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Breathing new life into ventilator control

The new SERVO-U includes an elegant man/machine interface and new-wave touch-screen controls

In 1991 **Jens Viebke** graduated from Stockholm's Royal Institute of Technology (KTH) with an MSc in Chemical Engineering. In 1996 he gained a PhD in Polymer Technology at the same institution and, in 2001, he added an Executive MBA degree from the Stockholm School of Economics to his credentials. He has held several key management positions within the Life Science sector, including Section Manager at Fresenius Kabi (1996-1999), Strategy Manager at Accenture (2000-2002), Head of R&D Biotechnologies at GE Healthcare Life Sciences (2006-2008), Head of Business Strategy at GE Healthcare Life Sciences (2008-2009), and Chief Marketing Officer at GE Healthcare Life Sciences (2009-2010).
Jens Viebke has been President of Maquet Critical Care in Sweden since October 2010.

To deliver the next step forward in mechanical ventilation, Jens Viebke, CEO of the Maquet-Getinge Group, decided to take a step backwards by first talking with the people who would be using the system.

Long before there were any prototypes, he said, the design team sought out clinicians and staff at intensive care units across the globe.

'We decided early in the programme to invest in user validation. We gathered input from hundreds of people working in intensive care units from North America, Europe, India, the Middle East and South America. We created cross-functional groups of physicians, nurses, respiratory therapists and biomedical equipment technicians – and, what is unique is that we kept talking to these groups at every stage throughout the whole development process,' he said.

The new SERVO-U ventilator platform is the result of this large-scale collaboration with intensive care experts from around the world.

'This has always been our legacy at Maquet,' said Viebke. 'It is how we can help hospital staff deliver the best clinical outcomes in the most cost-efficient ways.' Yet the design and development process to build a new ventilator from the ground up was an unprecedented effort in the company's history.

Despite cultural and organizational differences, and beyond the divergences in clinical practice, a common thread emerged around the ease-of-use needed in the complex setting of an ICU.

'Irrespective of geography, people in ICUs were interacting with equipment in the same way, responding to the interface in the same way,' he said.

In a next step toward a next-generation design, Dr Viebke decided to invest in expertise for the man/machine interface that was becoming central to the emerging design brief. 'When you get away from the engineers who normally design medical technologies and bring in man/machine and graphical user interface professionals you can take the programme to another level,' he explained.

Maquet's own research found ICU user groups consistently referring to consumer electronic devices as benchmarks for interfaces and, not surprisingly, they pointed specifically to the new wave touch-screen controls pioneered by Apple with its iPad or iPhone.

'One of the reasons for the success of those devices is that despite very different levels of understanding, users can take advantage of a lot of functionality,' Dr Viebke explained.

The result of this re-engineering is the highly intuitive touch-based interface that is the most striking feature on the SERVO-U platform.

Suddenly the complexity of managing a critical life-support system becomes easier while making patient information and therapy options more accessible.

MAQUET at Medica Hall 12 / C63 + D63

Behind the straight-forward, even elegant simplicity of the interface is a sophisticated processing platform that delivers both information and recommendations based on context. In other words, what you need to know is intuitively displayed when you want to know it, based on the patient condition and the actions of the user.

With SERVO-U users can customise the interface, for example selecting views that suit a preferred workflow from basic displays of waveforms and values to advanced views with a comprehensive value sets. Touch screen controls provide dynamic images and visual feedback that enhance user confidence in tailoring treatments to the individual patient, whether through automatic calculations for ml per kilogram of predicted body weight, or therapeutic workflows and monitoring of outcome related values to support the use of the ARDS Net strategy and NAVA (Neurally Adjusted Ventilatory Assist).

The intuitive interface, offering help menus, recommendations and prompts, facilitates fast learning curves for physicians and staff alike. Training can take place one-to-one at the bedside, as well as through large screen presentations for groups.

Like the consumer electronics that inspired the interface, SERVO-U bristles with connectivity features whether plugging into a central monitoring station or accommodating the export of trend reports, data sets or screen shots.

The new ventilator system also takes an innovative approach to 'alarm fatigue', which Dr Viebke called a common, but critical concern in an ICU.

'We have created an easier access to alarms that help staff to identify the causes for the alarm, and SERVO-U can suggest solutions for the conditions triggering the alarm,' he said.

SERVO-U is a completely new platform designed to create a more intuitive way of working, he said, and the touch screen interface becomes the key in making patient treatment as flexible, fast and efficient as possible. Calling it a once-in-a-decade achievement, the CEO also said the next-generation platform is 'future-proof,' a secure investment it is designed to grow with the customer as new functionalities become available.

New solutions for imaging, IVD and therapy

Vendors and buyers unite at China's CMEF

The seventieth CMEF opened on November 3, with large crowds laying testimony that early Sunday morning to today's embracement for this event.

Xiamen – China's healthcare sector is booming. Improved access to care is still high on the government's agenda, attracting domestic and international interest. Many Chinese manufacturers are also active beyond the domestic market. From its inception in 1979, the bi-annual China International Medical Equipment Fair (CMEF) has embodied China's transformation through during recent decades, to develop into the largest medical technology and IVD event there and indeed in the Far East.
Products and solutions made in China, as well as those originating in Europe, the USA and elsewhere that target the Chinese market, were presented at CMEF) in Xiamen, Fujian Province. To name but a very few, exhibitors include China National Medical Equipment Co., China Resources Wandong Medical Equipment Co., Mindray, GE Healthcare China, Jiangsu Yuyue, Philips Healthcare, ShenZhen Landwind, Shinva, and Siemens. As usual, top-notch hospital management, technology, and go-to-market sessions accompanied the tradeshow. With a dedicated exhibit, organisers Reed Sinopharm Exhibitions has celebrated 35 years of successful CMEF events.

2,600+ domestic and international exhibitors

The CMEF autumn show turned out to attract crowds from China, East and Central Asia, Africa, Europe, the USA and further regions. Here's a selection of highlights from the exhibition floor.

1: Chen Zirui, Deputy Manager, Medical Domestic Marketing, Shantou Institute of Ultrasound SIUI

2: Andrew Feng, Regional Manager Europe, Shenzhen Comen Medical Instruments

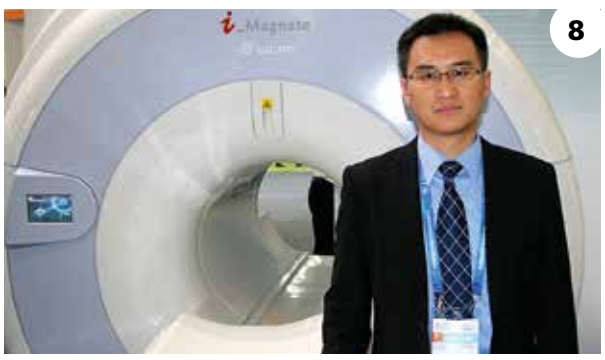
3: Yong, Vice President and Marketing Director, Neusoft Medical (left) with European Hospital reporter Michael Reiter

4: Alpha Zan, General Manager, Emperor Medical

5: Sofia Chen, Regional Manager Europe, Biocare

6: Michelle Zou, Overseas Manager, Shenzhen Basda Medical Apparatus

7: Lukas Lv, Manager, International Sales, and Emma Huang, Sales Manager, Yuwell



8: Xianhua Meng, Manager International Sales, China Resources Wandong

Shenzhen Basda Medical Apparatus – The first company to launch a Chinese-made 3-T MRI. According to the Overseas Manager Michelle Zou, the modality is based on Basda's own research– and a good price combined with high quality makes this MRI appealing to many markets. Highlights from the manufacturer include a 1.5-T MRI as well as a SPECT device and a gamma camera for nuclear medicine.

Shenzhen Comen Medical Instruments – Concentrating activities on patient monitors, Comen is the second largest manufacturer in China, says Andrew Feng, Regional Manager for Europe. The firm tailors patient monitoring devices towards the needs of the ICU, neonates, emergency transportation, and general wards. The company's strategy is to expand functionality to products by adding modules; devices for general wards come with fewer options.

Neusoft Medical – At CMEF, this firm focused on its 64-slice CT and its digital flat-panel mammography modality, which is currently going through its approval process. Subsequent to an exploding market, med-tech sales in China are currently stabilising, according to Guo Yong, Vice President and Marketing Director. Another driver in the med-tech market is growth in the private hospital sector. Over 40% of care providers are now private.

Biocare – Founded in 1996, this manufacturer of ECGs, patient monitors, and ultrasound equipment was the first in China to produce ECGs, according Sofia Chen, its Regional Manager for Europe. Biocare also leads the domestic market in terms of sales, she added. Today's products are sold to more than 100 countries. Biocare recently launched its iE15 digital 15-channel ECG, designed ergonomically like a notebook with a touchscreen and producing simple as well as complex analysis results. The firm also offers 18-channel equipment.

China Resources Wandong – Highlights at this booth included a 1.5-T MRI, digital X-ray modality for mammography, and DR systems. Demand for MRIs is increasing in China, explained Xianhua Meng, Manager of International Sales, adding that an increasing number of smaller hospitals succeed in finding investment money to buy high-tech machines. Loans and subsidies from regional governments support this technology innovation process, which in turn helps hospitals to position them in an increasingly competitive market.

Shantou Institute of Ultrasound SIUI – Performance improvements and a more user-friendly interface have helped make the company's ultrasound devices more attractive, storing and accessing patient data in a cloud made available by the company will greatly improve workflow and help reduce unnecessary use of staff resources for keying in data, confirmed Connie Chan, Manager of Medical Overseas Business.

Emperor Medical – For its colour Doppler ultrasound series the firm developed its own technology, said General Manager Alpha Zan, who describes the quality of the 2-D images as 'excellent, based on 15 years of research and expertise, and 3-D as well as 4-D images are enhanced by highly sensitive transducers'. At CMEF, Emperor launched the G60 ultrasound, in addition to the G70 and G30 models; their differentiation is by number of channels.

Yuwell – At the CMEF autumn show, Yuyue launched its new international branding in the English language. In future, the firm will be known as Yuwell. In line with market trends, the company is increasingly catering for the homecare sector as well as hospitals. A focus is on oxygen concentrators; the portfolio also includes blood pressure and glucose monitors and nebulizers, explained Lukas Lv, Manager of International Sales, and Sales Manager Emma Huang.

Bootcare by Telemedicine

Making professional wound management safer and more efficient

Wound discussion during a teleconference

Report: Anja Behringer

Mobile healthcare is a major buzzword nowadays: take the devices and the data to the patient, not the other way round. Mobility in this concept is not restricted to the hospital where devices and data flow freely from department to department, but encompasses follow-up care at home.

Whilst wound management has not been a major focus of telemedicine, it can benefit immensely from mobile devices – they support digital wound documentation to make wound management safer, more efficient and more cost-effective.

By law, wound documentation, which describes all criteria relevant for therapy planning, performance, control and follow-up, as well as prognostic evaluation, to ensure that approved medical and care procedures are being followed. However, beyond any legal aspects, written wound documentation is an indispensable quality control tool, since the differentiated parameters provide a detailed picture of the individual wound situation that can offer guidance for all parties involved in therapy and care.

