EUROPEAN HOSPITAL

THE EUROPEAN FORUM FOR THOSE IN THE BUSINESS OF MAKING HEALTHCARE WORK

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Doom and gloom but yes, there's hope and even health-promoting laughter...

As our year ends amid depressing global economic uncertainty, budget and staff cutbacks, threats to healthcare workers' pensions and much else, some events shine brightly through, writes EH Editor *Brenda Marsh*. 'These confirm that vision, courage and laughter can indeed cure many ills'

In this our final *European Hospital* issue for 2011 we are delighted to report the heart-warming story of Justus, a little boy with multiple congenital cardiac problems but the good fortune to encounter a paediatric cardiologist with the stoical courage to push the boundaries of procedures and thus bring continuing hope for Justus and his family (see pages 10-11).

We were also cheered by mighty MEDICA in Dusseldorf this November. As in recent years, our team distributed our official English show publication and welcomed a large number of business partners, readers and writers to our booth, all keen to make contact with us and share their positive responses to our work as well as their own for the future.

Phew! MEDICA and COMPAMED 2011 combined had 4,571 exhibitors and welcomed 134,500 visitors from over 100 nations. After four hectic days at this the world's biggest medical trade fair, Joachim Schäfer, Managing Director at Messe Düsseldorf, praised the operational excellence of medical device technologies on show and summed up: 'Professional organisations reported an excellent mood prevailing amongst exhibitors and of good business as a result of the high attendance of international and decision-making trade visitors.'

Eminent guests included EU Health Commissioner John Dalli (Malta), the United Kingdom's Minister for Trade and Investment Lord Green and the USA's Assistant Secretary of Commerce Suresh Kumar. John Dalli was impressed by the innovation-driven growth industry and Suresh Kumar declared: 'In the aviation or automotive field the leading trade shows are dominated by major corporations alone. By contrast, Medica is a business platform for thousands of small and medium-sized companies. The deals concluded here create new jobs immediately.'

All in all, the strong international feedback gives the medical technology industry a tailwind for exports.

So, there are the positive thoughts on employment and trade in our field.

Will we be at Medica 2012 next November? See you there!

EH China representative Gavin Hua with journalists Karoline Laarmann and Meike Lerner (right)

It is also rewarding to hear Siemens (page 12) indicate that increasing the power of a medical device is less important than increasing its explicit abilities in specific clinical procedures.

And, that other Godsend mentioned…?

Laughter therapy

Many of us followed the hilarious American TV series MASH years ago and still enjoy re-runs even today. In the face of frontline medical work the zany humour of doctors is often a life-saver. Thus the year ends with personal thanks to the British Medical Journal (http://www.bmj.com) for publishing in its December issue a funny study indeed. Here's the BMJ headline:

Caution advised when making fun of orthopaedic surgeons

What was the aim of the UK medics – P Subramanian, trauma and orthopaedic specialist registrar, S Kantharuban, core surgical trainee, V Subramanian, foundation year trainee, S A G Willis-Owen, post-doctoral research scientist, and C A Willis-Owen consultant trauma and orthopaedic surgeon – who created the study? To compare and verify the intelligence and grip strength of orthopaedic surgeons and anaesthetists.

Why? Because there is a stereotypical impression that orthopaedic surgeons are of lower intelligence but greater physical strength than average among the medical profession. 'This is often the subject of light hearted humour, particularly in jokes with anaesthetists,' the authors explain. 'A humorous anaesthetic colleague recently repeated the following popular saying when an operating table was being repaired with a mallet: "… typical orthopaedic surgeon – as strong as an ox but half as bright". Making fun of orthopaedic surgeons is a popular pastime in operating theatres throughout the country. This pursuit has recently spread to the internet; a humorous animation entitled *Orthopedia vs anesthesia** had received more than half a million hits at the time of writing.

'Several comparisons of orthopaedic surgeons to primates have been published, and the medical literature contains suggestions that orthopaedic surgery requires brute force and ignorance.

'The stereotypical image of the strong but stupid orthopaedic surgeon has not been subject to scientific scrutiny. Previous studies have shown that the average hand size of orthopaedic surgeons is larger than that of general surgeons. However, a search of the worldwide scientific literature found no studies assessing the strength or intelligence of orthopaedic surgeons. In the absence of a cohort of willing oxen as a control group, and given that the phrase is popular with anaesthetists, we designed this study to compare the mean grip strength of the dominant hand and the intelligence test score of orthopaedic surgeons and anaesthetists.'

The multicentre prospective comparative study

With the main outcome measures intelligence test score and dominant hand grip strength, 36 male orthopaedic surgeons and 40 male anaesthetists at consultant or specialist registrar grade at three district general hospitals took part in study, which took two weeks in all.

Results: The orthopaedic surgeons had a statistically significantly greater mean grip strength (47.25 (SD 6.95) kg) than anaesthetists (43.83 (7.57) kg). The mean intelligence test score of orthopaedic surgeons was also statistically significantly greater at 105.19 (10.85) compared with 98.38 (14.45) for anaesthetists.

Ah, so on to their …conclusions: 'Male orthopaedic surgeons have greater intelligence and grip strength than their male anaesthetic colleagues, who should find new ways to make fun of their orthopaedic friends.'

Final authors' cautionary advice: 'The comedic repertoire of the average anaesthetist needs to be revised in the light of these data. However, we would recommend caution in making fun of orthopaedic surgeons, as unwary anaesthetists may find themselves on the receiving end of a sharp and quick witted retort from their intellectually sharper friends or may be greeted with a crushing handshake at their next encounter.'

* *www.youtube.com/watch?v=3rTsvb2ef5k*.

And so, dear readers, we leave you with a smile and a promised welcome when you return to our pages in 2012.

Best wishes

The EH team

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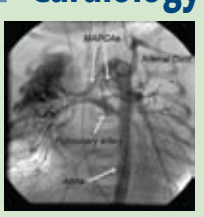

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Are you in charge of your department's budget? ☐ Yes ☐ No

How much influence do you have on purchasing decisions?

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relatively modern ☐ Yes ☐ No

state-of-the-art ☐ Yes ☐ No

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If so, what do you use of this kind?

Is your department linked to an internal computer network? ☐ Yes ☐ No

Is your department linked to an external computer network? ☐ Yes ☐ No

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Are you given ample opportunities to up-date knowledge? ☐ Yes ☐ No

Do you attend congresses or similar meetings for your speciality? ☐ Yes ☐ No

This information will be used only in an analysis for European Hospital,Theodor-Althoff-Str. 39, 45133 Essen, Germany, and for the mailing out of future issues and the EH electronic newsletter.

EH 6/11

Hospitals need to promote health for all

Care of staff is as important as patient care!


Doris Mack


Burkhard van der Vorst

'At the point where people are being admitted to hospital they are also likely to be prepared to deal with health promotion or issues of prevention. Therefore, health promotion is an important topic in the hospital, alongside standard care,' explains University Docent Dr Doris Mack, who heads the Department for Quality and Risk Management at the Salzburger Landeskliniken (SALK).

Health promotion in the hospital relates not only to patients but also to staff: 'Occupational health promotion is an important task for hospitals,' she emphasised at the Annual Meeting of the Austrian Network of Health Promoting Hospitals (ONGKG) in Salzburg, an event also attended by representatives from Germany, Switzerland and Italy. Currently the network is one of 38 within the *International Network of Health Promoting Hospitals and Health Services* (HPH) initiated by the World Health Organisation (WHO).

Numerous projects aimed at health promotion for hospital staff were introduced at the meeting, with a particular focus on exercise, smoking and mental health.

The SALK, this year's event host, is running some commendable projects: Staff members are, for instance, encouraged and supported to come to work by bicycle. Another project, 'Age-appropriate Working' is specifically aimed at staff members who have been in the job for more than 25 years. On offer is training on topics such as more spine-friendly ways of working, along with free advice on alcohol consumption, smoking and burnout prevention.

Coaching and supervision for the 5,000 staff members within this group of hospitals have become standard; the SALK sets aside an annual budget of €100,000 for this purpose. 'Occupational health promotion is a matter of course for us,' Burkhard van der Vorst, Managing Director of the SALK points out.

Prevention for hospital staff is obviously not only available in Salzburg. The range of health promoting measures in Austrian hospitals is extensive. For example, the Hospital of the Elizabethan Sisters in Linz offers a comprehensive training programme on burnout prevention. Lectures, seminars on self and stress management and relaxation, as well as workshops on occupational health promotion for senior management, are all being held.

Vienna's Emperor-Franz-Josef-Hospital provides its nurses with the services of a qualified personal and dietary trainer, whose coaching and advice helps to promote a healthy diet, fitness and exercise. The Vienna Hospital Association KAV runs the project 'Healthy work without limitations', particularly aimed at women in low income occupations (cleaners, caterers, kitchen and laundry workers) who were previously unable to benefit from projects on occupational health mainly due to language barriers.

The University Clinic for Medical Psychology and Psychotherapy at the University Hospital Graz offers staff relaxation training with music therapy in their lunch breaks.

The cardiac catheter laboratory at the County Hospital in Bruck an der Mur (Styria) runs the pilot project 'Active Break', when various types of exercise are offered to staff at lunchtime, such as movements aimed at mobilisation of the larger joints, particularly the spine, as well as exercises for the strengthening muscles of the torso and extremities as well as sequences for the improvement of flexibility of the joint structures.

Health promotion for hospital staff not only benefits the staff themselves, as expressed by Dr. Maria Metzler-Rintersbacher, Specialist in Occupational and Psycho-social Medicine at the Hospital of the Elizabethan Sisters in Linz: 'If the staff are well, patients will also benefit from this.'

Europe's healthcare sector faces strained labour relations

Current staff crises are leading Europe's hospitals to show strong interest in talent management, according to human resource management software provider *umantis*


Karin Burtscher

Just a quick glance through recent news throws up examples of critical unrest. In Slovakia, for example, the largest strike of doctors in the history of Slovakian hospitals ended with a compromise at the beginning of December 2011.

Out of around 7,000 hospital doctors, 2,400 had initially declared their intention to hand in their notices effective by the end of November, and had thus brought the Slovakian healthcare system to the brink of failure.

Paediatrics, anaesthesiology and surgery departments had almost 'collapsed' in several hospitals, forcing the government to declare a state of emergency, impose obligatory conscription to work and asking for help from neighbouring countries.

After tough negotiations, the government and medical union agreed on a three-stage salary increase, starting at the beginning of 2012.

Then there's Austria, where signs hint at trouble in Vienna after long and inconclusive negotiations. The Vienna Medical University, which employs scientific staff in Austria's largest hospital, the Vienna General Hospital, confirmed that from 1st February 2012 nightshifts and on-call shifts are to be drastically reduced.

Currently, 172 doctors work weekends and overnight, but from February this number will be cut to 145, a reduction affecting all clinics that are part of the hospital and bringing fear that surgical capacities may have to be reduced by up to a third.

However, the department likely to be most affected is the one that tends to be very busy at night: Accident and Emergency.

Talent management

Although, until now, talent management within the healthcare sector has been treated in an inadequate manner, surveys and customer statements in hospitals show that attracting the right applicants, developing employees and offering prospects is now being given a high priority.

Qualified staff shortages and employee perspectives

According to a Pricewaterhouse Coopers (PwC) and Darmstädter Wirtschaftsforschungsinstitut (Wifor) study, Germany alone will see a lack of 56,000 doctors, 140,000 nursing staff and other specialists. 'We are currently experiencing a very tense situation. In Europe we are already missing tens of thousands of nurses, medical technicians and doctors – and this number increases every year,' explained Markus Lüdi, Operations Director Human Resources at the Inselspital, Berne University Hospital. 'In addition, there are many new professions in healthcare for which planning should be made. As a hospital, we actively solicit these.'

In such conditions, each hospital really needs to present itself as an attractive employer. 'We have to and want to be an attractive employer,' said Karin Burtscher, Head of Human Resources of the Schwarzwald-Baar Klinikum in Villingen-Schwenningen. 'That's why we are going to enable our young doctors to acquire important management skills – beyond medical expertise. We want to retain our doctors after their specialist examinations and not lose their knowhow.'


Berne University Hospital

In view of these developments, the Talent Management software provider umantis registered a rapidly increasing interest in its software modules from the healthcare sector in 2011.

With its 7,500 employees, the Inselspital in Berne is one of Europe's largest hospitals, and it is the first large Swiss hospital to implement umantis Recruiting software, thus hoping to gain an advantage in competition for medical and nursing staff. 'Compared with private businesses, Swiss hospitals are years behind when it comes to talent management,' explained Operations Director of Human Resources Markus Lüdi. 'There's a need for a strong focus in this area. We are pioneers here and expect many advantages thanks to a modern and paperless application and staffing process – particularly with regard to speed and professional appearance towards applicants.'

The German Schwarzwald-Baar Klinikum, with its 2,800 employees, is the region's largest employer. Currently, they are implementing the umantis Employee Management software. Head of Human Resources Karin Burtscher: 'We have to precisely visualise the competencies and qualifications we have already, as well as define the one's we must systematically develop in the future. This picture only becomes apparent if target and performance data can be consolidated and clearly laid out. This is where software can be a great help.'

‘Shopping’ as a growth strategy

Celenus regroups on the rehabilitation market and aims for the top through acquisitions, *Susanne Werner* reports

The objective is ambitious: Based in Offenburg Baden-Württemberg, Celenus-Kliniken GmbH wants to double its turnover by 2015. Turnover is to increase to €70 million by the end of this year, and to €150 million in four years time.

