the RESPOND-CRT trial have shown that SonR perfectly meets this need. The high rates of responders together with the beneficial improvements in clinical outcomes indicate a significant advancement in CRT therapy, one that will allow us to better treat a larger number of heart failure patients.'

'Automatic optimisation with SonR was as effective as echo-guided optimisation - 75% v 70.4% - so the primary efficacy end point was met, that a clinical response was in favour of SonR but especially patients with

history of AF and renal dysfunction, and optimisation, using the SonR contractility sensor, showed significant reduction of 35% in rates of heart failure hospitalisation during long-term follow up.'

Implanted cardiac resynchronisation devices resynchronise the contractions of the ventricles of the heart by sending tiny electrical impulses to the heart muscle, helping the

heart to pump blood more efficiently throughout the body. The SonR sensor uses measurements of cardiac contractility to optimise cardiac resynchronisation therapy.

Singh, from Massachusetts General Hospital, Boston, explained that although echo-guided optimisation was considered the gold standard in terms of reducing the number of non-responders to CRT, it was not widely used because of the commitment of time and resources it requires, as well as patients needing to attend the clinic. He added that

the SonR can optimise AV and VV intervals on a daily basis and on weekly basis for both rest as well as for exercise so patient do not have to come into the clinic or have echo guided optimisation.

'The device using the sensors can automatically optimise the heart, overcoming the inadequacies of existing optimisation strategies and logistical issues with echo-guided optimisation strategies.'

Respond-CRT was a prospective, multicentre, randomised, double-blind study designed to evaluate

the safety and efficacy of the SonR system. 1,039 patients were enrolled at 125 sites in Europe, the USA and Australia, who were implanted with a CRT-D (cardiac resynchronisation therapy and defibrillation) device, which combines the function of an implantable cardiac defibrillator (ICD) with cardiac resynchronisation therapy (CRT).

Patients were randomised 2:1 to receive either AV or VV optimisation with SonR or echocardiography, with the study meeting all of its primary safety and efficacy end points. ■

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and versatility increase

from page 12

Hospital Zurich, who discussed how earlier management of atrial and ventricular arrhythmias is enabled by detection with ICMs, and Dr Niraj Varma, from the Cleveland Clinic, who spoke about improving outcome of ICD and CRT-D patients by continuous remote monitoring.

'Efficient workflow and robust transmissions are critical to leveraging the benefits of remote monitoring,' Varma said. Biotronik Home Monitoring facilitates this with daily automatic transmissions that preserve the highest order of data integrity, and are yet easy to handle.

'This is a key reason why this system has been associated with improved clinical outcomes in several trials and why the current remote monitoring guidelines are based largely on Home Monitoring data,' Varma explained. ■

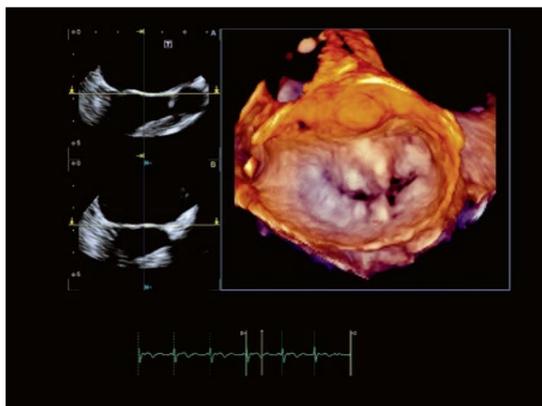
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'This is the future'. Medical scientists endorse a new platform

# Toshiba beams in on cardiology ultrasound



Live 4-D imaging: The new ultra wideband transducers have a wide coverage and an extremely good penetration up to 28 centimetres. An area of just one square centimetre can be seen and clearly defined

Next-generation Aplio i-series premium platform delivers high-frequency probes, advanced applications and ultra-fast processing

To sharply focus on the specialised requirements in echocardiography, Toshiba engineers built from scratch the Aplio i900CV with a total redesign of hardware and software. The new Aplio i-series is a premium addition to the award-winning Aplio 500 platform, which today is used in more than 31,000 clinical settings worldwide.

'The system works very fast with a reduced requirement for user interaction, which translates into a significant time saving for the echocardiography lab,' according to the head of cardiovascular imaging at the Hospital Clinico San Carlos in Madrid, Spain, Professor Leopoldo Perez d'Isla MD.

The impressive speed of the new architecture and the resulting time savings, 'means that we are improving the cost-effectiveness of the echo-lab, avoiding patient discomfort caused by unnecessary waiting times and increasing opportunities for patient examinations'.

The Aplio i-series jumps ahead to a next generation with an architecture that gives it on-board capabilities for ultra-fast processing of advance applications, and with a new range of high frequency and ultra-wideband transducers.

To maximise the potential of the new architecture, the Aplio i-series matrix transduc-

ers utilise a new lens material that effectively introduces a new technology. Thinner, lighter and with more flexible cables, a wide range of Aplio's i-series transducers feature the Intelligent Dynamic Micro Slicing (iDMS) capability.

New with the Aplio i900CV is a 3-D transoesophageal echocardiography (TEE) transducer that 'is exactly the tool we need,' according to Professor Hans-Joachim Nesser MD. The Head of the Cardiology, Angiology, Medical Intensive Care for the 2nd Internal Department at the Elisabethinen Hospital in Linz, Austria, stated, 'We have long wanted this, and here it is bringing the possibility to view aortic leaflets, or to measure mitral valve parameters where we can not only see the opening, but can even see the stitches where the valve has been repaired.'

Yet, thanks to the new ultra wideband transducers, a TEE exam is not always required. Nesser found that, with the wider coverage and what he called extremely good penetration up to 28 centimetres, 'We can evaluate the aortic valve area with a transthoracic approach. We are able to see distinctly four-chamber views, and have found really fantastic resolution in subcostal views.'

Continuous wave Doppler on the i900CV has a quality not seen before that enables a fast, excellent quality of signal definition that allows an easy diagnosis to determine myocardial performance.

After working with Cardiovascular Imaging Fusion on the i900CV, Nesser concluded, 'This is the future.

In one display using a hybrid format we see calcified segments of coronary arteries derived from CT along with a quantification of the stenosis thanks to 3-D strain imaging, and at the same time a superimposition to the myocardium derived by CT. Using a very nice tool called Activation Imaging, we can add measurements to determine torsion, an important parameter for a variety of diseases, or see areas where there is delayed contraction. We can see rest and stress, related to a specific coronary artery as a superimposition on a CT image, enabling us to make a decision as to intervention.'

Aplio i-series processors are so fast that the system boots up in 15 seconds. Aplio i-series platforms are 30% lighter with a panel streamlined by a reduction of 50% for buttons and controls.

The panel arm supports a 23-inch high-definition display and is so flexible it can fold flat for easier, more convenient handling. And the Aplio i-series platforms come with an optional second console, a detachable wireless tablet that displays real-time images and can control all operations.

The Aplio i-series rolls out in three versions where the Aplio i700 is designed as a multi-service platform across diverse medical specialties, and the Aplio i800 responds to the more exacting requirements of radiology and women's health departments.

Yet it is the advanced features and functionalities of the Aplio i900CV that are specifically designed to target specialised examinations and

interventions in cardiology.

At the heart of an enhanced image quality that was described as 'stunning' by clinicians is the iBeam technology. Electrical dynamic focus with individual matrix element control and multiplexing with ultra-fast processing narrows and sharpens the signal for real-time 3-D beam forming.

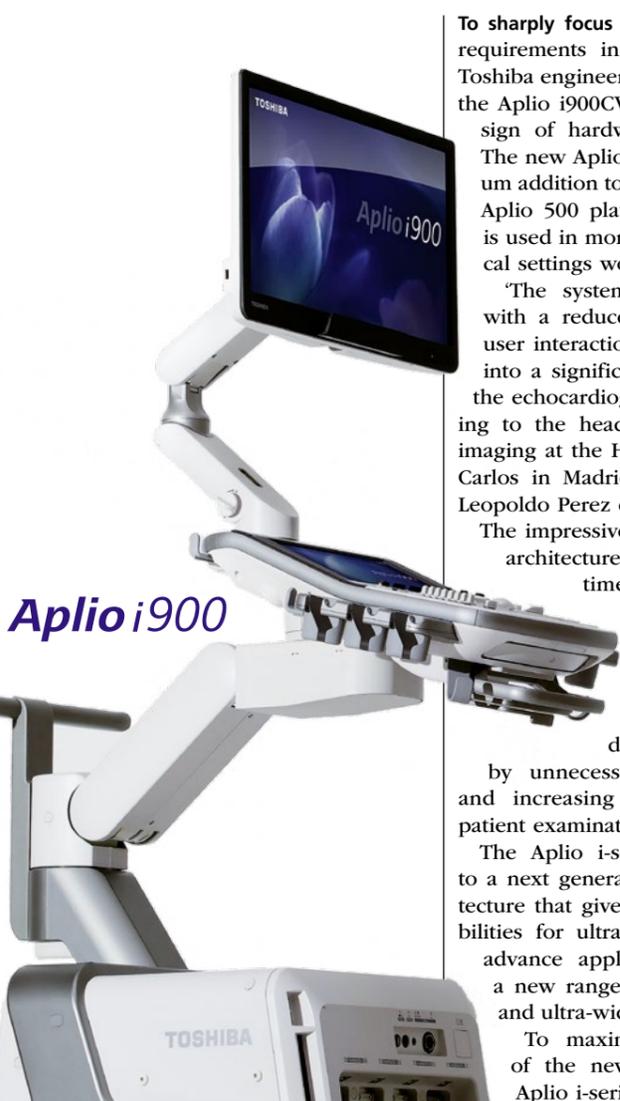
The advanced architecture in the Aplio i-series takes pioneering Toshiba ultrasound functions to a new level.

