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NEWS & MANAGEMENT 1-5

- Spain suffers massive healthcare deficit
- Weekend mortality in England's NHS is too high



PATHOLOGY 9-11

- Danes take pathology software worldwide
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Laughter is the best remedy

Cartoons in a guidebook affect kidney patients positively

Report: Mark Nicholls

It has long been suggested that laughter could be the best medicine – and now a group of researchers in the United Kingdom is applying that theory to help patients cope with long-term conditions.

At the University of Southampton in Hampshire the research team has used patient feedback to create a series of cartoons that demonstrate common experiences, problems and anxieties.

The cartoons were incorporated into a guidebook given to chronic kidney disease patients, who were asked their opinion on the use of cartoons and humour in regular patient information and then asked to evaluate the cartoons drawn for the guidebook.

Results showed a range of feelings towards the cartoons including amusement, recognition, hostility and incentives to action.

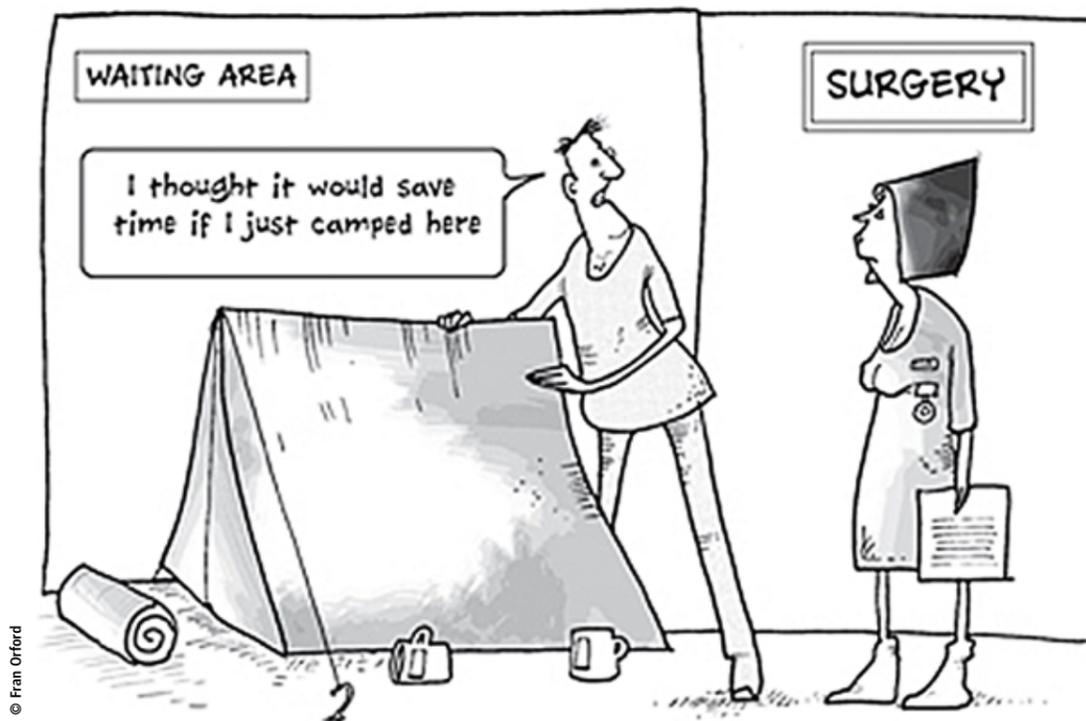
Overall, patients found the cartoons useful in lightening the tone of information and giving them insight and understanding not gained before.

The findings were initially published in the Health Services Research journal and the study was carried out under the auspices of the National Institute for Health Research (NIHR).

Inspired by patients' quotes

As the study leader, Associate Professor Dr Anne Kennedy, pointed out: 'Humour is frequently and naturally used by people with chronic illnesses, to help them adjust and understand what is happening to them. Our study has shown that cartoons could provide clarity to patients and be a way to engage with them. It is an untapped resource and could be a potential approach to support self-management.'

Dr Kennedy's team worked closely with cartoonist Fran Orford, who



© Fran Orford

Patient takes things into his own hands due to long waiting list for surgery. Other cartoons show diagnostic concerns when doctors request so many repeat tests

followed her brief, along with quotes and stories provided by patients. The cartoons cover a range of topics from 'uncertainty about diagnosis because being called into GP practice for so many repeat tests', a 'GP judging that the time is not right to tell a patient about yet another condition', 'making family decisions about meals and shopping' and 'exercise motivation – how dog-walking introduces you to others'.

Anne Kennedy believes health professionals could use the cartoon approach to help their patients engage more in the management of their own conditions. 'Cartoons can be challenging,' she added, 'and the difficult emotional responses some pictures evoke could be used to help people adjust to their situation, but they can also be used to dispel

some of their misconceptions. 'The word chronic is often misinterpreted as meaning terminal – reaction to the particular cartoon that demonstrated *chronic* did prove a bit shocking to some patients but it allowed the word to be talked through and it was a tipping point for patients to better understand what their condition was.'

Fran Orford believes his background (his 15-year experience in social work, working with vulnerable children) helped him set the right tone for the cartoons. 'I've drawn for hundreds of clients and am well aware that cartoons can perform a number of different functions, from simply amusing to inspiring. They can add a valuable visual 'tag' to grab the viewers attention in a way that words sometimes

don't. They can also help to lend text a little emotion.

Visual emotional creatures

'The messages were undoubtedly very serious, but people who suffer from a medical condition may have enough potential gloom in their lives without health messages being presented in a depressing way. The images weren't meant to detract from the seriousness of the message, but just present it in a different way.'

With humans being visual, emotional creatures, the cartoonist said it was not unreasonable for health professionals to experiment with providing information in an attention-grabbing way and that cartoons can help as part of the 'mix'. 'I hope patients using the booklet would



Dr Anne Kennedy is a Senior Research Fellow in the Department of Health Sciences at the University of Southampton. Her main academic interests concern the self-management of long-term conditions. To that end, she has developed a number of self-management support interventions and tested them in randomised controlled trials. Dr Kennedy has a long-standing belief in patient involvement in research.

like the fact that effort has been put in to make it as attractive as possible for them. I believe the cartoons would make it more likely that people would pick it up and read it, even if they hate the cartoons, the messages will still have more impact than uninterrupted text.'

Professor Anne Rogers, from the NIHR, who also worked on the study, said: 'Cartoons, drawn with patient input, have potential to help communicate important advice and to help patients self-manage their conditions while boosting moral.'



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CONTENTS

NEWS & MANAGEMENT	1-5
RADIOLOGY	6-8
PATHOLOGY	9-11
CARDIOLOGY	12-13
SURGERY/ICU	14-15
COMMUNICATION	16

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This information will be used only in an analysis for European Hospital, Theodor-Althoff-Str. 45, 45133 Essen, Germany, and for the mailing out of future issues and the EH electronic newsletter.

EH 2/14 

Spain's huge public

Healthcare funding cuts – and more expected

Report: Dr Eduardo de la Sota Guimón

The Spanish National Health System is organised following the principles of universal coverage and solidarity, to ensure equal access to healthcare services for all citizens. The system is financed from public funds – healthcare is a non-contributory benefit financed out of general taxation and included in the general budget of each Autonomous Community – and it is structured into two healthcare levels, primary and specialist care.

Under a decentralised functioning, the 17 Spanish Autonomous Communities can establish their respective package of services, which must include all the basic services that all the NHS users must be guaranteed.

Expenditure for public and private healthcare expenditure in Spain account for 6.0% and 2.4% of the GDP, respectively.

Consequences following the economic crisis

Spain's Public Healthcare System is running a huge deficit, which, coupled with the current Spanish public deficit crisis, has pushed the Ministry of Health to adopt spending cuts, and further cuts are expected.

According to the influential British Medical Journal, the Spanish gov-

ernment's reforms could lead to the dismantling of much of the country's healthcare system, which will involve 'potentially adverse health effects of the Spaniards'.

The study, led by Dr Helena Legido-Quigley, professor of global health at the London School of Hygiene & Tropical Medicine, concludes that the cuts are affecting with particular concern for the elderly, the disabled and the mentally ill. The researchers also say that there has been a significant increase in depression, alcoholism and suicide since the crisis began and unemployment (24% at the end of 2013) began to soar.

Therefore, with the crisis, there has been an increase in demand for healthcare services, while benefits and supply are being cut.

According to the study, the national health budget was cut in 2012 by 13.65%, making the Spanish healthcare budget one of the lowest in the European Union. In 2013 new cuts have been implemented in the dependency programmes for the country's elderly as well as the disabled (€1,108 million).

The saving measures are not evidence based. There has been no time for adequate planning. Therefore, major changes made by the Spanish government such as to exclude undocumented immigrants from free health services and increased co-payments for access



to medicines, prosthetics and some ambulance trips, are having important consequences. Hospitals are being privatised, some hospital and ambulatory centres have been closed and fewer surgical procedures are carried out.

Ambulatory and surgery waiting lists are increasing rapidly, and certain services are not provided during weekends. Emergency services are overloaded in many places. In March 2014, a child with an acute infection died in the Burgos province in the middle of the resources

10 new standards aim to improve weekend care in England's 1

Mortality risks rise 16% on Saturdays - 16% on Sundays

England's National Health Service (NHS) is taking steps to ensure that, for the first time, a consistent level of care is provided at weekends by focusing on healthcare seven days a week.

Within the NHS it is acknowledged that some services have been inconsistent at weekends – MRI, CT, ultrasound and X-rays have not been offered as promptly and wards and operating theatres have been left in the hands of junior and inexperienced staff.

After figures revealed that patients are more likely to die if admitted to England's NHS hospitals at weekends, the Government has acted to bring in seven-day working practices. Professor Sir Bruce Keogh, NHS England's National Medical Director, has outlined a plan to drive seven-day services across the NHS over the next three years, starting with urgent care services and supporting diagnostics.

There is a significant variation in outcomes for patients admitted to hospitals at the weekend across the country – a problem affecting healthcare systems around the world – seen in mortality rates, patient experience, the length of hospital stays and readmission rates.

Analysis of 14 million hospital admissions in England in 2009/10, for example, showed that the



During the transition to new NHS structures Professor Sir Bruce Keogh has continued in his role as Medical Director of the National Health Service (NHS) in England, with responsibility for clinical quality, policy and strategy and postgraduate education of doctors, dentists, pharmacists and clinical scientists.

Sir Bruce has also enjoyed a distinguished career in surgery and was President of the Society for Cardiothoracic Surgery in Great Britain and Ireland, Secretary-General of the European Association for Cardio-Thoracic Surgery, International Director of the US Society of Thoracic Surgeons, and President of the Cardiothoracic Section of the Royal Society of Medicine. In 2003 he received a knighthood for services to medicine.

increased risk of mortality at the weekend could be as high as 11% on a Saturday and 16% on a Sunday. The reasons are elements such as

variable hospital staffing levels at weekends; fewer decision-makers at consultant level and experience; a lack of consistent support services, such as diagnostics; and a lack of community and primary care services that could prevent some unnecessary admissions and support timely discharge.

60% more consultants

Sir Bruce has set out 10 new clinical standards that describe the standard of urgent and emergency care all patients should expect seven days a week, each supported by clinical evidence and developed in partnership with the Academy of Medical Royal Colleges. They describe how quickly after hospital admittance a patient should be assessed by a consultant; the diagnostic and scientific services that should always be available, as well as the process for handovers between clinical teams.

These include: All emergency admissions to be seen by a consultant within 14 hours; seven-day access to diagnostic tests, such as X-rays, ultrasound, MRI scans and pathology; patients in intensive care and other high dependency units to be reviewed by a consultant twice a day; weekend access to multi-disciplinary teams, including expert nurses, physiotherapists and other medical support staff.

health deficit



ing years. Of course, dissatisfaction among patients and professionals increases on a daily basis.

The damage has already been done. Nevertheless, the Government (now looking towards the next elections) has promised a change in this policy. The evolution of public deficit and thus the amount of public resources devoted to health and its planning allocation is yet to be seen in Spain. ■



Hospital Universitario Ramón y Cajal, Madrid



Hospital Universitario Rey Juan Carlos, Madrid

shortage, because the emergency services made the decision not to send an ambulance.

Risking disease escalation

If corrective measures are not implemented, the situation could worsen, with an increase of AIDS and tuberculosis, as seen in Greece, also suffering major cuts in health system and the risk of an escalation of problems with drugs and the spread of disease. Morbidity and mortality rates (very low in Spain) will probably grow during com-

NHS

1% on days

Sir Bruce pointed out that the increasing number of doctors being trained gives the NHS opportunities to work differently. Currently some 6,500 doctors take up entry-level posts each year and projections suggest a 60% rise in the number of consultants by 2020 if training and recruitment continues at the same rate.

'There are encouraging examples,' he said, 'for NHS organisations that have moved to making healthcare services more accessible seven days a week to avoid compromising safety and patient experience. We need to accelerate the pace and spread of these changes. In doing so, we can ensure the NHS leads the world in providing equality of access to consistent, high quality healthcare, seven days a week.'

Junior doctors 'feel clinically exposed and unsupported at weekends and hospital chief executives are worried about clinical cover,' Sir Bruce pointed out. 'It seems inefficient that, in many hospitals, expensive diagnostic machines and laboratory equipment are under-used at weekends, operating theatres lie fallow and clinics remain empty,' he added.