The strategy is clear, with the bulk of the growth envisaged via acquisitions. ‘We want to be amongst the top group of operators running rehabilitation clinics in Germany,’ says Dr Christoph Löschmann, member of the board and responsible for quality management, IT and marketing at Celenus-Kliniken.

Twelve clinics as well as a sports centre and a rehabilitation centre are already owned by the group, but it aims to run around 18-20 clinics. At the latest addition, a specialist clinic for psychosomatic rehabilitation opened in Freiburg in September, around 50 doctors, nurses and therapists will concentrate on the treatment of stress and pain-related diseases in the 115-bed clinic.

The Celenus group has around 1,200 employees in Germany and looks after around 2,000 inpatients.

Takeover: Marseille Kliniken rehabilitation clinics

Celenus-Kliniken has been on the market for about a year. Until spring 2010, the rehabilitation clinics were part of the Hamburg-based Marseille group. However, the Marseille-Kliniken sold off this part of their business because it was no longer a key focus. The sell-off resulted in the formation of Celenus-Kliniken GmbH, with Munich-based Auctus Capital Partners AG as the stakeholder.

MD Berthold Müller, who was involved in the sale whilst still at Marseille-Kliniken, as well as Dr Bernd Fromm and Professor Ulrich T Egle, are all on the management board. Dr Fromm is a specialist for orthopaedics, physical medicine and rehabilitation and Medical Director at the Gotthard-Schettler-Klinik in Bad Schönborn. Prof. Egle is a specialist for psychosomatic medicine and psychotherapy and Medical Director of the Klinik Kinzigtal in Gengenbach, which has been treating stress and pain-related diseases for several years, and demand has soared to the stage where it now has a waiting list for treatment.

The new clinic in Freiburg is to also ‘appeal to discerning patients with statutory as well as private medical insurance,’ Dr Löschmann says. The single rooms are luxuriously equipped, with some up to 40m² in size.

Regional networking

Eight out of 12 Celenus clinics are located in Baden-Württemberg. However, further growth is not to be limited to Southwest Germany. ‘We already have three locations in the new Laender and want to expand these,’ explains Dr Löschmann, who believes the rehabilitation market will become more regionalised in the future. Therefore, the next step is to form local clusters and drive the networking of hospitals and clinics in those respective regions. ‘We don’t want to build stand-alone institutions,’ he says. Celenus is to be seen as a parent brand and seal of approval for these locations.

A further objective: Despite good capacity utilisation in psychosomatics, there is no plan to concentrate on individual medical specialties. ‘We definitely want to offer complete solutions for the rehabilitation market,’ he says. ‘Orthopaedics, oncology and cardiology are already represented in our group. Neurology will be the next, important discipline.’

Efficient processes for future rehabilitation

Doubtless, rehabilitation is a central growth area in the healthcare market. After all, an ageing society is increasingly looking for ways to preserve health and employment for as long as possible. It has also gained more health-political importance, on a par with prevention. ‘Prevention before rehabilitation and care,’ is the new motto.

Whilst rehabilitation is gaining importance, the financial means remain limited. This also means that companies that are not economically viable are likely to disappear. This will particularly hit smaller clinics that are not part of a network or chain, whilst the remaining clinics will become part of larger networks. Result: Networking of local service providers is mandatory – with the joint objective of steering patients along paths of care across the sectors.

Slim line and efficient processes are vital for the survival of hospital operators: Celenus, Dr Löschmann points out, is therefore set up like a ‘matrix organisation’. Purchasing, quality management, financial administration, IT and marketing are largely centrally run via head office. Services and processes are scaled and run in the same way in all locations to allow a fast transfer of knowledge and decisions across the entire group. ‘The effects of synergy make the music here and the larger the company the more important they become,’ he adds.

More offers: Small and medium-size companies

Outpatient rehabilitation, so the experts - including those at the German Pension Insurance Federation - will become a lot more important and will be more closely linked with prevention.

The Celenus-Kliniken also wants to point the way here and has announced its intention to become more involved in occupational


Ulrich T Egle


Bernd Fromm


Berthold Müller

healthcare management. After all, employers should have a vested interest in seeing their employees stay healthy, Dr Löschmann adds, particularly in view of the increasing lack of skilled employees: ‘We want to become a centre of competency for employers.’

Celenus Managing Director Berthold Müller adds: ‘In view of the increasing number of sick days taken due to psychological problems we see a potential in offers for occupational healthcare management and the reintegration of the long-term sick.’ It would, for instance, be conceivable that Celenus doctors carry out check-ups and comprehensive diagnoses of employees’ health and then present a healthcare plan with the options on offer, from exercise training to dietary advice and psychotherapeutic support.

The group is already in contact with individual companies and offers such advice. Smaller and medium-size firms, which usually require external support in these matters, are the main target group.

The Global E-Health Forum

Global E-Health Forum. Hamburg 2011

Theme: E-health as a key enabler for designing personalised healthcare

This year’s theme ‘Designing Personalised Healthcare’ drew over 200 delegates from 30 countries to Hamburg in October for the Global E-Health Forum, where, in presentations and workshops, speakers from Canada, China, Egypt, New Zealand, Russian Federation, USA and various European countries presented their strategies and best practices.

Global think tank leaders and stakeholders from all healthcare sectors used the gathering to exchange views and discuss solutions for ensuring a sustainable, patient-centric healthcare delivery. The considerable potential of personalised healthcare in this context was acknowledged by all conference delegates. ‘We are all aware that demographic shifts, the impact of globalisation and an increased burden of chronic diseases and expensive treatments are considerable challenges for our healthcare systems,’ said Founder and Honorary Chairman of the Global E-Health Forum, Ljubisav Matejevic, during the official reception in the U.S. Consulate General in Hamburg. ‘We all agree that, in view of limited budgets and the increasing demand for high-quality healthcare services, new cost-efficient, reliable and interconnected systems need to be developed. And, I guess we all believe that e-health can make a significant contribution to ensure high-quality, sustainable healthcare system.’

How Canada, partner country of this year’s Global E-Health Forum, transformed their healthcare systems through e-health was explained by Richard C Alvarez, President and CEO of Canada Health Infoway.

The challenges and opportunities of personalised healthcare were presented by Chai Chuah, National Director, National Health Board Business Unit, New Zealand Ministry of Health.

Professor Wen Ze Huai of the Research Centre Guangdong Academy of Chinese Medical Sciences lectured on designing personalised healthcare for integrated medicine (combination of the practices and methods of traditional Chinese medicine with modern medicine) by using e-health.


PHOTO: COMMON SENSE GMBH

Panel discussion on Designing Personalised Healthcare

In his keynote address, Dr Eric M Liederman, Director of Medical Informatics, The Permanente Medical Group, explained how to achieve a balance between protecting privacy and security, and fostering high quality patient care by practical examples from Kaiser Permanente.

Markus Habetha-Eisenbarth, Project Manager for E-Health of Asklepios questioned what healthcare providers can learn from the industry and from social media regarding the development of e-health services.

During the panel discussion, e-health was clearly identified as a key enabler for the evolution process towards personalised healthcare. However, healthcare that is proactive, instead of reactive, gives patients the opportunity and responsibility to become more involved in their own health – an issue emphasised by several conference delegates who shared their thoughts via twitter during the panel discussion.

The ultimate goal of personalised healthcare will be to shape not only diagnostic but also preventive care to match each person’s unique characteristics.

Apart from the two-day conference programme, the Global E-Health Forum initiators – the Hamburg Chamber of Commerce, IBM and ICC Deutschland – also organised guided tours in five Hamburg hospitals, three being Asklepios clinics. The Asklepios Hospital Group again supported the Global E-Health Forum as a cooperation partner.

Details: www.global-ehealth-forum.com

Major forces in hospital design and construction

Digitisation and convergence of technologies

RTKL, the architecture and design subsidiary of Arcadis, handles large hospital projects worldwide, with its medical equipment planning group providing specialist consulting on complex medical equipment and IT solutions implementation. During a recent hospital construction congress (Klinikimmobilien in Frankfurt) we spoke with RTKL Vice President and Global Service Leader for Medical Equipment Planning & Procurement Services, Martin McIntire about this special field of work


Martin McIntire

'Only about ten years ago, the approach to medical equipment and technologies integration in hospital building projects was still an afterthought,' Martin McIntire pointed out. 'Other than a few select pieces of large-scale equipment that affected the size or construction of some of the spaces – imaging equipment, operating room lights, and central sterile equipment – the complexity and integration of technology was limited.

'Most of the equipment was standalone within the rooms and required few, if any, technology integration or considerations with other devices. The complexity of the equipment from manufacturers was also limited. There simply weren't many technology implications requiring specialised attention. Equipment implementation primarily could be managed by the architect and construction team. Today, this has vastly changed.

'It's no secret that technology is affecting the way we work, live, and play. Medical equipment and technology are no exception. Today's physicians and medical equipment manufacturers are pushing the limits to provide advancement in equipment and technologies that help save lives. The results are transcending into new hospital design and construction.

'New hospital buildings are designed towards a 50+ year lifespan. While flexibility remains paramount to any building's design, significant considerations and decisions are being placed on architectural design teams and hospital leadership regarding equipment and technology strategies and how they will provide patient care. These decisions affect how buildings are designed and operated.'

How would he define a digital hospital?

'The term digital hospital evolved over the past eight years – and should probably be re-defined. As every hospital strives to implement electronic patient records (EPRs) and automated hospital information systems (HIS) to streamline their business, more and more medical equipment is now IT-enabled and integrated as part of the overall solution for providing patient care. No longer is medical equipment limited to being just a few surgical lights, patient beds and IV poles scattered about a hospital. Equipment is sophisticated with expensive devices that connect and integrate into the building and the operating processes.

The ultimate goal for any digital hospital is to achieve a near paperless environment, with all patient information and procedure results being captured and communicated electronically by medical devices, physicians, and administrative processes.

Why should hospital managers consider advanced approaches?

'While the hospital's ultimate role and responsibility in society is to provide healthcare to people, hospitals are a business. Hospitals have customers (patients); hospitals provide services; they have personnel costs; they utilise products and services and consume a high degree of energy (electricity, water, gases, etc). Whether a hospital is owned privately or by a government agency, costs must be managed.

'Because hospitals are filled with extremely expensive medical equipment and technology, a thoughtful approach and solutions strategy is paramount. Equipment and technologies are being deployed to streamline manual processes, resulting in significant costs-savings on staffing. Technologies have provided great strides for newer, non-invasive procedures resulting in better patient turnover and ultimately better patient outcomes.

'Quantifying healthcare quality can be a challenging and complex process. Using technologies to streamline workflows helps to provide structure to measure patient outcomes and the ability to change practice for the better.

Which groups should be informed about potential approaches and involved in actual concept/realisation tasks?

'It should include the hospital's financial stakeholders (those who pay for the initiative), clinical/physician leadership (those who use the equipment/technology in healing); biomedical engineering and IT managers (those who help integrate, connect, and maintain equipment/technology), and the hospital's purchasing entity (those who source and buy the desired equipment/technology). All stakeholders must be informed of the approach and each participates in their respective role. Leaving one out breaks the cycle and doesn't allow for successful implementation.'

What about the regulatory aspects?

'Unlike your ordinary electronic device purchased at your favourite home technology or electronics store, healthcare devices are intertwined with supporting patient care and are instrumental in helping physicians save lives. The devices must adhere to more stringent regulations to comply as a medical device.

'Regulatory aspects include standards for interconnectivity with other devices (HL7, DICOM 3, etc.) to health safety and technical regulations for vendors, hospital technology managers, equipment service providers and installers concerning the implementation of medical equipment that is interconnected on the hospital network (ISO 80001). It is assumed that there is considerable risk to patient safety when multiple systems are connected together without regard to the effects of one system on another.

'Regulations include the U.S. Food and Drug Administration's good manufacturing processes that classify the device as medical, Underwriters Lab (UL), ISO and, in Europe, the CE Mark on a product or machine that identifies its compliance with safety requirements (health safety and environmental protection legislation) established by the European Union. The CE Mark is a requirement and not a voluntary process. All these regulations are focused on identifying responsibilities and the responsible organisations that will take appropriate steps to implement accordingly.'

Are there other benefits?

'While the primary intent of hospitals to deploy technology is to provide the best patient care, technology is clearly becoming a serious factor in the growing competitiveness and consumerism of hospitals and the image hospitals have in the

community. They are using technology to help position themselves as the "best in technology" and procedural outcomes to help attract patients. In today's society where consumers have access to countless internet information at their fingertips and want the best care possible, technology helps bridge that gap.

'It's not uncommon in some markets to see a billboard or magazine adverts by hospitals highlighting their best-of-outcome procedural results in areas such as paediatrics, cancer, cardiac disease, or even specialised imaging equipment, for example: *We have the city's only Open MRI*. While most hospitals would hardly consider something like this as marketing strategy, for patients who suffer a high degree of claustrophobia, something like the open MRI will make all the difference between choosing one facility over another.'

Process management for future hospitals

Architect Herbert Michael Küpper Dr-Ing demonstrates that full understanding of the working needs of a hospital is necessary to arrive at a successful new construction

Pressure on hospitals results on the one hand from certain structures caused by case-based lump sums and their proceeds and on the other from separate billing for medical services and operating costs.