- **Advanced Superb Micro-Vascular Imaging (SMI)** combined with the new transducers becomes more brilliant with reduced motion artefacts, for never-seen perfusion examination capabilities across all regions of human anatomy.

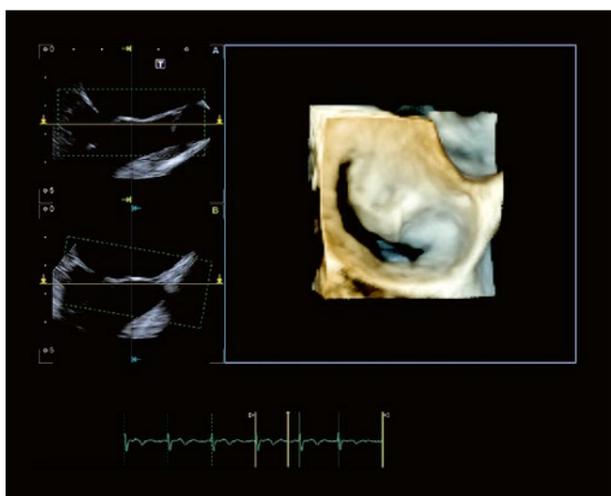
- **Quad Fusion capability** creates impactful viewing for interventional procedures or advanced diagnostics, with a simultaneous combination of CT/MRI images with real-time ultrasound and 3-D ultrasound rendering of a live procedure.

- **Super precise 3-D imaging** is boosted by Aplio i-series iBeam and thin slice acquisition to render near-photo quality images of anatomical structures.

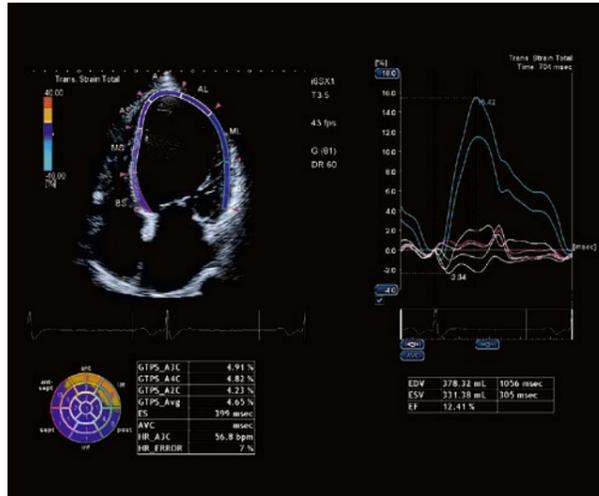
Professor Adrian Lim MD, from Imperial College London said that, beyond the obvious improvements in ergonomics and speed with the Aplio i-series platform, for users of previous models of Toshiba ultrasound systems, 'there is a very familiar workflow such that everything becomes intuitive the moment you step to the console.'



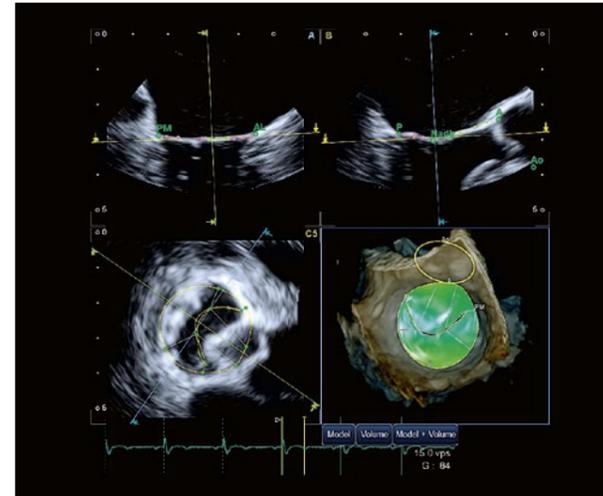
Aplio i900



At a simple touch of a button, Aplio demonstrates the mitral valve as seen by the surgeon to facilitate visual assessment of the leaflets for better surgical planning



Aplio's advanced Wall Motion Tracking technology provides immediate visual and quantitative access to global and regional myocardial wall motion dynamics in 2-D and 3-D



The automated MVA tool provides concise anatomic and functional assessment of the mitral valve. The function's quad display offers a clear overview of different scan planes

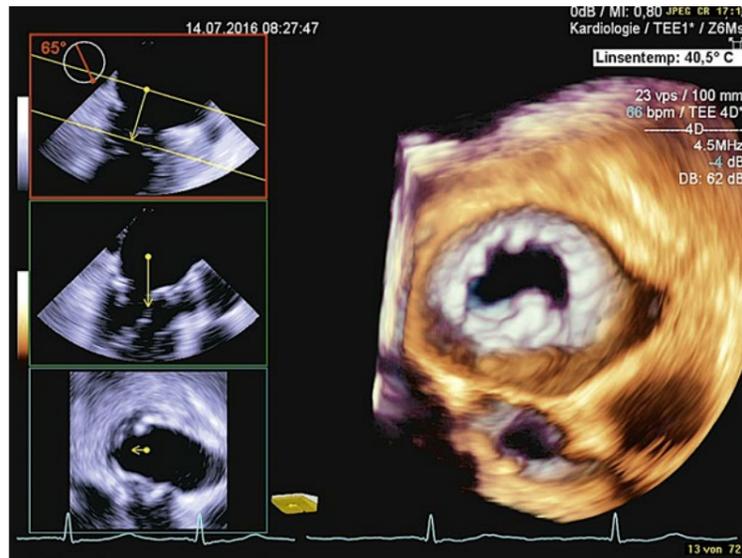
User reports on working with new Siemens equipment

# 3-D transducers prove their mettle in cardiology

One of the first facilities to purchase a complete set of the 3-D TEE transducer, including the equipment, was the Department of Cardiology and Angiology at University Hospital Magdeburg, as Thomas Groscheck, specialist physician for internal medicine at the echocardiography lab explains. Since July 2015 he has worked with the new Siemens transducer – and is enthusiastic.

'In our department we treat all types of cardio-vascular disease, from cardiac insufficiency to hypertension, valve repair and aortic valve replacement,' Thomas Groscheck explains. 'We perform all necessary studies prior to an intervention and do the follow-up for all cardiac patients, particularly those who underwent valve surgery or received a valve replacement.' This is where the 3-D TEE transducer comes in very handy.

'What's so special about this 3-D probe is that it is fast and offers high volume', the specialist explains. This allows live images with a high frame rate, particularly in 3-D, which is very interesting during valve interventions. 'I found the hardware and the software in the equipment to be very fast. Thus you get high temporal and spatial



The 3-D TEE transducer is fast and offers high volume

resolution with regard to valve visualisation in 3-D. This translates into much better quality than our previous transducers delivered.'

## Length of examination

In terms of time spent on examinations the new tool also offers benefits. 'The prep examination for a valve intervention takes ten minutes on average,' according to Mr Groscheck. 'Image acquisition and patient handling pre- and post-exam take about twenty minutes. After

that time all images are available, including the valve models.' Data acquisition is fast and the analysis can be speeded up when all tools for automatic valve assessment are used. The raw data that are generated and which, theoretically, can be read by any machine, are turned into DICOM images, which in turn can be viewed with any DICOM viewer.'

## Handling

Transducer handling has been

improved. With its plastic grip it is lighter than metal models. 'This makes the transducer easy to handle,' the physician reports. 'Nevertheless it takes some to get used to the new probe. The head is a bit more angular, not quite as round as we were used to. The location of the function buttons and the two knobs to control transducer head movement could be improved ergonomically. The control elements are no longer centred, which means the probe has to be held in a certain way in order to use it in an optimum way.' However, these are the only handling issues Thomas Groscheck encountered with the new transducers.

## Temperature advantages

There is one feature Groscheck is particularly enthusiastic about: 'With this transducer, temperature issues are a thing of the past. Finally! Although the device does have a cooling mode with reduced transmission performance, I have never been compelled to use it. Despite the fact that in 3-D mode the transducer heats up to about 40 °C, I always could easily complete longer sequences.' Thus interruptions due to overheating – a common problem in longer examinations with high sound intensity, particularly in 3-D – are no longer required. 'In



Thomas Groscheck is an internal medicine specialist in the echocardiography lab in the Cardiology and Angiology Department, University Hospital Magdeburg. Following his initial training as a nurse he attended medical school at Charité – University Hospital Berlin. He is currently completing his doctorate.