Without a doubt, as Sir Bruce underlined, the case for radical change has been both clinically and morally 'compelling'. ■

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Doctors are no longer exclusive healthcare professionals

Emerging and merging disciplines

Medicine as a profession has held a superior aloofness for many centuries, wary of losing its unique distinctiveness and esteem if 'tainted' with other professions. However, in recent decades the pressure of progress and whirlwind of change has swept the Hippocratic race off its professional Olympus. Today, medical people very much dwell among professionals in fields as old as theirs as well as alongside newly recognised disciplines. In a world where boundaries are scarce and mergers are the buzzword, integration has become the only way to exist, according to biomedical engineer **Carl Azzopardi**

The affiliation of the medical profession with that of engineering has brought a new dimension in the diagnostic power of the clinician in many fields. The two-dimensional limitation of the X-ray has exploded in the 3-D reality of MRI and 4-D ultrasonography, while open surgery and exploration has been replaced by the less invasive and thus safer endoscopic procedures.

In the latter field, biomedical engineering - now a new branch in both professions - has moved a step further with the introduction of capsule endoscopy, where the patient is relieved of a highly uncomfortable procedure, instead swallowing a capsule containing a minuscule camera that can capture up to 35 images per second. The capsule communicates wirelessly with a receiver, which the patient comfortably carries at home for about eight hours, after which the capsule is passed out and the clinician assesses the images.

The clinician can use many methods to process and classify the images - manually, which is obviously very laborious and time consuming, or using one of the many systems of artificial intelligence to facilitate the process. Professor of Engineering Kenneth Camilleri and engineer Carl Azzopardi, respectively the director and biomedical engineer at the Centre for Biomedical Cybernetics, University of Malta, recently launched software whereby the processing and classification of endoscopic images can be facilitated. 'The software can help the clinician in differentiating the mucosa of one gastrointestinal organ from another, thus classifying them and marking the valves (pylorus and ileocaecal) that are used for ori-



The capsule contains a minuscule camera that can impressively capture up to 35 images per second

entation,' Carl Azzopardi explains. 'With further adaptation, the software could eventually be made to go through the images automatically and pick up polyps, ulcers and tumours, if the right image features are detected and classified.'

This software is still in the research stages and, although preliminary studies look promising, there are still a number of teething issues with which to contend. 'One of the questions is how much the clinicians will trust the software and how much they will take responsibility for diagnosis,' Professor Camilleri points out. 'Ideally, the



Carl Azzopardi is a biomedical engineer at the Centre for Biomedical Cybernetics, specialising in clinical engineering, with a particular focus on medical imaging. He also heads the Biomedical Engineering Department at Saint James Hospital Group.



A typical set of capsule endoscopy images showing the small intestine. The small intestine walls exhibit a particularly yellowish-pink colour and a rough texture, arising from villi. These features are used to distinguish the images accordingly

software should be used as a diagnostic support and not replace the clinician's acumen.'

This is not the only project on which the Maltese team is embarking. Another research programme aims to process ultrasound images from a regular 2-D ultrasound probe, in order to collate them together and create three-dimensional representations of vascular anatomy in peripheral sites, such as the carotid or femoral artery. Currently, whilst 2-D ultrasound modalities are well established in clinical practice they are less effective than their counterparts, e.g. CT or MRI angiogra-

phy, especially when gauging low to moderate degrees of occlusions, where diffuse disease is present or where the patient suffers from cardiac arrhythmias,' the two engineers explain. 'Present 2-D ultrasound modalities are also not ideal for follow up studies, as 2-D imaging makes relocation difficult and is operator dependent.'

On the other hand, the team add that 3-D ultrasound probes themselves are very expensive and can only image a limited volume at a time, whereas present 3-D freehand techniques are qualitative at best, and have many artefacts.



Professor Kenneth P Camilleri directs the Centre for Biomedical Cybernetics and works extensively on the application of signal and image processing to biomedical engineering, with a particular interest in brain signal analysis and brain-computer interfacing

The project therefore aims to develop a hybrid combination of in-built position sensors and image processing techniques, to use normal, cheap 2-D probes to generate accurate and 'panoramic' 3-D models of vascular anatomy, enabling anatomical spatial relationships to be observed. The next step would then be to study novel means of quantifying the volume of atherosclerotic plaques, and to compare the diagnostic confidence of such a method with gold standards such as CT or MR angiography.

Capsule endoscopy and ultrasound imaging are both fields within biomedical imaging that are receiving much attention. In fact, there are similar research programmes at EU other universities that probe into different aspects of these topics.

At the University of Porto in Portugal, research is taking place on using structured learning methods for assessing Barrett's oesophagus using narrow band imaging in regular endoscopic techniques.

At the University Autònoma de Barcelona, researchers are using automated image processing techniques as a means to assess the intestinal motility of a patient using capsule endoscopy.

Meanwhile, at University College London, ultrasound imagery of the prostate is fused with 3-D MRI models to assist with pre-operative planning, whereas Cardiff University researchers are using 3-D Doppler ultrasound techniques to study neovascularisation in tendinopathy.

Shakespeare once asserted that, 'there is nothing so becomes a man as modest stillness and humility'. The 'sharing' of the interpretative and investigative acumen of the medical profession with that of engineering can be well seen as a catalyst in that sometimes hazy world of diagnosis where one deviation can spell nothing less than a human life.

KIMES 2014

Korea is Asia's fastest-growing medical technology market

Since opening as an exhibition in 1980, to stimulate the non-existing domestic medical device industry, the Korea International Medical & Hospital Equipment Show (KIMES) has developed to become one of the most important exhibitions for medical and healthcare industries in Northeast Asia.

In mid-March, when the 30th KIMES, organised by KOREA E & EX, Kmdica, and KMDIA drew more than 70,000 domestic buyers and 3,000 foreign buyers from 70 countries to Seoul, there was a notable rise in numbers from 2013 - when 68,203 visitors including 2,804 international buyers were registered.

Nearly 1,100 international medical firms - mostly medical equipment manufacturers - came from 38 countries including, the USA - 99, China -124, Germany - 77, Taiwan - 47, Japan - 68, Switzerland - 21, and Italy -19, to demonstrate over 30,000 medical, hospital and healthcare related products.

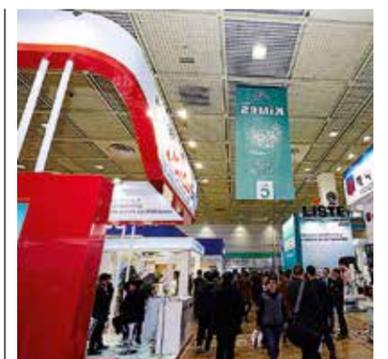
The range of exhibits at KIMES included consultation and diagnosis central supply, clinical examination, hospital accommodation, emergency equipment, radiology, medical information system, surgical apparatus, oriental medicine, cure apparatus, pharmaceutical, physiotherapy apparatus, obesity cure, healthcare, ophthalmic apparatus, medical device components, medical service, dental apparatus, disposable apparatus, and more.

During the four days, among almost 100 medical science and academic seminars and conferences were the International Radiologist Conference and the Seoul Physical Therapist Association Conference, as well as seminars on medical industry policies, medical staff, the industry and science, and a global trade conference.

The KIMES exhibition contributes significantly to exports as well to the export substitution effect in Korea. This year, KIMES is expected

to make KRW 1.6 trillion domestic consultations and \$510 million from export consultations.

KIMES has come a long way and continues to progress into global markets, paying attention to countries where medical industry development is further expected. A global network has been built up with overseas associations, related organisations, or KIMES' overseas agents in America, Europe, Southeast Asia, the Middle East and more.



Surgeon's suicide prompts a health and well-being programme

Burnout: The physicians' dangerous affliction

Burnout. The word jars – and it is particularly unsettling when associated with medical professionals. Burnout is a syndrome of emotional exhaustion, depersonalisation, and feelings of low personal accomplishment, Cynthia E Keen reports. 'When a physician is experiencing burnout, the health of patients may be affected.'

Nearly half of the physicians in the United States meet the criteria for professional burnout, according to Henry M Kuerer MD PhD, a professor of surgery with tenure in the Department of Surgical Oncology at the University of Texas MD Anderson Cancer Centre in Houston. The subject was this breast cancer surgeon's focus in March, when speaking at the 31st Miami Breast Cancer Conference.

Burnout symptoms include a lack of energy and focus on productivity; irritability and impatience; being



excessively cynical and critical, and not experiencing joy in life and work. Burnout is accompanied by a loss of professional satisfaction and loss of purpose. It may induce habits of excess in eating/not eating, excessive drinking, and/or use of drugs. All of these lead to decreased effectiveness at work.

In the USA, cancer surgeons face heavy workloads. By nature of their specialty, a percentage of the surgeries they perform will not have positive outcomes for their patients. In 2006, Dr Kuerer and colleagues decided to formally assess the extent of burnout within their field. They sent surveys to all members (over 1,500) of the Society of Surgical Oncology that evaluated demographic variables, practice characteristics, career satisfaction, symptoms of burnout, as well as quality of life.

36% of the members responded. Over half worked more than 60

hours per week and 24% reported that they performed more than 10 surgical operations weekly. Overall, 28% were experiencing burnout and 7% had symptoms of problematic alcohol use, Kuerer reported in the November 2007 issue of the *Annals of Surgical Oncology* (14:11, pp. 3043-3053). Two factors associated with a higher risk of burnout were being younger than 50 years of age and being a woman.

'Initially, I was surprised,' Dr Kuerer told *European Hospital* during our interview. 'But, after thinking about this, it made sense. Younger surgeons are just beginning to establish their careers. It can be quite difficult to establish oneself in academic research or with a solid solo practice. They may have had excellent and extensive training, but it's quite different to be on one's own. Confidence handling difficult cases increases with experience. Additionally, younger surgeons are

getting married and raising families. Women tend to assume the responsibilities of family life.'

Burnout is a taboo subject at some hospitals, but the MD Anderson Oncology Centre addressed it head on after a beloved surgeon unexpectedly committed suicide about 10 years ago. Dr Kuerer and Dr Thomas Buchholz, the hospital's current physician-in-chief, were among the founding members of the Faculty Health and Well Being programme. 'It took a devastating event for us to get momentum and resources to make this happen,' Dr Kuerer pointed out. 'The founding members represented different types of cancer experts, including behavioural psychologists. We worked hard to create a diversified, meaningful programme that MD Anderson staff would use and could trust.'

Services include confidential counselling and an ombudsman's



Dr Henry M Kuerer is a professor of surgery with tenure in the Department of Surgical Oncology at the University of Texas MD Anderson Cancer Centre in Houston. He also directs the Breast Surgical Oncology Fellowship Training Programme, which he helped to establish. Dr Kuerer maintains a busy clinical research programme, serves on the editorial board of several clinical journals, and has authored or co-authored more than 300 peer-reviewed scientific articles and textbook chapters. During national and international meetings, he is a frequent speaker on breast cancer surgery as well as burnout among physicians.

office to independently assess problems and provide advice. Peer-to-peer faculty coaching is emphasised. Seminars are held on such topics as recommendations for proper work-life balance, dealing with a highly stressful career and a disabled child or relative with Alzheimer's disease or being gay/lesbian/transgender. Physicians are taught techniques to communicate better with patients about terminal illness or unpleasant treatment choices. An on-site fitness centre has been opened.

'Surgical oncologists tend to be over-achievers, but they are not supermen or women. Burnout may be a taboo subject at their hospital. However, this should not stop them from seeking help. It is very important that we talk more about this subject, to encourage physicians to get help, make changes, and not jeopardise their mental and physical health and the careers they've worked so hard to achieve.'

THE CASIM CONFERENCE

Hospitals without boundaries – redefining healthcare management

With its next annual conference (11-12 June 2014) under the banner 'Boundary-less Hospital – Rethink and Redefine Health Care Management', the Centre for Advanced Studies in Management (CASIM) at HHL Leipzig Graduate School of Management reports its aim for an academic exchange on the challenges and opportunities in healthcare systems and for contributions from business economics to address them.

International keynote speakers on emerging healthcare trends, opportunities and challenges in the care sector in the 21st century, will include Dr Ulf Schneider of Fresenius and Dr Nicolaus Henke of McKinsey, and be followed by discussions on respective innovative strategic responses in the hospital sector and pharmaceutical industry.

On day two, the leading healthcare economics experts Professor Wilfried von Eiff of HHL; Professor Manfred Dietel from Charité and, medical experts Professor Michael Hallek from Cologne's University Hospital, Professor Christian E Elger at Bonn University Hospital, and Professor Friedrich-Wilhelm Mohr from the Leipzig Heart Centre, will elaborate on a vision of the future hospital.

Additionally, in two consecutive panels, future hospital characteristics and requirements will be discussed from business and healthcare economics perspectives.

Key aspects of the business economic panel are new chains of value creation, efficiency and quality management as well as electronic healthcare. By contrast, the medical panel will consider disease-specific requirements for effective and sustainable medical care systems. Finally, a panel discussion between leading healthcare decision-makers will critically reflect on the vision of and research findings on the future hospital unveiled earlier in the conference.