Budget control is a major cause of innovation slowdown in healthcare systems. Budgets stabilise the status quo. This consistency is now generally accepted. Hence the challenge to realise a growing demand for health services with reduced financing must be accepted.

Based on this, a central theme develops. The conclusion must be: Appropriate business strategies that accommodate increased requirements regarding quality and efficiency have to be incorporated.

This leads us to *processes* and *structures issues*.

Corporate structures are illustrated by process analysis and added value is visualised. Data from a building design model, and later those of a Building Information Model, integrate process data (medical utilisation) and building data. A three-step concept is presented, displaying the interaction between pathways with the required building structures, described in various models (intelligent and target-oriented categories). Thus simulations or variants (sensitivity analysis) can finally be compiled.

Step 1

The basis for target-oriented process control is to demand fundament planning for functional and spatial planning. The final result is a theoretical space allocation plan. Coherent parts are:

- Structures
- Services
- Reference areas

Structures and services build the basis for the reference area design. Information regarding processes and operational specifications are required. These are affected by following directly the area effective factors:

- Operational specifications
- Spatial standards
- Functional standards
- Processes

These are to be supplemented by:

- Energy criteria (HVAC, individuals, lighting, technology (installation degree)
- Algorithm of feasibility study

This space allocation plan is then converted to a spatial building model.

On this basis, project handling can be carried out with reliable functionality.

Step 2

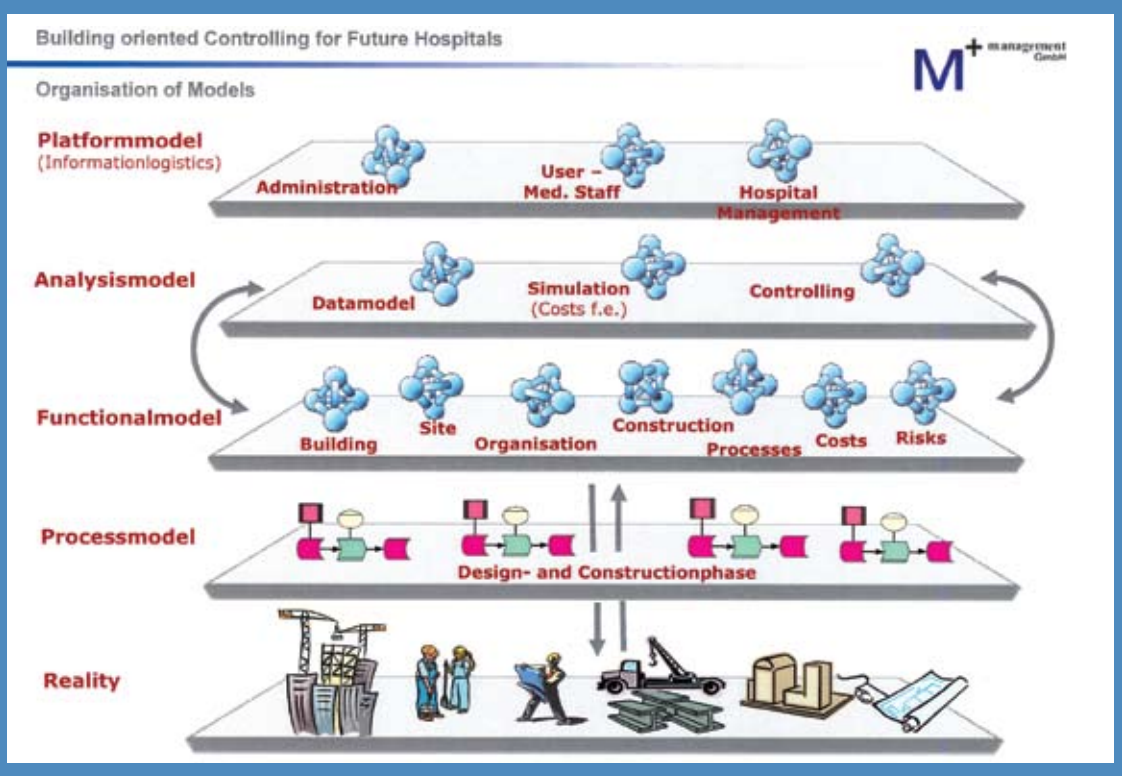
Space and area relevant services are at the core of analytically structured calculation of areas within functional and spatial planning. Definitions of these service catalogues often vary from the hospitals services documentation on hand because services are registered therein as a basis for proceeds, or as parts of a diagnosis-related allocation formula.

Thus the description of space-related performance parameters is not provided.

By using distribution systems and data transfer from existing hospital information systems, a data base of area calculations can be compiled. In this way, the interface between patient pathways, and hence the generated process costs and *space-related performance parameters*, can be established.

Performance parameters are:

- Personnel costs
- Material expenses
- Operational costs
- Capital costs



Building quality

The Digitally Verified Clinical Concept 2015

Being involved in a €68 million new-build and renovation project for the Riesa Elblandklinikum Riesa near Dresden, the privately held firm Unity AG developed a project management scheme customised around the hospital's assets and needs, and also produced a digitally verified clinical concept to optimise building and renovation activities in advance. Prior to this project, Unity AG had mainly gained experience in industry. When *Bettina Döbereiner* interviewed **Meik Eusterholz**, Project Manager of Unity AG, she asked why he had mentioned 'getting a bloody nose' when the firm first became involved in the healthcare sector.

'Seven years ago,' he explained, 'when we began to transfer our experiences from industry into the healthcare sector, we had critical discussions with experts who would not accept any comparability, saying a hospital was not a "disease plant". Since then the mindset has fundamentally changed, recognising the general tasks of patients' well-being and employees' working contentment.'

***So, today, what are Unity's objectives for itself and what guarantees can it give to a client*?**

'With process management, for example, waiting periods can be reduced and operating theatre pass-through times can be optimised. We'd like, for example, to see increased case numbers per operating theatre with the same amount of resources.'

Where might the hospital gain the most?

'Before implementing changes of processing in an organisation, it had better be checked computationally thereby avoiding faulty planning and unwelcome surprises. In this case, the digitally verified hospital ensures the overall possibilities of the building project and, investment costs as well as running costs can be reduced.'

What data basis is used to determine the actual state of the Elblandklinikum Riesa project?

'As a planning guide we take the data from the in use IT-systems, such as the HIS, or patient transportation software and others. In a sense, we take a look in the rear-view mirror in order to empirically assess, for example, on what days and at what times patients frequent the emergency room.'


Meik Eusterholz

How was the target state worked out?

'On the one hand, the target state has been discerned with the help of the identified potentials, i.e. weak points (amounting to about 400) and, on the other, in close cooperation with the staff and management. If, for example, there will be more minimally invasive surgery in the future, this will clearly affect operating theatre cycle-times.'

Did Unity develop the analysis and simulation software, or where did it originate?

'We've used standard software, e.g. Siemens plant simulation, for over ten years, to visualise complex production networks. With the software originally designed for material flow, we had to extend it for our own clinical purposes. So we developed simulation modules in order to effectively visualise each and every clinical process comprising emergency room, the therapies sector, surgical sector and discharge.'

You called this project unique for Europe; is it?

'Yes. As far as we know there were similar projects only in the US, where simulation methods were used for project planning.'

Did those projects serve as your models?

'No. We have learned from our own projects within radiotherapy and operating theatres. Having used simulation for industrial construction planning as standard for over more than ten years, the gain was obvious from applying that simulation to this kind of building project also.'

For you personally, what is most rewarding from this hospital project?

'The Elblandkliniken serves as an innovative partner for this particular project. All stakeholders are enthusiastic and very cooperative. The fantastic commitment of the staff is especially rewarding! Added to these is the great public interest.'

Step 3

In the final step, a data base illustrating the reciprocal effect between medical performance and space-related costs is obtained. Only now can processes be scaled in order to illustrate, regulate and control proceeds (case-based lump sums) together with process costs, all based on a building-related model. A dynamical spatial visualisation is then compiled, leading to the additional benefit hospitals want:

- Complete data and knowledge of process costs
- Reciprocal effects between processes and areas
- Added value can be assigned precisely to areas, rooms and functional sections
- Hence areas that are not adding value can be either eliminated or optimised
- Transparency and clarity by gaining information superiority
- New approaches for realisation of energy efficiency (the energy-neutral hospital is the final product of targeted data modelling)
- A convincing basis for debate in order to establish and implement sustainable corporate strategy

The methodology can be also used to document existing or new processes and describe the associated information that has to be exchanged between parties. The output from the standard can be used to plan a more detailed specification, which can form the basis to establish a Building Information Model for hospitals.

Convenient, quality-assured mammography reporting

iSOFT Radiology reporting has been upgraded with complementary and double mammography reporting. This upgrade is available to iSOFT RIS users with immediate effect. The new workplace profile contains reports for correction and release, as well as the examinations to be appraised.

The profile contains additional patient information, such as previous reports or special treatment notes. Opening images is easy: all the viewers installed at the workplace are available for selection. The report can be entered directly in the profile, without having to open the editor. Additional input assistance, such as

- entering free text
- entries via radio buttons, checkboxes and drop-down menus
- displaying and editing graphics, with the option of setting different types of markings in the graphics, e.g. spot, ring=centre, rotatable and prolongable signs of scarring (+++++++)

support rapid capturing. The report workflow for medical professionals is efficiently laid out using various selection criteria. One or more examinations can be selected and reported in a structured manner directly in the profile, without having to open an additional editor.

The integrated graphics module allows to set different types of markings (spot, ring=centre, rotatable and prolongable signs of scarring).

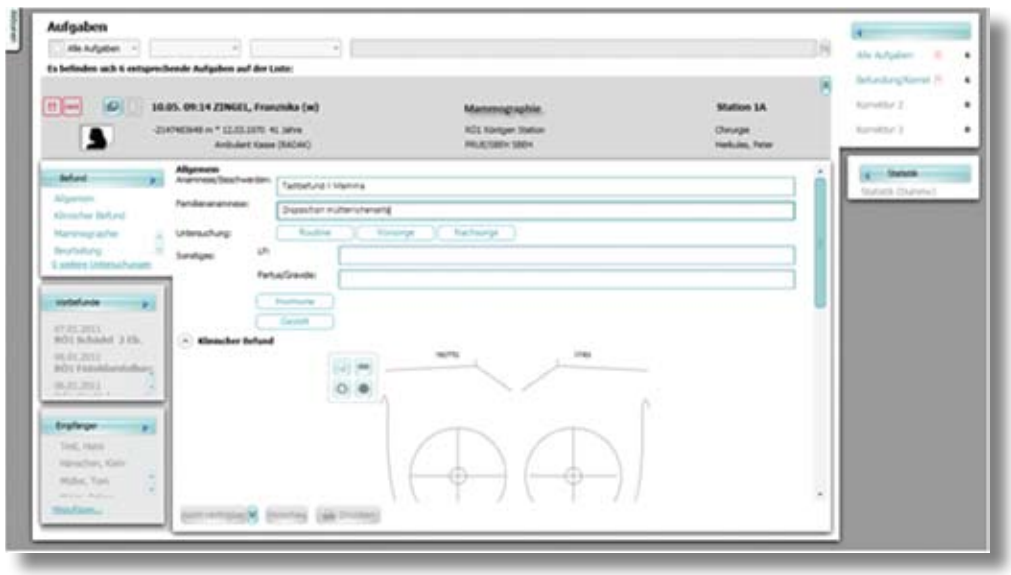
When entered, the relevant values are immediately filled in the fields provided and are added to the report. When making entries, the reporter can use subforms, such as medical history, clinical report (palpatory findings), mammography, MRI, ultrasound, and conclusion.

Within the creation of the second report, the values from the first and second reports entered as BIRADS are compared. The result of this comparison is used to decide whether a consensus report is indicated.

If a consensus report is required, the report is automatically moved to a corresponding, personalised list. Prerequisite for this automatism is that both reporting physicians are entered during the service acknowledgement. If necessary, a third reporter can also be added. Creating complimentary reports is also possible. First and second reports may only be viewed by the reporting physician before they are released. This ensures maximum protection of sensitive data and high quality of reports.

iSOFT's Mammography Reporting provides useful tools to help plan and organise work: for example highlighting the priority by marking urgent reports. It is also possible to offer handling support for the reporter by entering notes for the subsequent workflow. Naturally the physician is able to see all important information, such as order-related data, previous reports and images.

The new Mammography Reporting module is enhanced by an ergonomic GUI (Graphical User Interface), which allows easy operation of mouse and keyboard.



The new Mammography Reporting module

The integration of a knowledge database makes creating reports considerably easier and increases the quality of reports.

Nowadays, radiologists see a rapidly increasing number of images, whilst at the same time being subjected to increasing quality demands. The new functionality in iSOFT Radiology helps to complete the tasks more efficiently and to the highest quality standards.

The core of the new functionality is a comprehensive diagnosis database with access to all diagnoses used everyday in radiology - with concise information, reference images, series of sectional views, and anatomical images for all reports. The new functionality is generally available in iSOFT Radiology and can be used independent of the user profile.

Thanks to the complete radiological literature stored in the system, the user is always able to consult specialist articles and textbooks simply by entering search terms. The user can then transfer content from this literature into the report.

A convenient search and transfer function accesses the comprehensive knowledge database directly from iSOFT Radiology. This way, supporting information on diagnoses, illnesses and clinical pictures, as well as the recommended method of choice, can be provided.