3-D mode, the 3-D TEE transducer works for minutes without any temperature problems. That makes life much easier for patient and physician alike. Obviously, patient safety has been considerably improved with this device,' Groscheck points out.

## Hand in glove

The overall interaction of all elements and components of the new transducer convinced the expert. 'With a bit of training using the transducer is no problem. Transducer, software, and processing programmes for the valve models – they are all well aligned and integrate easily in any daily workflows. Even though the device with all its functions and settings might seem a bit technologically intimidating at first, actually using it is a real pleasure particularly because it works without a hitch and the individual components work hand in glove,' Groscheck sums up.

55% of heart recipients now survive for 10 years

# Transplants – a much neglected topic

A small report in the press prompted examination of a much neglected topic. The report read 'Heart Centre at University Hospital no longer carries out transplants', and referred to the University Hospital Frankfurt, one of the 22 Heart Centres that perform these transplantations.

So what happened? Only four transplants were carried out there between 2010 and 2013, and in 2014 and 2015 only two to three were performed per year. Why? The same report also mentioned that around thirty patients per year wait for donor hearts at this hospital. Donor hearts continue to be in short supply, and organ donation is the problem.

There have been no improvements in that situation, not only in Frankfurt, or all of Germany, but also across Europe and globally. The ratio between those who received donor hearts and those waiting for donor hearts is increasingly unfavourable. Figures from Switzerland show an 'average' European example: When 33 people received donor hearts in 2005 not even double that number, i.e. 63, were waiting for donor hearts at the time. Ten years later, in 2015, the number of transplants 'only' increased to 40, whilst the number of patients on the waitlist increased to 134.

In Germany, says Professor F W Mohr, president of the German Society for Thoracic and Cardiovascular Surgery, more than 1,000 patients are currently

waiting for donor hearts. However, only 320 hearts were actually transplanted. 'The average patient has very little chance of receiving a donor heart. The organs donated are only allocated to particularly urgent cases,' Mohr explains. At the beginning of the 1990s still more than 420 heart transplants a year were carried out.

The allocation of donor hearts in eight European countries (Germany, Belgium, Netherlands, Luxembourg, Austria, Slovenia, Hungary and Croatia) is coordinated by Eurotransplant based in Leiden, Netherlands. The allocation is based on medical criteria, with no consideration given to national or any other criteria. Eurotransplant works with a catchment area of 135 million people across Europe. There are similar organisations in Scandinavia, covering about 25 million people, or for Eastern Europe, along with the internationally active Society for Heart and Lung Transplantation based in Addison (Texas, USA).

A look at international figures and developments helps to better understand the situation. As is known, the first ever heart transplantation was carried out by Professor Christiaan Barnard and a 31-strong team in South Africa in 1967. The number of operations increased to 100 transplants (worldwide) in 1980 and to 4003 in 1990, with reported figures of 4203 in 1992, 4364 in 1993, 4429 in 1994 and 4396 in 1995. According

to the Society for Heart and Lung Transplantation, a total of 80,106 heart transplantations were carried out in 300 officially designated centres between 1967 and 2007.

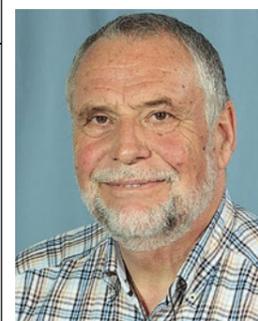
From the mid-1990s the numbers decreased continuously to around 3,000 per year. Significantly better and more effective prophylaxis and major advances in treatment, along with the lack of donor organs, are considered the reasons for this decline.

In January 2016 more than 10,000 patients were waiting for donor hearts across the eight European countries coordinated by Eurotransplant. If it had not been for advances in treatment the number of those waiting for donor hearts would be much higher still, say the specialist medical societies.

However, documenting advantages and disadvantages with statistics does not do justice to the topic of heart transplantations.

The history of heart transplants is also one of particular success. As is known, the first person to receive a donor heart, transplanted by Prof. Christiaan Barnard in 1967, 'only' survived the operation for 18 days. In those days the prospects of a 'longer' life after the operation were also generally not particularly rosy.

However, over the course of the years and decades not only the surgical procedures and the expertise and routines improved but also the direct care and aftercare for patients.



Walter Depner, writer and consultant specialising in the laboratory field

One of the main problems was, and remains, rejection of the donor organ. Not least through the discovery and development of the immune suppressor Cyclosporine has it been possible to achieve major success in this field. This ring-shaped, small protein which consists of 11 amino acids was discovered by the Swiss biologist Hans Peter Frey in 1969 and was publicised in the 1970s. It then led to the development of other, very effective drugs.

It is assumed that the current, five-year survival rate is around seventy-five percent and the ten-year survival rate is still at around fifty-five percent

To conclude, there are three things we can hope for: Firstly, that the number of those requiring donor hearts will continue to fall due to improved medical knowledge and prophylaxis, along with healthier lifestyles in large parts of the population.

Secondly, that the number of organ donors increases rather than decreases, and lastly that the survival rate continues to increase closer towards the 100% mark through more experience, knowledge, routine and capabilities of the surgeons, along with advances in technology and aftercare.



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Break-through techniques tap software to reveal disease causes

# Exposing the secrets of the heart

Coronary interventions often rely more on art than science as the decision to treat a patient tends to be based on what clinicians can see, a subjective interpretation of cardiac imaging.

Two new techniques have emerged for cardiovascular diagnostics that are enabling software to help surgeons and cardiologists measure, and thereby better manage cardiac disease. Both rely on powerful computer processing to expose the secrets of the heart.

Bon-Kwon Koo MD, from the Seoul National University Hospital in South Korea, has successfully shown how building on technique recommended in cardiology guidelines, called fractional flow reserve (FFR), a retrospective computational analysis of CT exams can pinpoint the plaque rupture that, up to two years later, would cause a confirmed medical emergency for a patient.

The creator of the FFR technique, Nico Pijls MD, from the Catharina Hospital in Eindhoven, the Netherlands, has since developed a technique for the quantitative assessment of microcirculatory blood flow and resistance, the vital irrigation of heart muscle.

Without FFR, a cardiologist has to subjectively interpret fuzzy angiographic images to decide if the blockage is so severe it needs a stent

to re-open the vessel. Introduced by Pijls 20 years ago, FFR is an invasive technique in which a catheter is pulled across a suspected coronary lesion to objectively measure differences in blood pressure on either side of a blockage and gives the cardiologist evidence to decide whether to place a stent or not.

Koo builds upon this critical measurement, but uses a non-invasive technique. Instead of pushing a catheter into the patient, a super-computer analysis of the patient's CT angiography exam can determine blood pressure measures on either side of suspected lesions.

This technique has been validated in studies sponsored by HeartFlow, based in Redwood City, California, and the company now offers this service to cardiologists.

Going one step further, physicians at 11 heart centres in Europe and Asia initiated a study, led by Koo, to test a hypothesis that going backwards, they could look at CTA exams and identify not only which patients were at risk for a plaque rupture, but specifically identify the plaque that was going to rupture.

For the EMERALD study, sponsored by HeartFlow, Koo added computational fluids dynamics and fluid-structural interaction simulation to the FFR-CT calculations for 226 coronary plaques among the 71 patients enrolled.

Emerald investigators first identified patient cases where the culprit plaque rupture had been documented using angiography, or intravascular imaging such as OCT or IVUS. Then the investigators searched the patient file to find a CT exam that had been performed ahead of the medical emergency. The average among enrolled patients was an exam performed one year earlier.

These CT images were then run through the Emerald algorithms to assess plaque composition, lesion geometry and the haemodynamic forces. Results from the retrospective Emerald study were presented in May this year in Paris, at the interventional cardiology conference, EuroPCR.

'Non-invasive haemodynamic data from CT was a better discriminator of lesions causal of ACS than stenosis severity or adverse plaque characteristics,' Koo concluded.