Details: hhl.de/casim-conference-2014

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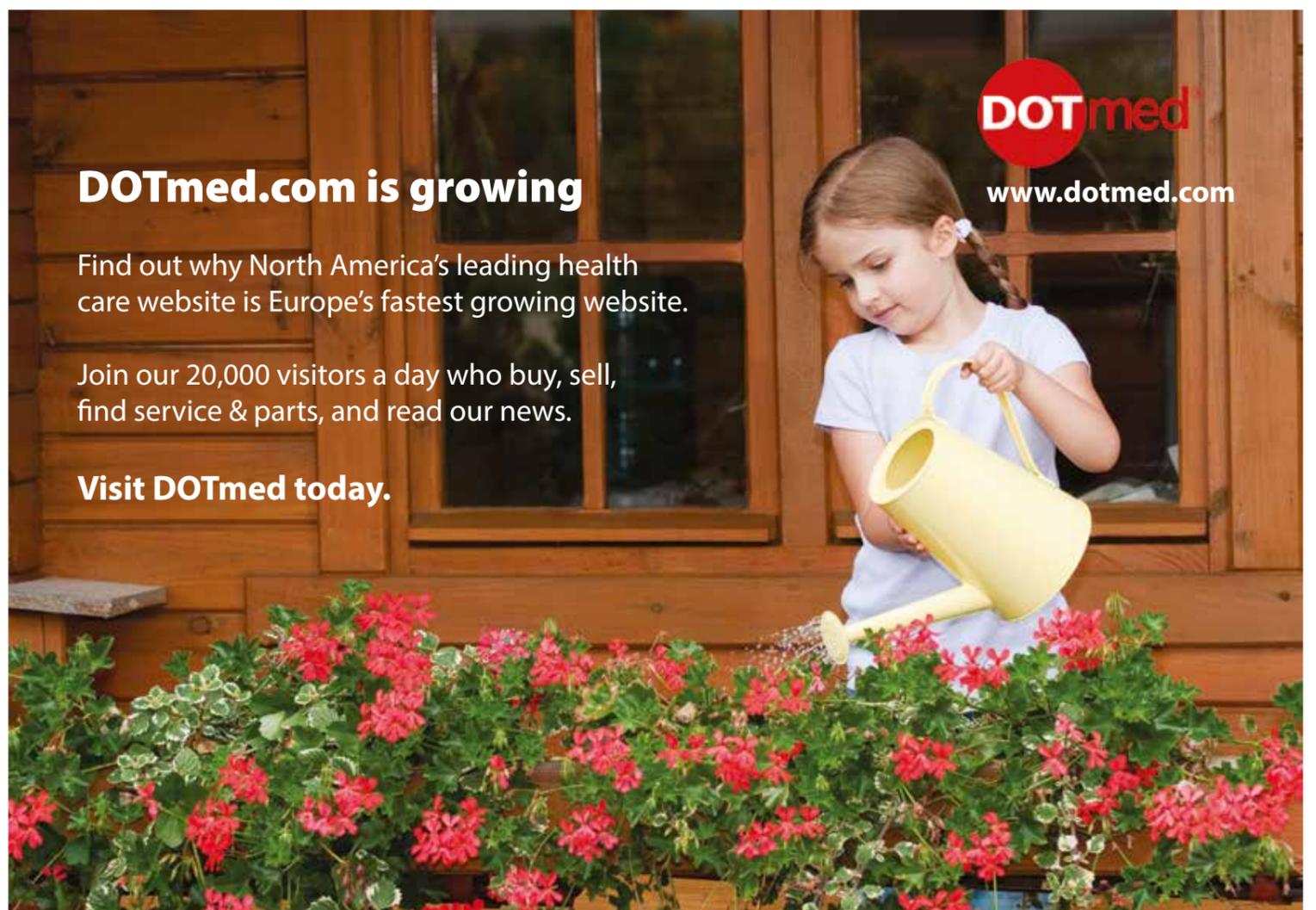
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'Helping to protect our most precious citizens, our children'

Amongst the historic churches and palazzos of the Northern Italian city of Parma lies the University of Parma, which, founded in the 12th Century is one of the oldest academic establishments in the world. The city is served by Parma University Hospital (Azienda Ospedaliero-Universitaria Di Parma) a large and renowned hospital offering 1,218 public beds.

In 2013 the Hospital completed the building of the 'Pietro Barilla' Children's Centre, the largest dedicated paediatric facility in the region (named after a revered Parma descendent and founder of the multinational Barilla Food Chain). Inside the building's ultra-modern façade (pictured) it provides 99 beds over a surface area of about 14,000m² divided between neonatal observation, Intensive neonatal care, intensive paediatric care and onco-haematologic outpatients.

Light, child-friendly rooms and large recreational areas provide a homely and reassuring environment for patients. The architecture and interior design, developed by Architect Sergio Beccarelli from Policreo S.r.l. and Associates, facilitate high efficiency medical procedures without appearing cold or unwelcoming; a successful example of the humanisation of healthcare architecture.

In 2012, the Children's Hospital issued a tender for a comprehensive patient monitoring system based on patient-driven medical care. The devices needed to provide high-speed communication capability, prompt failure recovery, 24/7 monitoring and be operation-



Mindray equipped the Pietro Barilla Children's Hospital in Parma with its comprehensive patient monitoring system.

al over numerous clinical applications throughout many medical departments and across a variety of points of care. Engineer Ennio Amori, Director of the Medical & IT Technologies Department at the site, helped to conduct a preparatory Health Technology Assessment (HTA) as a preliminary part of the bid selection procedure. Amori and his technical working group considered architectural issues such as performance, reliability, manoeuvrability, user-friendliness, stability, scalability and interoperability. On the purchasing side, warranty, competence, maintenance support, software and IT support, proactive com-

munication and overall cost balance were part of the bid selection procedure, evaluated by an Official Public Commission. Professor Giancarlo Izzi, Paediatrician and Director of the Children's Oncohaematology Facility also participated in selecting the type of patients needing monitoring and assessing the ability for system integration with the hospital's HIS/ADT/EMR and PACS networks. The networking capacity was also considered to assess if the patient monitors could be run from separate or shared network and use digital telemetry or wireless communication (WiFi).

Ennio Amori said, 'After the offi-

cial award of contract to the successful tender, Mindray thoroughly analysed the clinical and spatial scenarios and discussed the various possibilities with clinical and nursing end users and clinical engineering personnel. These discussions helped shape a very detailed proposal of the architectural layout covering the Neonatal Intensive Care Unit (NICU) and the surgical department, the isolation ward for contagious diseases and the onco-haematology department.'

Around 60-70 sets of Mindray's BeneView T1, T5 and T8 patient monitors were chosen to equip the Children's Hospital. The BeneView T1 monitor was selected for the Children's General Ward for its small size, portability and comprehensive

patient monitoring information. As a module, the T1 connects to the BeneView bedside patient monitor and can be quickly unplugged to follow and monitor the patient throughout transport and points of care. Thus, BeneView T1 offers seamless data transfer and guarantees the continuity of monitoring information. Multiple monitoring parameters are handled by the T1 including ECG diagnosis, respiratory care, non-invasive blood pressure, oxygen saturation, body temperature, heart rate and other basic parameters.

When connected wirelessly to the Hypervisor VI central monitoring system, all information from BeneView T1 can be viewed from the nurse station, or from any bedside monitor in the network. What is more, there is a TV screen in every ward at the Parma Children's Hospital, allowing children to watch their favourite TV programmes. However, when the doctors come in during a regular ward round, the cartoon will shift to the information from T1, so the doctors can have a clearer view of patient monitoring parameters from the big screen.

Ennio Amori: 'In our eyes, the bidding medical equipment suppliers are meant to act as consultants and partners and not mere equipment providers. We now consider Mindray such a valuable partner, advising us on appropriate monitoring devices for each application, providing the hospital with comprehensive training and support and answering the needs of our tender perfectly.'

Nicola Pagliarulo, General Manager of Mindray Medical Italy added, 'We are particularly proud of our patient monitoring solution at Parma Children's Hospital. There's nothing more satisfying than seeing how Mindray technologies provide life-saving support for even the most fragile and vulnerable newborns at Parma. I can safely say that this is the most gratifying and heart-warming part of my job.'



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Robust R&D and

There are five big names in ultrasound that sell three out of four systems. Then there is Esaote, the biggest name among hundreds of small companies competing for a place in what is by far the largest, and most innovative market for medical imaging.

After joining Esaote last year as CEO, Carlos Alonso studied this landscape dominated by giants and came away smiling with a plan for moving the company and its 1,360 employees forward.

'The big opportunity that the big name companies are giving to us is the customer, which more and more is becoming just a number for these big conglomerates. For us, customers are the centre of our strategy,' he said.

That has not always been the case, according to his analysis. New products and technology have been the main focus with one-in-five people at the company working in research and development. Esaote can proudly claim to hold 120 international patents and the success of its products speaks for itself, earning annual sales of €325.3 million worldwide. Major research centres



CEO Carlos Alonso joined Esaote last year and wants to move the company forward.

are found in Italy, the Netherlands and China while Esaote works with dozens of universities and hospitals in scientific and clinical collaborations.

Alonso notes that another strength of the company is a strong entrepreneurial culture that has expanded the business into dedicated MRI scanners and healthcare IT systems to manage the data. Deals and partnerships have also expanded the company's footprint to where 70% of sales are generated in international markets.

Samsung Medison

Only the sky's the limit for future healthcare devices

About four years ago, Samsung Electronics Co. – specialist in electronic components and mobile phone sets, was recognised by its revenues as the world's largest IT company, displacing Apple Inc. In 2010, as part of an ambitious ten-year development plan, Samsung bought a majority stake (43.5%) in another South Korean firm – Medison, the well-known manufacturer of ultrasound equipment. At the time, Samsung stated that the ultrasound diagnostics device segment was a 'logical entry point into the healthcare equipment market' due to 'technological similarities and potential synergies' with its existing electronics, IT products and technologies. Samsung also forecast that, by 2020, it would invest 1.2 trillion from the healthcare business to generate 10 trillion in revenue. A month later, in June 2010, the firm launched its first healthcare product, a portable blood test kit. Subsequently, how has the Samsung bond affected Medison, Daniela Zimmermann asked Wayne Spittle, Executive Vice President for Samsung Medison

Interview: Daniela Zimmermann

'It's 70 years young and a very big company,' Wayne Spittle Executive Vice-President of Samsung Medison emphasises, before adding startling back-up figures: 'Samsung is 20% of the GDP of Korea. Twenty-two percent of the total export capability of Korea is Samsung. If you drive from the airport, there's a large bridge on the right, 21 kilometres long, built by Samsung.'

'The Samsung Medical Centre has over 2,000 beds and sees close to two million out-patients per year. You see, Samsung not only manufactures healthcare equipment but also builds hospitals. We are actually building hospitals in Saudi Arabia and Singapore, for example, and looking at ways to vertically integrate solutions through great design.'

'Healthcare solutions are not only the equipment, but also the building and its construction. Samsung's design is modular. By building in modules we actually can cut costs by, for example, energy-efficiency; putting in LED lighting can become quite significant: 90% less heat, so air conditioning requirements are even less. You can build in environmental management.'

'By putting all these modular tech-



Wayne Spittle, Executive Vice President for Samsung Medison

nologies together, you end up with a green and more efficient hospital,' he underlines.

'Then we have software solutions to connect electronic medical records (EMR) to mobile devices. We do this with our diagnostic imaging – with pathology results. The results from an IVD (in vitro diagnostic) test can be sent via a mobile phone, via an SMS, or pushed into the EMR. All these results come together for clinicians to make a differential diagnosis.'

Samsung's solutions are already used beyond hospitals, e.g. in Scotland where some people live

2.5 hours away from a hospital. 'They have chest pain, call an ambulance, and blood tests can be done in the ambulance to determine if the patient has had a myocardial infarct with results transmitted to the hospital. Those 2.5 hours can save a life,' the Vice President points out. 'A lot of our features – connectivity, automatically sending results by SMS, using time spent in an ambulance – these are new ways to address healthcare needs. We're looking at different markets from a different perspective.'

'Many companies have stayed with their traditional view, and they go after traditional markets. We look at healthcare and see new opportunities. The IVD market is going to grow immensely, because 70% of people in hospital are chronic disease sufferers and need to be monitored outside the hospital.'

This is being done in big markets, he explains. In Italy, for example, Samsung is working with pharmacies for IVD testing. A doctor writes a prescription; the patient takes it to a pharmacist who has the tests, and full blood tests and work ups are produced. 'In the UAE,' he adds, 'the problem for IVD tests is the heat. We're working on a programme in collaboration with the Ministry of

Health. If a blood sample is taken and transported, the heat can affect the sample. Instead, we are setting up a mobile IVD system, connected so that patients can be tested at home and the test results go straight into their medical records.'

Imaging

Last January saw another big step in the expansion of Samsung's medical imaging business plan – the acquisition by subsidiary Samsung Electronics America Inc. of the Boston-based firm Neurologica. Founded a decade ago, the latter

develops medical imaging products, including portable computed tomography (CT) scanners, e.g. BodyTom and CereTom. 'Neurologica gave us a foundation to build on,' Wayne Spittle explains. 'So, we're building a very innovative CT, an innovation that will take us through the next level.'

'The acceleration is just beginning. Medical imaging is not like the mobile phone market, or the TV market, where new models are

Continued on page 8

COMPANIES: ESAOTE

120 international patents

Building on these strengths, Alonso has outlined strategies for a renewed, agile Esaote that will expand strongly to win more customers in more markets.

'Esaote is going to grow from portfolio optimisation,' he said, revisiting the product pipeline, identifying gaps and creating a complete offer for global markets.

'We want to have a full portfolio with portables, with tablets, with systems from low to premium. Today I have gaps in my ultrasound portfolio for premium systems, which gives you a clue of where I would go if we were to make an acquisition,' said Alonso.

'Ultrasound and dedicated MRI with healthcare IT, that's it for Esaote,' he said, adding, 'You'll never see this company going to CT or to big MRIs.'

'In a next step we need to be sure images integrate with our healthcare IT systems for analysis, for diagnosis and good clinical decisions. Then we go to the next step, which is interventional products where we are very good, with technologies for planning, for image guidance and navigating, and for image fusion.'

Here is another clue. In interventional systems we are only using laser as the ablation technology. There are other technologies, radio frequency, microwave,' he said.

Face to face with customers

Another area of focus is sales and marketing effectiveness, he added, with robust go-to-market models. Which leads to his third strategic area, geographic expansion by increasing the local presence for Esaote with its distributors.