The user does not need to enter an additional password. The automatic login takes place via single sign on.
The workflow-supporting call is possible from the following profiles:

- Order sheet - e.g. to optimise information entered for an order
- Quality manager - e.g. to check the method of choice
- Report profile - e.g. to verify the report or create relevant secondary diagnoses
- Report form - e.g. for support when reporting

For further information on iSOFT Radiology and Mammography Reporting, go to *www.isoft.de* or call +49 (0) 2327 – 568 207

PROSTATE CANCER

Radiotherapy with androgen deprivation therapy (ADT) improves survival compared with ADT alone

Men with locally advanced prostate cancer (without spread) who receive radiotherapy (RT) on top of their androgen deprivation therapy (ADT) have greater overall survival compared with men on ADT alone, according to Dr Padraig Warde, Radiation Medicine Programme, Princess Margaret Hospital, Toronto, Canada, Matthew R Sydes, MRC Clinical Trials Unit, London, UK, and Dr Malcolm Mason, Cardiff University School of Medicine, Wales, and colleagues.

The advantages of combined treatment, they conclude in their article published Online First by *The Lancet*, should be discussed with all men with this condition.

This trial, the first that has been adequately powered to compare these two treatment strategies, assessed patients with locally advanced (T3 or T4) prostate cancer (n=1057); or organ-confined disease (T2) with either a prostate-specific antigen (PSA) concentration more than 40 ng/mL (n=119) or PSA concentration more than 20 ng/mL and a Gleason score of 8 or higher (n=25) Patients were randomly assigned to receive lifelong ADT and RT, or ADT only.

1,205 patients were randomly assigned (602 in the ADT only group and 603 in the ADT and RT group); median follow-up was six years. At the time of analysis, a total of 320 patients had died, 175 in the ADT only group and 145 in the ADT and RT group. The addition of RT to ADT improved overall survival at seven years (74% ADT/RT vs. 66% ADT). Serious long-term genito-urinary or gastrointestinal toxicity from RT was uncommon and low numbers of serious adverse events were recorded in each group.

'This trial provides convincing evidence that local control of disease in the prostate improves survival in patients with locally advanced prostate cancer,' the authors say, concluding: 'Our findings suggest that the benefits of the combination of ADT and RT should be discussed with all patients considering a curative treatment approach.'

Details: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61095-7/abstract

Quantum leap

Diagnostic capabilities increase by a magnitude for a regional radiology centre

Moving from 6-slice scans to a 64-row CT, Vierzon Hospital steps up to advanced functionalities and explores the potential for new types of examinations, *John Brosky* reports

In the rich farming country of France's Centre region, the machine that most often makes the front page of *Le Berry République*an is a tractor, so the recent arrival of a state-of-the-art CT scanner at the Vierzon Hospital earned special attention.

With the scandalous shortage of medical imaging scanners in France, the announcement that a regional medical centre received funding for a CT with advanced functionality could even be considered a headline event nationwide. (See *European Hospital* MRI Alert! 11/12/2009).

'We've been working for seven years with a 6-slice CT, so moving up to 64 rows is a quantum leap for us,' said Adib Sayegh MD, the head of imaging services at the Centre Hospitalier Vierzon, who has been working for four months with the new Hitachi Scenaria 64. 'We're acquiring up to 1,000 slices for some exams now with sharper images and finer resolution and examinations are faster, between five seconds and 15 seconds, which is great for patients.'

'We now see things more clearly, sometimes in three dimensions,' he added, highlighting a capability for vascular reconstruction for carotid artery exams. The suite of functionalities from Hitachi also includes advanced software for examining plaque structures and stenosis.

'The new CT has what it takes to do advanced heart scans, but we currently do not perform coronary exams as there is not a cardiologist practicing at our hospital,' Dr Sayegh pointed out. 'We do everything else, but not heart exams.'

The capability to perform virtual colonoscopies, on the other hand, found immediate application at the centre. 'This is truly excellent, the ability to fly-through the colon searching for polyps,' he said. 'We can also compare two sets of exams to see if there has been a change to a tumour or a great number of polyps. There are a lot of possibilities because this is completely new.'

The Scenaria 64 combines several functions to reduce radiation exposure significantly, such as iterative image reconstruction, Intelli EC automatic exposure control and

US community hospital develops its own unique app

Accessing patient files on smartphones physicians can view laboratory and radiology reports, vital signs and all relevant patient data

A community hospital has created an original computer application to enable its doctors to access electronic patient records (EPRs) instantly via their own smartphones.

The app, devised by the IT team at the Holy Name Medical Centre in Teaneck, New Jersey, USA, also offers direct phone links to a patient's nurse and emergency contact person via iPhone, Android, Blackberry and other mobile devices.

Dubbed MicroHIS, the technology is a component of Holy Name's internal computer system, WebHIS, and is available free to Holy Name's medical staff. The app gives physicians necessary information to make patient care decisions without delay, while affording them the convenience of reviewing their patients' charts and speaking to the patient or key members of the care team from a location other than their home, office or the Medical Centre.

The physician can view laboratory and radiology reports, vital signs, and other aspects of the medical record as soon as they are posted to the 361-bed Medical Centre's computer system simply by clicking on the MicroHIS icon on their mobile device and logging onto the secure network that ensures patient privacy. This calls up a list of their patients with their essential medical information. The device also flags up abnormal test results.

By touching the bedside phone number next to the patient's name, the doctor is instantly connected to the patient's room. Physicians can also search for a patient by hospital unit; when that patient's location is found, the doctor adds the patient to his own list with a touch.

Mike Skvarenina, the hospital's Assistant Vice President for Information Technology, pointed out that the Holy Name Medical Centre has been writing its own software for clinical applications for many years, chiefly because although similar technology is available through outside manufacturers, there are differences in personalisation and service. 'The real advantage in designing our own software is that we can react in a heartbeat to feedback from our staff. We are in total control of our application and its functionality.

'We are always open to suggestions as to how we can further develop MicroHIS and are waiting for more input from the doctors,' he added. 'There's a feedback button on the app through which they can make suggestions to us.'

The flexibility of the MicroHIS means that IT staff can modify the system and the functionality of an application in as little as 10 minutes to an hour, he pointed out. 'When you work with a vendor, you have to go through the bureaucracy. It could take weeks, months, or longer and after all that time, they may decide they're not interested in making a modification.'

MicroHIS has been upgraded recently to receive out-patient reporting and the physicians have also asked IT staff to add the operating room schedules.

The MicroHIS app has received a very positive response from physicians and, Mike Skvarenina added: 'We know they must like it…because they are using it.'

The benefits are for patients, he explained, by doctors being able to access their data quicker, and also for the hospital through more effective and efficient use of staff time. However, at this stage there are, he confirmed, no plans to market MicroHIS commercially.

Intelli IP interactive processing. Yet Dr Sayegh said the impact of these capabilities remains an unknown that will be the subject of a study by the imaging group.

'It is simply too soon to tell,' he said, 'and all exams are all programmed to deliver the lowest dose possible. It is a priority for us, and we systematically record the dose levels.'

An all-inclusive approach by Hitachi led to the choice of the Scenaria 64, he explained. Where most offers proposed a basic scanner with a menu of upgrades for different features and functions, Hitachi from the beginning uniquely offered a single package that 'included everything from the guarantee, pre-installation training, dose reduction, advanced examinations, really more than we had called for in the specification.'

Co-operation between Hitachi and Tera Recon regarding the post-processing server and workstations is a real plus. 'This was very attractive for us with the ease of use, the quality of image display and capabilities that are well-known worldwide,' said Dr Sayegh.

The new scanner at Vierzon has also proved very attractive for other French radiologists. 'We've become a reference centre and receive visits of physicians from Paris, the South of France, from all over really, who want to see the potentials,' he confirmed. 'This has given us the chance to get to know other radiologists,' he added, 'to make contacts that expand our references for when there are problems or questions.'

Seeking the best pluripotent stem cell

Susanne Werner reports on the views and revelations of international researchers gathered to deliberate the future potential of reprogrammed human adult stem cells and personalised medical treatments

Biomedical scientists worldwide are seeking techniques to improve and safely use stem cells harvested from adult somatic cells and, in the future, develop new, individual treatment methods. How that can be achieved was one of the key topics at a three-day conference, 'Stem Cells in Development and Disease', hosted in September by the Max-Delbrück-Centrum (MDC) in Berlin-Buch, which drew around 450 leading international researchers to Germany.

Stem cells can be harvested from embryonic cells as well as adult human cells and are considered 'miracle cures' for future developments. The researchers are currently working on reprogramming adult stem cells in such a way that their effect is similar to that of embryonic stem cells, thus enabling their safe use in therapy.

Professor Walter Birchmeier, head of a research group at the Max-Delbrück-Centre for Molecular Medicine (MDC), underlined the large potential of stem cells: 'Harvested from adult body cells they have distinct advantages for research into diseases, and possibly one day also for individualised therapy.' However, warned Professor Rudolf Jänisch, of the Whitehead Institute in Cambridge (USA), 'A lot more time will pass before they can be safely used than is currently often stated.'


Rudolf Jänisch

Adult stem cells can be differentiated into certain cell types

The first bone marrow transplant was carried out around 40 years ago and stem cell therapy, in which the patient's blood stem cells are exchanged for those from a healthy donor, has shown particular potential in leukaemia treatment. Researchers and doctors have fine-tuned this procedure and increased the survival rate for leukaemia significantly.

Researchers are currently looking for the optimal stem cell that can be re-introduced into the organism without rejection. The key is the reprogramming of body cells, i.e. somatic cells, into so-called induced, pluripotent stem cells, the so-called iPS cells. These are harvested from adult somatic cells – e.g. from the skin – and can then be differentiated into certain cell types, such as nerve or cardiac cells, so their application in many medical areas is conceivable.

One of the best-known conference participants was molecular biologist and geneticist **Professor Rudolf Jänisch**, a pioneer of transgenic research and developer of the mouse model on the basis of which many diseases have now been researched.

His current adult stem cells research, carried out at the Whitehead Institute, part of the Institute of Technology (MIT) in Massachusetts, USA, sounds as exciting as it seems promising. The central point is that scientists use the body's own genetic materials, but also mechanisms and processes to kick-start an individual healing process. 'Therapy with adult stem cells is in contrast to conventional transplant medicine,' he said. Speaking of a possible way of treating toxic liver disease, he said: 'We are already able to harvest skin cells. They would then have to be differentiated to liver cells and reintroduced into the body as iPS cells via the portal vein. The iPS cells then receive signals from their surroundings and know what they are supposed to do in the body.'

Human application is years away

Prof. Jänisch and his team are also among the first researchers to use iPS cells for therapy in mice, but he warned, trying to dampen expectations of impending "miracle cures", 'It will take years before this type of treatment can be used in humans,' he pointed out. 'There are still a lot of technical problems. I'd never commit to a specific timeframe.' Genetic causes can usually partly explain diseases to a certain degree. 'A genetic mutation increases the likelihood of a certain diagnosis,' he explained. 'Some diseases have a clear, genetic cause, others are more complex. It depends on the


Walter Birchmeier

PHOTOGRAPHS: PETER HIMSEL

interaction of cells, the genome and the environment, such as lifestyle or diet.'

'We are at the beginning of a comprehensive understanding of the biology of stem cells,' added molecular biologist Prof. Birchmeier, whose cancer research team is currently working on basic questions about human stem cells and cancer cells as well as on model systems with fruit flies, flatworms, fish and mice. The basic prerequisite for successful application is that the disease actually allows the transplantation of cells. Therefore, the most promising areas are research into diseases of the liver, blood and diabetes. 'Diseases such as Alzheimer's are probably very difficult for this type of treatment. It is improbable that countless nerve cells should be replaceable,' he said.


Hans Schöler

Change helped by a single gene

iPS cells still present many problems and questions. 'We are currently looking for transcription factors that increase the rate of successful reprogramming. This is currently still a chance process. We want to use it to find the best possible stem cells,' Prof. Jänisch said. Only very few donated somatic cells can be changed into iPS cells and become pluripotent, he added.

Professor Hans Schöler and his team at the Max-Planck-Institute (MPI) for Molecular Biomedicine in Muenster were the first to succeed in changing adult human cells into pluripotent iPS cells with the help of a singular gene, the Oct4. 'Among other issues, this lowers the dangers of transferring pre-cancerous cells for any later potential therapeutic applications,' explained Prof. Schöler, whose institute is conducting research into cardiovascular diseases, neural problems and selected cancerous diseases.

Finally, Prof. Birchmeier expressed everyone's fascination by the issues around the nature of stem cells, as well as the extraordinary potential they may have for regenerative therapies.

In the animal kingdom exoskeletons provide stability and protection for many creatures, such as crustaceans and insects. They are also an inspiration for scientists working at the interface of bionics and medical technology to develop fascinating orthopaedic aids, _Anja Behringer_ reports

Amanda Boxtell

Eythor Bender

Andy Hayes

Robotic walking aids for paraplegics

A 'wearable' robotic exoskeleton that helps paraplegics to walk recently went on show in Europe.

Initially, exoskeletons were developed for military purposes, to help soldiers carry heavy weaponry, for example. Over the last few years the adaptation of such devices began for their medical use. In this field, leading research companies include Argo Medical Technologies (Israel), Rex Bionics (New Zealand), Ekso Bionics (USA) and Cyberdyne (Japan) – which offers a robotic system called HAL (Hybrid Assistive Limb).