Moving to a prognostic potential, Koo suggested the combination of all plaque characteristics might fur-

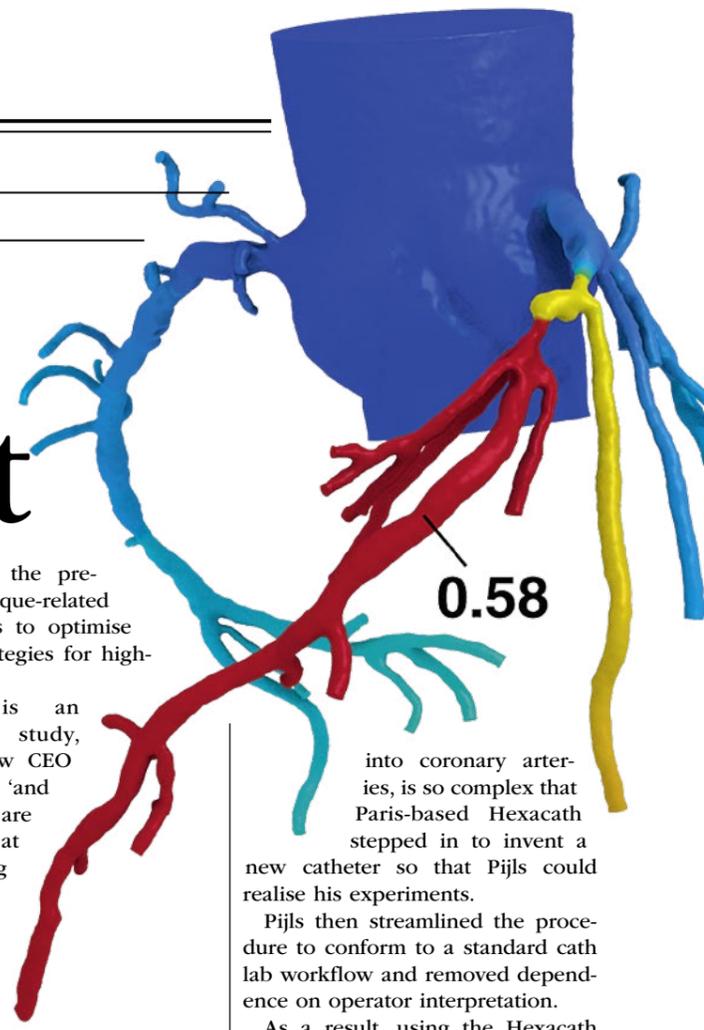
ther improve the prediction of plaque-related clinical events to optimise treatment strategies for high-risk patients.

Emerald is an exploratory study, said HeartFlow CEO John Stevens, 'and it shows we are very good at identifying the plaque at high risk for rupture eight times in 10, which is not just good

but extraordinary. For the moment we still have several hundred more patients cases for validation'.

Dr Pijls also presented his novel approach for measuring microcirculatory in myocardial irrigation at EuroPCR 2016, and when he had finished the panellists applauded in admiration and one of the audience stepped forward to say: 'it blows my mind.'

The calculations for this novel cardiac quantification are so complex it took the software engineering of St. Jude Medical to capture them. The procedure, which required a controlled injection of saline solution



into coronary arteries, is so complex that Paris-based Hexacath stepped in to invent a new catheter so that Pijls could realise his experiments.

Pijls then streamlined the procedure to conform to a standard cath lab workflow and removed dependence on operator interpretation.

As a result, using the Hexacath RayFlow monorail infusion catheter combined with one of St. Jude's pressure wires for FFR, and then standing back to watch the results on the St. Jude monitor, an interventional cardiologist can measure volumetric blood flow directly in selective coronary arteries during cardiac catheterisation and simultaneously, with the same guide wire, calculate the absolute myocardial blood flow, collateral flow, and myocardial resistance.

'We don't know yet what it all means, but at least we have a method to measure it,' Nico Pijls concluded.

Despite unknown valve leaflet durability...

# TAVI is approved for lower risk patients

Younger patients will receive artificial valves shown to degenerate at five years for half of all patients, John Brosky reports

The Medtronic CoreValve Evolut R System received its CE Mark of approval this August to treat aortic stenosis in patients with an intermediate risk for undergoing conventional surgery for a valve replacement. This is a controversial indication for transcatheter aortic valve implantations (TAVI) – one that has been eagerly sought by some clinicians but resisted by others.

director of the structural heart programme at the University Hospital in Bonn, Germany, stated: 'The highly-anticipated intermediate risk indication marks an important milestone for the industry as we look to safely expand TAVI access to younger and less sick patient populations.'

A Medtronic spokesperson told European Hospital that 'A majority of the patients treated with TAVI in

etration with the indication for a vastly larger population of patients at intermediate risk for SAVR is not known, though widely expected to be significant.

Evidence from head-to-head clinical trials has indicated that SAVR and TAVI are fairly evenly matched for efficacy, though with different complication profiles. Traditional surgery poses

a greater risk for

Yet little is known about the durability of TAVI valves that were first introduced in 2002 and did not reach a significant patient population until 2007. Unlike surgical valves,

the delicate valve leaflets for TAVI devices are squeezed, or crimped, to fit into the catheter that snakes through the femoral artery. Once in place, the valve stent holding the leaflets is expanded.

Placing a prosthesis that is expected to last eight years in an 80-year old patient at high risk for surgery has

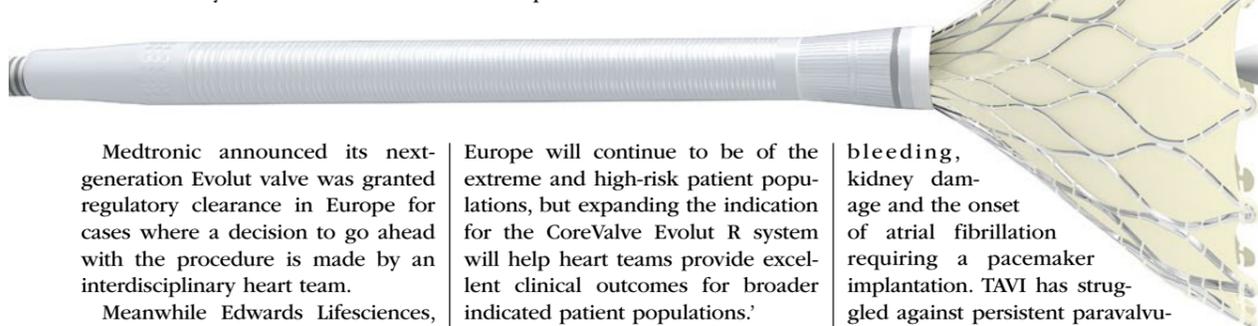
been seen as a benefit for extending the patient's life from an expected one year out to eight years, which is widely accepted as being the expected limit of TAVI valve durability.

The question of placing the shorter-term TAVI device in a 70-year-old patient who could undergo surgery and receive a time-tested SAVR valve is at the heart of the current controversy. The extension of TAVI to lower risk patients was the focus for The Great Debate in May 2016 at EuroPCR, which pitted three leading clinicians on either side of the question.

The debate at EuroPCR quickly centred on valve durability because earlier the same day, at the same congress, results from the first effort to study valves beyond the three- to five-year follow-up in manufacturers' studies was released. Danny Dvir MD from St. Paul's Hospital in Vancouver, Canada, effectively punctured the balloon of TAVI enthusiasm with a report titled 'A First Look at Long-Term Durability of Transcatheter Heart Valves: Assessment of function up to 10 years after implantation'.

Among the 378 patients enrolled, Dvir reported that the median time to degeneration of the implanted valve was five years, and at eight years, some form of valve degeneration affected half of all patients with early TAVI devices.

'Everyone should know there is the phenomenon of valve degeneration, so that when we target younger patients, the lower risk patients who may survive longer, their valve may fail,' he advised.



Medtronic announced its next-generation Evolut valve was granted regulatory clearance in Europe for cases where a decision to go ahead with the procedure is made by an interdisciplinary heart team.

Meanwhile Edwards Lifesciences, the dominant provider of TAVI devices in Europe, reported to investors that it filed for a CE Mark to expand into this same indication with its Sapien 3 TAVI valve in the second quarter of 2016, and that it expects approval in late 2016 or early 2017. In the Medtronic announcement Professor Eberhard Grube MD,

Europe will continue to be of the extreme and high-risk patient populations, but expanding the indication for the CoreValve Evolut R system will help heart teams provide excellent clinical outcomes for broader indicated patient populations.'

TAVI procedures currently hold a 37% share of the market in Europe, against traditional surgical aortic valve repair (SAVR) according to estimates from Wells Fargo Securities. Medtronic devices are used in 31% of those procedures against a 52% share for Edwards Lifesciences. The opportunity to expand TAVI pen-

bleeding, kidney damage and the onset of atrial fibrillation requiring a pacemaker implantation. TAVI has struggled against persistent paravalvular aortic regurgitation and a high pacemaker implantation rate.

Yet, for patients at lower risk for traditional surgery, who tend to be younger, the key concern among clinicians is the durability of the valve leaflets on TAVI devices. SAVR valves have a long history regarding durability that stretches to 25 or 30 years.



Cardiovascular disease research

# Testosterone clue to male heart deaths

New research suggests that testosterone could be involved in explaining why men have a greater risk of heart attacks than women, Mark Nicholls reports

As men appear to have higher risk of cardiovascular disease (CVD) than women of a similar age – with vascular calcification a strong predictor of mortality and morbidity from CVD – a team from the University of Edinburgh hopes that exploration of a link between gender and calcification could help unlock the pathway to new therapies.

The researchers have been looking at whether sex hormones could be the common ground, focusing on testosterone as the primary and most well-recognised androgen in men. They hypothesised that exogenous androgen treatment induces vascular calcification and could explain this gender disparity and that testosterone may be key in explaining why men have a greater risk of heart attack.