Dr Bernhard Clasbrummel, Director of the Clinic of Orthopaedics and Trauma Surgery Zollernalb in Balingen, Germany, has been interested in telemedicine since it first appeared on the healthcare scene about 15 years ago. Still enthusiastic about the technology's potential to change the prevailing healthcare paradigm, he also has a clear view of the realities: while the cost advantages of telemedicine in wound management are praised unanimously, mobile technology has yet to conquer everyday clinical practice and routine. We asked the expert – who had used telemedicine resources for wound management ten years ago on the Spanish island of Mallorca – to answer three questions, beginning with which manufacturer he works with in telewound care.

'Our applications are manufacturer-neutral. Many big manufacturers do not invest in this issue. We save the wound record on a web-based platform that can be accessed and used by everybody involved,' Dr Clasbrummel explained.

'Firstly, wound documentation ensures information flow between physicians and nurses and thus ensures that no contradicting measures are taken, no matter who performs the wound care at any given point. Secondly, written wound documentation plays a major role when liability issues arise regarding the medical or care services. Next, verbal agreements, for example those made in shift or ward meetings, do not satisfy the legal quality of care requirements.

'A precise initial wound assessment, the basis of the wound documentation, will promote urgently needed interdisciplinary cooperation. If, for example, the development of a diabetic ulcer is detected, coordinated action by diabetologists, angiologists and surgeons can prevent major interventions such as an amputation.

What's new in modern wound management?

'Telewound care is still new. 15 years ago, although all those involved welcomed it, nothing much has happened since 2000. Despite the fact that theoretically telewound management is widely accepted, in practice there is no significant progress because nobody wants to pay for it. The medical advantages are undisputed, but without money nothing happens. A wound costs between €4000 and €5000. Ideally, you have two physicians from different disciplines – without doubt a pretty costly approach, but if you take a closer look you'll see major long-term benefits: your outcomes are much better, there's faster healing, shorter length of hospital stay, top quality, satisfied patients, and all this will be unambiguously documented and accessible in your digital wound record – but, every society has to decide how much health it can afford.

'The meticulous collection of data for wound documentation forces physicians and nurses to work systematically and look at the individual wound situation precisely and in-depth. Using more than a dozen differentiated and tried and tested wound parameters, data are collected and a confident assessment of progress, stagnation and setbacks is possible. Consequently well-founded decisions on therapy adjustments, which may spare a patient from enormous suffering, can be made.'

Envisioning the future of telewound management

'Today, we only have documentation models but no payment models. I'm confident, however, that eventually professional wound management will be paid for separately, particularly in out-patient care.

'Above all the GP needs solid documentation, which can be assessed when need be by a relevant specialist physician. We simply need to ensure that such a cooperative system can function without a hitch. Due to the major social impact, correct wound documentation should be mandatory.'

In 1991, after Private Docent **Bernhard Clasbrummel MD** graduated in medicine in Freiburg, he trained as a surgeon at the Bergmannsheil hospital in Bochum's Ruhr University and, in 1994 founded the working group Clinical Microsystems Technology. From 2000 to 2005 he was speaker for the Telemedicine Centre of Excellence Teltra (Gesellschaft für telematische Traumatologie mbH). He was appointed Medical Director at Evangelisches Krankenhaus Witten in 2006 and, since 2009, has been Medical Director of the Clinic of Orthopaedics and Trauma Surgery in Balingen, Germany. Currently he focuses on clinical care in a regional trauma centre, including the clinical assessment of telemedicine projects.

C.diff associated diarrhoea

Probiotics could help prevent hospital outbreaks

Report: Mark Nicholls

Diarrhoea caused by Clostridium difficile, which remains an issue in hospital settings, has been the focus of Cochrane Collaboration scientists, who now suggest that taking probiotics at the same time as antibiotics could help to maintain a healthy balance of bacteria in the gut, particularly as antibiotics can disturb the ecosystem of organisms normally present in the digestive system.

Although some people infected with C.diff show no symptoms, others suffer diarrhoea, colitis or, if severe, even death.

With data from 23 randomised trials involving 4,213 patients who were on antibiotic treatment for a variety of reasons examined, the review team found that 2% of patients given probiotics developed C.diff-associated diarrhoea compared with 6% of patients in the control group (typically taking placebos).

Dr Bradley Johnston, Assistant Professor at the Institute for Health Policy, Management and Evaluation at the University of Toronto and part of the Cochrane team, said: 'Our systematic review was the first to show that some probiotics agents are both safe and effective for the primary prevention of C.diff associated diarrhoea. The pooled estimate in terms of reduced risk of C.diff associated diarrhoea was 64%.'

The researchers explored whether different probiotic species could explain the results, or whether dose was a factor. 'We did not find any statistically significant difference based on probiotic species or dose but did find a trend to suggest that multiple species and higher dose (at least 10 billion colony forming units per day) seems to be more effective than lower dose,' explained Dr Johnston. 'A viable dose may be one of the most important factors when considering a probiotic agent, though there still needs to be more work on that.'

He believes implementing the appropriate dose and strains of probiotics in hospitals could provide cost savings and improve quality of life, although he accepts some clinicians may be nervous about giving live bacteria to patients, especially if they have multiple co-morbidities. 'If patients are immune-compromised,' he said, 'we suggest there's not enough evidence yet to use it in this population, but it looks like certain probiotic agents are safe in otherwise healthy adults and children.'

C.diff associated diarrhoea, especially in older adults, is a huge issue in many hospitals and nursing homes, he added, pointing to data from University of Ottawa that suggests as many as one in 10 individuals who contract C.diff die from the complications of severe diarrhoea. 'For those who acquire C.diff, it has a major impact on patients' quality of life; and the cost of treating such cases is substantial, with the average being around $10,000 per case,' Dr Johnston pointed out.

The review also showed that people taking probiotics had fewer unwanted side-effects than those on placebos, including stomach cramps, nausea and taste disturbances.

The Cochrane team acknowledge that the total number of patients studied has been relatively small. However, a randomised trial (pub: The Lancet) on lactobacilli and bifido bacteria in the prevention of antibiotic-associated diarrhoea and Clostridium difficile diarrhoea in older inpatients (PLACIDE), with some 3,000 patients involved from five centres in the UK, appears to add weight to the Cochrane Collaboration findings. 'Although the results were non-significant, when we pool the Lancet data with the previous trial data, the pooled estimate for C.diff diarrhoea suggests a risk reduction of approximately 60%, Dr Johnston said.

Bradley Johnston MD is a scientist with Child Health Evaluative Sciences at The Hospital for Sick Children Research Institute and an assistant professor at the Institute of Health Policy, Management and Evaluation of the University of Toronto.
Academic interests include the methodology of systematic reviews, randomised trials and clinical practice guidelines.

The baseline risk of C.diff diarrhoea is critical when considering the use of these agents, he suggested. The Lancet trial had a very low baseline risk, which might help explain why the results were non-significant. In a hospital where there is an outbreak of C.diff diarrhoea, he pointed out, prescribing certain probiotic agents at certain doses has the potential to have an immediate impact on preventing hospital acquired C.diff diarrhoea, as well as providing cost savings.

Some Canadian hospitals are already looking closely at this data and considering implementation of probiotics in outbreak settings.

Dr Johnston suggested a next step is for large head-to-head randomised trials to establish which probiotic agents work best in otherwise healthy adults. Additional work needs to be completed on the safety of probiotic agents in immune-compromised patients, and those with serious and multiple co-morbidities.

Blood pressure monitors

Specialising in BP monitors, Omron Healthcare BV of Hoofddorp, the Netherlands, is extending portfolio with two new designs for medical professionals. With the launch of HBP-1100 and HBP-1300, Omron reports that it has combined the firm's core expertise of accurate, reliable blood pressure monitoring with insight into professional's needs to offer optimal solutions for use in both busy wards and GP's offices'.

With roughly one in three adults diagnosed with high blood pressure and statistics that show hypertension in children* is on the rise, demand for a universal solution to suit all ages and sizes is increasing – thus the two new monitors have a range of cuffs from 12 cm to 50 cm circumference to provide accurate, comfortable blood pressure measurement for any and all patients.

'Professionals can confidently measure blood pressure in patients with specific cardiovascular conditions such as arrhythmia by switching between auscultation and oscillometric mode,' the company adds. 'The durable designs, engineered for intensive use in professional medical facilities, can be used by a practitioner on the move or in a consultation room.'

Details: www.omron-healthcare.com

Omron is at Medica
Hall 09 / A55 + A58

Patient logistics c hospital construc

The Institute of Operations Research seeks routes to efficiency

Report: Michael Reiter

Until recently, hospitals were constructed the way they had been built through centuries. Today, however, hospital design is shifting towards patient logistics, opening up very new perspectives. Hospital budgets, quality of care, and patient satisfaction will profit from this transformation, predicts Ines Arnolds, a researcher in Professor Stefan Nickel's team in the Institute for Operations Research at Karlsruhe Institute for Technology (KIT), Germany.

Hospital designers and planners had relied mostly on experience and existing campus outlays for inspiration. Tenders, too, would typically include requirements based more on legacy knowledge than on data derived from processes or expertise gained from daily routine.

Legal requirements and architectural aspects added important influences, Ines Arnolds points out. 'Obviously, legal requirements and utilisation of experience are a must. However, processes should play a larger role in the design process.' This could help tap a variety of potentials, according to the KIT team. The group's research has discovered numerous shortcomings in existing approaches.

Mostly, long-term perspectives regarding resource and capacity planning are a focus for hospital design. However, the emerging building will also influence significantly short-term aspects, i.e. operational workflows.

Most architectural designers have assumed that the information they take into account is fixed and real (determinist). However, uncertainty can impact on data, e.g. on future patient figures for certain diseases, as can processes – the flow of patients, materials and staff, depending on outcomes and re-convalescence. The design process should reflect those uncertainties. 'Processes should determine how buildings are designed, and not vice versa,' he advises. 'Planning should integrate methods for logistical analysis.'

Processes come first

What would be a more suitable approach? Before entering the design phase of a new construction, an analysis of processes is necessary. In particular, clinical pathways for in- and out-patients in the building should be investigated, providing information on the movement routes of patients as well as staff.

In the layout, by adapting function rooms and departments to the processes that occur in the building, including patients, materials and staff flow, distances travelled can be reduced, 'Reducing distances means savings in resources,' Ines Arnolds points out. 'Increased efficiency leaves more time to spend on care, which in turns leads to improved patient and staff satisfaction.'

Earlier detection of Down's syndrome

UK researchers develop a new non-invasive test for routine screening

Report: Mark Nicholls

Down's syndrome (also referred to as trisomy 21) is a genetic disorder caused by the presence of all or part of an extra copy of chromosome 21 in a person's DNA.

Current screening for Down's syndrome and other trisomy conditions includes a combined test done between the 11th and 13th weeks of pregnancy. This involves an ultrasound screen and hormonal analysis of the pregnant woman's blood.