'I need everyone at Esaote to be focused on these three different strategies with the customer at the centre,' he said, products that respond to customer needs, distribution channels that reach more customers, and what he called an on-the-ground presence to bring the company face-to-face with its customers.

'The end-user of our products is the real customer. We need to focus on them, visit them. We need the endorsement of key opinion leaders, working with doctors who are satisfied customers.'

China, which has become the second largest market for Esaote after

its native Italy, provides a case study for how this renewed local strategy will play out, he said: 'We hold the fourth market share position there. The challenge is how we continue to grow and maintain our market position. We plan to increase our penetration in the provincial and regional hospitals and later in very small, local clinics/practices.'

'This is what we have in Russia, what we call front-end people, who have the relationships and customer information. People on-the-ground means we are looking at a market through our own eyes,' Alonso pointed out. 'It means we can sometimes help to organise the distribution lines for a single distributor, among different distributors, or even selling direct at times. This always increases sales.'

'This year our priority is to create this on-the-ground presence in Scandinavia, Australia and New Zealand, and Mexico. Next year we will add three more.'

'This way, with a clear value proposition, with a clear strategy, Esaote will continue expanding internationally,' the company's CEO concluded, with palpable confidence. ■

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Striding onto the world stage

Asian firm, Neusoft, brings a full portfolio of equipment and software

Even a giant must learn to walk by taking small steps first. Founded in 1998, and as a wholly-owned subsidiary of Neusoft Corporation, Neusoft Medical has moved deliberately to build its strengths, becoming the premier developer and manufacturer of advanced medical equipment in China – and the first in that country capable of building a computed tomography (CT) scanner.

With strong roots in software development, Neusoft Medical also collaborated with Philips in a joint venture to design and build high quality medical equipment for the global market.

Neusoft Medical then began to take giant steps, combining its own strengths in research and development, software development and system integration in collaboration with top medical institutes and academic institutions.

In 2013 Neusoft Medical and Philips shook hands in a friendly agreement to end their joint venture, so that each company could continue growing at its own pace. With more flexibility and momentum for innovation, the Chinese firm will stick to an active product strategy to enrich product lines, including CT products, and to further accelerate its expansion in the global market, especially in those fast-growing emerging markets.

'Our goal is to become a leading medical equipment manufacturer globally while reaching the greatest possible market share in China,' Jiang Genmiao, President of Neusoft Medical, explained during an exclusive interview with *European Hospital* at CMEF in Shenzhen. 'Internationally we will expand support for sales and service where we already have established subsidiaries in the United States, United Arab Emirates, Peru and Vietnam. This year we are starting similar efforts to



Jiang Genmiao, President of Neusoft Medical of China

establish subsidiaries in Russia,' the company's president revealed.

'Our approach is to deliver high value and high performance, and we are a company that can deliver both! For Neusoft Medical, quality is the way we win business. We will increase sales volume by assuring a high level of customer satisfaction. Customers look beyond the initial purchase price by also considering the on-going maintenance costs. This is why our focus is on quality and performance that delivers value to customers. Thanks to our strengths for innovation in software development, we can also continue to add value for our customers by continually bringing new functions to the purchased equipment. We are committed to continuous innovation and investment, both for enhancing existing products and for introducing new products.'

Among its offerings Neusoft Medical has also developed computer assisted detection and diagnosis (CAD) software that includes UroCARE, MammoCAD, OsteoCARE, CardioCARE, CT Perfusion, NeuLungCARE and NeuColonCARE. ■

Underway: The Eurosafe Imaging Campaign

EU radiation exposure rate rises ca. 50% in two decades

It was long overdue: Seven years after the arrival of the USA's Image Wisely and Image Gently Campaigns, a European campaign for greater radiation protection in diagnostic and interventional imaging has arrived.

Initiated by ESR President Guy Frija, and launched at the 2014 European Radiology Congress (ECR), the Eurosafe Imaging Campaign seeks appropriateness in medical imaging, optimisation of radiation doses based on diagnostic reference levels and the ALARA principle for further dose reduction without loss of image quality, and more.

Imaging diagnostics exams increase annually. In 2008, 3.6 billion exams with ionising radiation were performed worldwide. Statistics show the EU radiation exposure rate per head has almost doubled in two decades, mainly due to CT exam increases.

The European campaign aims to cooperate with specialist associations, lobbies, the healthcare industry and others, to improve patient safety and achieve a wide coverage. Poster presentations at the launch showed efforts towards better radiation protection (appropriately in the M-Building at the UN Office, close to the International Atomic Energy Agency (IAEA) area). Organisations focusing on child safety during CT exams presented numerous posters; the industry posted only five. Is radiation protection still in its infancy for this group?

Izabella Dantas, Global Marketing Director of Unfors RaySafe, calls for more industry support: 'The Eurosafe Imaging Campaign offers the optimal framework for better promotion of the subject of radiation protection and improved safety in the X-ray examination room. Unfors RaySafe did not hesitate in joining this campaign as changes in behaviour and awareness can only be achieved with joint forces.'

This Swedish firm (acquired in February 2014 by Fluke Biomedical) is among market leaders in radiation protection. Its CEO, Magnus Kristoferson, is proud of its campaign support: 'It fits perfectly with our company's philosophy'. Unfors RaySafe measurement devices ensure diagnostic X-ray machines work according to regulations and radiation doses are set correctly. In



RaySafe's i2 is integrated with Philips Allura Clarity System's monitor so that, when only glancing at the data, staff can track dose exposure in real time

2012 the firm launched its RaySafe i2 solution for real-time dosimetry for medical staff and, in 2013, with RaySafe S1 software for dose tracking in patients. 'All three business segments are equally important,' Izabella Dantas points out. 'However, we're currently seeing a gradual sensitisation among the public regarding radiation protection for patients and medical staff. Public awareness is increasing due to the increase in radiation exposure.'

RaySafe S1 offers an easy to integrate, software solution that records when and where a patient was exposed to radiation and at what level, thus preventing repeat exams far more effectively. It also helps to query the indication for an examination and show alternatives. Dantas: 'When a doctor requests an examination, the software offers a comprehensive decision aid, based on detailed patient data and also diagnostic reference levels,' she says. 'The software therefore offers safety and transparency – important for patients as well as the hospital because, if a department does not work as it should, that becomes apparent at this stage and can stim-

ulate further thought as to how standards can comply with going forward. The use of RaySafe S1 facilitates individual dose optimisation for each patient and therefore an increase in productivity for the entire hospital.'

Staff protection is the third part of the solution for radiation protection. With RaySafe i2 their radiation exposure is tracked in real-time and they can act, e.g. use an additional protective shield or change position in the room. 'The wearing of a second, active dosimeter over protective clothing is specifically recommended by the IAEA. Philips equipment for cardiovascular intervention already integrates real-time dosimetry in the system and Siemens Healthcare now offers integrated real-time dosimetry for selected X-ray systems. Obviously, Unfors RaySafe wishes to achieve such integration with all industry partners to ensure real-time dosimetry becomes an industry standard,' Dantas says.

The campaign will expand its scope and make E-learning, criteria for safe radiological examinations and further radiation protection sessions available at congresses. The ECR's Dedicated Radiation Protection session was packed. CEO Kristoferson: 'I had trouble getting in – no free seats were left. This initiative has met with more response than the organisers imagined in their wildest dreams.'

Details: <http://www.eurosafeimaging.org/>
<http://raysafe.com/>



Izabella Dantas

Magnus Kristoferson

Only the sky's limit for future healthcare

continued from page 7

introduced. We want to introduce a model that builds on solid innovation and quality. My role, especially, is to ensure we have the building blocks that meet market requirements. It is a good strategy.'

Asked whether those building blocks need to be bought, the VP points out that no company is currently under review, but quickly adds: 'We're open to good opportunities. I think a lot of opportunities for further innovation through collaboration also make sense.'

Ultrasound

Samsung Medison had forecast its introduction of a high-end premium ultrasound system; nothing has yet been seen. 'We've just released the UGEO RS80A,' Wayne Spittle coun-

ters. 'That's the high-end system. It's awaiting marketing clearance and with that, perhaps in a few months, we'll officially launch it.'

'It's absolutely fantastic, creating a paradigm shift in many areas, for example, how we actually do ultrasound beamforming. Traditionally this has been very hardware driven. We are increasingly doing synthetic beamforming, using software to do a hybrid beamforming. This technology allows us to adapt and do things very much faster. On the new system, hybrid beamforming is allowing higher frame rates. In the beamformer, you have a bandwidth of transmitted signals. We can transmit in one bandwidth and also receive in another bandwidth. We're doing some very innovative things

in ultrasound,' he confirms.

'In September, or October, we'll release a second version with fusion, initially with MRI. Through software we've created some unique features. The best example is a breast imaging capability that automatically traces the breast lesion and predicts the BI-RAD score. It looks at the texture and outline. It's an assistant for detection, not a diagnosis.'

As a next step, Samsung is working on 3-D volume and, he adds, 'We feel very excited about the potential to develop MRI. Once again, we will use innovation to create something unique but, from Samsung, short-term will be CT, mid-term is MRI and, in the long-term,' Wayne Spittle comfortably foresees, 'the sky's the limit.'

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Oocyte modification

Aiming to eliminate inherited mitochondrial defects

Report: Cynthia E. Keen

USA - Oocyte modification to eliminate inherited mitochondrial defects in a human embryo was the subject of a globally scrutinised Food and Drug Administration (FDA) hearing held in February. This coincided with the opening on 27 February of a three-month public comment period by the UK Department of Health on draft legislation that would legalise this research in the United Kingdom.

One type of oocyte modification, in which an oocyte that carries a mitochondrial disease from the mother is 'repaired' yet still carries the other genetic information from the original mother and father – has been colloquially called 'three-parent' in vitro fertilisation (IVF).

This is a process in which the nuclear genome of a woman who carries mutations in her mitochondrial DNA (not located in the nucleus, but rather in the cytoplasm) is inserted into a donor egg from a healthy woman whose nucleus has been removed but which carries normal mitochondrial DNA in the cytoplasm.

It is then fertilised with sperm from the father. The defective mitochondria, which float outside the nucleus in the egg's cytoplasm, are left behind. The fertilised human embryo would then be placed inside the mother's uterus and a child would be born with all of the characteristics of its parents but free of mitochondrial defects.

Inherited mitochondrial defects,



Dr Evan Y Snyder is a professor at the Sanford-Burnham Medical Research Institute in La Jolla, California, where he directs the Centre for Stem Cell Biology & Regenerative Medicine as well as the institute's Stem Cell Research Centre and Core Facility. Additionally, he is a professor and faculty physician at the University of California-San Diego's Department of Paediatrics and its Biomedical Sciences Graduate Programme. Dr Snyder chairs the Cellular, Tissue and Gene Therapies Advisory Committee of the USA's Food and Drug Administration. He has also authored/co-authored over 170 articles published in peer-reviewed journals.

which occur in one in every 5,000 births, are devastating. Mitochondrial diseases usually affect tissues that are highly dependent on energy, such as the brain, heart, and muscles. Severe clinical problems include neurological damage, heart failure, or blindness. Premature death before adulthood is common.

Shoukhrat Mitalipov, a senior scientist in the Division of Reproductive & Developmental Sciences of the Oregon National Primate Research Centre at Oregon Health and Science University in

Beaverton, developed a means of performing oocyte modification on the eggs of primates and eliminating mitochondrial DNA mutations in the offspring. After conducting successful preclinical trials with these laboratory primates, he contacted the FDA to ask what would be required to receive authorisation for a clinical trial in humans.

That is why the hearings were held. Dr Evan Y Snyder MD FAAP, Professor and Director of the Centre for Stem Cells and Regenerative Medicine at Sanford-Burnham Medical Research Institute, La Jolla, Professor in the Department of Paediatrics at University of California-San Diego, and chair of the Federal Drugs Administration Cellular, Tissue, and Gene Therapies Advisory Committee told European Hospital that the FDA had not received such a request before.

The FDA then instructed the committee to hold public hearings to consider scientific, technologic, and clinical issues relating to genetic modification of human eggs and embryos.

Specific topics for discussion:

- the animal and in vitro studies that would be necessary to support the safety and prospect of benefit of mitochondrial manipulation technologies before human clinical trials could be initiated;
- design considerations, controls, and benchmarks for such clinical trials if and when they were ever to be initiated, and

- the risks for study participants and any children born from the studies.

The hearing was not intended to address issues of ethics, public health, or public policy. However, the world's media and individuals and organisations concerned about the ethics of human genetic modification immediately focused on the possibility of FDA approval of 'designer babies'.

'What the committee determined was that the technical advances that Dr Mitalipov made were an impressive tour de force. His research shows much promise in the ability to eliminate the risk of mitochondrial disease in children borne by a woman with mitochondrial gene mutations. Mitochondrial diseases are horrible and incurable,' Dr Snyder said.

'However, we did not believe that the preclinical data-to-date supported the initiation of clinical trials at this time. We formulated the content and structure of what we believed would constitute the most informative and rigorous preclinical studies, as well as what would constitute the most reassuring and rigorous clinical studies – but, all of this, at present, is hypothetical. My colleagues and I on the Advisory Committee felt, by and large, that there was a lot more pre-clinical research needed before a clinical study should be considered by the FDA.'

Dr Snyder estimates that this will take at least another five years of work. The committee had too many unanswered questions, and the majority of its members did not feel that the laboratory monkeys in the preclinical research had been followed long enough, through enough generations. 'There were too many unknowns. What organs would be affected? Could gene manipulations be transferred across generations? Should the treatments, therefore, be limited only to male offspring in preclinical and clinical trials, or

would critical knowledge, including benefits, be obtained from also examining female offspring? Would there be unintended consequences on brain and other organ development. Would unknown health problems materialise as the primates aged?' Although very impressed by Dr Mitalipov's research, the recommendation to the FDA was for much more pre-clinical research.