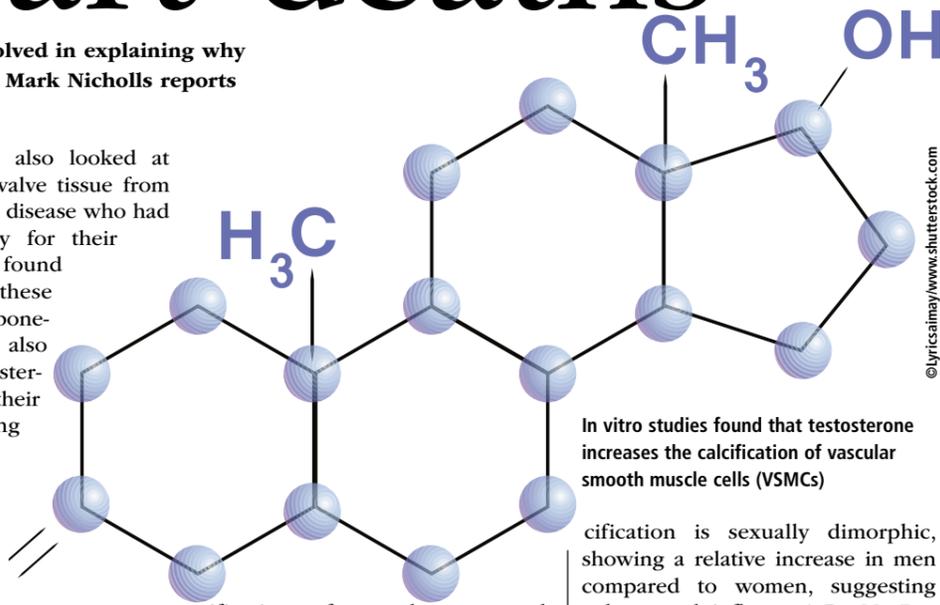
Initially the study focused on the effects of testosterone on blood vessel tissue from mice and found that the hormone triggers cells from the blood vessels to produce calcification, which causes blood vessels to harden and thicken.

In addition, when the mouse cells were modified, by removing the testosterone receptor so that they could no longer respond to testosterone, the cells produced far fewer

calcium deposits.

The researchers also looked at blood vessel and valve tissue from humans with heart disease who had undergone surgery for their condition. They found that cells from these tissues contained bone-like deposits and also carried the testosterone receptor on their surface, suggesting that testosterone may trigger calcification in humans.

The work was co-ordinated by Dr Vicky MacRae, Group Leader and Reader at The Roslin Institute and Royal (Dick) School of Veterinary Studies at the University of Edinburgh. 'Vascular calcification, a pathological process which involves the deposition of hydroxyapatite crystals in cardiovascular tissues, powerfully predicts mortality and morbidity from cardiovascular disease' she said. 'This study addressed the hypothesis that testosterone induces vascular calcification. Our in vitro studies found that testosterone increases the cal-



In vitro studies found that testosterone increases the calcification of vascular smooth muscle cells (VSMCs)

cification of vascular smooth muscle cells (VSMCs). Furthermore, testosterone-induced calcification was reduced in VSMCs lacking the androgen receptor (AR) through which the biological actions of testosterone are predominantly mediated.'

With androgens playing a role in inducing vascular calcification through the Androgen Receptor (AR), researchers suggest that androgen signalling may represent a potential therapeutic target for clinical intervention.

'The prevalence of vascular cal-

cification is sexually dimorphic, showing a relative increase in men compared to women, suggesting a hormonal influence,' Dr MacRae added. 'Our data showing a direct effect of testosterone on accelerating vascular calcification may therefore be key to explaining why men have a greater risk of heart attacks.'

At present, there is no comprehensive pharmaceutical treatment to inhibit the development of vascular calcification. However, the Edinburgh team say this study furthers existing knowledge of the basic mechanisms underpinning this pathological process, and highlights androgen signalling as a novel potential therapeutic target for clinical



Vicky MacRae PhD is Group Leader and Reader at The Roslin Institute and Royal (Dick) School of Veterinary Studies at the University of Edinburgh. Her group undertakes research on bone formation and vascular calcification, examining the mechanisms of differentiation and calcification in growth plate chondrocytes, osteoblasts, vascular smooth muscle cells and valvular interstitial cells.

cal intervention.

Research is on going to understand the pathways behind the process and whether the results have implications for patients with heart disease.

'Calcification is particularly difficult to treat, as the biological processes behind the disease are similar to those used by our body to make and repair bone,' Dr MacRae explained.

'By finding this link between testosterone and calcification we may have discovered a new way of treating this disease and also reducing heart disease.'

Funded by the British Heart Foundation (BHF) along with the Biotechnology and Biological Sciences Research Council (BBSRC), this research focused on testosterone was a collaborative study across a number of different research groups within the University of Edinburgh in Scotland.

Will antimicrobial resistance finally overcome us?

# Carbapenem resistant strains

Jane MacDougall

The increasing numbers of bacteria resistant to the newer generations of antibiotics is a public health problem on a global scale. Bacteria have an extraordinary capacity for adaptation, mutating permanently to overcome the action of our increasingly impotent antimicrobial armamentarium. A situation further

aggravated by the use of the powerful 'large spectrum' antibiotics, creating further pressure towards acquired resistance.

Extended-spectrum beta-lactamases (ESBL) are enzymes that confer resistance to most beta-lactam antibiotics; these include penicillins, cephalosporins and aztreonam. Community and hospital-acquired ESBL-producing Enterobacteriaceae

are prevalent worldwide and include common gut microflora, such as *Escherichia coli*. Infections with ESBL-producing organisms are associated with poor outcome and high mortality rates. However, because the reliable identification of ESBL-producing organisms is challenging, their prevalence is likely to be underestimated.

The first ESBL-producing organisms were isolated in the 1980s; today there are hundreds of different ESBL-producing strains resulting from successive mutations. The emergence, particularly in hospital, of resistant *E. coli* creates a vicious circle; the use of large spectrum antibiotics essentially leads to the emergence of greater numbers of resistant bacteria.

Christian Cattoen, from the Valenciennes Hospital Group in France, explained how this occurs '... the antibiotics are excreted from the body via the liver, therefore arriving in the digestive tract in bile. The normal gut microflora sensitive to the antibiotics is wiped out and in the void that is left, the resistant strains of *E. coli*, even if only present in very low numbers can now rapidly multiply. Nature abhors a vacuum!'

To combat these bacteria a family of antibiotics, now nearly 20

The superbug known as carbapenem-resistant enterobacteriaceae

years old was developed – the carbapenems. The original molecule with anti-b-lactamase activity was derived from Gram-positive bacterium *Streptomyces clavuligerus*. However, by the 2000s the first carbapenem resistant strains had been isolated. Resistance to carbapenems is now appearing at regular intervals worldwide from different mutations. The discovery of new producers of carbapenemases, a form of b-lactamase, is a worrying trend. 'While still highly effective against ESBL-producing organisms and other multi drug resistant organisms, both Gram-negative and Gram-positive, the use of these antibiotics must only be considered as a last resort,' Cattoen insisted.

In 2015, the World Health Organisation issued a warning about the spread of bacteria resistant to carbapenems, drawing attention to the fact that they were now a global phenomenon.

This rapid increase and spread of dangerous bacteria turns the spotlight on the clinical laboratory. Firstly, in helping to reduce the use of broad-spectrum antibiotics by concentrating on new methods for returning an antibiogram in a timely manner, so the clinician can initiate appropriate treatment for the isolated pathogen. Recently developed rapid antimicrobial susceptibility testing methods include classical agglutination assays, molecular

testing methods, e.g. qPCR, DNA microarrays, Luminex xMAP assays and next generation sequencing. Additionally, there are fluorescence in situ hybridisation (FISH) and mass spectrometry-based methods, e.g. phyloproteomics, assays using stable isotope labelling of amino acids, mass spectrometric beta-lactamase assays, PCR/electrospray ionisation-mass spectrometry (PCR/ESI MS), mini-sequencing and mass spectrometry-based comparative sequence analysis (MSCSA) all aiming to rapidly identify and determine the susceptibility profile of pathogens.

While, not immediately available to all laboratories, clinical laboratories should certainly think about incorporating techniques, such as DNA chips, to more easily identify carbapenem resistant bacteria, so that infected patients can be quickly isolated and the hospital's contingency plan for containment implemented. 'The clinical biologist should be fully implicated in this procedure,' Cattoen advised. The reliability of our results is primordial, the better the techniques we have, the sooner we can raise the alert and put processes in action, that the clinical laboratory needs to be at the heart of.'

\* Source: JIB – Journées Internationales de Biologie. Press Conference and Scientific Session. 24 June 2016





*Achieving a faster workflow*

# A modular approach to urinalysis

Jane MacDougall

The reasons why doctors request urinary analysis are varied – perhaps to detect a possible or suspected infection, or to screen for kidney diseases.

In all cases a reliable and rapid result is the major aim. Urinary microscopy and culture have been the mainstays of urinary analysis for many, many years both of which require time and specialist handling.

When microscopy is performed, in addition to the numbers and types of bacteria present the number of squamous epithelial cells and leucocytes also need to be assessed, to serve as indicators of contamination and infection respectively.

The fully automated UN-Series from Sysmex offers a modular approach to urinalysis including analysers, digital imaging, samplers and software. Now available in Europe, these were introduced at JIB this week.

The different systems all aim to provide quality results for clear diagnosis while significantly increasing workflow and reducing human error for an overall result of improved clinical laboratory efficiency in the work-up for kidney and urological diseases and urinary tract infections.