Ekso Bionics, a spin-off of the University of California at Berkeley, develops and manufactures exoskeletons that help paraplegics to stand and walk. Formerly called eLEGS, Ekso is currently undergoing in-depth tests at ten major rehabilitation medicine centres in the US for its potential integration into therapy plans. The firm has now also entered the European market.

Ekso, a wearable, battery-powered robot, helps wheelchair-bound people to stand up and walk. Four engines move the legs. The user controls the steps via sensors in handheld crutches. The sensors understand the user's intention, compute the movement and instruct the device to perform the movement.

The battery lasts four hours and the paraplegic testing the system in Europe reported that the harness is not tiring.

However, the robot will suit only about 10% of paraplegics because it requires a body height of 1.50 to 1.90 metres, a body weight below 100 kg and a maximum hip width of 43 cm. Additionally, the torso has to be strong enough to use crutches or walking aids and the user needs to be able to change positions without help.

Robotic exoskeletons offered by Ekso Bionics' three competitors follow similar approaches, except for the device developed by Rex Bionics, which does not include crutches.

Battery life is 2, 4, 5 resp. 8 hours and the weight of the devices varies between 18 and 35 kg.

The exoskeletons were designed for different pathologies and have different objectives.

All the firms entered European markets in 2011 and are currently

conducting studies.

HAL is being tested at Bergmannsheil hospital in Bochum, Germany. Ekso, which is planning a pan-European study, has recruited hospitals in Barcelona, Glasgow, Norway and Denmark and is now looking for a partner in Germany. Ekso Bionics CEO Eythor Bender has spoken with to rehabilitation centres in Hamburg, Heidelberg and Murnau, Bavaria.

Unlike the competitors who offer leasing programmes for their devices, Ekso Bionics will sell its product. The current price tag is €100,000, after completion of the test phase the target price for private users is €50,000. 'Comparable to the price of a mid-sized car,' Ekso Managing Director Andy Hayes points out.

All four companies will launch their most recent products in 2013 – if the tests go according to plan. The studies must answer basic issues: Which patient can use which robotic device in what stage of the particular medical condition and which physiological conditions in terms of circulation, muscles, bone density and cerebral functions have to be met. However, one thing is clear: For a wheelchair-bound person the prospect of being able to stand and walk with the help of a robotic device is exceptionally motivating.

The world's largest foot ulcer study

Magdalena Annersten Gershater at Malmö University, Sweden, has carried out the world's largest diabetic foot ulcer study, involving 2,480 patients, to ascertain what factors are related to whether diabetic foot ulcers heal with or without amputation. 'People who have had diabetes for a long time often develop poor blood circulation in their legs, which hampers healing,' she explains, adding that the study also shows that age as such is not a risk factor. 'The study also shows that deep infections, vascular disease, the location of the sore, male gender, and other disease all increase the risk of amputation.'

In terms of healing, she said, '65 percent of the patients healed without amputation. What was decisive for the ulcer to heal was that the sore is superficial, that the patient has not had diabetes for long and that blood circulation is normal.'

Toes or front of the foot amputation resolved 9% cases, while 8% underwent leg amputation.

Source: The Swedish Research Council

The BRANSIST alexa

A multipurpose digital angiography system

The multipurpose BRANSIST alexa, which aims to provide total support for advanced catheterisation procedures, features a 12 x 12-inch flat panel detector (FPD) – an ideal size, the manufacturer Shimadzu points out, for covering interventions from head-to-toe, from brain blood vessels, cardiac and abdomen to peripheral blood vessels in the upper and lower extremities.

SUREengine, a real-time high speed image processing unit, ensures excellent image quality while reducing the exposure dose to the patient. The BRANSIST alexa offers many functions, including real-time DSA, RSM-DSA, road mapping and cardiac function analysis software. The total system design enables safe and stress-free operation during interventions.

The high-precision C-arm

To support procedures and reduce examination time, the C-arm must provide rapid positioning, accurate repositioning, simple operation and adequate performance. 'The C-arm is capable of single-plane positioning of up to 25 degrees per second,' Shimadzu reports. 'The BRANSIST alexa's controller enables intuitive operation of the C-arm just like an extension of the operator's body. Two types of C-arm controllers are available: the lever-type Cyber-Console and grip-type CyberGrip.'

The C-arm system covers a variety of cardiac, general angiographic and digital subtraction procedures including interventional studies, neural studies and peripheral run-off exams.

All C-arm movements are microcomputer-controlled to prevent collision with the table or patient.

'The six-axis triple-pivot construction offers wide body coverage through C-arm flexibility: a longitudinal coverage of 190 cm and a transverse coverage of 140 cm,' Shimadzu adds.

Direct Memory

The system adopts the Direct Memory type C-arm position memory, highly appreciated by hospitals. 'Rather than storing numbers and angle displays, this memory intuitively indicates the angle to swing the C-arm with respect to the patient. So easy to handle that the operator intuitively understands how to operate the system.'

RSM-DSA patented technology

Shimadzu's expertise in high-speed image processing has resulted in real-time subtraction applications, lowering the X-ray exposure dose, reducing the volume of contrast medium, and eliminating the need to restrain a patient. RSM-DSA technology is especially useful for interventions in the lower extremities and examinations in the abdominal region where, the manufacturer explains, the effects of breathing and intestinal gas motions readily occur.

Details: www.shimadzu.eu/medical
medical@shimadzu.eu

Processing and printing ECG and spirometry results in just seconds

Swiss manufacturer Schiller is palpably proud of its new touch screen systems. With just a touch to the large, high-resolution colour display, 12-lead ECGs and pulmonary function tests can be recorded, selected and printed in seconds.

'Both ECG systems are designed for resting ECGs as well as spirometry, whereas the MS-2015 is equipped with a larger screen and will soon be complemented with exercise ECG,'

MS-2015

MS-2010

the company reports, adding: 'Full connectivity to EMR systems and the SEMA-200 ECG management system enables streamlining ECG workflows and improving efficiency. The MS-2010 and MS-2015 both simplify diagnostic ECG interpretation by delivering high-quality clinical analysis reports for thrombolysis within seconds whenever and wherever needed.'

In addition, patient data management has seen considerable improvements, Schiller points out, itemising these as:

- Onscreen review of ECG to save paper and prevent costly repetitions of ECGs
- Export of ECG records in XML, DICOM or PDF format via SCS (Schiller Communication Server)
- Automatic storage, transmission and printing of resting ECG data
- Barcode scanning: the barcode reader option helps reduce errors by automating the input of patient data
- 3, 6, 3x4, 2x6 or 12-lead ECG display
- 12 lead ECG real-time printout (manual mode)

Details: www.schiller.ch

Transcatheter aortic valve implants

With Transcatheter aortic valve implants (TAVI) forming some 20% of all heart valve replacement procedures today, and the technology constantly developing, the 'real art' to the intervention's success lies in precise patient selection and procedure performance carried out by a multi-disciplinary and effective team, according to Simon Redwood, Professor of interventional cardiology at King's College London and consultant interventional cardiologist at St Thomas' Hospital, London. *Mark Nicholls* reports

Top European cardiologists and surgeons gathered at a PCR London Valves October event to hear about the latest developments in transcatheter aortic valve implants. In the session* *Impacting TAVI patient and procedure outcomes: technique or technology? A European perspective* – co-chaired by Dr Marie-Claude Morice, Director of Interventional Cardiology at Institute Hospitalier Jacques Cartier, Massy, France, and Professor Hendrik Treede from the University Heart Centre, Hamburg – Prof. Simon Redwood's presentation covered *practical steps for a simple, successful femoral procedure.*

He said: 'Before we start a procedure, the key consideration is to plan very carefully. Patient selection is hugely important and we must not miss any of the steps of the screening process. The procedure is straight forward: patient selection is the key and the real art.'

The TAVI procedure is indicated for patients who represent high risk for standard open surgical aortic valve replacement (SAVR) and usually have a logistic EuroSCORE of > 20.

Professor Redwood said there are number of critical steps to ensure a successful procedure: that the annulus is measured accurately; that all patients should be discussed by a multi-disciplinary team (including interventional cardiologists, cardiac surgeons, cardiac anaesthesiologists, imaging specialists, and carers of the elderly); that the site of the femoral puncture is chosen carefully; once the sheath is in to flush regularly; and to image after closure to ensure no vessels have been damaged.

Other important steps, he said, were to find good projections, ensure there is adequate balloon dilation and devise the positioning carefully, take into account the patient's anatomy, and check the patient with a contrast injection. Prof. Redwood advised those planning to conduct TAVI to 'see and participate in as many cases as you can so you can manage complications that may occur.'

His conclusion: 'I would say that careful planning is the key to success, a team approach is best – and do not rush the valve deployment.'

The session referred to the two current market leaders whose devices are available to physicians for implantation in appropriate patients; the SAPIEN device by Edwards Lifesciences (a balloon-expandable tubular metal stent with a tri-leaflet valve fashioned out of bovine pericardium mounted within), and the CoreValve device (a self-expanding valve prosthesis consisting of a nickel-titanium frame with a tri-leaflet valve fashioned out of porcine pericardium mounted within).

Also during the session, Dr Ulrich Schäfer from the Asklepios Klinik St Georg, Hamburg, Germany, identified current clinical challenges surrounding TAVI. He said the crucial areas to focus were on reducing vascular complications and identifying and tackling patient complications.

Meanwhile, Professor Gino Gerosa from the Department of Cardiovascular Surgery, University of Padua Medical School, Italy, looked at what is on the horizon for 2012, examining current devices and future devices that will be available including smaller sheaths and larger valves.

The session heard that devices 'on the horizon' included Edwards Ascendra 3 delivery system, Edwards 29 mm valve via Transfemoral, the Edwards Embrella Embolic Deflector and other further refinements.

The question was also raised over whether the future will see younger patients treated, or those with a lower risk score. 'One of the things we do not have results for is the durability of the valve,' warned Prof. Gerosa. 'I would be cautious to use it on younger patients at this stage.'

Dr Philip Kahlert from the Department of Cardiology at the West German Heart Centre, in Essen, raised the issue of neurological outcomes from TAVI and how they can be improved, with the well-documented increased risk of stroke following a procedure.

While TAVI substitutes for more invasive procedures where the chest is opened and the survival is equivalent, the risk of stroke is higher. Measures, he said, that could reduce the risk of stroke from dislodgement and subsequent embolisation of debris from the aortic arch was to avoid extensive manipulation of the device during procedure and to consider cerebral embolic protection devices. 'Stroke is a special concern during TAVI and strategies are needed to reduce the risk of cerebral embolism and neurological events and further clinical trials are needed to address this important issue,' he pointed out.

Prof. Treede predicted that the number of TAVI cases could double over the next three years. Up until June 2011, there had been 35,000 TAVI cases in some 34 different countries.

'We now need to have proven longevity of the valves, fewer complications and avoid complications such as paravalvular leakage, good registry data and as a surgeon I'd also say we still need to consider transapical TAVI as an alternative,' he added.

Dr Morice later told European Hospital: 'It was a good opening session and shows what we can learn from the experience of others – for example, the need for the slow inflation of the device. We are making such good progress with TAVI, particularly when you now see that 20% of valve implantations are with TAVI. We have the enthusiasm and the skill, though we must not push too hard too fast, but it's all extremely positive and this shows how the industry can really work so well with surgeons long-term and how important that partnership is. It also highlights the importance of the relationship between improved technology and technique.'


Marie-Claude Morice


Simon Redwood

Over the two days, the PCR London Valves event included a range of sessions looking at complications with TAVI and how to tackle them; innovations; imaging of patients before, during and after TAVI; a series of LTT sessions; plus live demonstrations from Bern University Hospital and from St Thomas' Hospital, London.

Session also offered 'tips and tricks' and a discussion on future developments, including potential ways in which transcatheter heart valve therapies will be used in treating patients.

The ethos of the course followed on from the 2010 themes and concentrated on the practical aspects of optimising the outcomes for transcatheter valvular procedures with a key focus being on 'practical help for the heart team'.

** Session supported by an unrestricted educational grant from Edwards Lifesciences*
Website: www.pcrlondonvalves.com

CONGENITAL

Justus: A very special case

The German Paediatric Heart Centre (DKHZ) is one of the largest of its kind in Europe. Over 25 years the centre has treated big and small patients with congenital heart defects, every now and then being faced with rare, individual cases that present very particular challenges. In any one year, consultant paediatric cardiologist Professor Martin Schneider MD encounters perhaps five such non-textbook cases. Among these was Justus, born with a unique, mixed form of congenital heart defect that resulted in a variety of coronary diseases

Before his first birthday, Justus had undergone two operations and six cardiac catheterisations. The fact that he is still alive and that his health is actually improving is due to the expertise of paediatric cardiologist Professor Martin Schneider, who has performed minimally invasive interventions since the early '90s.

The professor believes he has benefitted from his initial start in his medical career as a cardiac surgeon – a career path hardly taken nowadays. 'If you want to carry out surgical interventions as a paediatric cardiologist you have to think like a surgeon,' he explains. 'But paediatric cardiologists in Germany tend to have a background in paediatrics and don't want to be surgeons. Furthermore, training times are usually extended by several years due to the required specialisation, so it is extremely difficult to find junior specialists in this field.'