At that point, will the FDA need to tackle the question of ethics and public policy? Probably so. Will the hearings have a positive impact on research in the United Kingdom? Current regulations set by the Human Fertilisation and Embryology Act (HFEA) 1990 only permit eggs and embryos that have not had their nuclear or mitochondrial DNA altered to be used for treatment. The act does allow for additional regulations to be passed by Parliament that would allow DNA modifications of an egg or embryo to prevent the transmission of serious mitochondrial diseases.

The public comment period about draft legislation is an important step for the UK's Department of Health to take.

Dr Doug Turnbull, is a professor of neurology and director of a \$5.8m centre for mitochondrial research established by the Wellcome Trust in January 2012. He is Professor of Reproductive Biology. Dr Mary Herbert heads the research team that has been developing pioneering IVF techniques using abnormally fertilised zygotes, which they believe are viable options for humans. They are hopeful that members of Parliament will pass the legislation needed to continue their research.

The UK's Nuffield Council on Bioethics June 2012 report recommended that 'if these novel techniques are adequately proven to be acceptably safe and effective treatments, it would be ethical for families to use them'. Families with children with these horrific defects undoubtedly concur. ■

Focus: How to develop and implement portable lab technologies

THE AACC FORUM

This April, in San Jose, California, the portable lab took central stage at the American Association for Clinical Chemistry's (AACC) annual forum for emerging clinical diagnostic technologies – a most appropriate topic for the Silicon Valley venue where so many world-changing computer and communications innovations have been born, *Cynthia E Keen reports.*

Known as the Oak Ridge Conference for 45 years, the renamed forum still focuses exclusively on pre-commercial technologies identified by AACC as having commercial potential and be used in clinical labs within five years. It attracts technology-oriented scientists, engineers, computer software gurus, academic researchers, laboratory executives, vendor representatives, and venture capitalists.

The keynote speaker was from Micronics, developer of 'near patient' IVD products for disease diagnosis and treatment monitoring, with technology based on microfluidics (the ability to substantially reduce sample and reagent volumes and process all assay steps within closed-system disposable devices). Company president Karen Hedline explained how a point-of-care (POC) company evolved from R&D to its commercial launch of a single use, disposable blood typing device, and its acquisition by Sony.

Among discussions were temporary human tattoos that contain novel potentiometric and amperometric biosensors, POC breath testing for biomarkers of human disease, and DNA amplification devices for



Jason Y Park PhD directs the Advanced Diagnostics Laboratory at Children's Medical Centre and is assistant professor of pathology at UT Southwestern Medical Centre, Texas

infectious disease diagnosis, DNA sequencing, nanotechnology etc.

The smart phone revolution

Forum organiser Dr Jason Y Park spoke with European Hospital about smartphone technologies are revolutionising portable lab testing.

For the last 30-40 years, new point-of-care (POC) products have made clinical testing more accessible to patients at clinics, doctor's offices, or at home. Non-prescription pregnancy tests are an excellent example. 'Remarkably, within the last two or three years key components of many modern lab diagnostic equipment are electronic, having a computer processor or sensor,' he said. 'Contained in smartphones, they have powerful common Apple or Android platforms. I predict an

explosion of devices for lab diagnoses utilising smartphones. They will become the hub for multiple analytic devices that use their optical and communication capabilities.

The evolution of new technologies will feed off one another, he said. 'ElectroZyme, a start-up company founded by two biomedical engineers in 2012, has developed a proprietary platform sensor technology in the form of a temporary tattoo, used to analyse chemical constituents of sweat and electrolyte levels in real-time. The tattoos are being designed to send signals and measurements to a smartphone, to upload this information to the cloud for retrieval and analysis by a clinical laboratory. This technology has the potential to enhance the performance of athletes,' he explained.

Since the USA's FDA issued guidelines for mobile medical apps in 2013, a relevant session on government regulatory issues was presented by a Washington D.C. specialist.

Dr Park ends: 'The portable lab will expand affordable clinical lab services in ways we can't even imagine, with tremendous impact on improving healthcare quality.' ■

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Danes take pathology software wo

Easing the overwhelming *in vitro* diagnostics burden

Report: Brigitte Dinkloh
and John Brosky

Having convinced medical labs across Denmark that its suite of image analysis software can provide a solution to the crushing burden of *in vitro* diagnostics (IVD), VisioPharm is offering it to pathologists worldwide.

The problem is clearly visible: the increasing number of diagnostic

tests for an ever-greater number of patients, but with fewer and fewer pathologists to review and report on test results. In Denmark, for example, 200 pathologists serve a population of five million. Across the bridge, Sweden also has 200 pathologists but 10 million people.

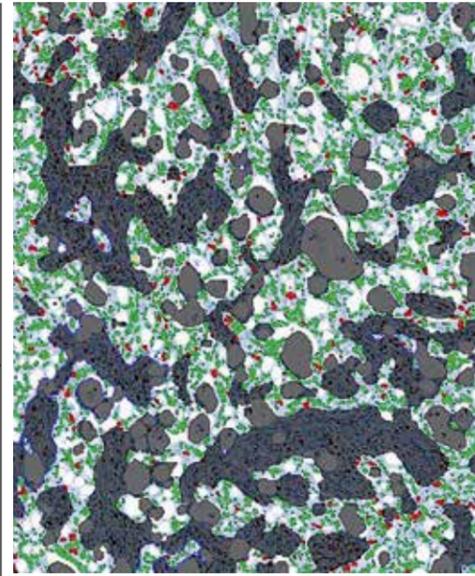
Looking inside the laboratories, the situation becomes even more complicated, according to



Dr Michael Grunkin, founder and managing director of VisioPharm

VisioPharm's founder and CEO, Dr Michael Grunkin. 'There are two major difficulties for pathologists, one has to do with data quality and the other with costs and the turnaround time for any kind of IVD,' he explained.

'All over the world there is a consolidation of resources for pathology. Budgets are being cut constantly. Yet, there is a need to increase the capacity for patient throughput and reduce the cost per patient – all of



The Virtual Double Staining (VDS) breast cancer application highlights the difference between tumour and stroma. In this image the stromal cells are positive and negative cells are automatically identified and the software is computing the labelling index

this while maintaining, or improving, data quality.

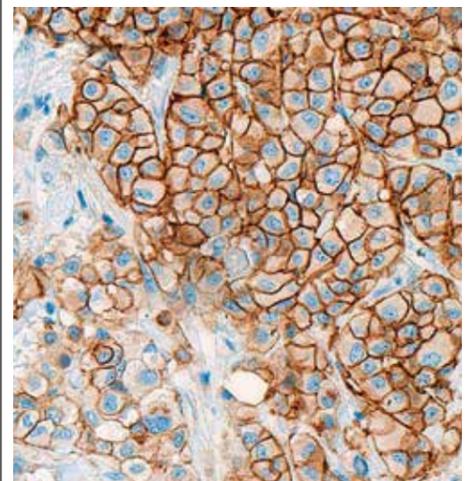
'Data quality is a huge problem, both for the reproducibility and the diagnostic accuracy of results of tests. One of our partners, working with 400 pathology labs worldwide, did a quantitative study showing there is a tremendous variation between pathologists, as well as variability between pathology labs. As a patient this means that if you go to two different pathology labs the treatment decision could be completely different simply because of this variability.'

More tumour panels will be launched as soon as 2015

'These are the problems we set out to solve and we have been able to improve the reproducibility of results significantly. Our software saves time, improves testing and improves reproducibility. It's better, faster, cheaper, and we have massive amounts of clinical data to support this,' Dr Grunkin emphasised.

Developed and refined over 12 years and featured in over 450 scientific publications, up to now, VisioPharm has deployed more than 350 of its digital pathology systems worldwide.

Thanks to advances in scanners and the processing power of computers, specimen slides can now be digitised and automatically read with the results fed into a data system for a more standardised interpretation by pathologists.



The first image shows the original image of a breast cancer IHC Pathway stain. The second shows the detected HER2 protein expression. The HER2-CONNECT quantifies the HER2 protein expression. This method is optimised wrt HER2 gene expression, and has been validated wrt gene amplification. In a multicentre study, significant sensitivity/specificity has been demonstrated, leading to

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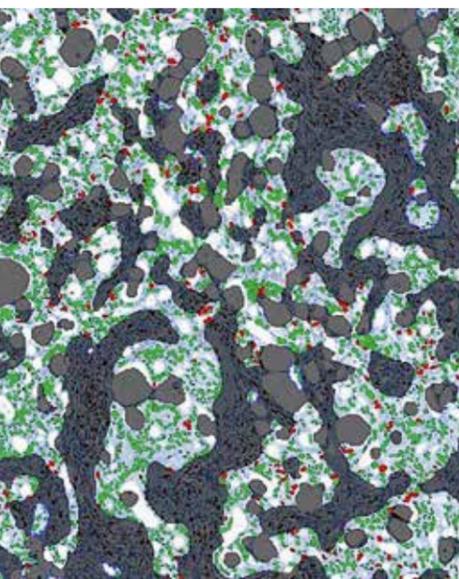
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Worldwide



tion is a novel method for automated discrimination of tumour regions (red and green cells respectively) and used in

Now VisioPharm is bringing these same advantages to standardise the results of Immuno-histochemistry from IVD tests to deliver results faster and at lower cost.

'This means we can automate certain steps in the diagnostic workflows to the point that non-pathologists may be able to perform technical aspects of testing and analysis and then pass these results to the pathologist for review. This becomes very important because it allows clinical labs to efficiently utilise their pathology resources,' explained Dr Grunkin.

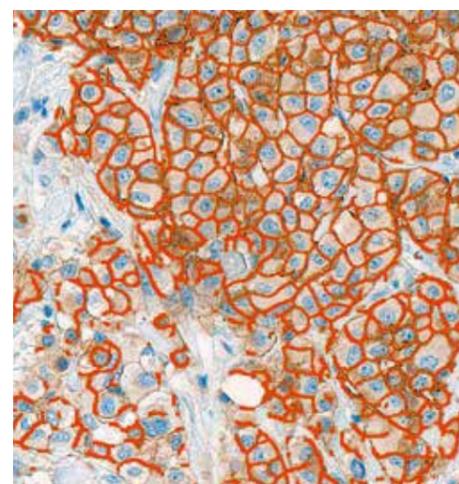
'For our first release we've focused on IVD tests used for breast cancer. We will have other tumour panels as soon as next year, probably for malignant melanoma, or skin cancer, and after that for gastro-intestinal cancer and prostate cancer.'

Studies to validate time-savings for pathologists

The VisioPharm CE-IVD diagnostic image analysis software for breast cancer was granted the CE Mark of approval in 2013.

Currently the company is conducting a multi-centre evaluation study to document the quality of the data generated automatically, and also to validate the time-savings for pathologists.

Centres participating in the study are located in Sweden, Norway, Switzerland, Ireland, Germany and the United States. Preliminary results are due by the end of 2014.



cancer biopsy stained with the Roche-Ventana HER2-membranes. This classification based on membrane morphology alone. The study has demonstrated a very high sensitivity and specificity with significant reductions in 2+ classification without loss of accuracy. This leads to cost savings in reflex testing.

Virtual microscopy at Charité's Institute of Pathology

CLICK – and tumour growth is known in seconds

Ten slides are scanned – digitised – per day at Charité University Hospital in Berlin. Although this number is negligible compared to the 1,000 to 2,000 slides analysed every day under a conventional microscope, Professor Manfred Dietel, Director of the Institute of Pathology at Charité, believes that scanning slides and working with digital images will gain importance over the next few years, Bettina Döbereiner reports.

Some years ago telepathology – a complex but well developed procedure where histology specimens are photographed using a camera mounted on a microscope and transmitted – was thought to be the wave of the future.

Enter digital pathology, and telepathology was virtually doomed. At Charité this happened six years ago, and today six slide scanners support the pathologists in their daily work.

The scanner provides 20x magnification and, while in a next step another 40x to 60x magnification may be generated, 20x is entirely sufficient, Professor Manfred Dietel explains: 'This has proven to be ideal for our purposes.' Scanning a slide takes between two and ten minutes depending on resolution and size.

The digitised slides – which average a five to six gigabyte volume – are stored centrally at Charité. To enable colleagues around the world to access the slide data easily on the Charité servers, the Institute of Pathology team developed a dedicated streaming procedure based on NASA technology, which does not transmit the entire huge data volume but only those sections on which the external viewer is currently working.

Another in-house development is tumour board software that facilitates many procedures and workflows*, such as jumping back and forth between stained slides. Sections can be selected so that the corresponding areas are shown when the stains change. Even more important from the pathologist's point of view are the software's quantification functions that allow determination of important

prognostic factors by a mouse click and within seconds.

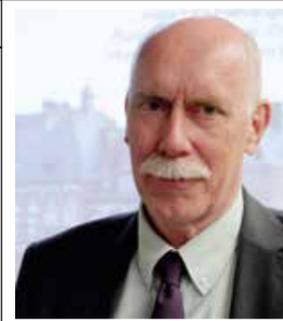
The software calculates the exact percentage of positive and negative oestrogen and progesterone receptors in properly stained digitised specimens to support decision-making with regard to an anti-hormone therapy. Another example: From a slide stained with the antibody Ki 67, and digitised, the software can determine the exact percentage of growing tumour cells – i.e. tumour growth.