The detection system is based around fluorescence flow cytometry. The highly sensitive detection level allows the machines to identify, with high precision, different particles within the urine sample. The incorporation of a new blue laser enhances bacterial screening capabilities, allowing rapid classification, while a new depolarised side light scatter easily discriminates between red blood cells and crystals.

Coupling to a fully-automated imaging system enables turnaround times to be significantly reduced. Built into the analysis software are smart algorithms and different diagnostic parameters, enabling casts and epithelial cell differentiation, which will help lead to the efficient and accurate diagnosis of kidney disorders.

The new system has expanded on the older series' original five parameters; red blood cells, white blood cells, bacteria, casts and epithelial cells to include nine others; squamous cells, non-squamous cells, hyaline casts, non-hyaline casts, fungi, spermatozoa, crystals, mucus and white blood cell clumps. This has been made possible due to the inclusion of new reagents to stain nucleic acids and surface membranes; both result in better differentiation of bacteria, fungi, white blood cells, epithelial and other cells. The company claims the enhanced detection system means fewer false positives and negatives and therefore a reduced re-testing rate.

'In turn, this workflow is optimised thanks to dedicated work area management software that helps with smart rules and quality control reagent management,' the company reports.

'The easy-to-use system also can be used to analyse other body fluids, such as cerebrospinal, pleural, ascitic, joint, etc..

Sysmex adds that it hopes, with this completely scalable offering, that the company has tackled one of the key challenges faced by laboratories: balancing diagnostic/analytical needs with the available hardware and software.

Further information is available at [www.sysmex-europe.com/urinalysis](http://www.sysmex-europe.com/urinalysis) and at the micro-website [www.art-of-particles.com](http://www.art-of-particles.com)

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- > New Possibilities in Liquid Biopsy: Understanding Molecular Changes in Real Time
- > Advances in Next Generation Sequencing for Clinical Diagnostics
- > Poster Session – Emerging Clinical & Laboratory Diagnostics

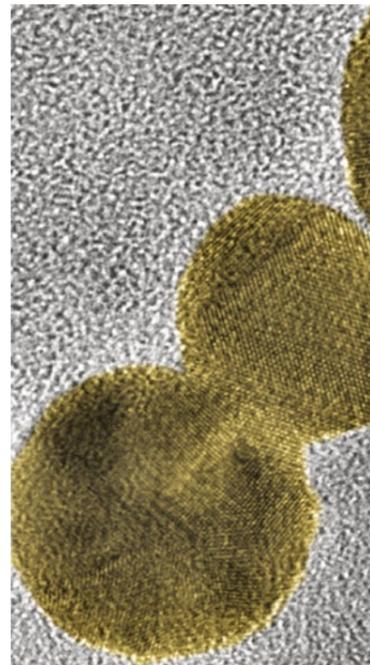
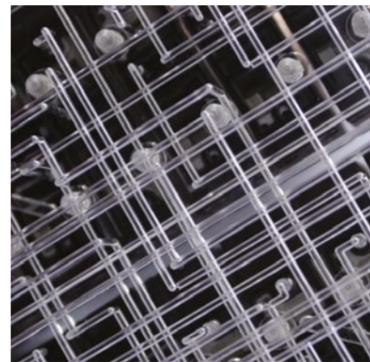
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Lower limb trauma – the critical choice

# Reconstruction or amputation

Report: Mark Nicholls

'Amputation v. reconstruction' – a vital issue – was debated by two leading surgeons during the Microsurgical Lower Limb Reconstruction session at the Advances and Controversies in Reconstructive Microsurgery (ACRM) 2016 conference, held in the United Kingdom this May.

Consultant Plastic Surgeon Umraz Khan, from North Bristol NHS Trust presented a plastic surgeon's view, while Ben Davis, a Consultant Orthopaedic Surgeon at the Norfolk & Norwich University Hospital, discussed the perspective of an orthopaedic surgeon.

During our *European Hospital* interview, Khan explained that an important question is 'What constitutes a useful limb?' and any decision to amputate or salvage a traumatised lower limb depends on a

number of requisites being in place.

'An important requisite is that there must be no chronic pain,' he continued. 'The difference with the lower limb is that it bears weight and if every time a patient puts their foot down it hurts, they will limp and that will have a detrimental effect on the more proximal joints, the hip joint or the back, for example.'

'The patient then becomes addicted to painkillers and they are better off losing the limb. Pain is an important consideration and a reconstructed limb really should be pain free.'

He also stresses that 'reconstruction should be within the realms of possibility' and, whilst surgery may be technically possible, if it leaves the patient with significant morbidity the solution is not to do reconstruction.

Scoring systems are available to help a surgeon to decide, although he said the clinical experience of the surgeon remained the critical factor. Advances in technology and surgical practice have changed the approach to lower limb trauma, and the prospect of limb transplantation is also on the horizon. 'We are able to grow bone, which we could not do reliably before,' Khan pointed out.

'If someone had bone loss it was almost certain amputation in the past, whereas now we can grow bone in a frame and the plastic surgeon is involved in providing microsurgery for that.'

The demographic of patients is changing, shifting away from young adult males involved in road accidents towards older active early retirees.

Amputation rates are falling and, Khan explained, 'While there are



**Ben Davis** is Consultant Trauma, Orthopaedic and Limb Reconstruction Surgeon at the Norfolk & Norwich University Hospital. His research interests lie in outcomes in trauma surgery, non-union, fracture healing and external fixation.



**Umraz Khan** is a consultant plastic surgeon at the North Bristol NHS Trust. He publishes regularly on different aspects of patient trauma with a specific area of research focused on ways of improving functional outcome.

while the success of the Paralympic Games and publicity surrounding the rehabilitation of military personnel highlights the amazing potential of prosthetics, the level of rehabilitation and the motivation of these individuals is not representative of the general population.

'At the same time as prosthetics advance, so does the technology and understanding of tissue engineering and implants, creating salvage options where previously none existed,' Davis added.

In terms of salvage, 3-D printing and tissue engineering are likely to enable the bespoke creation of mechanical and biological implants for individual problems and more reliable and sophisticated implants for limb lengthening are already available and being used with great success, he pointed out.

some patients who have a futile reconstruction and have a delayed amputation either through infection or pain, which used to be up to 30 percent two decades ago, but has come down to about three to four percent because we are making the right decisions about the patient – and it is the surgeon's experience and decision making that has a massive impact for the patient in the long-term.'

Davis, who believes that salvage of a limb, or as much as circumstances allow, is the preferred option, highlighted the bespoke nature of every case. 'There is a tendency for surgeons to assert very blunt and incorrect conclusions about the rapidity with which patients can be mobile and active after amputation, but those conclusions are generally wrong,' he suggests. 'Amputation is, by definition an all or nothing event that should be reserved until it is clearly necessary.'

During the ACRM session, Davis highlighted how the 'decision regarding amputation and salvage of the lower limb is complex and there is no algorithm, formula or protocol that can be applied to an individual patient.'

Both surgeons acknowledge the significant development of prosthetics, however, Davis warns that

'In prosthetics, the use of osseointegration is under-going a resurgence of interest and the possibilities created with computerisation, robotics and power assistance will continue to drive forward prosthetic possibilities,' Davis explained.

But, he warned that, when looking to amputate or salvage, the patient's wishes and perspective are paramount in the decision-making. 'From a patient's perspective, having your own stable functional limb is unlikely to ever be bettered,' he said. 'If, however, a patient is living with a chronically painful, poorly functioning limb and has reached the end of the salvage options, or has reached the decision him or her self that they no longer wish to continue with the salvage, then amputation can be a very positive step forward.'



Belgian firm designs platform specifically for hospitals

## Medics gain a suite for 3-D printing

'Since its foundation Materialise has providing leading-edge, 3-D visualisation and printing solutions to its extensive list of hospital, academic and medical device customers,' explains the Belgium-based manufacturer Materialise. 'The new open and flexible platform of software and services forms the foundation of certified medical 3-D printing, in clinical as well as research environments, enabling medical professionals to revolutionise patient treatment,' the firm explains.'

'The platform includes planning and design software tools, 3-D printed anatomical models and

surgical guides, and patient-specific implants,' the company reports.

'Launched during the American Association of Orthopaedic Surgeon's Annual Meeting (AAOS), the Suite also introduces Materialise Mimics inPrint, a new software solution that enables surgeons to create accurate medical models for 3-D printing in hospitals without the need of advanced clinical engineering support.

'With this suite, we have drawn together medical software and services, both established and new, into a single, neutral platform that facilitates the further integration

of 3-D planning and printing into hospitals. For example, the system allows clinicians to 3-D print by connecting data from all modern imaging systems to the ever-expanding range of 3-D printers now on the market.