Methods such as chorionic villus sampling (CVS), which involves taking cell samples from the placenta, and amniocentesis (sampling amniotic fluid), are also used to detect abnormalities but both are invasive and carry a risk of miscarriage.

Led by Kypros Nicolaides, Professor of Foetal Medicine, researchers from King's College London and King's College Hospital (part of King's Health Partners Academic Health Sciences Centre) have developed a new test that they report can be given earlier in pregnancy and is more accurate than current checks. Their findings have been published in two papers in the journal Ultrasound in Obstetrics & Gynaecology.

Several studies have shown that non-invasive prenatal diagnosis for trisomy syndromes using foetal cell free (cf) DNA from a pregnant woman's blood is highly sensitive and specific, making it a potentially reliable alternative that can be done earlier in pregnancy than the current screening for the condition. With colleagues, the King's researchers have now demonstrated the feasibility of routine screening for trisomies 21, 18, and 13 by cfDNA testing.

Testing done in 1,005 pregnancies at 10 weeks had a lower false positive rate and higher sensitivity for foetal trisomy than the combined test done at 12 weeks. Both cfDNA and combined testing detected all trisomies, but the estimated false-positive rates were 0.1% and 3.4%, respectively.

Professor Nicolaides: 'This study has shown that the main advantage of cfDNA testing, compared with the combined test, is the substantial reduction in false positive rate.

'Another major advantage of cfDNA testing is the reporting of results as very high or very low risk, which makes it easier for parents to decide in favour of, or against, invasive testing.'

A second Ultrasound in Obstetrics & Gynaecology study by the group, which included pregnancies undergoing screening at three UK hospitals between March 2006 and May 2012, found that effective first-trimester screening for Down's syndrome could be achieved by cfDNA testing contingent on the results of the combined test done at 11 to 13 weeks. The strategy detected 98% of cases, and invasive testing was needed for confirmation in less than 0.5% of cases.

The research team concluded that screening for trisomy 21 by cfDNA testing contingent on the results of an expanded combined test would retain the advantages of the current method of screening, but with a simultaneous major increase in detection rate and decrease in the rate of invasive testing.

Kypros Nicolaides is Professor of Foetal Medicine at King's College London. His research interests are on foetal medicine with special reference to haematology, and on pre-term diagnosis of chromosome abnormalities. At King's College Hospital, Prof. Nicolaides also heads the Harris Birthright Research Centre for Foetal Medicine, a leading clinical unit and research centre for the assessment and treatment of unborn babies, caring for more than 10,000 patients annually.

drive ction

To accommodate uncertainties in data and processes, simulation and optimisation from the area of Operations Research are combined. Multi-phase simulation scenarios help create of a robust layout, which will show high performance even when flows of patients, materials and staff are uncertain. The potential key performance indicators are the time and distance travelled by patients and staff. At a later time the simulation model can be used to test new models based on workflows in working hours, or for building modifications. Despite increased orientation towards processes, knowledge and resource gaps about operations research still hamper acceptance among decision makers of this new approach, he says, pointing to the reason why the method has not yet been applied to any project. 'The challenge for researchers is to work together with architects and hospital managers and convince them that this is the suitable path for the future.'

Ultrasound-guided surgery proves better for palpable breast cancer

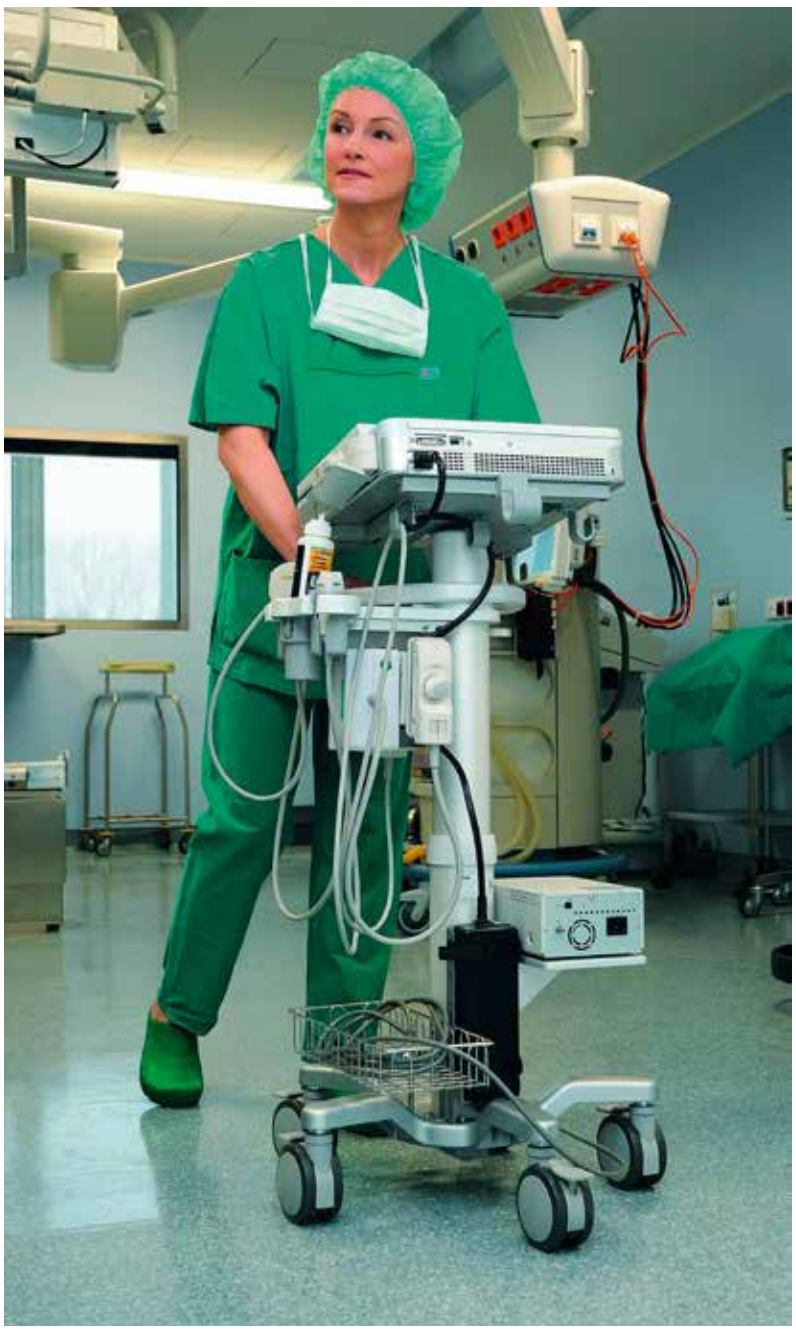
Toshiba ultrasound equipment is helping provide a better oncological and cosmetic outcome for women recovering from breast cancer treatment and surgery. Daniela Zimmermann discussed intraoperative ultrasound-guided breast surgery with surgeon Dr Monique Petrousjka van den Tol, from the Department of Surgical Oncology, VU University Medical Centre in Amsterdam, the Netherlands

A breast cancer diagnosis is traumatic for any woman. Yes, survival rates are high, but other factors make the treatment process towards recovery is a daunting experience. Surgery and radiotherapy effects are important factors, but for many women it is concerns over the cosmetic impact on a body area that can be central to their identity.

Breast conserving surgery is the treatment of choice for early-stage breast cancer, with the aim to achieve tumour-free resection margins and a satisfactory cosmetic appearance. However, the accuracy of the margins impacts on the risk of local recurrence, the need for re-excision, mastectomy and additional boost radiotherapy, all of which have a cosmetic impact.

Conducted in the Netherlands and published in *The Lancet,* the COBALT (Cosmetic Outcome of the Breast After Lumpectomy Treatment) trial examined the benefits of intra-operative ultrasound guidance for palpable breast cancer excision.

The study – in which the researchers used the Toshiba portable ultrasound system VIAMO and 14 MHz ultrasonography probe – builds on the dissertation of Dr Nicole Krekel[1] from VU University Medical Centre (VUmc), Amsterdam, which attracted much attention not only due to its findings but also the use of a powerful photograph of a naked woman with shaved hair and a striking gesture with a breast marked for incision for the cover of the work. After seeking expert advice (legal and at VUMC senior executive level), it was felt the image was relevant, appropriate and portrayed the gravity of the subject matter.



Ultrasound versus palpation-guided surgery

With the hypothesis that ultrasound-guided surgery has the potential to improve surgical accuracy for palpable breast cancer, the study compared ultrasound-guided surgery with palpation-guided surgery with respect to margin status and extent of healthy breast tissue resection.

Presently, the standard practice for palpable breast carcinoma excision is guided by pre-operative diagnostic images and the surgeon's skill, which can be less accurate. Figures suggest positive resection margins in up to 41% of patients and surgeons tend to over-excise healthy breast tissue to attain negative margins

Dr Monique Petrousjka van den Tol, at the Surgical Oncology Department in VUMC, played a leading role in the COBALT study. 'We looked at patients who had a breast sparing operation and we saw that the main reason for bad cosmetic results was the volume of tissue taken away,' she explained. 'We started thinking about why so much tissue was removed when we operated on small tumours.

'We studied 780 pathology reports and looked at the tumour size. We made a mathematical formula and said that, when we remove a tumour, we'd take out 1cm of healthy tissue - that was our goal, so we designed a ratio of "tumour-plus-1cm".'

Dr van den Tol and the team believe ultrasound offers an effective alternative guidance technique during surgery over needle localisation, although they acknowledge that studies in this area are limited.

Ultrasound offers greater accuracy

To augment the dissertation presented by Dr Krekel, who works with Dr van den Tol at VUMC – 132 women with palpable T1-T2 invasive breast cancer were invited to participate in the study; the patients came from VUMC, the Red Cross Hospital in Beverwijk, the Alkmaar Medical Centre, Waterland Hospital, Purmerend, and Gelders Vallei Hospital, Ede.

Participants were randomly assigned to either ultrasound-guided surgery or palpation-guided surgery. For those in the ultrasound-guided group, Dr van den Tol explained how the surgeon located the tumour by palpation and ultrasound and compared the findings with pre-operative digital ultrasound images. The tumour diameter was measured and marked on the skin.

Monique Petrousjka van den Tol

Toshiba is at Medica Hall 09 / D05

During the ultrasound-guided surgery, she said, a surgeon and assistant focused on the incision purely on ultrasound images compared to palpation-guided surgery where surgeons used their fingers to guide the dissection and constantly checked from ultrasound to pathology to measure the amount of healthy tissue and avoid removing more than necessary.

'Ultrasound imaging helps to make the tumour and margins for palpable breast cancer very visible. We can even lower the ratio below 1cm for some patients,' the surgeon explained.

Cobalt study analysis

Analysis of resection margins showed a reduced proportion of invasive tumour involvement with intraoperative ultrasound, with tumour-free margins in 63 (97%) of 65 patients who underwent ultrasound-guided surgery compared to 57 (83%) of 69 individuals in the palpation-guided surgery group. Seven (11%) patients who received ultrasound-guided surgery and 19 (28%) who received palpation-guided surgery needed additional treatment.