At birth, Justus was diagnosed mainly with 'pulmonary atresia with intact ventricular septum'. The pulmonary valve, normally pumping venous blood from the right ventricle into the pulmonary arteries, was closed. 'This also means that the right ventricle, which normally pumps deoxygenated blood from the body into the lungs, is underdeveloped as it is not functional,' Prof. Schneider points out. 'Instead, blood supply is ensured via a hole between both atria (atrial septal defect) and via the ductus arteriosus.'

In foetal blood circulation, when the lung is not yet active, blood flows directly from the pulmonary artery into the aorta via this duct. After birth, the duct

A new ice age in cardiology

Hypothermia via endovascular cooling to reduce infarct volume

Could hyperthermia be of value in myocardial infarction treatment? The question seems redundant. For although hyperthermia became standard care for post-cardiac arrest patients, when no studies proved that cold can reduce the infarct volume or heart tissue death for segment elevation myocardial infarction (STEMI) patients, this application of the method became merely a note in medical history.

However, a team of researchers working with Professor David Erlinge at the Department of Cardiology, Lund University Hospital, Sweden, breathed new life into the approach when they published data from a pilot study in 2010. Their work had produced surprising results – it's all to do with timing and an endovascular cooling catheter, as explained by Prof. Erlinge and Dr Göran Olivecrona during a study presentation at Lund.

Prof. Erlinge: 'One problem that could not have been solved earlier is the large tissue damage caused by reperfusion. Modern drugs cannot reach the area at risk before reperfusion but only a few minutes after that and therefore show no significant effect.'

Believing that hyperthermia could be one way to tackle that problem, the Swedish experts began their initial trials with 22 pig hearts. Result: When using hyperthermia before reperfusion and as early as possible during ischemia, it significantly reduces reperfusion injuries. However, 'Hypothermia with infusion of cold saline alone does not reduce the infarct size. The basis of our trials was a combination of cold saline (4C), 1.000 ml iv infusion in five minutes as a "kick start" for quick initiation of hypothermia together with an endovascular cooling catheter (InnerCool, Philips). Most relevant for success is the timing: Ideally the patient should be cooled down to 35 degrees C as a target temperature before reperfusion,' Dr. Olivecrona explained.

Philip's Innercool System

Based on that finding, the cardiologists began a safety and feasibility pilot study (Rapid intravascular cooling in myocardial infarction as adjunctive to percutaneous coronary intervention = RAPID MI-ICE) with 20 patients. Beside safety and feasibility, reduction of infarct size was set as a secondary outcome.


David Erlinge


Göran Olivecrona

Published in May 2010, the results revealed that a rapid induction of hypothermia with 1-2 l cold saline and endovascular catheter is safe and feasible in awake patients with acute MI. Furthermore, all patients reached the target temperature of <35 C before reperfusion without notable delay in therapy. The induction of mild hyperthermia in STEMI patients prior to performing an angioplasty can save 38% of heart tissue than with the procedure alone and even the troponin T release was significantly reduced.

As a next step, with 120 patients Lund University is now spearheading the multicentre trial *'Efficacy of Endovascular Catheter Cooling Combined With Cold Saline for the Treatment of Acute Myocardial Infarction'* (CHILL-MI) to reinforce the pilot study findings. By early 2012, CHILL-MI will be enrolled in cardiac centres across Europe, e.g. Copenhagen (Denmark), Düsseldorf and Frankfurt (Germany), Vienna, Graz and Innsbruck (Austria).

HEART DEFECTS


Martin Schneider

closes within a few days. However, in children with a pulmonary atresia, this vessel has to be kept artificially open with drugs or a stent to guarantee blood supply in the opposite direction, i.e. to the pulmonary artery. Additionally, a catheter is normally used to 'burn' a hole into the closed pulmonary valve with a high frequency wire and the heart valve ring is permanently widened with a stent so that the right ventricle starts to pump blood into the pulmonary artery in the right way. The 'burnt out' valve must be replaced at some stage. In older children, this intervention is now also possible via a catheter.

In the Justus case things were far more complex. Untypically for this heart defect, he had so-called major aortopulmonary collateral arteries (MAPCAs), vessels that run directly from the main artery (aorta) to the lungs and which have a high system pressure. Due to these competing blood vessels his actual pulmonary vessels were underdeveloped because they were exposed to increased pressure from the MAPCAs. 'These vessels can be closed after opening the pulmonary valve either interventionally via coil embolisation or surgically through unifocalisation,' Prof. Schneider explains. 'The surgeon diverts the MAPCAs by connecting them with the pulmonary artery. This is a long and difficult operation, mostly with unsatisfactory results, as the vessels of these MAPCAs were exposed to high pressure and are therefore comparable to those of an 80-year-old suffering high blood pressure.'

For Justus this intervention to promote the growth of the pulmonary arteries was completely impossible because his pulmonary arterial disease goes hand in hand with coronary anomalies – coronary sinusoids – an undesirable connection between the coronary vessels and the right ventricle which, although small, contains such a high pressure due to the closed pulmonary valve, that parts of the coronary vessels are supplied through the right ventricle, i.e. backwards.

Prof. Schneider had never seen the phenomenon in this type of cardiac defect. It was considered beyond treatment. 'If the pulmonary valve is opened through an intervention this would artificially lower the high pressure in the right ventricle and therefore endanger coronary blood circulation, which could lead to a fatal heart attack,' he explains. 'So, neither the cardiologists nor the surgeons could open the pulmonary valve. A connection between the right ventricle and the pulmonary artery was also not possible because the pulmonary vessels were too small.'

Was this a hopeless variation of pulmonary atresia? Prof. Schneider drew on a hope – although Justus had limited heart function due to the coronary sinusoids, the boy had a comparatively large, fairly functional right ventricle. Using a procedure never performed before, the professor succeeded in closing the connection between the left and right coronary artery and the right ventricle by implanting several closure systems into most of those undesired connections. With the last of the connections, the vessels leading into the right ventricle were very finely spread. 'I catheterised directly into the right ventricle and looked for the delta of the coronary artery that led into it so that I could close it with a coil. Unfortunately, the coil was too large – and could not be retracted. It was left in a stable position in the right ventricle and removed after a few days during the planned cardiac surgery.

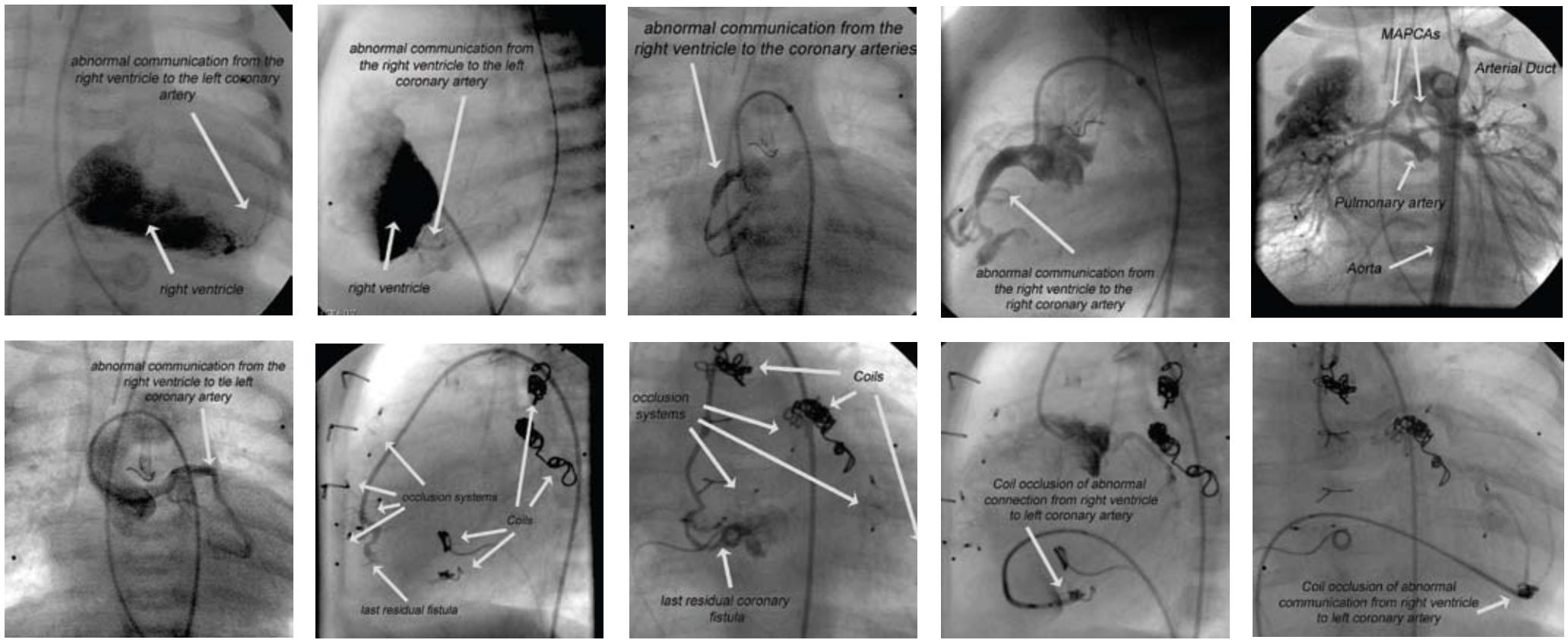
This surgical operation to establish a connection between the right ventricle and the pulmonary artery had only become conceivable because the connections of the coronary arteries had now been closed, and because the underdeveloped pulmonary artery had started to develop due to a stent in the duct, inserted during an earlier cardiac catheterisation.

Immediately after the surgery the flow between the right ventricle and pulmonary artery was so good that the MAPCAs could be closed with coils and umbrella devices in the cardiac cath lab.

'The objective of these interventions in the treatment of such complex heart defects is not only to repair something but also to promote the growth of the underdeveloped structures. Only if the structures can be exposed to more blood flow will they develop,' Prof. Schneider points out.

The right ventricle now stands a very good chance of normal development – something even he describes as a 'real miracle'. Exactly what the future will bring for Justus remains to be seen. There are no comparable cases to enable guesswork. A lot depends on whether or not any further complications with the coronary arteries occur.

Inserting a stent might be possible when the boy reaches adulthood. 'The older Justus gets, the better the chances of working with implants,' explains Prof. Schneider, because 'the materials currently available have been designed for adults. Congenital heart defects therefore differ from the norm in many ways.'



A conceptual shift for medical device manufacturers

A scanner's performance ability may be high, but what it can perform has become the bigger issue

Much has changed for medical device manufacturers. Take scanner development; whereas the aim has long been to increase multi-slices, produce higher field strengths and sharper images, optimise the ergonomics and then launch the new product at a specific group of customers, in recent years this approach became insufficient. 'The trend has definitely moved away from technological features to clinical topics,' Okan Ekinci MD, Global Director of Cardiology at Siemens Healthcare, explained during a discussion with Meike Lerner (European Hospital).

'New procedures and technologies must be integrated into overall clinical concepts. Our objective therefore no longer comprises only the development of new modalities; we must create business cases and look beyond the obvious'.

Speaking of current trends, Dr Ekinci explained: 'In the past, medical technology companies were exclusively regarded as product suppliers who introduced their devices and implants to the hospitals, with doctors then researching how best to use these products. Nowadays this is no longer possible as developments have been so rapid that no hospital can promptly represent all innovations. Customers now frequently approach companies with the request to work jointly with them on how to utilise the technologies in a meaningful way on a daily basis.

'One example of this is the use of new CRT implants. For at least a third of the patients we know that these implants will not result in the desired improvement – and this can be traced to a less than optimal patient-triage. To predict patients' responses better, modern imaging modalities for cardiology should be consulted that can deliver more information about the state of the heart – where the scar tissue is, where the best vein for placing the CRT probe is and how can the implantation be navigated in better way. Our products must offer answers to such clinical questions.'

So it's convenient for Siemens if the application of a new CRT system goes hand in hand with the acquisition of a new CT or MRI scanner...

'The sale of large devices is certainly our business, but, along with the entire healthcare system, we have to be committed to the sustainability principle – meaning that the acquisition of large devices must reduce pressure on the healthcare system rather than create it. Therefore our strategy is to anticipate clinical developments in our product development.

'This often gives the user the chance to explore new clinical paths without having to make additional investments. For example, since 2007 our 1.5-T MRI systems have been equipped in such a way that each scanner can carry out complete cardiac examinations. This means that all establishments that have since purchased a 1.5-T Siemens MRI could carry out cardiac examinations. A further example is the development of solutions for interventional valve replacement in the heart catheter laboratory, which we began a few years ago. Now that this minimally invasive procedure is becoming increasingly important we are making a large solution portfolio ranging from the use of 3-D to complete hybrid operating theatres available to those who are interested. All in all you could say that we are preparing the market for future business cases.

How do you know what implant manufacturers have in the pipeline or are likely to introduce in the near future?

'We cooperate with different companies and joint customers. These are so-called "early adopters", i.e. centres that lead the way with pacemakers, valves or imaging. With such customers we can work on certain clinical cases. We carry out clinical studies and then publish the solutions. This also allows us to accentuate trends ourselves.'

So could trends become distorted or artificially created, in the interests of the companies involved?

That's very unlikely because we have chosen a very customer-centred approach with our reference centres, for instance. In practice, this means that we searched for institutions that already have a successful, interdisciplinary way of working, which have broken down the boundaries between heart surgery, cardiology, nephrology etc. and that are trendsetters in their field. We defined the Centre Cardio-Thoracique in Monaco as our first reference centre, the second one being the Contilia Heart and Vascular Centre at the Elisabeth Hospital in Essen, Germany. Cooperation with these centres allows us to capture and address emerging clinical trends at an early stage.