'The system also includes software for predictive planning and communication; patient-specific guides that transfer a co-created surgical plan to the operating theatre (OT); and patient-specific models and implants that enable surgeons to treat complex cases. 'For more than 25 years, Materialise has been identifying meaningful applications



3-D printed anatomical bone model by Materialise

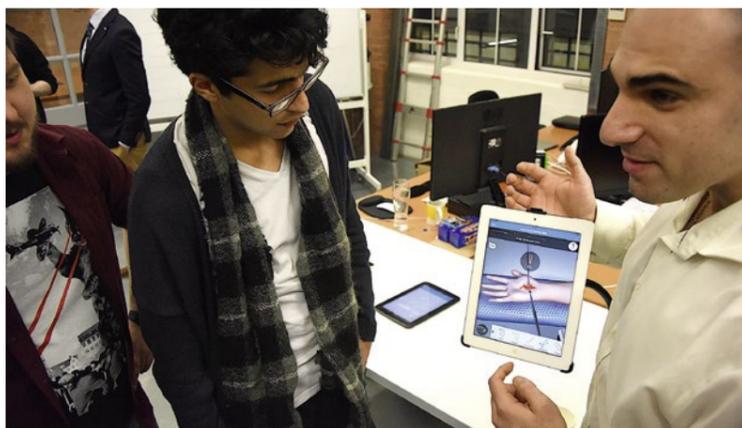
of 3-D printing and developing the backbone of software and solutions needed to successfully bring them to market,' said Wilfried Vancraen, Materialise founder and CEO. 'We see incredible potential for 3-D printing in hospitals, but have also recognised that many existing solutions have slowed adoption of the

technology. Therefore, we developed the Materialise Mimics Care Suite to help hospitals to better integrate 3-D printing and begin unleashing the benefits it offers, which include potential cost savings and patient care improvement.'

Surgeons adopt mini mobile technology asset

# Pulling an operating theatre out of a pocket

The reprocessing of medical devices in Europe is very inconsistent, according to a European Commission survey carried out in the 27 EU member states among politicians, medical devices manufacturers and reprocessing companies, as well as doctors, hospitals and related parties.



Touch Surgery has been developed on the basis of cognitive task analysis, breaking down a portfolio of operations into a series of steps and decision points

Report: Cornelia Wels-Maug

Dr Jean Nehme, a London-based trainee plastic surgeon, reflects on his own training – a decade spent attending lectures, revising textbooks, passing examinations – but did he actually practise a surgical operation? 'In training, you spend many months learning how to operate, without performing any opera-

tions. It took me a long time to learn to do it the right way and there are very few rehearsal and foundation tools accessible,' he explains. With a shortage of surgeons, trainee surgeons cannot get the valuable experience they need.

That's why Nehme, and three other surgeons, decided to tackle the problem. In 2013 the team created 'Touch Surgery', a mobile

surgery simulator that runs on iOS and Android mobile devices. This provides a cognitive map for operations, allowing users to learn and rehearse a surgical procedure step by step on a virtual patient in 3-D in an interactive way.

Nehme believes a successful surgery relies about 75% on cognitive skills e.g. visual and pattern recognition and 25% on technical skills. Therefore, Touch Surgery has been developed on the basis of cognitive task analysis, breaking down a portfolio of operations into a series of steps and decision points. Users are guided with a few swipes and pinches as to where to make incisions, how to remove organs and then sew patients up again. They can also test themselves at each step against a choice of tools and parts of the body. A 'gamification' element allows users to upload their scores and compare them against the top and average score.

The free app currently has a portfolio of more than 40 virtual surgical simulations, co-authored by expert surgeons at leading international associations and medical institutions. In this way, Touch Surgery wants to facilitate the dissemination of surgical best practices and novel procedures and to improve patient

outcomes. With more than one million users in over 225 countries in the three years since its launch, the company clearly meets a universal need for this tool. It appeals not only to trainee surgeons but also to established surgeons to help them keep abreast of advances in medical technology.

Patients also find it a useful tool because it assists them to better understand the procedures they are about to receive. The app has been fully endorsed by surgical societies such as the Royal College of Surgeons of Edinburgh and the American Society for Surgery of the Hand (AASH), and is also integrated into leading residency programmes in the USA, for example by the Stanford School of Medicine, Harvard Medical School, Penn Medicine, NYU School of Medicine.

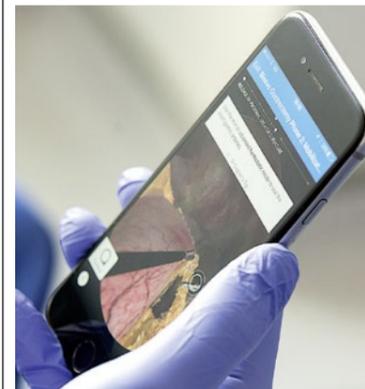
More recently, the company applied the technology in the virtual reality space, allowing multiple teams across different locations to collaborate on establishing a knowledge base of surgical techniques and best practices.

What's next? Touch Surgery is keen to put this technology on wearable hardware to make it part of the operating room to provide a decision system to assist surgery.



Dr Jean Nehme is a London-based trainee plastic surgeon. In 2013 he and some colleagues created 'Touch Surgery', a mobile surgery simulator that runs on iOS and Android mobile devices.

The firm also looks into applying cognitive mapping in robotics. With a background in medical engineering, gaming, simulation and animation design – with animators who worked on films like Avatar, Finding Nemo, Gravity and Skyfall – the team looks set to come up with more innovation for the operating theatre. This certainly appears to be a firm to watch.



The free app currently has a portfolio of more than 40 virtual surgical simulations

Differences in European guidelines for reprocessing

# Staff qualifications are vital

The reprocessing of medical devices in Europe is very inconsistent, according to a European Commission survey that was carried out in the 27 EU member states among politicians, medical device manufacturers and reprocessing companies, as well as doctors, hospitals and related professional parties

Report: Anja Behringer

The survey made it apparent that only half of all countries (46.5%) have legal guidelines for medical device reprocessing. However, this actually does not mean that wherever these legal guidelines are in place disposable medical devices can also be reprocessed. In France, for instance, this is prohibited.

Almost half of those surveyed believed that most disposable medical devices (84%) such as balloon catheters, flexible endoscopes, or instruments for minimally invasive surgery couldn't be reprocessed without posing health risks for patients. The various disinfection agents have advantages and disadvantages, with an increasing number of patients becoming allergic to some.

## Three regulatory classes from A to C

In Germany, guidelines regarding the type of devices and liquids they come into contact with are particularly detailed. According to the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO), medical devices are assigned to three regulatory classes from A to C, with the more complex devices

assigned to category C. To ensure hospital hygiene for patients and staff, reprocessing of sterile devices is one of the 'building sites' where disinfection and sterility are of the

utmost importance. This applies to the entire decontamination, cleaning, disinfection and sterilisation through to sterile materials manufacture. Hygienic reprocessing of medical devices, such as catheters, syringes or endoscopes, can be manual, automatic or semi-automatic. Numerous companies offer sterilisers, or disinfection agents, but their utilisation should be carefully con-

sidered due to different effectiveness and particularly due to side effects. Flawless hygiene and sterility of medical devices is ensured either by internal hospital staff – although there is no actual, recognised job description for this type of work – or can be out-sourced. Due to a lack of resources and know-how, complex and thermo-sensitive medical devices cannot be reprocessed in

the hospital. They must be disposed of and replaced after each one-time use. Hospital central sterilisation units are being increasingly pushed to their limits by the continuous requirement for investments into new equipment and processes. This must be considered when looking at the possible cost savings achieved through the reprocessing of expensive disposable products because the use of insufficiently reprocessed products can cause infections, repeated hospital stays and therefore additional healthcare costs.

The demands on the staff are also rising, as described by the KRINKO and the Federal Institute for Drugs and Medical Devices (BfArM) in their recommendations in 'Requirements for Hygiene in the Reprocessing of Medical Devices'

## Proving knowledge

Hospital staff must be able to prove knowledge of medical instruments (also department-specific), knowledge of infection prevention and control, and microbiology (including transmission routes), as well as of risk assessments and medical devices classification based on the recommendations.

Key aspects of reprocessing:

- Appropriate preparation (pre-treatment, collection, pre-cleaning, disassembly)
- Cleaning, disinfection, rinsing and drying



Hygienic reprocessing of medical devices, such as catheters, syringes or endoscopes, can be manual, automatic or semi-automatic

Continued on page 24

Robotic surgery still has to prove its mettle

# Haptic feedback is a possibility

Robot-assisted surgery still meets with considerable scepticism even though Intuitive Surgical's Da Vinci system has been around for more than a decade. However, few surgeons and researchers are seeking ways to expand the surgical toolbox. Not so the members of the working group 'Surgical technology and training' at the General, Visceral and Transplantation Surgery Department, University Hospital Tübingen: they are particularly interested in haptic feedback for robot-assisted systems. 'Several systems are about to be launched. These are exciting times,' says Andreas Kirschniak, Head of the Tübingen working group and surgeon by training.

## Why the scepticism?

'We are caught between the technological viability of these innovations – their use and potential benefits – and their economic viability,' explains surgeon Andreas Kirschniak, at Tübingen University Hospital. 'In countries with case-based reimbursement schemes, particularly in Germany, the fact that using these systems frequently does not make economic sense is the major obstacle,' he points out. If the use of a robot-assisted surgery system costs more than the insurers will reimburse, hospitals quickly question the legitimacy of such technologies.