Ultrasound-guided surgery also resulted in smaller excision volumes, reduced unnecessary resection of healthy breast tissue and could contribute to improved cosmetic results and quality of life for the patient. The improvement of margin status also saw less additional treatment.

An additional, a boost of radiotherapy was deemed sufficient for six women in the ultrasound-guided surgery group and re-excision in one patient because extensive DCIS was present at the surgical margin. In the palpation-guided surgery group, 11 women received an additional boost of radiotherapy, three underwent re-excision and five had a mastectomy.

Dr van den Tol: 'We know radiotherapy is another important factor in cosmetic outcome, we know it should be done in every breast-sparing operation, so we need to do it, but we need to have as low dose as possible and operate radically so we don't have to boost radiation.

'Overall, the COBALT trial results show that intraoperative use of ultrasound significantly increases the surgical accuracy of palpable breast cancer compared to palpation-guided surgery.

'Surgery performs better, we are more radical in a higher percentage of patients and that leads to less re-operation,' she added. 'We didn't have to perform any ablation therapy in patients in the ultrasound group, but we did have patients we needed to ablate in the other group.'

The researchers do, however, acknowledge that ultrasound has its limitations with lobular carcinoma because the tumour is less rounded and harder to see.

Spreading the word

There are critics of the approach, with concerns that it will change demands on surgeons and limit the role of radiologists. However, Dr van den Tol pointed out that VUMC surgeons worked closely with radiologists over the study and also compared the results on more expensive ultrasound equipment to Toshiba's portable Viamo and found that the image quality was comparable for breast cancer surgery. 'We could always make the lesion visible with a basic ultrasound machine and did not need expensive equipment,' she confirmed. 'We also saw a learning curve, where surgeons could adapt to this procedure among ten patients.'

Dr van den Tol has been teaching the technique to surgeons at other centres, carrying her portable Viamo with her. Researchers maintain that intraoperative ultrasound can improve a surgeon's performance and that surgeons should gain competence in ultrasound use to guide their surgery and avoid the need for a radiologist to be present. In the case of non-palpable breast cancer surgery, of course the intraoperative use of ultrasound will need further radiologist assistance.

Cosmetic advantages

Ultrasound guided surgery has clear advantages from a cosmetic perspective and reduced the need for further treatment, as well as reducing psychological distress in the patient along with health costs.

While a strict cost-effectiveness study has not been conducted, Dr van den Tol said the team looked at re-operation, radiation boost and cause of death.

Findings: if 30 patients or more per annum have surgery in a hospital, it is cheaper to use ultrasound than palpation-guided surgery.

The team is enthusiastic about the implementation of the technique and will continue the COBALT study to further assess cosmetic results. 'We've proved that ultrasound-guided surgery is better for palpable breast cancer[2],' the surgeon confirmed, 'and if we do have better cosmetic results we have that extra motivation.'

1. http://tinyurl.com/o64xfyu
2. http://tinyurl.com/lpae7fk (YouTube)

DIEP flap reconstruction

Breast cancer surgery improvement – without muscle damage and implants

Pierre Perrot, CHU de Nantes

In France, every year 15,000 women undergo complete or partial mastectomy due to breast cancer. Only about a third of them, i.e. around 5,000 patients, use the possibilities reconstructive surgery offers and 70 percent of those women opt for an implant although it is associated with a risk of infection because the body might react negatively to the foreign object. In addition, follow-up surgery may be required due to symmetry problems and capsular contracture.

Deep inferior epigastric perforators (DIEP) flap surgery is an autologous and muscle-sparing reconstruction procedure without an implant. The method, which originated in the USA, is taking hold in Europe.

DIEP, pioneered by Professor Laurent Lantieri, who has made headlines with spectacular face transplantations, has been performed in France for more than ten years. In early 2012 Professor Lantieri opened a research centre for breast treatment and reconstruction at Hôpital Européen Georges-Pompidou in Paris.

Among the physicians trained in DIEP flap reconstruction was Dr Pierre Perrot, physician at the Burn Centre and Plastic Surgery Department of the Nantes university hospital, who has performed the intervention in Nantes for the past year.

During our *European Hospital* interview with Dr Perrot, he said that the procedure has proved successful. 'Today, we perform it about once a week and in the past twelve months we've had approximately 40 patients. At this point, we cannot schedule more interventions because we would need more trained surgeons here in Nantes.

'One advantage of DIEP,' he explained, ' is the fact that the procedure does not require an implant. It's also a muscle-sparring technique whilst the Latissimus dorsi flap technique, or TRAM flap – a precursor of DIEP – require the removal of a muscle. In DIEP surgery, skin, fat and perforator vessels are harvested from the abdomen. However, unlike TRAM flap surgery, the rectus abdominus muscle remains intact and the abdominal wall is not damaged. Thus abdominal strength is preserved and the likelihood of a hernia, often a consequence of TRAM, is lessened.

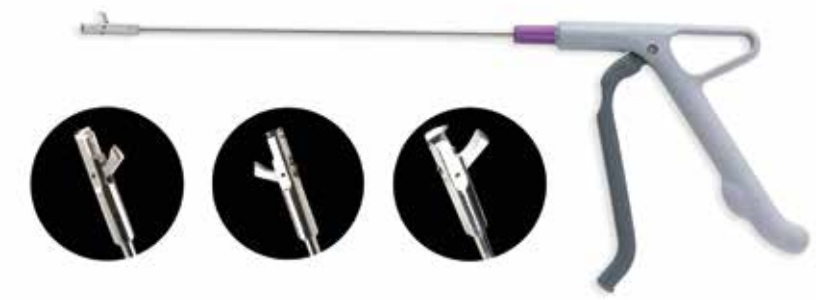
'Basically the tissue removed in an abdominoplasty will suffice for the breast reconstruction. That means patients may even benefit from a flattened tummy.'

Breast reconstruction in DIEP

'After removal of the perforator flap, microsurgical procedure connects the flap to vessels, chest or armpit skin. This step holds the highest risk, since the vessels are only about one to two millimetres wide. In five percent of patients this is where the procedure fails. If the vessels can be successfully attached, DIEP as such, will probably be successful. In a follow-up procedure a few months later, we see flap improvements and reconstruction of the nipple-areola complex.'

'The procedure is not suited for patients who underwent previous abdominal surgery because their abdominal tissue cannot be used. Smoking is a further contra-indication, as is severe obesity. The patient, however, does not have to be very thin; quite on the contrary a little tummy is an advantage.

'DIEP is exclusively performed following a mastectomy and in some cases both breasts can be reconstructed in one session – particularly in cases of prophylactic mastectomies where the patient is genetically disposed to developing breast cancer.'



The single-use cervical biopsy punch

Launched at Medica 2012, DTR Medical's Rotating Cervical Biopsy Punch is more than a timely development in light of an increasing need for cervical cancer screenings and human papilloma virus (HPV) testing.

Cost effective instrument availability helps in the smooth running of clinics and guarantees a good quality biopsy every time, the manufacturer explains. 'It's clear to see why it has been received so well in the market, with notable positive feedback, which includes *"The rotating punch biopsy is slick, easy to use and sharp"* and *"The reusable forceps [biopsy punches] consistently produce inadequate samples - cross-cut, crushed or torn - this causes confusion and further unnecessary follow-up. I want to use these disposable forceps [Single-use biopsy punch]"*

The rotating jaw provides first time sharpness and a precise cut with a cleaner wound that heals quickly, DTR adds. 'Alternatives commonly lack a precise cutting jaw, creating poor biopsies with continued wound trauma, which leads to longer patient recovery time.

'This addition to an extensive range of single-use gynaecology instruments is a truly fit-for-purpose instrument that can enhance existing procedures.'

Based in Swansea, South Wales, since 2005 DTR Medical has produced quality sterile single-use disposable surgical instruments for ENT/maxillofacial, gynaecology, orthopaedics, neurosurgery and general surgery.

DTR is at Medica Hall 16. Stand F30.

Details: www.dtrmedical.com/.
Phone: +44 (0) 01792 797 910.
Email: info@dtrmedical.com

Stabilised LED-backlight technology

NDSsi is at Medica Hall 10. Stand F14.

Medical imaging markets were redefined by NDSsi, which confirms that it was first to introduce LCD displays into operating theatres and the first to advance to LED-backlight technology. In medical informatics, NDSsi also developed the Ultra-Wideband wireless video solution ZeroWire, the world's first matrixed video router/switcher (ConductOR) and the first video scaling and formatting appliance (ScaleOR).

'NDSsi's industry's first stabilised LED backlight, available in all Radiance G2 HB surgical displays, assures consistent brightness of images over the life of the display without any dimming or compromise in luminance output,' the company reports. The result, it adds, is a new level of image clarity and consistency, with enhanced brightness, contrast and colour.

'The new Radiance G2 HB displays usher in a new era of backlight innovation in HD surgical visualisation technology,' said Jens Ruppert, VP & GM Surgical Business Unit at NDSsi. 'For the first time, surgical teams can count on working with high-bright images that will remain precise and consistent in their luminance output over years of usage.'

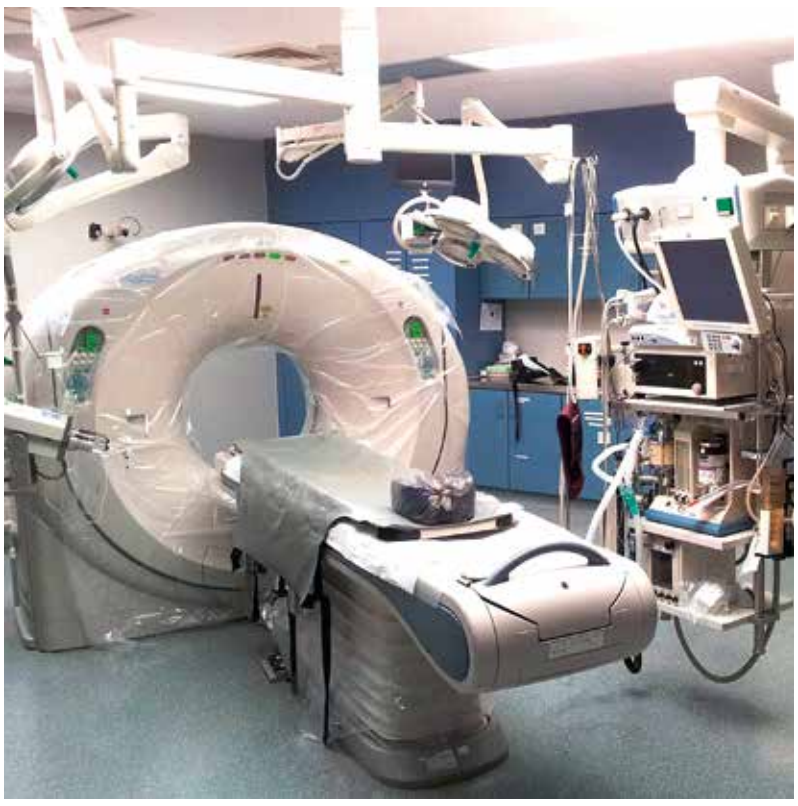
The backlight stabilisation in the Radiance HB products is calibrated to 500 cd/m², the company points out. 'Specification comparisons show that no other surgical display in the industry can achieve the luminance benchmarks of the Radiance G2 HB displays.'