What developments are currently in the pipeline?

'A good example of the interaction of hospitals, other industry players and us, is the development of a solution that significantly reduces radiation exposure during catheterisation. With interventions that need frequent manoeuvring of the catheter – such as electrophysiological interventions – numerous fluoroscopy scenes are being recorded. The new product will enable us to record a fluoroscopy scene just once. The link with a novel catheter positioning system will facilitate manoeuvring without radiation. And, by the way, this is a new trend. It's not a certain modality that is at the forefront of this development but a superior objective – in this case dose reduction. Which modality should be the preferred solution in individual cases depends on the indication and is a decision made by the hospital. For instance, there's currently some discussion around the question of whether it's better to plan an interventional aortic valve replacement via CT or rotation angiography.

Does that mean the boundaries between modalities and their application are becoming increasingly blurred?

'The boundaries are blurred on an equipment level as well as on the application level. With regards to the equipment, we should certainly highlight the Siemens Biograph mMR, the first and only fully-integrated whole-body MR-PET system. We anticipate improved early detection of diseases through the integration of molecular and morphological imaging.

'However, new integration trends with regards to applications are far more frequent: Multi-modal diagnosis with Echo, CT and catheter, image fusion, FFR and OCT in the catheter laboratory and MRI-augmented EP are just a few examples of developments currently in demand in the hospital. New cardiac interventions should only be considered in a multi-modal context. Whilst this entails medical progress, it is a challenge for doctors because the traditional focus on just one individual modality no longer reflects the requirements of future diagnostics and treatment adequately.

'For us this means our devices have to interact along clinical paths, much like players in an orchestra. Integration and interoperability are merely the basic requirements. We need to test numerous combinations for clinical treatment standards to find out which scenarios can be marketed in which ways. It's no longer simply enough to emphasise how many slices a device has. You have to create an entire concept, a business case that encourages all those who are part of the healthcare system – which increasingly includes medical insurers – to rethink.'

How would you like to become involved in this process in the future?

'Acknowledging the last-mentioned developments, we created a business segment for healthcare consulting. As a global company, we have collaborated with best practice centres worldwide, have captured their experiences in a structured way and also developed a process maturity concept based on what we can now also advise customers in the case of changing clinical paths.

'One example of this is the treatment procedure for ACS (acute coronary syndrome). More than 90% of patients admitted to A&E departments with chest pain have not actually had a cardiac infarction. In Germany many of these patients often remain in hospital for up to three days, occupying what should be emergency beds etc., meaning that the resulting costs, which should be avoidable, become enormous. In many centres in the US patients with chest pain and unremarkable laboratory and ECG results are therefore examined via CT scanner. Patients with inconspicuous coronary results can so be discharged within just a few hours.

'With less than one millisievert, the examination dose is significantly lower than that of the annual background radiation. This model is currently also being tested in several centres in Germany. However, here comes the big "but": Even if a cost reduction for the healthcare system can be proven, hospitals currently have no incentive to change their clinical processes. To the contrary: Whilst the full DRG flat rate can be charged for a three day in-patient stay, the hospital receives only a minimal payment for a CT examination and subsequent discharge of a patient. Service providers therefore need to create a financial incentive to implement the new concept in practice and to engage the hospitals in these cost savings. Incidentally, in terms of figures, the CT scanner required to implement these workflow changes could actually be financed through the savings.

'Medical technology manufacturers are therefore not merely a passive link in the value added chain within the healthcare system but involved in its reorganisation.'


Okan Ekinci

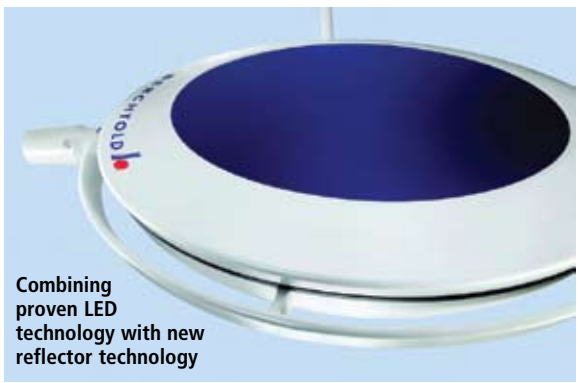
Surgical lighting

The new Chromophare F Generation

Jochen Weisser, Technical Director at Berchtold, supervised the development of the new surgical lighting system

BERCHTOLD GMBH & CO.KG

Berchtold has been among the world's leading manufacturers of quality surgical equipment for almost 90 years, today offering operating theatre lights, tables, ceiling supply units, video and camera systems, information and communications systems and customised surgical solutions. Recently the firm launched a radically new surgical lighting system. We asked Jochen Weisser, the firm's technical director, what triggers the birth of such concepts



Combining proven LED technology with new reflector technology

Speaking of the origins of the Chromophare 5 Generation system, Jochen Weisser recalled that initially requests had come from various sources. 'Sales wanted to offer something new, marketing were asking for another product with a unique market position and our development department had already been working for a while on the revolutionary idea of marketing a completely new lighting technology.'

Where there market demands that influenced the development?

'LED operating theatre lights are in demand and the trend. Customers want to buy them, even though they are more expensive than, for example, our halogen or gas discharge light, which provide a comparable light output. Apart from this, we were no longer 100% satisfied with our previous LED lighting range. It was obvious what was required of us: a high performance product that offers the best conditions for working in the operating theatre.'

How long did it take from initial concept to the now marketable Chromophare F Generation?

The LED light system was intensively developed and tested for two and a half years, a period in which new ideas occur that cannot be added in, he explained. 'So that leads to new ranges. We try to keep development cycles very short. For a developer this means they are busy with new ideas, at the latest, when the new product is on the market.'

What was the biggest challenge during the F Generation production?

'Our traditional Chromophare light was equipped with a large reflector and a central light source in the middle. With this we have been offering the best surgical light with optimum depth of illumination for decades.

'In previous LED lights on the market, light from warm and cold white LEDs mixed outside the light head in the surgical field, which caused coloured hue shadows there. That was our challenge: to effect a mixing of light within the light head using the reflector to eliminate these coloured hue shadows.

'For this purpose we combined proven LED technology with a new reflector technology. We also had this patent protected. The LEDs shine from the side into the reflector and this mixes the light inside the light head. The already mixed, and thereby homogeneous, light then shines into the surgical field.'

Who is key in the creation of a new lighting range?

'Twelve people work in our project team. Quality Assurance does the product testing. Here it is principally about compliance with standards and the delivery conditions of our component suppliers.

'The core team also includes representatives from the field of electronics, software engineers and lighting technicians as well as a product designer.

'The manufacturing and servicing departments are also involved, so that the product is good to produce and easy to service in use. Technical and strategic purchasing and product management also play a role.

'All these disciplines enrich the development process and contribute significant aspects.'

The E Series of Chromophare LED lights won a 'red dot' quality seal in 2009. What makes a good design?

'Surgical lights should look appealing, offer outstanding lighting of the surgical area, be user friendly, reliable and easy to clean.

'The product designer avoided grooves, sharp edges and screws and created smooth surfaces that facilitate cleaning. We also carried out cleaning studies in the operating theatre with a prototype. That shows us what causes problems in the light head. Surgeons tested the handling of the lights in the theatre: The correct handling technology provides the basis for the design.'

Trauma networks ensure effective cooperation

Improved cooperation, a database for artificial joints, antibiotics against pathogens – orthopaedic specialists and surgeons are banking on different ways of increasing patient safety, *Susanne Werner* reports

Some 30-35,000 people are severely injured in accidents every year in Germany, and they all need instant competent care. To ensure this, the German Trauma Society (DGU) has initiated the development of trauma networks in many areas of the country. Meanwhile, there are 22 networks across the nation where members of the entire rescue chain jointly prepare for emergencies.

The trauma networks were among central topics this October at the German Congress of Orthopaedics and Trauma Surgery in Berlin, an event attended by about 12,000 specialists. Also discussed were the new endoprosthesis register and new ways to prevent infections during surgery.

Statistics show two mass accidents or disasters, involving at least 10-100 fatalities and between 50 and 100 injured in need of immediate help, occur annually in Germany. Trauma surgeons, specialists in disaster medicine, anaesthetists, paramedics and members of the armed forces are then tasked with making the right decisions within minutes and with optimally tending affected patients.

This also requires optimum networking of different treatment locations as well as clearly defined workflows. These deployments are prepared and regularly simulated for training purposes in the context of the trauma networks so that the injured and severely injured can be treated quickly and comprehensively.

The first step for hospitals aiming to set up trauma networks is to agree on their cooperation in emergencies. They carry out a self-evaluation to check which competencies and services they can contribute towards the developing network and where possible gaps might occur.

In a second step, hospitals negotiate respective cooperation contracts and work out in quality circles what the efficient course of action at the emergency sites should look like and what problems might occur in the process. 'Trauma networks ensure cooperation between hospitals and counteract the current health-political trend that's more suited to stoke the competition between hospitals,' said DGU president Professor Tim Pohlemann MD. Meanwhile, he added, those in charge of nationwide networks are now well prepared for larger accidents, with up to 500 injured patients. The number of fatalities following large accidents has been halved over the last 25 years through more efficient and faster surgical care of light to severely injured patients.

The joint database

The development of the endoprosthesis register in Germany is being carried out to improve patient safety and quality of care. After all, artificial hip or knee implants are among the most common forms of surgery in this country – around 400,000 patients were fitted with an artificial joint in 2009 and around 35,000 of these had replacement surgery in the same year.

Therefore, the German Association of Orthopaedics and Orthopaedic Surgery (DGOOC) has taken the initiative in partnership with the AOK Federal Association, the Association of Health Insurers, prosthesis manufacturers and the Federal Office for Quality Assurance at the Institute for Quality and Patient Safety (BQS), to set up a central database.

The main objective of the endoprosthesis register is to ensure future high quality care, to identify clearly the reasons for the replacement of a recently fitted joint and reduce this need in the long term.

The database will capture hospital billing data and data on implants collated under consideration of data protection guidelines and will match and compare this information with product data supplied via a database provided by the manufacturers.

The test phase to check the data structure and transfer has already begun in selected hospitals. An enhanced pilot phase will start at the beginning of 2012, and general data capture will begin in the second quarter of 2012.

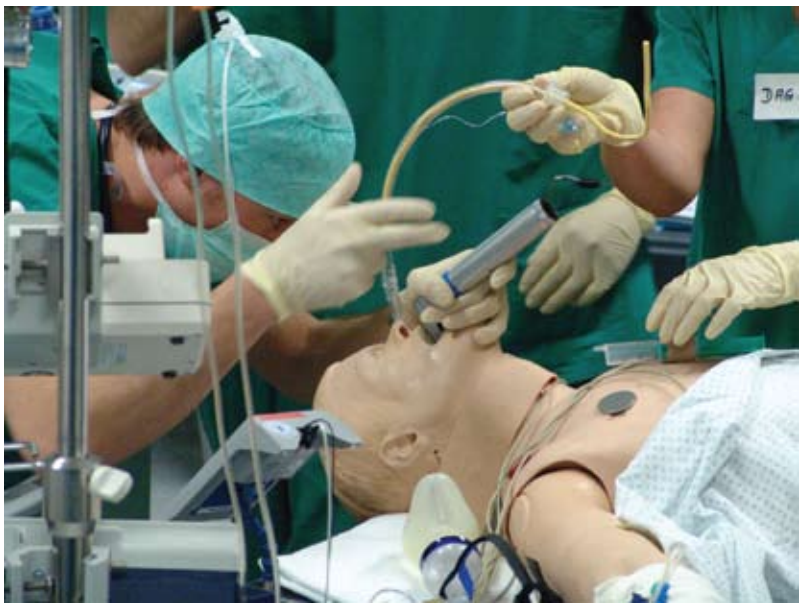
The first results are expected towards the end of 2013. 'The outstanding system we now have at our disposal will constitute the best collation of data available worldwide within a few years' time,' predicts Professor Dieter Kohn MD, President of the German Association of Orthopaedics and Orthopaedic Surgery (DGOOC).

Training against medical errors

Surgical simulations can save lives, *Anja Behringer* reports

Medical errors occur more frequently than traffic accidents and clearly better systems are needed to improve patient safety. Thus the importance of medical training using human simulation models is increasingly emphasised in Germany

Marcus Rall MD, Head of the Simulation Centre at the University Hospital Tübingen



Having extensively studied the causes (and particularly human factors) of medical errors, **Dr Marcus Rall** heads the *Tübingen Patient Safety and Simulation Centre* (TÜPASS) at the University Hospital in Tübingen. 'Simulator training is not an obligatory part of training, which is why only individuals attend. However, it is more effective to train the whole team to establish a safety culture. This also promotes motivation and a good working atmosphere in the hospital.'

Just how important he considers this preparation is demonstrated by his work and involvement, amongst others, with the Society of Simulation in Healthcare and the European Society of Anaesthesiology (ESA), for which he heads the subcommittee on Patient Safety.

Faced with today's simulator trainee doctors see not only a real looking human form, but one that can blink, has pupils that react to light and also reacts to around 80 types of medication as a real human would. Vital functions are realistically displayed on monitors in the same way this is done in an operating theatre or an intensive care ward.