Moreover, the software makes 3D histology possible. Anywhere from several dozen to 200 slices need to be cut off a paraffin block and scanned consecutively in order to be able to recognise the growth pattern of certain objects. While this sounds very exciting, Prof. Dietel is cautious: 'At this point, I do not consider the additional information 3D histology cur-

rently offers for diagnostic purposes to be relevant.'

The benefits of digital pathology are easily described: It can do anything conventional microscopy and telepathology can do – and more. The slide data are much easier and faster to quantify and images are transferred by a mouse click.

In difficult cases, for example a rare sarcoma, a second opinion can be obtained from experts anywhere around the world. The same holds true for intra-operative exams: When the pathologist in the sterile operating theatre is unsure, he can directly consult an on-campus colleague. For the many weekly tumour board sessions at Charité, the pathologists often prepare digitised slides to show, for example, remaining tumour cells at a margin of resection. Teaching and research also profit from the new



Professor Manfred Dietel has been Director of the Institute of General Pathology and Anatomical Pathology at Charité University Hospital Berlin, Germany, for more than twenty years. He received his medical training at the University of Hamburg where in 1983 he was called to the Chair of Pathology and Anatomical Pathology and at the same time served as Senior Resident at the University Hospital. In 1989 he was appointed Director of the Institute of Pathology at Christian Albrecht University Kiel, Germany. Four years later he joined Charité. His research focuses on molecular tumour pathology, evaluation of biomarkers, resistance mechanisms and virtual microscopy.

technology. Students can look at case studies and, digital pathology is frequently used in research for documentation purposes in antibody tests.

Prof. Dietel expects digital pathology to gain significant ground in all areas of application over the next five years, particularly regarding quantification. 'New algorithms provide information for classification. We are very active in this area and indeed recently published an article, Dietel points out*. Whilst these complex algorithms are designed to differentiate between tumour cells and other tissue cells there is still one major limitation: Prof. Dietel explains that, unlike in the USA, where slide digitisation is reimbursed with approximately \$60, German health insurers do not pay for this service at all.

* Some of the virtual microscopy applications used at the Charité Institute of Pathology are distributed by the spin-off company VMscope GmbH Berlin.



Norman Zerbe, staff member at the Charité Institute of Pathology, shows the 'Tumour Board System'. This software, an in-house development, uses a streaming technology that was also internally developed to be suitable for virtual microscopy. The scanned slides can be evaluated with a virtual microscope campus-wide – and even worldwide – from any internet-enabled PC. This image shows the digitised slide in conventional HE staining, which gives the pathologist a first impression.

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2-4 June: The British Cardiovascular Society's annual conference

Previewing the impact of new technology on tomorrow's world

Report: Mark Nicholls

Under the banner 'Tomorrow's World', delegates at the British Cardiovascular Society (BCS) annual conference, to be held in Manchester this June, will explore what lies ahead in imaging, cardiac rhythm management, acute coronary syndromes, regenerative therapy, and more, as changing technologies impact on interventional cardiology and cardiomyopathy.

As well as this year's programme being the biggest yet, with 76 plenary sessions, there are also sponsored symposia from Janssen and CamNutra. Additionally, the USA's Mayo Clinic will provide the Cardiology Review Course, with representatives from Rochester, Minnesota, delivering some of the sessions.

The conference also embraces its 18 Affiliated Groups, many of whom have dedicated sessions/linked days in the sub-specialties. This brings sub-specialty societies, nurses, technicians and patients to the confer-

ence. This is an opportunity to bring together the multi-disciplinary team, which is how we all work - as a team.'

Valvular heart disease is the focus of another session: Genotype connections in familiar sudden cardiac death syndrome; diagnostic and therapeutic challenges in HCM; electrophysiology in adult congenital heart disease; TAVI and implications of multi-modality imaging in patient selection, procedural guidance and outcomes; sports cardiology, and discussions on Primary PCI posing the question, should we change practice? In the light of inquiries and investigations in recent years over performance at several UK cardiac centres, a particular focus will also be on ways to continue to provide high quality service as well as improve cardiovascular outcomes.

Education

'There's a dedicated training day for trainees and revalidation for the cardiologist is facilitated through our E4R education for revalidation track and new Lifelong Learning sessions,' Dr Sarah Clarke, BCS Vice President



for Education and Research, points out. 'There are tracks for imaging - which aim to show everybody what all modalities of imaging can offer - clinical science translational research looking at cutting edge clinical science coming into clinical practice, and basic science, from bench-to-bedside.

A fall in industry attendance, due to regulations and the economic climate, has created extra exhibition space - now turned into the Education Hall, for interactive zones such as simulation, where people can refine their technical skills in angiography, PCI, TAVI, renal denervation, pericardiocentesis and transeosophageal echo, helped by an experienced trainer. An imaging village will provide dedicated workstations in CT, MRI and nuclear medicine for delegates to improve their interpretation skills, with trainer

guidance, and there are a live echo station, ECG station and resuscitation workshops for individuals or teams, as well as interactive poster sessions for 250 posters.

Last year the BCS introduced 'hot topics' in Education Hall - short 15-minute presentations of FAQs, key messages and 'how to' sessions covering selected cardiology, research and professional topics as well as interviews with various VIP guests. 'They were so successful that this year we have 112 hot topic sessions over the three days in four zones, one of which the BHF is coordinating,' Dr Clarke explains. 'It's a very educational, interactive and inclusive conference and has grown over the years. This year will be the biggest in terms of what we offer from an education point of view and in delegate numbers. We have also worked hard to inject more liveliness into it and making it not only educational but fun too. It's about delivering education in a slightly different way.' How? With a cardiology quiz and 'cardiology rocks' session in which a drummer from the group Skunk Anansie will



Consultant cardiologist **Sarah Clarke MD** is Clinical Director for Strategic Development at Papworth Hospital, Cambridge, with a special interest in interventional cardiology. As Clinical Director of Cardiac Services from 2006-12, Dr Clarke implemented the Primary Angioplasty Service for Papworth's heart attack patients as well as the roll out of the PPCI service to the East of England. As BCS Vice-President for Education and Research, she is responsible for delivering the Annual Conference and she chairs the Programme Committee (2011-14).

demonstrate the amount of cardio-pulmonary exercise a drummer will go through during a rock concert.

Dr Clarke: 'We hope delegates with have an enjoyable educational experience, plus an opportunity to interact with colleagues in a dedicated environment.'

Disappointing HTN-3 trial results challenge the future of procedure

Renal denervation for resistant hypertension

It was the quiet before the storm. At the end of March, during the American College of Cardiology (ACC) meeting in Washington, the future of renal denervation was about to be decided with the presentation of the Medtronic-funded Simplicity HTN-3 clinical trial.

Over the past two years an industry-led bandwagon for renal denervation has been rolling across European and American cardiology meetings promising that resistant

hypertension - hard-to-control high BP - can be effectively treated with a mechanical intervention to ablate nerve endings in the renal artery, as an alternative to the billions of dollars spent each year on pharmaceutical remedies.

It all came to a screeching halt with the announcement by Medtronic (Minneapolis) in January 2014 that its pivotal United States trial failed to meet the primary endpoint for efficacy. 'It is still early days,' said



Jim Reekers

Dr Jim Reekers, in his presentation during the ECR session *Renal artery denervation in the management of resistant hypertension*.

'It is a promising technique, it is a safe technique,' he added. 'We know from the pathophysiology that it should work. We have evidence, but not too much. We have contradictory evidence now from what appears to be a pretty good trial. For the moment, we are in troubled waters,' he explained, updating the scattered participants.

Professor of interventional radiology at the University of Amsterdam and former president of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE), Reekers joined with fellow presenters in assessing the fallout from the Medtronic announcement.

Asked what they will be seeking in the HTN-3 results, he replied: 'As a scientist, I will be looking for a critical appraisal of the trial. If it measures up to those standards, I think we are done.'

'I know industry will be looking for something else, trying to shoot holes in this trial,' he said.

Could the company that paid for the HTN-3 study attempt to destroy its own study? Reekers: 'Yes. That is essentially it. Medtronic has been responsible in bringing out the press release - and it's important to remember that even Medtronic does not know the real causes of missing the efficacy end point, has no idea of what the data are because it is truly an independent trial.'

Marc Sapoval, is a professor of Clinical Radiology and Chairman of Cardio-Vascular Radiology at the Hôpital Européen Georges Pompidou (Paris). He is also the lead investigator for the DENER-HTN Renal Denervation in Hypertension study of 120 patients over 36 months that will be published in June 2014. The trial included a randomised arm for bilateral renal denervation using Medtronic's Simplicity catheter.

'I have no special information [about HTN-3] but I believe there will be negative results from the way it will be analysed,' he replied. 'I suspect in the sham control arm the patients probably took their drugs and their level of blood pressure decreased more than was expected. I also believe that technology matters, so perhaps some other devices will be more effective. As I showed in my presentation the depths of the renal nerves require a penetration depth of up to six millimetres, so that, if ablation was only two millimetres, it may not have been effective enough.'

'This is only one trial, it will not close the topic,' he continued. 'Yet this is a very high-risk field for companies. We saw the example of Covidien, which was very deeply involved. They simply shut down all their work because of investment issues. They expected that, with positive HTN-3 results, they could just follow behind and win FDA

approval for their device in two years. Now the return on investment is not there any more because the FDA is not ready to accept these devices.'

Gerard Goh, an Interventional and Diagnostic Radiologist at St George's Hospital in London, has presented a sweeping review of approved and proposed devices for renal denervation. 'There are a lot of unanswered questions about the HTN-3 trial design,' he pointed out.

So what did the results presented at the ACC show? Resistant hypertension patients taking at least three drugs (including a diuretic) to control their BP had participated in the carefully controlled, Medtronic-funded but independent Simplicity HTN-3 blinded trial. Unfortunately, the authors concluded that, six months after renal-artery denervation, compared with a sham control, the procedure had not shown a significant reduction in systolic BP.

Nonetheless, study leader Dr Deepak Bhatt, at the Harvard-affiliated Brigham and Women's Hospital, said he remains cautiously optimistic about renal denervation, which remains an investigational procedure in the USA.

Gerard Goh also believes there may be a benefit to a negative result: 'All other companies that have invested so much will now need to design their own trials accordingly and we are going to get a much better idea of renal denervation as a whole.'

Jim Reekers added: 'Now that the field of renal denervation is open, whatever the level of evidence that is available at this moment, there will be a solution. The market has been opened and we have not seen the last of the innovation and ingenuity people are exploring.'



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Different quality requirements trigger dispute among German cardiologists and cardiac surgeons

Transcatheter aortic valve implantations (TAVI)

The Guidelines on Management of Valvular Heart Disease, updated in 2012 and published by the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery, explicitly require transcatheter aortic valve implantations (TAVI) to be performed solely at heart centres with cardiac surgery on-site. This is exactly the requirement that makes German cardiologists balk. The ensuing debate between cardiologists and cardiac surgeons is jeopardising the planned joint certification for physicians and heart centres that carry out TAVI.

Report: Bettina Döbereiner

'We do not pin our quality requirements solely on an on-site cardiac surgery department but think that other preconditions need to be met,' explained Professor Christian Hamm, President of the German Cardiac Society. As far as TAVIs are concerned, he added, close and effective cooperation between cardiac surgeons and cardiologists so that certain quality criteria are fulfilled is more important. Hamm is convinced that, in certain circumstances, this can indeed be possible without a dedicated cardiac surgery department. Not negotiable, he points out, is a full on-site cardiac surgery team with at least two heart surgeons on duty. Moreover, the necessary equipment, e.g. a heart-lung machine, must be available, operational and used routinely at the facility.

Professor Jochen Cremer, President of the German Society for Thoracic and Cardiovascular Surgery begs to differ. TAVI, the cardiac surgeon emphasises, is an invasive procedure associated with clearly life-threatening

risks. Current figures culled from the German Aortic Valve Registry and international meta-analyses, Cremer adds, indicate the risk of acute peri-operative complications requiring immediate cardiologic or cardiac surgery intervention to be at around four percent. Additionally, in one to two percent of the cases open-heart surgery with a heart-lung machine is immediately necessary as the data of the AQUA quality report 2012* and GARY indicate.

The know-how of specialised physicians, support and nursing staff, as well as an adequate infrastructure with state-of-the-art technology provided 24/7 by a dedicated cardiac surgery department, the professor concludes, is thus indispensable for patient safety and preparation, performance and follow-up of TAVIs. 'No matter how qualified, two cardiac surgeons who come running with their little travel cases cannot replace these requirements,' Prof. Cremer points out.

In 2012, the AQUA Institute reports, 18 centres in Germany performed TAVIs without on-site cardiac surgery. These facilities, however, carried out a mere 3.5 percent of all such procedures and only three among the 18 did so on any extensive scale: two centres recorded 50 implants each and one centre recorded roughly 100 TAVIs. Since the percentage of heart centres without a dedicated cardiac surgery department is so small, there are no reliable data to analysis whether the results of these centres differ from the results of facilities with on-site cardiac surgery and a cardiology department.

While this point of contention currently paralyses cooperation between the two professional associations regarding TAVI-performing centres, cardiologists and cardiac surgeons unanimously support other important quality requirements of the European TAVI guidelines, e.g. TAVI is indicated exclusively for older patients with severe symptomatic aortic stenosis (AS), who are not suited for conventional procedures and whose life expectancy is beyond one year. Moreover, the decision whether TAVI is an option should ideally be made by a heart team comprised of cardiac surgeons, cardiologists and, if necessary, other specialists such as vascular surgeons or angiologists.