All Radiance G2 displays will ship with NDSsi's proprietary Colour Correction Technology (CCT)*, a dynamic colour calibration solution, the report adds. 'CCT ensures accurate, consistent colour across all screens. The stabilised LED backlight is warrantied for 5 years or 25,000 hours, whichever comes first.'

Details: www.ndssi.com

Polytrauma whole-body CT in the shock room

Optimised scan protocols reduce radiation exposure



Toshiba Aquilion 32 CT scanner in the shock room at Bergmannstrost hospital

Whole-body CT scans during shock room treatment of polytrauma patients are on the increase since their advantages are obvious: they are a fast and comprehensive examination that allows immediate therapy-relevant decisions.

For his doctoral thesis Stefan Reske evaluated the whole-body CT scans of trauma patients performed at the Clinic for Imaging Diagnostics and Interventional Radiology at Bergmannstrost hospital in Halle, Germany. 'We decided on an interdisciplinary level that trauma patients who fulfil certain criteria upon admission undergo a whole-body CT scan in order to exclude severe internal trauma which may cause decompensation later on. Since not every patient admitted to the emergency department suffers from severe – meaning life-threatening – injuries we as trauma radiologists have a particular responsibility to make every effort to reduce radiation dose as far as possible during diagnostic imaging. Time is of the essence in trauma care as about every three minutes mortality increases by one percent,' explains Stefan Reske, assistant physician at Bergmannstrost hospital in Halle which features a renowned trauma centre where radiologists, trauma surgeons, anaesthetists and neuro-surgeons work hand in hand.

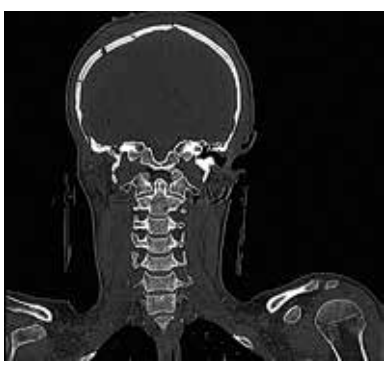
An extremely tight whole-body CT protocol had existed for several years when, in 2010, Stefan Reske was asked to review all patients to whom the protocol had been applied and to determine radiation exposure during the scan. 'The result was a rather high effective dose of on average 45 mSv for a whole-body scan from head to toe. The completely automated protocol comprised basically two mandatory scans: firstly a native head and cervical vertebrae scan followed by a contrast-enhanced scan from the base of the scull to the pubic bone in order to detect injuries of the vessels and the internal organs. When upon initial exam of a patient the trauma surgeon suspected injuries to the legs an optional third scan covering the legs and feet followed,' Stefan Reske explains.

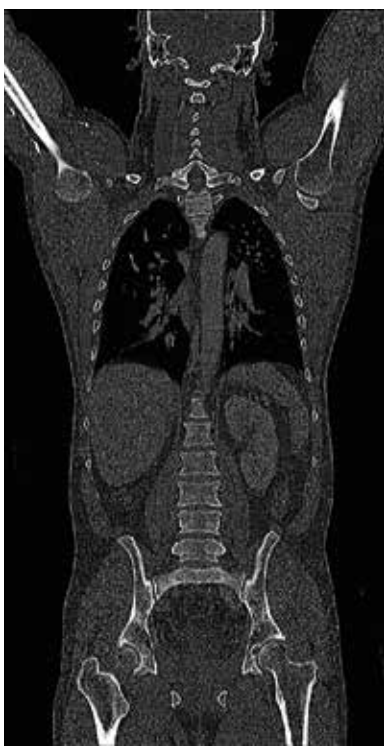
'Today, modern CT scanners feature an iterative reconstruction function which allows a significant reduction in dose – a technological option that unfortunately had not been available to us. Therefore in the course of my project we adapted the original protocol and are now using two differently weighted ones,' the young physician points out. In addition to a time-optimised protocol, which apart from some minor technical changes is identical to the original one, there is now also a dose-optimised protocol. The crucial modification of the dose-optimised version is the fact that the arms are positioned behind the head. The interdisciplinary shock room team decides which protocol will be used. If the patient is stable and there are no indications of a trauma on the upper arms and shoulders the dose-reduced examination is performed. With instable and severely injured patients the time-optimised protocol will be used.

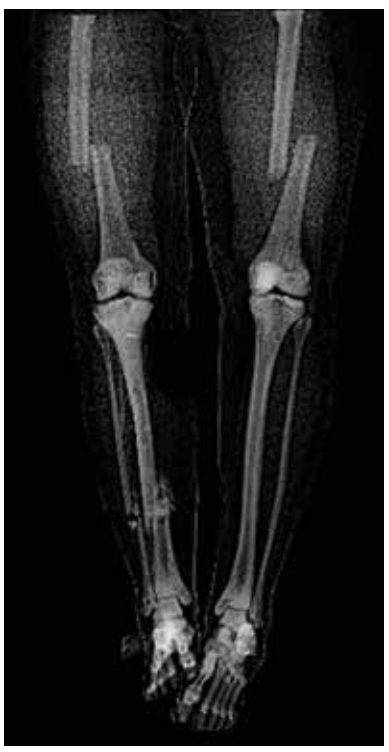
'Compared to the old protocols the new time-optimised one can reduce effective dose to 31 mSv while the dose-optimised version may decrease dose by approximately 40 percent to 26 mSv. In the meantime further potential to reduce dose by optimising the protocols has been identified. Realising this reduction is a major task in my current project,' Stefan Reske reports.

* Reprint from RöKo HEUTE 2013, the official publication of the German Radiology Congress

Typical dose-optimised polytrauma whole-body CT with obligatory scans of head and neck as well as chest and abdomen and optional leg scan. The arms were repositioned before the chest and abdominal scan







Stefan Ulrich Reske MD first trained as a paramedic before his medical studies at Friedrich Alexander University Erlangen-Nürnberg. After his 2007 graduation he joined the Delitzsch district hospital as an assistant physician, but in 2010 opted to take up radiology, since serving at the Imaging Diagnostics and Interventional Radiology Clinic at Bergmannstrost hospital in Halle (Saale).
A Dresden native, Dr Reske is emergency physician and participates in the emergency service in the German Federal State of Saxony-Anhalt.

A European home for emergency diagnostics

The European Society of Emergency Radiology (ESER) held its 2nd Annual Scientific Meeting this June, in Milan

The rapidly growing importance of emergency radiology is underlined by the 10-15% annual increase in the number of emergency medicine scans performed in just the last few years. Clearly knowledge exchange in emergency radiology had become necessary. Thus due to an initiative by 25 European experts, the European Society of Emergency Radiology (ESER) was founded in October 2011 under the umbrella of the European Society of Radiology (ESR). Among those experts is Professor Ulrich Linsenmaier, Medical Director at the Institute of Diagnostic and Interventional Radiology at three hospitals in Munich, Germany. In conversation with *European Hospital*, Prof. Ulrich explained why Europe needs a dedicated society in this field. 'We had been thinking about creating a forum for resources in teaching, research and science on the European level for some time,' he said.

'Emergency radiology has progressed immensely over recent years due to, for example, innovations in multi-detector computed tomography – MDCT – and whole-body exams. Therefore, we urgently needed a platform for all those colleagues who are increasingly confronted with emergency diagnostic imaging in their every-day work. Before, European radiologists had to turn to the American Society for Emergency Radiology – the ASER – for support. In the USA, emergency radiology has a 25-year long tradition.'

Is the situation so different from that in the USA?

'Yes, for several reasons. The organisational structures of the radiology societies, for example, and hospital infrastructure are different. In the US, emergency radiology developed in highly specialised trauma clinics, while in Germany we had to struggle hard for radiology to be integrated into the emergency department, the shock room and the operating theatre, and be acknowledged as a clinical discipline. In other European countries though there are very strong emergency radiology departments with hundreds of members – in Italy and Spain, for example.'

What are the ESER objectives?

'We follow a process-oriented approach – which is a major innovation in radiology because the sub-specialty previously focused on anatomical or organ-specific issues. However, the emergency patient usually presents with a complex accumulation of medical issues. Here, process-orientation means that we develop a concept that maps all body regions, from the head through the chest and abdomen to the musculoskeletal system. We do not perceive ourselves as rivals of other specialists but want to bring together the specific resources in emergency radiology.'

Private Docent **Ulrich Linsenmaier MD PhD**, attended medical school in Italy, Germany and the USA. In the latter he also worked in large trauma clinics. Today, the professor is Medical Director of the Institute of Diagnostic and Interventional Radiology at the hospitals München-Pasing, München-Perlach and Augustinum München and teaches at Munich's Ludwig Maximilian University. As an interventional radiologist, Dr Linsenmaier's main focus is on emergency medicine and emergency diagnostic imaging in trauma patients and patients with acute diseases. He has published more than 80 articles and books. Since 2011, he has presided over the European Society of Emergency Radiology (ESER).

Will you prepare guidelines?

'We are currently developing a European textbook. In three volumes, this will cover all issues in emergency radiology. The first volume on abdominal imaging was published in 2012 by Springer; volume II will be on the chest and cardiovascular system; volume III on the head and spine. 'We are also proud that the European Journal of Radiology introduced a dedicated section on emergency radiology. This is the first European specialty publication to provide regular space for emergency radiology issues.'

What would your one wish for the future be?

'While ESER already has more than 200 members I'd be delighted if more German radiologists joined us so we can create a German section that represents emergency radiology competently on the national level.'

Further details: www.eser-society.org

* Reprint from RöKo HEUTE 2013, the official publication of the German Radiology Congress

New digital radiography mobile

Italray is at Medica Hall 10. Stand A70.

Italray Srl, an ISO 9001/2000 certified company, will soon celebrate its first 40 years (est. 1974) successful operation. With its main production facility and HQ in Scandicci, in the Florence area, the firm's core business is medical imaging with a special focus on digital X-ray imaging.

The company's activities range from product development to manufacturing, marketing, installation and service. 'We take care of our products throughout their entire lifecycle,' Italray confirms, adding that it provides customers worldwide with 'a complete answer to their radiological needs – from the small mobile unit to X-ray generators, tilting tables, digital fluoroscopy systems, up to the complete digital radiology room'.