The current Robotic Versus Laparoscopic Resection for Rectal Cancer (ROLARR) study (<https://clinicaltrials.gov/ct2/show/NCT01736072study>) was expected to offer renewed hope that the robotic industry can deliver systems which indeed will improve oncological outcomes. 'Unfortunately the study did not yield the expected

results. There are indications of a trend towards improved outcomes, but statistical significance could not be reported,' Kirschniak says. The bottom line for physicians is simple: Does it make sense to acquire such expensive equipment – with the total cost of ownership going beyond the acquisition price and including substantial amounts for training and operating costs.

'We are smack in this tension between economics and viable healthcare innovation,' he regrets, although still convinced that robot-assisted surgery will prevail: 'Particularly with interventions that require closures in minute spaces through minute accesses, such as d'Hoore rectopexy, a robot is unbeatable.'

## Enter haptic feedback

'When your fingers touch the tissue you feel how strong it is, you feel its elasticity, the pressure you are exerting,' Kirschniak explains, 'and, even with forceps and a needle holder,

you do get haptic feedback to a certain degree.' But on the next level, in laparoscopic interventions when long instruments are used, haptic feedback is close to non-existent. 'This is where the robot enters the stage. It can exert far more force than a human surgeon. When the surgeon at a workstation asks the robot to pull the tissue, it executes the command, no matter what,' says Kirschniak. Today, robotic systems do not provide feedback on the force they apply in vivo. 'But, two systems are scheduled for launch in the course of the next two years that offer precisely this type of haptic feedback.'

For Kirschniak this is a major benefit since any intervention, be it with or without robotic assistance, has to be as gentle as possible on the patient. 'In a joint project with Darmstadt Technical University (financed by the German Research Fund), we developed such a robot. And it works very well,' Kirschniak is

pleased to report. The force applied in the new robot is not measured at the tip of the instrument in the sterile area but in the adjacent non-sterile area and the values are fed back to the surgeon.

## We will see...

'Imagine your tests have shown precisely how much force you can apply on a certain tissue without causing micro-trauma!' That, Kirschniak believes, would be major progress because, in almost all surgical interventions, tiny and often invisible ruptures occur, mostly because every patient is different,



Andreas Kirschniak MD heads the 'Surgical technology and training' working group at the General, Visceral and Transplantation Surgery Department at Tübingen University Hospital. His clinical focus is colorectal and pelvic floor surgery, robot-assisted surgery and the surgical treatment of chronic inflammatory bowel disease.

every tissue is different.

'I'm truly convinced that this new technology will be used in numerous indications particularly due to the robot's ability to move 'around the corner' and in minute spaces,' Kirschniak emphasises. 'True, robotic surgery still has to prove its mettle, but once the first robots with haptic feedback are commercially available I am sure the market will react and new applications will be developed.'

# Shadow-less clear homogenous lighting

Made in Italy, the STARLED7 NX design is naturally handsome, practical, compatibility with laminar flows and provides excellent light quality. 'The special optics of its LEDs generates a shadow-less, clear and homogeneous light assuring visual comfort and best working conditions,' Acem SpA confirms. The 57 next generation LEDs are circularly placed and split into seven,' and, the manufacturer adds, the device generates an IR-free light, excellent colour temperature and a practically endless life cycle at low consumptions.

With high illumination level of 160.000 lux, a colour rendering index of 95 and colour temperature of 4.500 °K the exact chromatic scale of human body colours can be achieved, Acem points out.

'The lamp is provided with ACRIS, an innovative system realised by ACEM that ensures, by the use of a microprocessor, the control of electrical curves typical of LEDs to remain unaltered over the time but maintaining a long life cycle (about 50.000 hours),' the firm adds.

Other assets include light field dimension adjustment through optical-electronic management, I-Sense control panel, adaptable and adjustable illumination levels for different tasks, and more.

'This light allows visualisation of the operating field as well as the surrounding environment clearly and is particularly suitable for minimal invasive surgery and for preparation and treatment during an operation, monitoring of the patient and microscope operations,' Acem adds.

On demand, the removable and

sterilisable central handle can house a video camera to record surgical operations accurately and the video

camera can also be placed on a separate arm. Details: [www.acem.it](http://www.acem.it)



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Neurological diseases are often underestimated, underfunded and not diagnosed

# No health without brain health

Report: Brigitte Dinkloh

A largely aged population is already a reality in some countries, and this will become a worldwide problem by 2047, when the number of the Earth's old people is likely to surpass the number of young people. Far-reaching social, health and economic consequences are predictable, not least an increase in neurological diseases such as stroke, dementia and Parkinson's disease.

The World Federation of Neurology (WFN) has dedicated this year's World Brain Day, to be held on 22 July, under the heading *Brain Health and the Ageing Population*. 'Politicians and health authorities are concerned about the ageing population and the challenges this presents, but mental health is often still not on national and international health agendas,' laments Professor Raad Shakir, President of the WFN.

Currently, 800 million people, or 12% of the world population respectively, are over 60 years old. By the 2050 this number is expected to increase to 2 billion people, representing 21% of the population. Whilst the majority (70%) currently live in the highly developed countries, by the middle of the century the predominant number of those aged over 60 (80%) will be found in less developed countries. With an ageing population the proportion of healthcare expenditure they take up – currently around 50% in developed nations, will increase to more than 65% by 2030 and, around 2050, this process will also happen in the less

**World Brain Day**  
July 22nd, 2016

**Brain Health in an Aging Population**

**800 million** are older people in 2016, expected to be **2 billion** by 2050.

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developed countries.

With ageing the frequency of stroke, dementia and Parkinson's disease increases. Neurological diseases already have more of an

impact than cardiovascular diseases and cancer. Stroke is the most common neurological disease and the number one cause of disabilities. 'Yet, stroke is a treatable and avoid-

able disease. With effective intervention the outcome for patients can be improved and the severity of the disease lowered. The best precaution against stroke is controlling high blood pressure and to stop smoking,' explains Professor Mohammad Wasay, from Karachi, current chairman of the WFN Public Awareness Committee.

He also describes dementia as avoidable and treatable, although genetic predisposition also plays an important part. Around every ninth person worldwide currently suffers dementia. It is a challenge for society as a whole, because those affected require increasing amounts of care and care facilities. With around an estimated 818 million dollars spent on the 46 million people affected worldwide, dementia is already the most expensive brain disease. It is predicted that, by 2050, dementia will affect 131 million people.

Professor Wolfgang Grisold, WFN General Secretary, is calling for more investments in neurological treatments and care. 'Limiting healthcare expenditure is not a suitable option, in view of the increasing number of those affected. Society must bear the cost of adequate and humane care of older people and neurologists should be advocates for these patients,' he believes.

Extending rehabilitation capacities and capacity for long term care should be among the highest priorities of an ageing society. Palliative medicine is also likely to play an increasingly important role, because only palliative medicine with a neurological orientation will be able to limit the effects of an incurable disease and improve quality of life.

'Although we have already taken some big steps towards diagnosis

and treatment of neurological diseases, there's an ongoing disparity regarding access to treatment. This becomes particularly clear with the distribution of hospital beds available in neurology worldwide. In Africa there are only 0.3 beds available per 100,000 inhabitants; in Southeast Asia it is 0.8 beds. The lower the household income of a region the lower the number of hospital beds for neurology, neurosurgery and paediatric neurology,' Grisold points out. 'The situation is particularly bad in Cambodia, Myanmar and parts of Africa, which is absolutely unacceptable.'

The declared objective of the world federation is to ensure access to neurological diagnosis and treatment for patients worldwide. 'I hope that World Brain Day can support us with this objective,' he adds.

\* The World Federation of Neurology (WFN) was founded on 22 July 1957 with the objective of promoting the quality of neurology and brain health worldwide. This NGO is a union of 119 national neurological societies, which cooperates closely with other healthcare organisations, such as the WHO and the Alzheimer's Society. World Brain Day has been held since 2014 with an annually changing key topic.

## Staff qualifications are vital

Continued from page 22

- Checking for cleanliness and soundness
- Care and maintenance
- Functional testing
- Labelling
- Packaging and sterilisation
- Documented release of medical devices for use/storage

There are also spatial and organisational aspects to the process, along with the provision of procedural, working and legal instructions.

The documentation states: 'It is assumed that somebody is suitably qualified if these contents were covered in the course of their recognised training in a respective medical profession and if this training was successfully completed. If the contents were only partially covered during this training, or were not covered based on the most up-to-date guidelines they will have to be covered or brought up to date through the attendance of suitable, further on-the-job training. Without proof of training in a respective medical profession specific training is necessary.'

## Quality assurance includes water hygiene

There is no recognised apprenticeship/profession in the reprocessing field. One manufacturer therefore offers an academy for training and advanced training in this subject.

Some manufacturers of flexible endoscopes also carry out hygiene and microbiological examinations as stipulated by the Robert-Koch-Institute and the BfArM during manual and automated reprocessing. Quality assurance not only includes the inspection of medical devices as to potential contamination but also the hygienic innocuousness of water supplies and water used for rinsing. The reprocessing industry claims the savings potential to be up to fifty percent of the original costs of medical devices.

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