In recent statements cardiologists and cardiac surgeons alike underlined the utmost importance of complying with the above-mentioned indications in view of the fact that the 2012 AQUA report had shown that an inordinate number of transcatheter aortic valve implants was performed on healthy people (*1: 1.9% = 177 patients) and on patients with mild systemic disease (* ASA2: 7.7% = 722 patients). It can be assumed that no severe AS was present. Currently there are no reliable data regarding patients with estimated low or intermediate surgical risk undergoing TAVI, which might confirm at least comparable outcomes of TAVI and conventional surgical procedures, both Professor Hamm and Professor Cremer pointed out.

Cardiologists and cardiac surgeons do agree that TAVIs should be limited to heart centres performing a sufficient number of such interventions per year by highly experienced specialists. What exactly a 'sufficient number' might be is still under discussion. Whilst neither the European guidelines nor the cardiologists have

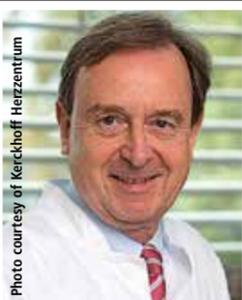
proffered concrete figures, the cardiac surgeons suggested a minimum of 50 procedures per surgeon and 100 procedures per centre per year as a precondition for TAVI certification.

At this point it is entirely open whether cardiologists and cardiac surgeons will arrive at a joint position. Possibly, G-BA, the German government's Expert Panel on Health, will decide the issue. The panel is currently discussing regulations to define

structural quality requirements for TAVI. From the patient's point of view a joint position by cardiologists, cardiac surgeons and heart centres on TAVI certification is desirable.

* In its annual report AQUA-Institut (Institute for Applied Quality Improvement and Research in Health Care GmbH) analyses all services provided in German hospitals that need to be documented. The German Aortic Valve Registry (GARY) was established in 2010 and is jointly maintained by German cardiologists and cardiac surgeons.

* ASA = American Society of Anaesthesiologists Classification, physical status classification system.



Following practical training in the cardiology department at Eppendorf University Hospital in Hamburg, in 1999 Professor Christian Hamm became the first director of the cardiology department at the Kerckhoff-Klinik in Bad Nauheim. In 2004 he became the clinic's medical and managing director. Since 2013 he has headed the Cardiology Clinic at Giessen University Hospital. Dr Hamm is also Professor of Cardiology and Angiology at Justus Liebig University, Giessen, and medical and managing director of the Kerckhoff Cardiac Research Institute (founded 2012). He became a Board Member of the European Society of Cardiology (ESC) in 2004 and has presided over the German Cardiac Society (Deutsche Gesellschaft für Kardiologie – DGK) since 2013.



After practical training at the Clinic of Thoracic, Cardiac and Vascular Surgery at Hanover's Medical University (MHH), Professor Jochen Cremer spent three years as managing senior physician at the cardiac and vascular surgery clinic at Christian Albrecht University (CAU), Kiel, before returning to MHH to co-establish the minimally invasive surgery programme. In 1998 he was appointed Chair of Cardiac and Vascular Surgery at CAU and has headed the Centre for Surgical Medicine at Schleswig-Holstein University Hospital since 2004. In 2008 he took up his directorship of the hospital's Clinic of Cardiac and Vascular Surgery Clinic. The professor has presided over the German Society for Thoracic and Cardiovascular Surgery since 2013.

Circulatory support

PUMPING SYNCHRONOUSLY WITH THE HEART

With the introduction of i-cor - a new business field for interventional cardiology - Xenios AG* also launched the circulatory support system *Synchronised Cardiac Assist i-cor*, which the company reports to be the first system that links mechanical circulatory support to the heartbeat.

'This innovation opens up new therapy options for patients suffering cardiogenic shock and during high-risk interventions in the cardiac cath lab,' the firm explains. 'The technology, which is based on a miniaturised pulsatile pump for physiological cardiac

support, combines myocardial protection and organ perfusion by assisting the weakened heart with synchronised pulses. With this ECG-triggered pulsation, i-cor actively improves coronary blood flow while only slightly increasing afterload as compared to conventional methods.

'Pulsatile perfusion is essential to endothelial function, which ensures adequate tissue perfusion in the organs. Maintaining organ function aims to reduce multi-organ failure and to improve clinical outcomes. Oxygenation and CO2 removal integrated in

i-cor allows heart and lung treatment. Thus i-cor offers physiological circulatory support in the ICU and cath lab.'

* Xenios AG was founded in 2013 by Novalung GmbH and Medos AG. The company's core technology platforms are artificial lungs, blood pumps, vascular access devices, temperature control and biocompatible surfaces. Its brands - Novalung, Medos, i-cor and Xenios Pediatrics - are extracorporeal therapy systems for use in pulmonary and cardiac failure cases.

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New imaging for ischaemic heart disease

Myocardial Perfusion Scintigraphy (MPS) with Positron Emission Tomography (PET)

Report: Mark Nicholls

A session at the forthcoming British Cardiovascular Society annual conference (2-4 June, in Manchester) will hear about the latest imaging techniques for acquired heart disease, with PET technology playing a key role in those advances.

Within the session 'Future perspectives - New imaging techniques in acquired heart disease*', Dr Parthiban Arumugam will examine what PET can offer in this context.

MPS with Single Photon Emission Computed Tomography (SPECT) is an established non-invasive technique for the diagnosis and management of patients with coronary artery disease and is the most commonly used functional test to detect inducible ischaemia.

However, Dr Arumugam, who is the Clinical Director of Nuclear Medicine at Central Manchester University Hospitals (CMUH), will highlight how the oncology-driven increase in PET scanner availabil-

ity, along with the introduction of the generator-produced PET tracer Rubidium-82, has enabled the growth of MPS PET as a new imaging tool for detecting CAD.

Speaking to European Hospital Journal ahead of the Manchester conference in June, he explained that his presentation would cover the technology of cardiac PET, before looking at the clinical aspects including routine use of perfusion imaging with blood flow quantification which, in the last four years, has moved from being a research tool to a mainstream functional imaging technique for detecting CAD, particularly in the USA. The discussion will primarily focus on myocardial perfusion using the PET tracer Rubidium-82.

Dr Arumugam said PET was only used in specialist research centres until recently because the tracer was not widely available. 'Now that it is commercially available and there has been marked growth in the number of PET scanners around



A consultant in Nuclear Medicine and Clinical Director of Nuclear Medicine at Central Manchester University Hospitals (CMUH), Dr Parthiban Arumugam is also the immediate past president of the British Nuclear Cardiology Society. Additionally, he is the Clinical Lead for Nuclear Cardiology at CMUH with a special interest in quantitative myocardial perfusion assessment.

the country to support oncology imaging, there is the potential for those scanners to be used for myocardial perfusion using Rubidium-82 as well,' he explained.

The widespread use of PET was

previously limited because of the capital cost (~£1.5m/€1.8m for a PET/CT scanner) but oncology-targeted funding has seen an increase in PET/CT scanners.

Centres with a reasonable clinical workload for SPECT and access to a PET/CT scanner may well be able to justify establishing a cardiac PET service.

Delegates will hear of the importance of forming a strong business case for such a centre, not only to secure access to a PET/CT scanner, but because the monthly cost of the tracer can be as much as £30,000/€36,000.

Other techniques including dobutamine cardiac stress echo and cardiac MR will be discussed during the session but, according to Dr Arumugam, cardiac PET is unique in that it is currently the only modality that can offer quantitative myocardial blood flow measurement for routine clinical use.

He explained that many of the potential artefacts associated with SPECT imaging, which affect diagnostic accuracy, are overcome by this new technology. Additional

patient-centred benefits include a lower radiation dose and a much shorter stay in the department compared to SPECT.

'The diagnostic accuracy of MP PET is superior to MPS with SPECT and the ability to quantify myocardial blood flow in millilitres per minute per gram makes PET an exciting modality. You can look at early disease and non-ischemic pathology routinely as well as for research purposes.

'From the session, delegates should be able to understand the basics of PET/CT cardiac imaging and appreciate the advantages compared to present technologies for function testing for ischemia, and discover the emerging role of myocardial perfusion quantification and its impact on patient management.

'I am hoping to educate delegates about what the technology means, what the future of cardiac PET promises and the impact it will have on clinical management.'

* This session is scheduled for Tuesday 3 June, from 8.30-10 a.m.

Surgical lighting

The NeXt generation of LED lamps

STARLED5 NX is a new surgical lamp with NeXt generation LED technology, explains its Bologna-based manufacturer the ACEM Medical Company. 'It boasts an excellent light quality. The special optics of its LEDs, generates a shadowless, clear and homogeneous light assuring visual comfort and best working

conditions both for the surgeon and medical staff.'

The firm also points out that the lamp provides 'perfect illumination under every condition generating a IR-free light without heat, an excellent colour temperature and a practically endless life cycle at low consumptions'.

The 43 LEDs produce a light spot of 21cm at 1m with a high illumination level of 135.000 lux (160.000 lux optional) for a steady life cycle of about 50,000 hours, the company reports, adding that, due to a micro-processor the ACRIS system 'ensures the control of electrical curves typical of LEDs to remain unaltered over the time but maintaining a long life cycle.

The colour rendering index of Starled NX is 95 and its colour temperature 4.500°K. These two values allow reproduction of the exact chromatic scale of the colours of the human body'.

The system's control system I-Sense also provides simple, quick, precise management and the lamp can produce focused or ambient light (using the ENDO function), with the special optics enabling accurate adjustment of the light spot diameter to ensure sharpness in the operating area. Smart ergonomics also ensure easy positioning.

For easy cleaning, the lamp is made of a smooth and resistant material and the central handle is removable for sterilisation.

This handle can also house a video camera, on demand.

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Delirium – an u risk factor

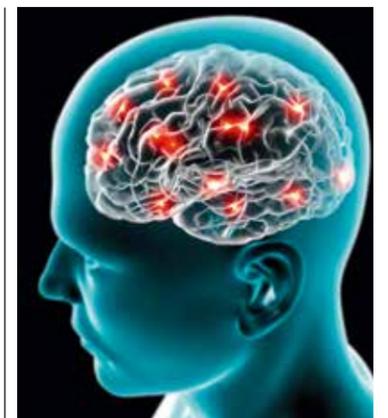
Symptoms of delirium – disorientation, anxiety, hallucinations – can occur post-operatively (particularly in older people). A patient's age, medical condition and type of surgery are contributing factors. Those cases affected by delirium are at increased risk of longer-term cognitive impairment. Anja Behringer reports

Delirium is a particularly common comorbidity in the context of hospital treatment. The causes of delirium are manifold and many patients recover only slowly. Some of the terms still commonly used such as 'transition syndrome', 'OBS' (Organic Brain Syndrome) or 'ICU psychosis' trivialise the clinical picture, as they don't do justice to the high rate of complications, the European Delirium Association emphasises: 'Waiting for the transition syndrome to pass amounts to medical malpractice.'

The mortality rate is also increased and the condition always necessitates intensive care. As yet there is no real treatment available to shorten the duration of delirium, and even just recognising the symptoms requires a lot of experience from anaesthetists and other medical and nursing staff.

In a recent randomised, controlled study, Professor Claudia Spies MD and her colleagues at Berlin's Charité University Hospital showed that the incidence of post-operative delirium can be lowered significantly – by around 22.9% – by neuromonitoring the depth of anaesthesia with EEG. The brain's electrical activity is measured by recording frequency fluctuations on the scalp.

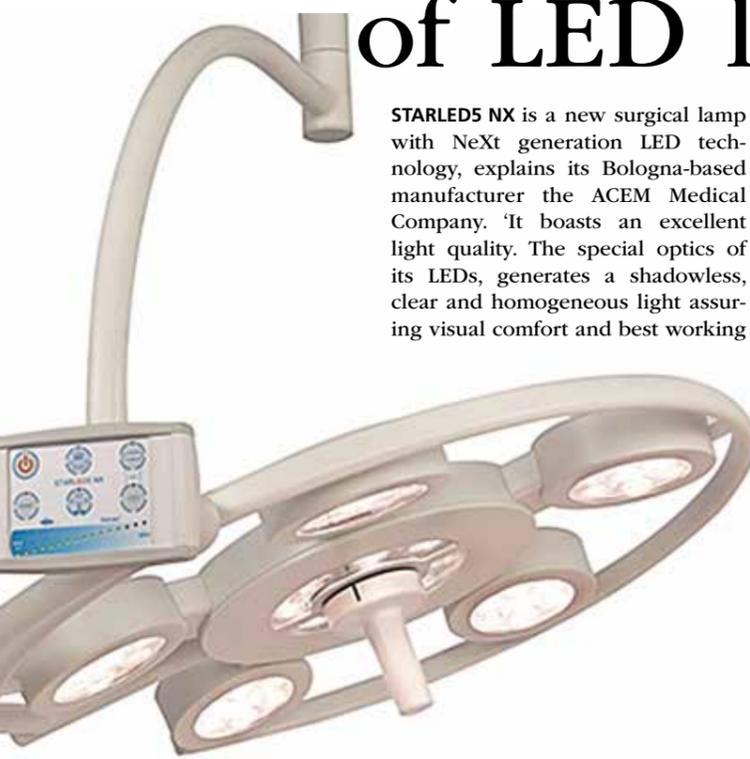
1,155 patients over aged 60 were split into two groups. In the intervention group (n=575) the anaesthetists monitored the depth of anaesthesia during surgery with an EEG. In the control group (n=580)



monitoring was blinded. 'The EEG shows the effect of the anaesthetic on the brain. It allows us to administer anaesthetic more precisely, to detect changes in the patient during the anaesthetic and to react to them,' the professor explains. 16.7% of patients in the intervention group were found to have postoperative delirium after surgery, but the proportion in the control group was 21.4%. The results of the study were published in the British Journal of Anaesthesia.