Italray's new XFM

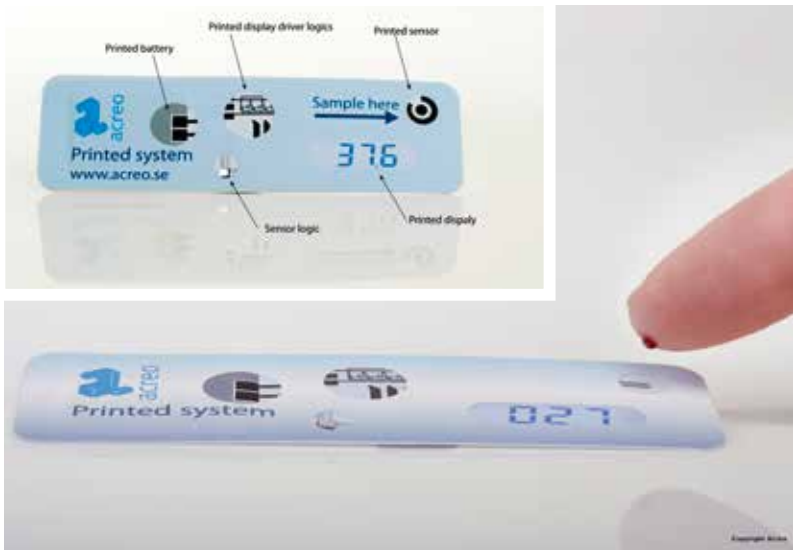
This, the company reports, is 'the innovative answer to any need of diagnostic imaging all around the hospital: from department to ward and intensive care units. The high frequency generator and a wireless detector grant high resolution and detailed 100% Dicom images'.

The compact lightweight device, with an optional motorisation system, makes XFM the unique solution for easy moving and working anywhere in a hospital, the firm concludes.

Details: http://www.italray.it

Printable IVDs put diagnostics in a patient's pocket

John Brosky reports on a credit card size tester that enables self-monitoring of blood glucose



Using electrically conductive, ink-like materials, a Swedish consortium has created a fully functional prototype for a self-monitoring blood glucose (SMBG) test that could be disruptive for in vitro diagnostics.

The low-cost test was developed by a consortium funded by the Swedish government, which includes the research institute Acreo Swedish ICT in collaboration with the Biosensors and Bioelectronics centre at Linköping University.

The printed biosensor on the card reacts with a sample, in this case a drop of blood, and the reaction is converted to an electronic signal that can be processed with the resulting measurement displayed.

The next generation, the developers explained, will be fully printable, except for a tiny silicon chip.

Göran Gustafsson, vice president for Printed Electronics at Acreo said the institute is now looking for commercial partners to take this platform to the market. 'We hope to find companies with specific requirements for diagnostics in medicine but also in processing, food handling and defence,' he said.

Assuming mass production, a biosensor card could be delivered for 50 centimes (€0.48) each, according to Anthony Turner, who heads the Biosensors group in Linköping. 'We have seen rapid advances in printed electronics to make more flexible, low-cost portable and wearable electronic devices, while in parallel there has been a great advance in printing various biological materials.'

The Swedish consortium has converged these two trends in a single-use, disposable platform with all the features of a complete analytical instrument that can be produced on a large-scale, 'and by that we mean billions of units,' he explained.

While the proof-of-concept demonstration of the Swedish biosensor platform used glucose, the SMBG market is not likely to be an entry point for the device, Anthony Turner added. 'We are looking beyond diabetes at literally hundreds of applications. There are all the disease areas the western world is preoccupied with, such as cancer, heart disease, or infectious disease, as well as health management issues, such as elderly care and aging. Then there is the maintenance of well-being where we try not to get sick in the first place,' he said, adding that the platform can be applied to individual food safety checks for people with allergies, or for environmental conditions, such as water quality.

He sees this yet-unnamed, credit card size, low-cost, all-in-one diagnostic instrument as a game changer, empowering consumers and patients to take charge of their own health concerns. 'In the future it may seem crazy that people would take a half day just for a blood work-up, and then wait three days for results that give a 55% accurate diagnosis. Digital health will bring a paradigm change, not just in diagnostics but in the way we maintain our health.

'We'll see the end of centralised facilities as a lot of healthcare routine will be done through much more mobile health resources that deliver the information we need about our health at our convenience, at home, in our office…' Wherever.

Point-of-care-testi emergency depart

Advice: test, test and test again

Report: Cynthia E Keen

Over the past 10 years the use of point-of-care testing (POCT) in in European and North American hospitals has steadily increased, stimulated by the objectives of accelerating diagnostic treatment, increasing efficiency and improving patient outcomes. Its use, however, remains controversial. Last month the American Association for Clinical Chemistry (AACC) conducted a three-day online conference on the role of POCT in patient care.

For many hospitalised patients, point of care testing begins in an emergency department (ED). In one conference session, a pathologist and a supervisor of POC services for two different multi-facility healthcare enterprises discussed how their organisations used POCT and what needed to be done when implementing a POCT programme in an emergency department.

Dr Valerie Ng, PhD, Chair of pathology for Alameda Health System, is also director of clinical medicine at Highland General Hospital, one of the seven healthcare facilities in the California county east of San Francisco Bay. She believes that the adversarial attitude about POCT that existed between laboratory and hospital departments has changed dramatically in the last five years. 'There's a role for POCT in emergency departments.'

Most hospital emergency departments are seriously overcrowded. If a POC test is performed appropriately and accurately according to protocol, if trained members of staff are available, if turnaround time for results is faster, and if the POCT achieves a goal that can be financially justified, Dr Ng is in favour. POCT can help make an ED function more efficiently and help improve patient outcomes.

It also can seriously harm or kill a patient, such as when the blood type of a patient needing a transfusion is mixed up with another patient. 'It just doesn't succeed without thorough analysis and preparation. Much work needs to be done to determine if a specific POCT procedure is appropriate. Some will be. Others won't – and don't assume that having an electronic medical record system will make things easier. Electronic records actually complicate the process because transactions with every

element must be tested and validated,' Dr Ng cautioned.

The two key points to consider are how quickly a result is needed. Will POCT decrease a patient's length of stay? How will it affect patient management? Sonya Evans, POC coordinator of Greenville Health Systems, with six hospitals located across some 280 kilometres in northwest Georgia, agrees.

Her organisation established a multidisciplinary POC Committee to assure standardisation, clinical utility of any POC test, cost effectiveness, and clinical staff/regulatory compliance. Written policies and procedures are mandatory and enforced by both organisations, as well as standardised training. Staff members who don't complete training updates are electronically 'locked out' of access to electronic POC testing forms.

The use of a POC D-dimmer test to exclude pulmonary embolism was an example given. ED physicians at Dr Ng's hospital opt for a three-to-six hour rule out rather than a 90-minute one. For this reason, that test is performed by the central lab. Using POCT to identify elevated lactate that indicates sepsis is different. Speed in

A box totally designed for safety

Kartell is at Medica Hall 03. Stand B95.

Designed to transport tubes, containers, vials, plastic bags and ready-to-use syringes whenever an air-tight seal is required, Kartell Labware Division's Safety Box is made of polycarbonate and is fully autoclavable.

The box is completely clear to enable inspection for possible container leakage before opening, and is reported to provide a high degree of safety when transporting antiblastic drugs from the preparation Centre to the site where they will be administered.

'The cover has a hermetic silicon safety seal to ensure containment of fluids or anti-tumour drugs and protects against leakage and/or accidental spill from bottles or seepage from plastic bags,' the manufacturer points out, adding that four safety locks prevent accidental opening if the box is dropped. 'Inside the box, bevelled edges and the special design of the bottom guarantee safe, simple and efficient cleaning,' Kartell adds. 'An indelible biological hazard symbol is moulded on the outside of the cover. The box also includes a stainless steel AISI 304 handle for ease of transport and an instruction sheet on use and maintenance.'

Details: http://www.kartell.it

ng in tments

treatment is of the essence, not only for patient survival but also, in the USA, to meet federal metrics that determine financial performance incentive payments or penalties.

The ease of performing a POCT must also be evaluated, as well as the precision required to achieve accurate results. Only lab professionals should administer some tests, Ms Evans advises. Equipment or test kits may not function as well in A&E as in a lab.

The cost of a test must be evaluated against reimbursement and its value to patient and hospital. A POC creatinine test is more expensive, but has rapid turnaround. For this reason, the additional cost can be justified for a patient who needs a MRI exam. Efficient workflow without scheduling delays in a MRI suite is very important and worth the higher POCT cost.

Other advice: test, test and test again. Review all procedures with the staff members who will be performing the POCT to determine obstacles or hidden pitfalls before the implementation date. Monitor often and consistently. Be prepared to make adjustments immediately – and test them – when points of failure are identified. Use written procedures. Develop checklist forms. Establish metrics for on-going measurement. Train, train and retrain. Involve the IT staff if electronic records are involved. Make sure that data transfer from point-to-point-to-point are comprehensive and accurate and that everyone who needs to see the data has electronic access to it.

Finally, keep hospital administration informed. Otherwise, budgets may be affected.

The 2nd European Neurotech Investing & Partnering Summit

Drugs, devices and diagnostics for the brain aim to cure Alzheimer's, depression, & even more

Michael Reiter reports

Neurotechnology manufacturers address conditions across neurology and psychiatry, explained Casey Lynch founder and managing director of the USA market research group NeuroInsights. This broad spectrum ranges from neurodegenerative diseases, e.g. Alzheimer's, to psychiatric disorders such as schizophrenia, and to traumatic injuries that include stroke and chronic pain. NeuroInsights co-organises the biennial European Neurotech Investing & Partnering Summit. Held in Helsinki this September, the second provided an overview of this growing market, with presentations from more than 50 CEOs and industry experts.

Neurotechnology has three key areas: diagnostic and therapeutic devices, and drugs, which include radiopharmaceuticals. 'Overall, this is a very exciting market,' Casey Lynch underlined. 'We started out with NeuroInsights ten years ago, and the development has been extremely dynamic ever since. There is a huge unmet patient need: for example, 30 percent of epilepsy and depression patients still are not getting effective treatment, and neurodegenerative disorders like Alzheimer's and Parkinson's only have short term symptomatic interventions. Companies take risks developing new products – some of which will inevitably fail. On the other hand, the potential wins for companies and investors are enormous.' In neurotechnology, according to Casey Lynch, there are more ups and downs, more surprises, and more successes and failures than in other med-tech segments. One neurotech area that is promising but underfunded is biomarkers and tracers; many venture capitalists perceive that diagnostic companies are not able to provide good exits.

The panel discussion at the Helsinki European Neurotech Investing & Partnering Summit demonstrated that neurotechnology is still an emerging niche with serious challenges – but huge potential

Coming from a neuroscientific background, Casey Lynch is the managing director and founder of NeuroInsights

One of medicine's most dynamic fields

The brain is a highly complex electrochemical organ – and researchers come in from all angles to create treatments. These approaches range from small and large molecules, to cells and neurostimulation devices, he explained. Alzheimer's is an area that shows highly intense research and development, while stroke is at the other end of the spectrum – with hardly any drugs in development, but quite a few devices in the pipeline. The ageing population is stimulating demand even further. 'if we don't come up with disease altering treatments for age related disorders such as Alzheimer's and Parkinson's,' he predicted, 'our healthcare systems will soon be bankrupt.'

Approval is a challenge

In Europe the approval of devices requires manufacturing regularity and certification of processes – whereas in the USA manufacturers need to show safety and efficacy of their products through clinical trials. Thus devices in Europe reach the market two to three years faster, he pointed out. For pharmaceuticals that target chronic diseases, trials are needed that run long enough to show safety. For certain areas, e.g. obesity, where regulators fear widespread use in the healthier population, there are additional impediments, such as cardiovascular safety studies that might keep investors from risking their budgets.

On the other hand, the fragmented approach regarding reimbursement makes Europe a difficult market for manufacturers. Therefore, some neurotech companies are looking at Australia, for example, because its healthcare system is unified regarding reimbursement. Eli Lilly buying Avid Radiopharmaceuticals is a case in point – they bet big on Alzheimer's but are coming up against some difficulty in gaining reimbursement. It is a long and expensive process to develop markers along with the therapy to demonstrate that this will be beneficial – and achieve reimbursement coverage.

'Our second event in Helsinki again attracted a great number of delegates,' Casey Lynch said. With so many opportunities in neuropsychiatry, drug and device companies will continue their dialogue to find ways to cooperate; the European Neurotech Investing & Partnering Summit provides a suitable platform for them. 'Plans are that we will again bring together the key players in neurotechnology in Europe in two years from now.'

The swelling burden of disease

Report: Michael Krassnitzer

'Neurological problems are responsible for between 4.5% and 11% of the total burden of disease,' explained Professor Eduard Auff MD, from the University Clinic for Neurology at the Medical University of Vienna, and President of the World Congress for Neurology (WCN 2013). Quoting the figures from the World Health Organisation (WHO), he noted: 'This is much higher than the number for diseases of the respiratory tract, gastrointestinal diseases or malignant tumours,'

Based on WHO predictions, this burden of disease will increase dramatically in the coming years. The prevalence of neurological diseases continues to be underestimated, but should be given higher, health-political priority, he stressed during the scientific congress held in Vienna, Austria this September.

According to the WHO, the number of so-called DALYs (Disability-Adjusted Life Years – the number of lost life years due to early death combined with the loss of life years due to disability) resulting from neurological diseases worldwide will increase from 92 million in 2005 to 103 million in 2030 – an alarming increase of 12%. There will be a particularly drastic increase (estimated to be around 66%) in lost life years due to Alzheimer's and other forms of dementia as a result of demographic developments alone. Conversely, however, the number of years lost due to infectious neurological diseases such as poliomyelitis, tetanus, meningitis and Japanese encephalitis is predicted to decline by around 57%.

According to Professor Auff, 'This is a good example of what can be achieved with targeted prevention and treatment.' However, only a comparatively small number of people is affected by these diseases: 'The lion's share of DALYs due to neurological problems, more than 55%, is made up of cerebrovascular diseases such as stroke and cerebral haemorrhage. 12% is due to Alzheimer's or other forms of dementia, 8% due to epilepsy or migraine,' the expert explained.

Although the number of people suffering multiple sclerosis (around 2.5 million worldwide) is lower than that of – almost endemic - neurological diseases such as stroke or dementia, MS is one of the most frequent neurological diseases among young adults, along with epilepsy. 'In MS therapy the trend is more and more towards personalised treatment, customised for each patient,' Professor Eduard Auff reported.
These days, next to interferons and glatiramer acetates, monoclonal antibodies are also available that can impact on the underlying immunological process in different places and which can prevent the invasion of the brain by activated lymphocytes, i.e. aggressive immune cells.

Costs resulting from neurological diseases are high – in Europe alone estimated to be around €798 billion annually, according to recent figures published by the European Brain Council along with the CDBE2010 Study Group.

Only 37% of this figure represents direct healthcare costs, with the remainder direct, non-medical costs (23%) and indirect costs (40%) resulting from sick leave and early retirement. The study included data on 19 diseases. Incidentally, the burden of disease is spread unevenly from a global perspective: some neurological diseases occur in different parts of the world with different frequency or affect different parts of the population.

'Confronting the growing burden of neurological disease adequately requires a well-balanced overall concept for basic and applied clinical research,' the WCN president. Emphasized. 'This, along with cross-national cooperation for studies and clinical trials, should result in progress for the affected patients.'

Eduard Auff, President of WCN 2013

This is important so that the enormous diagnostic and therapeutic progress seen in neurology in recent years can be further advanced. 'The treatment of acute stroke has changed significantly due to essential organisational improvements and the setting-up of stroke units, along with new interventional treatments,' the professor pointed out.

The result is a clear reduction in mortality and subsequent disability, respectively. For multiple sclerosis, fast and accurate diagnosis and early treatment with modern medication can now impact on the progress of the disease as never before, delaying the onset of disabilities. 'For many neurological diseases, study results from the field of neurogenetics have provided us with new insights for systematic classification, and frequently, pathogenetic relationships have also become clearer,' Prof. Auff concluded.

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Tackling MRSA

A universal decolonisation approach shows impressive results

Report: Mark Nicholls

Decontaminating every patient in an intensive care unit is a far more effective approach to controlling infections in hospitals, according to a new study.

Carried out in the USA, the researchers found that giving all patients in adult intensive care units a daily bath with antiseptic soap and an antibiotic ointment in the nose removed antibiotic-resistant bacteria from their bodies and protected them from serious bloodstream infections.

Now a hospital group at the study centre – the Hospital Corporation of America, the nation's largest hospital chain - is adopting universal ICU decontamination.

The Randomised Evaluation of Decolonisation Versus Universal Clearance to Eliminate (REDUCE) MRSA trial took place in two stages from 2009-2011 with a multidisciplinary team from the University of California, Irvine; Harvard Pilgrim Health Care Institute; Hospital Corporation of America (HCA); and the Centres for Disease Control and Prevention (CDC) focusing on 74 adult ICUs and 74,256 patients, making it the largest study on this topic.

The researchers found that using germ-killing soap and ointment on all ICU patients can reduce bloodstream infections by up to 44% and significantly reduce the presence of methicillin-resistant Staphylococcus aureus (MRSA) in ICUs.

During the work, the effectiveness of three MRSA prevention practices were evaluated: routine care, providing germ-killing soap and ointment only to patients with MRSA, and providing germ-killing soap and ointment to all ICU patients. In addition to being effective at stopping the spread of MRSA in ICUs, the study found the use of germ-killing soap and ointment on all ICU patients was also effective for preventing infections caused by germs other than MRSA.

Lead author Dr Susan Huang, Associate Professor, Infectious Disease School of Medicine and Medical Director (Epidemiology and Infection Prevention) at University of California, Irvine, said: 'These findings are significant in three ways. First, it suggests that simple bathing with special soap and a nose ointment can provide a 44% reduction in bloodstream infections from all pathogens and a 37% reduction in MRSA clinical cultures. Second, it provides an answer to the longstanding question of whether to target high-risk pathogens one by one or to target high-risk people as if they are all at risk for high-risk pathogens. We found that targeting all high-risk people was a superior strategy.

'Third, she continued, 'this trial was conducted using the usual infrastructure for quality improvement campaigns in hospitals. This suggests that findings can be replicated in a wide range of hospitals.'

The universal decolonisation strategy, she added, was the most effective and easiest to implement. It eliminates the need for screening ICU patients for MRSA. The next step is to implement the strategy within hospitals and researchers are in the process of doing a formal cost-effectiveness assessment.

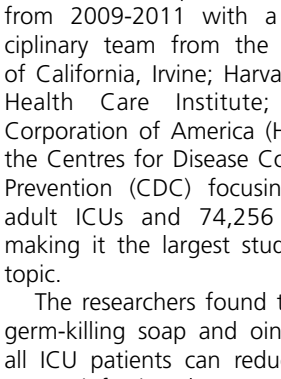
'We suspect that the large reduction in infections will cause this strategy to be highly cost-saving,' added Dr Huang. 'The benefits are related to a lower risk of having MRSA clinical cultures for any reason and a lower risk of a bloodstream infection.'

HCA says the findings suggest a major change in healthcare practice that could save lives. As a result of the findings, HCA is in the process of implementing universal decolonisation in the adult intensive care units at its affiliated hospitals.

Jonathan B Perlin MD, President of the Clinical and Physician Services Group and Chief Medical Officer of HCA, said: 'The Reduce MRSA study proved that universal decolonisation is the best practice to prevent infection from MRSA and other dangerous bacteria in high risk ICU patients.

'These compelling results convinced us to implement this protocol in HCA hospital adult ICUs. Universal decolonisation should be a new part of a comprehensive infection prevention effort that begins with hand hygiene and includes a number of proven practices.'

The researchers noted that this trial took place in HCA facilities, mostly in community hospitals, rather than academic institutions and that it was conducted by hospital personnel rather than specially trained researchers. Therefore, unlike some clinical studies, these results are likely to be applicable to nearly all US hospitals.



Jonathan B Perlin, President, Clinical and Physician Services and Chief Medical Officer of HCA (Hospital Corporation of America), provides leadership for clinical services and improving performance at HCA's 163 hospitals and more than 600 outpatient centres and physician practices.
Current activities include implementing electronic health records throughout HCA, improving clinical core measures to benchmark levels, and leading patient safety programmes to eliminate preventable complications and healthcare-associated infections. Before joining HCA in 2006, he was Under Secretary for Health in the USA's Department of Veterans Affairs.

Dr Susan Huang is Associate Professor at the Infectious Disease School of Medicine and Medical Director (Epidemiology and Infection Prevention) at the University of California, Irvine. Her research focuses on the clinical epidemiology of highly antibiotic-resistant organisms, including the estimation of risk for infection and assess to practical means for prevention. These involve studying the risks of nosocomial MRSA and vancomycin-resistant enterococcus (VRE) transmission plus strategies to mitigate transmission.

EU doctors not 'trained for pain'

Despite one in five EU citizens suffering chronic pain, doctors across Europe are woefully under-educated about pain management, according to a major EU survey unveiled at The European Pain Federation (EFIC) Congress, held in Florence, Italy (October 10th).

The findings, from the APPEAL (Advancing the Provision of Pain Education And Learning) study – the first Europe-wide study on pain education, show an 'alarming' lack of dedicated teaching about pain in undergraduate medical schools in Europe, say researchers. Even medical schools with compulsory courses on pain allocate an average of only 12 hours within a six-year degree programme – just 0.2 percent of the medical student teaching time.

Dr Emma Briggs, King's College London lecturer; Chair of the British Pain Society Pain Education Special Interest Group

According to EFIC President Professor Hans G Kress, from Vienna, Austria), more than 80 million people in Europe suffer from chronic pain – meaning pain that occurs repeatedly over three months or longer. This pain, he said, is currently inadequately treated. 'More than half of chronic pain patients suffer for two years or more before they receive adequate treatment. Lack of knowledge about pain among physicians has long been recognised as a key barrier to effective pain treatment and management.'

The APPEAL study involved 242 undergraduate medical schools in 15 EU countries and found that 82 percent of these schools have no dedicated courses on pain that are compulsory for all students.