'As there are only a few therapeutic procedures available for the treatment of postoperative delirium this type of prevention is the best option,' said Professor Christian Werner MD, president of the German Society of Anaesthesiology and Intensive Care Medicine (DGAI) commenting on the significance of the study.

Bearing in mind that postoperative delirium goes hand in hand



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The 6th Annual SIMPAR Meeting

Gathering to beat pain

This March, the Complesso Monumentale Santo Spirito in Sassia, Rome, was the unique and original venue for a unique scientific conference dedicated to the fight against acute and chronic pain. Attracting more than 600 delegates from 40 countries, SIMPAR (www.simpar.eu) aims to spread and support a wider scientific and cultural awareness. Jane MacDougall interviewed Professor Massimo Allegri, President of organising committee, about the meeting and his own pain research projects.

'Pain is a really complex disease that involves and requires a deep knowledge of pathophysiology and pharmacology. Furthermore, working in pain management, you have the opportunity to really help people who need a holistic approach to their health. It is these reasons that have always fascinated me about this discipline,' Professor Allegri said, explaining his initial interest in its management.

'The SIMPAR Meeting was born as a result of an idea my Research Director, Professor C A Redi and I had, seven years ago.

'Within this multidisciplinary group we have created a new multimodal approach to pain from bench-to bedside and back-to-bench in order to provide everyone involved in pain research and clinical practice with new insights.

'The idea was that the SIMPAR meeting would become the place where doctors and researchers could discuss together in order to facilitate a new approach to pain,



one of the major social concerns in medicine today.'

'We've always tried to organise a meeting that is really innovative but also closely related to our clinical and research fields. As I'm an anaesthesiologist, treatment of acute pain is one of the most important lessons taken from my residency. Furthermore, the multidisciplinary approach to chronic pain has led us

to create a large pain clinic. Apart from these clinical aspects, I think that the real benefit of the SIMPAR meeting is the involvement of basic science evaluating the newest translational aspects in order to draw a new insight into how we could approach the management of acute and chronic pain patients. SIMPAR is the first meeting in which all these researchers are together to learn from each other and facilitate our even more effective approach to patients.'

To cover the multiple aspects of pain that needed discussion three separate symposia – acute pain, chronic pain and basic scientific research – were organised.

In a hospital, acute pain is generally associated with surgery. Around 30% of patients report severe pain during the first 24 hours post-operatively, which also constitutes a major risk factor for developing persistent pain after surgery. Good pain man-



Massimo Allegri is assistant professor at the University of Pavia, in Italy. He started his career in Foundation San Matteo Hospital and is now the Head of Research in Acute and Chronic Pain of University of Pavia.

agement can increase patient recovery, improve outcome and decrease in-patient times – but what is good pain management? When should analgesics be given, pre- peri- and/or post-operatively? What type of drug should be given, at what dose? Can we identify which patients will need what type of pain control before operating? Are there certain patient types that are at higher risk of suffering pain? The role of the anaesthetist as leader in the coordination of perioperative care is widely recognised but as yet not one 'best practice' has been determined. These topics were discussed, in a multidisciplinary way.

Chronic pain is an enormous health problem. It occurs in the context of numerous diseases and syndromes and is, in itself, a disease process. Current European statistics estimate that a syndrome associated with chronic pain affects around 20% of adults, reducing productivity and increasing healthcare costs.

Working from the proviso that chronic pain is a disease in its own right, from mounting evidence that it is linked to functional and structural changes in the brain, its pathophysiology and management were discussed over several sessions. Pharmacological solutions in the management of non-cancer chronic pain are limited to either opioids

or NSAIDs. Therefore, debate of the advantages and disadvantages of these two major pharmaceutical groups, by speakers from the USA, Christopher Gharibo, Europe, Eija Kalso and Asia, Kian Hian Tan was extremely important as a step towards new SIMPAR's 'choosing wisely' statements for the pharmacological treatment of chronic pain. The complications from long-term use of either group transcending from a medical to socio-economic problem relatively easily and opening the way for many diverse viewpoints. A similar compare and contrast session between the different continents was made discussing the use of radiofrequency (RF) treatment to destroy the pain receptors and hence reduce chronic pain. Richard Rauck (USA) advocated water-cooled RF, José de Andres (Europe) talked about pulse-doses and Dr Tan about the practice of creating continuous lesions in Asia.

The basic science sessions enabled delegates to find out whether research was any nearer to providing the answers to the questions raised above. The response being yes a lot of progress is being made and no, for the moment there are no clear answers.

What is apparent from GWAS studies is that there is a strong genetic component determining an individual's response to pain. Further study of these genetic differences can help define markers to identify which patients are particularly at risk of developing chronic pain and also provide new drug targets. The identification of new drug targets and the resultant development of innovative analgesic therapies will certainly fulfil an unmet need and be greeted favourably by all those involved in pain management.

Under-recognised

with an increased risk of cognitive dysfunction and mortality, and the treatment options available are not satisfactory, the prevention of the problem with the help of monitoring during anaesthesia is a priority.

The question arises whether or not postoperative delirium may not also be a sign of a pre-existing impairment of mental function. This would explain its greater incidence in line with increasing age of the patients, as well as the increased incidence of long-term cognitive deficits following delirium. Very deep phases of anaesthesia thus correlate with postoperative delirium.

It is up to the anaesthetist's skill to determine the correct depth of anaesthetic and not only to adapt it depending on the surgery phase but also to the patient's individual need for anaesthetic. Monitoring would also help to avoid the dreaded intra-operative awareness reported by some patients, or would at least help to make it become evident.

The causes of delirium can be infections, pain or psychological and physical strain, such as experienced after surgery. Delirium can also be caused by undesired side effects of medication, and patients taking a large number of different drugs are at particular risk due to the confusing medicinal interactions.

In addition, nurses on surgical units are not always sufficiently trained to prepare patients for surgery in the best possible way. This mainly concerns pre-operative warming, premedication and infection prevention and control guidelines, as reported by a nurse.

Non-medicinal strategies to prevent delirium are helpful. Anne Pizzacalla and her team from Hamilton, Canada, have been working with the HELP since 2004. This was developed at Yale Medical School to prevent delirium in older



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eSMART: mobile phones help patients through chemotherapy treatment

Report: Cynthia E Keen

Coping with the side effects of chemotherapy treatment is challenging for people with cancer. When fatigued or nauseous, it is not easy to assess if these conditions are acceptable treatment side effects or require medical assistance. A University of Surrey-led programme called eSMART (Electronic Symptom Management using ASyMS Remote Technology), used in the United Kingdom for the past decade, is expanding to five other countries through a €6 million European Commission grant.

eSMART uses mobile phone technology to remotely monitor patients. Patients use a mobile phone to report any side effects they are experiencing and send this to a dedicated computer. The computer automatically monitors the patients'

responses and sends alerts to clinicians based in their hospital if any of the symptoms reported need management.

Patients also receive information on their mobile phone on how they themselves can manage their symptoms. They can also view graphs of their symptom reports. Symptoms that can trigger alerts for medical intervention include pain, signs of infection, nausea and vomiting, diarrhoea, mucositis, hand-foot syndrome, and extreme fatigue.

The five-year long randomised clinical trial will be conducted across 17 sites in Europe, in Austria, Greece, Holland, Ireland, Norway and the UK. 1,108 patients aged 18+ who are prescribed at least four cycles of first-line chemotherapy to treat breast, colorectal cancer or haematological cancers, will be invited to participate.

Half will use the eSMART system and the others will receive standard care. Professor Nora Kearney, head of the University of Surrey School of Health and Social Care, is principal investigator.

The programme's primary objectives are to reduce the symptom burden and improve the quality of life of people with breast, colorectal, and haematological cancer receiving chemotherapy. Data will also be evaluated regarding changes in clinical practice as a result of implementing the ASyMS system and cost benefit. Roma Maguire PhD, professor of cancer care at the University of Surrey, told *European Hospital* that eSMART will demonstrate how smartphone technology can improve the outcomes of people with cancer while simultaneously addressing the increasing demands on acute services

across Europe. 'We hope that this trial will reduce social and economic barriers in cancer care. Not everyone has equivalent access to the support they should have from the doctors and nurses who treat them,' she said.

There are 11 partners supporting the pioneering work of the researchers at the University of Surrey, including the European Cancer Patient Coalition, NHS 24 Scotland and the University of Dundee, Kings College London, University College Dublin in Ireland, the University of Athens, Amsterdam Medical Centre, Oslo Universitetssykehus HF in Norway, Vienna's Medizinische Universitaet, and the University of California San Francisco in the United States. Docobo, a UK remote monitoring telehealth services provider, is the sole commercial partner.

'Patients absolutely love the system. They are very concerned when they get chemotherapy because it's a frightening experience. After their chemotherapy they are sent home to manage their side effects. eSMART reassures them that someone is looking after them all the time,' Professor Kearney explained.

The technology has the potential to provide similar support for patients with cardiac disease, diabetes, chronic lung conditions, and those receiving palliative care. Professor Maguire



Roma Maguire is a Professor of Cancer Care within the School of Health and Social Care at the University of Surrey. She also holds an Honorary Nurse Consultant post within NHS Lanarkshire, where she works on lung cancer follow-up. The professor had worked in various clinical settings including general surgery and intensive care before consolidating her nursing career within the areas of nursing research and oncology. She also has significant experience in the conduct and management of multi-site clinical research trials and mixed methods research, and has co-authored more than 30 articles and abstracts published in peer-reviewed journals.

told *European Hospital* that the Surrey research team is working on developing software programmes for these conditions. 'With the proliferation of smartphones in use throughout Europe, we are hopeful that this clinical trial will validate and generate funding for the expansion of remote healthcare monitoring services. The potential to help patients is so great with this type of technology.'

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Subscriptions

Janka Hoppe, European Hospital,
Theodor-Althoff-Str. 45, 45133 Essen, Germany

Subscription rate

6 issues: 42 Euro, Single copy: 7 Euro.

Send order and cheque to:

European Hospital Subscription Dept

Printed by: WVD, Mörfelden-Walldorf, Germany

Publication frequency: bi-monthly

European Hospital ISSN 0942-9085

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ASyMS

Advanced
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System

The Healthcare Information and Management Systems Society

The not-for-profit Chicago-based organisation HIMSS aims to boost electronic health records, analytics, mobile and other technologies by 'meaningful use' or other financial stimuli. Cornelia Wels-Maug reports on highlights at the HIMSS 14 conference and exhibition

In his keynote address, Mark Bertolini, CEO of health insurer Aetna, quantified the misuse of resources in the US healthcare system to be approximately US \$765 billion annually, 'that's 30 percent of all healthcare spending' he explained.

This makes for a staggering waste of resources that might be better employed elsewhere.

Keynote speaker Hillary Rodham Clinton also pointed to the costs of delivering healthcare and the waste of resources in the process and juxtaposes those with the role of IT: 'Right now we know that IT is helping to increase efficiency and save money and improve quality of care'. She proposed to 'rethink healthcare IT'. Clinton argued that this decade provides us 'with the opportunity to build the IT infrastructure needed to both eliminate waste and deliver better healthcare outcomes'.



Hillary Clinton



Mark Bertolini

Bertolini was more forthcoming with how to put cost cutting into practice when he stipulated to 'creatively destroying the current business model to enable a new one that will have an impact on our health-

care cost by.....move[ing] the care as far away from the highest cost areas to doctor's offices, to ambulatory facilities, to minute clinics all the way down to the home' and by 'connecting private exchanges here and around the world to ACOs'.

The age of accountable care

The Affordable Care Act mandates the establishment of accountable care organisations (ACOs) in the US. Just as in previous years, ACOs were a central topic at HIMSS. They alter the business relationship between payers, providers and patients completely. In the new model, providers will only be paid for quality patient outcomes, not for the number of patients seen or procedures approved. This implies that both payers and providers need to reduce costs and improve care for the populations they manage. As a consequence, there is a growing urge for payers to come up with innovation in payment models, revenue cycle management solutions and analytics, as exhibited by the likes of WellPoint and Humana at HIMSS. Especially the analysis of large datasets (often referred to as big data) is crucial to establish the effectiveness of medical treatments. Clinton summed this up pointedly, 'It's important to be guided by evidence about what works and what doesn't ... not ideology or personally held beliefs'. Grounding therapies on evidence to advance population health ran like a mantra throughout the show.



For ACOs to work there needs to be a constant flux of patient information between the involved stakeholders, this emphasises the importance of interoperability. In response to this, HIMSS significantly expanded its Interoperability Showcase and launched a new benchmarking 'Continuity of Care Maturity Model' that 'measures the readiness of an organisation to deliver continuity of care as well as the maturity of a healthcare system in the continuity of care delivery'. It is modelled after the HIMSS Electronic Medical Record Adoption Model (EMRAM). This also exemplifies the extent to which interoperability and connecting health information systems remain alarming impediments in the US and elsewhere. Security of data and privacy, along with identity authentication were further challenges that were discussed in various forms during HIMSS.

Can healthcare learn from Amazon?

The healthcare sector lags behind the application of IT compared to

other industry verticals, especially the financial and retail sectors. Which lessons can it learn from those earlier adopters? Ed Park, COO of Athenahealth, a vendor of cloud-based medical software, suggested learning from Amazon by borrowing its core philosophy: 'Putting the customer first' by 'connect[ing] healthcare and its key audiences like never before'.

In Amazon-like style, he sketched a vision of a healthcare system that makes recommendations 'for patients (around which physicians patients might choose based on a preference for a past physician) or for doctors (that suggest if you found treatment X effective for disease Y, you might appreciate treatment W for disease U)'.

Whether Ed Park's vision will find a broad consensus remains to be seen; however, it opens the mind to exploring new paths to better patient outcomes.

That this vision is strongly based on the innovative use of IT is what to look out for at HIMSS.