'With the exception of France and a handful of schools in other countries that have made headway in the provision of pain teaching, there is a striking lack of dedicated teaching on pain across Europe,' said Dr Emma Briggs, lecturer at King's College London, and Chair of the British Pain Society Pain Education Special Interest Group. 'This raises the question as to whether the provision of pain education in undergraduate medical studies is fit for purpose to address the current and growing unmet public health need.'

Professor Hans G Kress, President of the European Pain Federation

Based on the findings, the APPEAL researchers say that medical schools and relevant policymakers must ensure that medical undergraduate pain education is fit for purpose. They recommend the introduction of compulsory pain teaching for all EU undergraduate medical students and the establishment of a European framework for pain education, developed jointly by pain specialists and educators and drawing on the EFIC® Core Curriculum in Pain Management, to ensure consistency in pain teaching within the EU.

www.efic.org/index.asp?sub=40275570Ac7l08

Is copper preventing nosocomial infections?

What's so special about copper?

The properties of copper in helping prevent nosocomial infections were debated this October at the Infection Prevention 2013 conference, when touch surfaces (collectively termed 'antimicrobial copper') may indeed have a role in providing patients with a safer, more hygienic environment.

Professor Tom Elliott, Consultant Microbiologist at University Hospitals Birmingham NHS Foundation Trust, addressed the question: 'Can the use of copper help prevent infection?'

From his own pioneering clinical trial and a recently-reported multi-centre trial in the USA, the conclusion is that copper and copper alloy

The antimicrobial activity of copper has long been recognised – in people in Ancient Egypt, Greece and Rome used copper in various medical

Antimicrobial copper is the most effective touch surface material, killing greater than 99.9% of bacteria within 2 hours of exposure

treatments to help prevent infections. However, its ability to rapidly kill bacteria, viruses and fungi that settle on its surface has now been comprehensively demonstrated in the laboratory, and is also evident in clinical settings.

In the first clinical trial – carried out at the now-closed Selly Oak Hospital in Birmingham between 2007 and 2008 – it was shown that microbial load on frequently-touched surfaces, such as taps, light switches, grab rails, bedside tables and toilet seats, could be reduced by greater than 90% if these items are replaced with antimicrobial copper equivalents. These observations have been subsequently supported by similar studies in healthcare facilities across the world.

Most recently, a preliminary report on the effect of antimicrobial copper touch surfaces on the incidence of nosocomial infections (HCAIs) in an ICU environment showed a patient's risk of acquiring an HCAI is reduced when only six key touch surfaces in their vicinity are made from antimicrobial copper.

Hosted by the Infection Prevention Society (IPS), the Infection Prevention conference is the UK's largest infection prevention and control event of its kind – it was staged at the massive ExCel venue in London.

'This supports the use of antimicrobial copper touch surfaces as an adjunct to existing infection control procedures, in conjunction with continued regular surface cleaning and disinfection.

'These trial results raise a simple question,' Professor Elliott says. 'Why select a material other than antimicrobial copper when specifying surfaces that may be vehicles for the spread of infection? With the advent of multiple antibiotic-resistant bacteria causing HCAIs, some of which are very difficult to treat, such an approach – with the continuous antimicrobial activity of copper – is potentially even more relevant and important in today's healthcare setting than ever before.'

The next generatio

A well-blended intense cone of light from three reflectors

Starled3 NX, a lamp manufactured by the ACEM Medical Company, is based on the next generation LED technology, assuring cold light, long life and low energy consumption, the Italian company reports. 'The lamp is suitable for countless applications both for surgery and the operating room. It is also ideal for diagnosis, the dental sector, gynaecology, dermatology, general medicine and surgery.'

Starled3 NX grants a homogeneous and shadowless light thanks to its special LED optics created by ACEM, which directs light beams according to needs, the firm continues. 'The visual area is perfectly illuminated assuring both excellent visual comfort and working conditions.

'Its next generation LEDs produce an unparalleled quality of light with a colour temperature (CCT) of 4.500°K and colour rendering index (CRI) of 95. Starled3 NX has a light intensity of 130.000 lux with a low energy consumption of 55W. The life cycle of its LEDs is about 50.000 hours.'

The lamp's three reflectors produce a well blended and intense cone of light focused via the automatic adjustment of the light spot

Bioactive cab nosocomial i

Following five years of development, Integral Process is ready to supply its full range of patient cables made of anti microbial material. Due to the anti microbial properties this reusable product prevents cross contamination and hospital acquired

Integral Process a
Medica Hall 09 / C

on LEDs

diameter, the firm continues.

The slim, practical, compact and easy to move and position design enables several uses and it is reported to be suitable for the laminar flows of an operating room.

Due to the Endo NDO function (light for endoscopy) possibly this lamp could also be used for minimal-invasive surgery.

Easy-to-clean in shape and materials, the lamp has a removable, sterilisable, easy-to-grip handle promising maximum hygiene. This includes the I-Sense panel which provides simple touch control for light intensity adjustment, Depth of Field - for a deep light, Endo for endoscopy, light spot diameter adjustment to focus the operating area, Sync to synchronise controls of the combined lampsStarled3 NX double (twin dome configuration) and Starled3 NX plus Starled5 NX and/or Starled7 NX.

Starled3 NX can be wall or ceiling mounted (single/double configuration with other Staled NX lamps) and trolley mounted (battery on demand).

CEM at Medica
all 10, booth D31.

ples against infections

(nosocomial) diseases. 'There's no cost increase for the cable, but a very large cost reduction for the community in avoiding cross contamination,' the manufacturer points out.

'Full studies have been carried out in hospitals and the results are impressive. This new option for patient cables is,' the firm adds, 'exclusive to Integral Process.'

Visitors can check out these cables at Medica this year.

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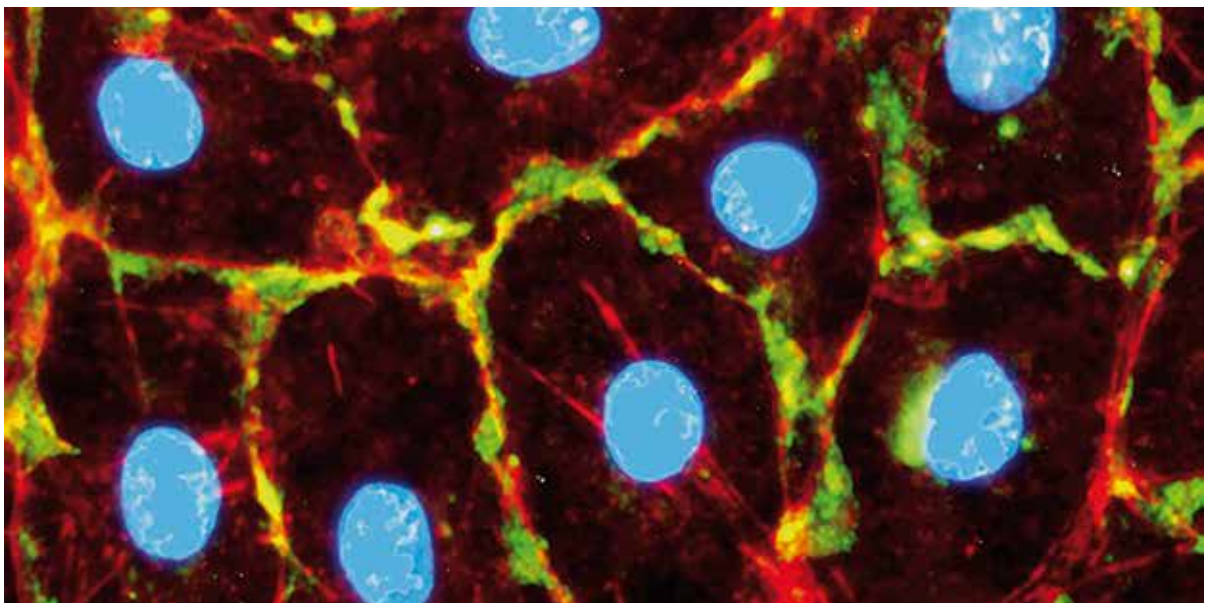
C37.

European nanomedicine research

The European Technology Platform for Nanomedicine (ETPN) is an industry-led initiative jointly set up with the European Commission in 2005 to advance the application of nanotechnology in healthcare research. *Dr Jörg Raach* reports on its current aims in cancer care.



Cancer diagnostics - Nanotechnology is currently being used in oncology to improve early tumour detection, imaging procedures and targeting of cancer therapies. Cancer biomarkers, indicators that are being produced by the body in spreading tumour cells, play an important role in cancer detection. However, in the early stages of the disease, due to their concentration in the body, these markers are difficult to detect safely and efficiently. The targeted delivery of nanoparticles in the suspected tumour area can prompt the cancer cells to increase the production of biomarkers significantly. Consequently, the biomarkers are detected more easily and cancer can be diagnosed much earlier than with a biopsy. This in turn means that a suitable therapy can be initiated in this early stage of the disease that is less stressful for the patient and very likely provides better outcomes.

Iron oxide nanoparticles can be coated with a special substance that docks easily onto tumour cells. Due to their magnetic properties they are particularly well suited for MRI scans. Their se and concentration in the tumour, as visualised in the MR image, facilitate precise mapping of lesions and allow the surgeon to better plan tumour resection.

Therapy - In cancer therapy nanotechnology is employed for targeted drug delivery and basic therapies. Nanoparticles can be injected into a tumour and activated by magnetic fields, X-rays or light to produce heat in a defined area. Thus tumour cells can be destroyed without harming surrounding tissue. A second strategy to deliver substances in oncology is encapsulating chemotherapy agents or genes in nanoparticles. This reduces the amount of necessary medication significantly and also diminishes adverse effects. Both methods have been successfully coupled with gold nanorods already; they transport drugs to the tumour where they are stimulated by infrared light. The heat triggers the drug release and supports cancer cell destruction.

Fourteen companies are already marketing 77 nanomedicine products for cancer therapy and 82 clinical trials are underway.

The research network - Founded in 2005, The European Technology Platform Nanomedicine (ETPN) is an EC initiative along with large companies (inter alia Philips, Siemens, UCB), SMEs and research institutions to conduct medical nanotechnology research and promote joint projects. Since its inception ETPN has published several strategic documents that define requirements and roadmaps for research in nanomedicine. ETPN is also involved in many EU-funded projects that aim to create a suitable social and economic environment as well as the structural preconditions for the efficient translation of research and development into innovative nanomedicine products (see *www.etp-nanomedicine.eu*).

Since 2012, the NanoMed 2020 project has been interlinking around 200 European research institutions, hospitals and firms to further explore the potential of nanomedicine.

The 18-months project receives €500,000 in EU funding.

NanoMed 2020 partners

VDI/VDE-IT (Coordinator).
www.vdivde-it.de

CLINAM Foundation.
www.clinam.org

Instituto de Salud Carlos III.
www.isciii.es

Bioanalytik Muenster e.V.
www.bioanalytik-muenster.de

Nanobiotix.
www.nanobiotix.com

Fondazione Don Carlo Gnocchi ONLUS.
www.dongnocchi.it

SINTEF.
www.sintef.no

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S2

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S20

S11

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