The surgical teams practise dealing with emergency situations with a particular focus on the decision-making process, as effective communication within the team is vital – bearing in mind that hierarchical structures can also be the cause of incidents.

The surgical scenarios are not only instructive for trainees but expert medics can also use them to practise rare surgical techniques or crisis situations.

Team training is compulsory in aviation tuition and other elements from the world of aviation, e.g. checklists and safe communication, are taught as part of the simulator training at the Interdisciplinary Medical Simulation Centre in Dresden University of Technology (ISIMED), from which a team visits hospitals to train in patient safety.

Acknowledging critical incidents and near misses, clarifying the causes of those events and thus avoiding mistakes and potential harm for patients has become a central topic for in- and out-patient care. One way to achieve this is the use of error reporting and training systems for critical events: **C**ritical **I**ncident **R**eporting **S**ystems (CIRS). So far, these reporting systems have only been used either within institutions or on a national level. Therefore, in partnership with healthcare institutions in Berlin, the Berlin Chamber of Physicians and the Agency for Quality in Medicine have founded the regional network CIRS-Berlin. This offers participants in the project the opportunity to collate information on critical incidents and near misses in a joint reporting pool.

To ensure potential errors do not even occur, the World Health Organisation WHO) has compiled a simple safety checklist, which may initially appear banal, but is actually based on the most common treatment errors that occur – with serious, negative results for the patients.

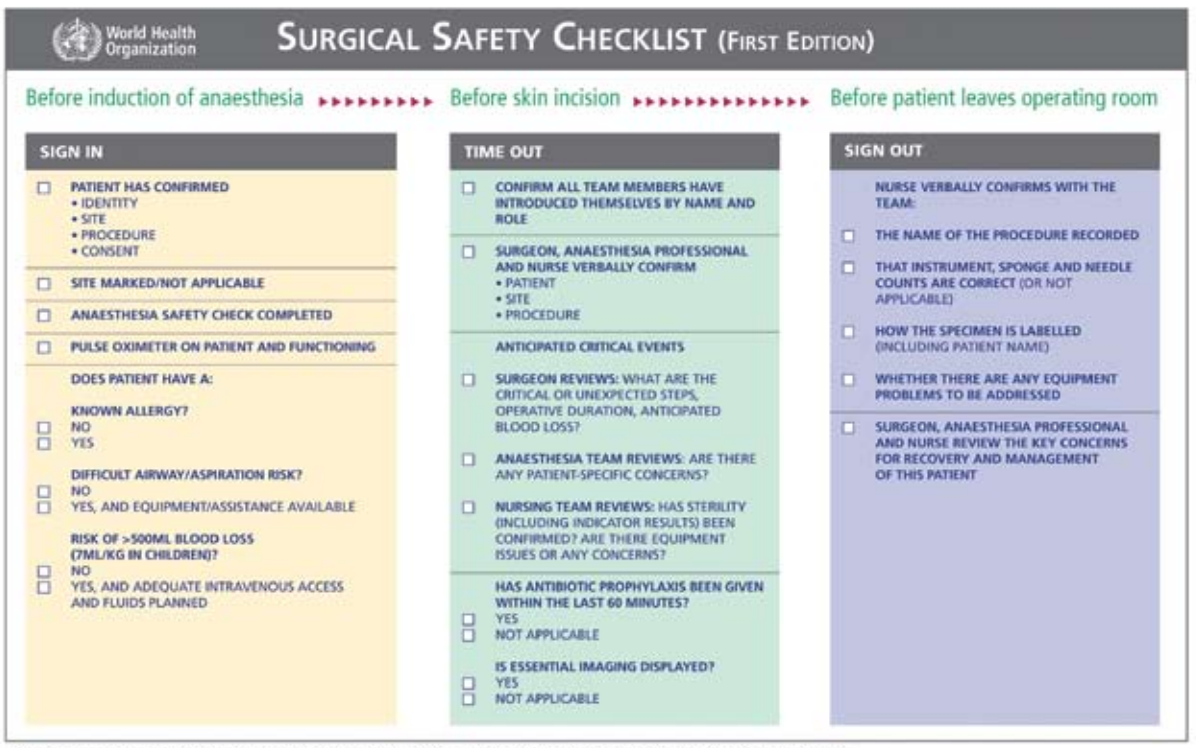
To assess the effect of the list, members of the *Safe Surgery Saves Lives Study Group* examined the treatment history of 7,688 non-cardiac surgery patients aged over 16 years, in eight socially and technologically different hospitals, for three months prior to (3,733 patients) and three months after (3,955 patients) implementation of the list.

The main results, published in the *New England Journal of Medicine* (MEJM) conclude:

The rate of all significant complications during treatment and 30 days after treatment decreased statistically significantly from 11% before the use of the list to 7% afterwards; mortality during and after surgery fell from 1.5% to 0.8%. Cases of postoperative infections and the need for unplanned, further surgery also decreased significantly. This success was seen in all social settings.

Hospitals took between a week and a month to integrate the checklists into their daily workflows.

Experiences in hospitals with different organisational structures have shown that the introduction of these safety checks costs neither a lot of money nor time.



The WHO Surgical Safety Checklist

The ascent of image-guided surgical interventions

Medical imaging is no longer limited to diagnosis and evaluation. New, high resolution imaging systems enable very precise positioning of lasers, endoscopes and micro-instruments for surgery near the nerves, spinal cord or blood vessels and for selective tumour destruction, with minimum levels of pain and low complication rates. Many of these interventions can be carried out as out-patient treatments, says EH correspondent *Holger Zorn*, reporting on the foundation of the School of Image-Guided Interventions in Magdeburg, Germany this October

Jens Ricke

Be it vascular replacements, internal bleeding or tumour treatment – nowadays a surprising number of very different minimally invasive interventions can be carried out. However, this requires precise, well-rehearsed cooperation between specialists. The International School of Image-Guided Interventions (DAfMT) has made it its business to teach these interdisciplinary strategies and procedures. It sees itself as an educational establishment for micro-therapeutic procedures, but also a platform for international dialogue between doctors.

'We wanted to set up an interdisciplinary group that at last makes innovative image-guided treatment accessible to the medical fraternity,' explains radiologist Professor Jens Ricke, founder and president of the academy, where the key training elements are courses that intentionally go beyond the limitations of specialist medical fields and comprehensively convey the knowledge required for microtherapy. 'At the moment we are strongly concentrating on interventional radiology, endoscopy and minimally invasive surgery,' explains surgeon and programme co-founder, Professor Hans Lippert.

The academy also carries out preclinical microtherapy research and development.

The launch has already been successful. The first course on selective internal radiotherapy was held in June. 'We worked with a mixed group of doctors from different European countries – they came from Belgrade, Rijeka, Ljubljana and Gdansk, to name a few,' explains gastroenterologist, co-founder and international overseer of the academy, Professor Peter Malfertheiner.

Patients with hepatocellular carcinoma particularly profit from the interdisciplinary treatment strategies. To exhaust all options, surgical as well as radiological interventional procedures for local or loco-regional tumour therapy are taught alongside internist and oncological skills. The academy offers two courses on this topic – transarterial chemo-embolisation (TACE), supported by Cook Medical, and on selective internal radiotherapy (SIRT), supported by SIRTeX Medical.

In the case of TACE, the femoral artery is punctured using the Seldinger technique and a microcatheter of 2.3F – 3F in size is then inserted via the hepatic artery and guided towards the target area. A high dose of chemotherapy drugs, for instance consisting of Mitomycin C, Lipiodol and Spherex, and enriched with a contrast medium, is then selectively, regionally applied to the tumour, with the supplying vessel then being occluded. Three parameters determine clinical success: the cytostatics concentration within the tumour, contact time between the substance and tumour cells, and the arterial hypervascularisation of the tumour. As healthy liver tissue is supplied via the portal venous system at 75% and only 25% via the hepatic arteries, whilst liver tumours are supplied at up to 95% via the arterial system, the tumour tissue is systematically destroyed and the healthy liver parenchyma (through the portal venous perfusion) is preserved.

In the case of SIRT, the femoral artery is also punctured and a microcatheter is inserted into the hepatic artery. However, no cytostatics are administered via the catheter, but millions of small, radioactive spheres, so-called SIR-Spheres microspheres. These are 20-60 µm in size and impregnated with Yttrium 90, an isotope produced during uranium fission with a half-life of 64 hours. It releases beta radiation over a relatively short distance (2.4mm in human tissue), which means that more than 97% of the radiation reaches the tumour within the first two weeks of treatment. Thus a higher dose of radiation can be applied locally than with conventional, external radiotherapy.

The SIR-Spheres-Therapy was developed at the Cancer Research Centre CRI in Perth, Australia, in 1987 and has been FDA cleared since 2002 and also CE certified.

Highly precise imaging for microcatheter guidance is vital not only for the success of these two techniques but for all types of image-guided interventions. The academy uses the open 1-Tesla high-field MRI 'Panorama' manufactured by Philips, modern multislice CT scanners suitable for fluoroscopy manufactured by Siemens and Toshiba, and the robot-based flat-panel C-arm Artis Zeego manufactured by Siemens. The latter is not only found at the Centre for Radiology at the University Hospital Magdeburg, where the founders of the academy operate, teach and research, but also at the Institute of Medical Technology and Research (IMTR) in Rottmersleben and at the INKA (Intelligent Catheter) Angiography Laboratory of the Experimental Factory at the University of Magdeburg. There, Professor Georg Rose, Chair of Medical Telematics and Medical Technology, says: 'Not only catheters suitable for MRI are developed here but also strategies for energy supply at the catheter tip and for the transfer of information.'

In addition, as the laboratory always needs to be ahead of clinical practice, it now has a 7-Tesla MRI scanner at its disposal – the first of its kind in Europe.

Leipzig's futuristic operating theatre


IRDC's advanced operating theatre

The next generation of integrated operating systems celebrated a world premiere in clinical use this November in Leipzig, Germany. EH Correspondent *Holger Zorn* was there when Professor Gero Strauss entered the Surgical Deck of the International Reference and Development Centre for Surgical Technology (IRDC) as 'Commander'

Dr Leonard Horatio McCoy, chief medical officer aboard the Starship Enterprise, was dismayed when he glimpsed medicine in the 20th century during the 4th Star Trek Movie: 'This looks like the Dark Ages,' he shouted. Today, if he returns to Earth and visits Leipzig he will undoubtedly change his tune.

'The surgeon's modern workplace is increasingly reminiscent of the cockpit in a passenger plane, with the surgeon acting as First Officer,' explains consultant surgeon Professor Gero Strauss, Director of the IRDC and Head of Development at the Innovation Centre Computer Assisted Surgery (ICCAS) at the Medical Faculty of the University of Leipzig, and an ear, nose and throat consultant at Leipzig University Hospital.

Nine displays on the Surgeon's Command Post, the Surgical Deck, ensure that all necessary information is available. A look into the human body goes beyond HD quality. With highly precise navigation technology and automatic warning systems in the background, the surgeon navigates more precisely and safely than ever before through sensitive tissue, past blood vessels and nerves. Perfectly implemented information systems display details such as vital signs and images about the internal patient in real time.

Electronic patient files or 3-D CT and MRI images are available on demand. Up to 40 data sources are available during just a routine operation. The surgeon is also networked with the outside world and can consult external experts.

Optimised safety

In the Leipzig operating theatre the cables are shorter because medical devices hover over the patient, reducing drag and shear stress on sensitive instruments. 'The IRDC is refining a unique specialist surgical concept. Architecture and ergonomics were adapted to the workflow of the surgical teams and thereby completely reorganised,' Prof. Strauss points out. Coordinated technology lifts staff pressure and reduces routine tasks, enabling more reliable surgical work, reducing errors and ensuring the theatre is utilised more effectively.

The division into two separate, well-defined work areas for anaesthesia and surgical teams has also created a clearer work layout. Two emergency boxes in the cockpit, opened at the touch of a button, contain all emergency instruments and drugs.

Surgeonic

The new software Surgeonic tackles the patient's digital data and surgical progress. It also makes intelligent connections, including automatic warning and collision avoidance.

If need be, the navigation and monitoring technology of the world's first *Surgical Management and Guidance System* can support a surgeon like an autopilot, assisting during particularly lengthy interventions and raising the alarm if previously determined limits are exceeded and a situation becomes critical, with the data appearing on the cockpit navigation panel, and as a flash in the microscope as well as presenting as audio signals or verbal warnings.

The system can suggest surgical steps or alternative routes. Special programmes and a digital scalpel facilitate even the tightest access for instruments and the steepest angles and filter out undesired movements. 'The navigation components are adapted seamlessly,' says chief engineer of the Surgical Deck, Professor Tim C Lüth, Chair of Micro Technology and Medical Device Technology at Munich's Technical University. 'The complex technical details and numerous new functions are integrated in a clearly laid out way and easily operated.' The future operating theatre is a joint project of Leipzig and Munich

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universities and medical device manufacturer Karl Storz supplying the core Karl Storz Surgical Cockpit (KSSC) in the integrated operating theatre 'OR1'.

Dräger Medical supplies workspaces for the surgical and anaesthesia cockpit.

Trumpf Medical Systems supplies patient positioning systems and links them with the OR1 and the KSSC.

Carl Zeiss Meditec provides the surgical microscope OPMI Vario S81.

The patient information system from Siemens Enterprise Communication offers all possible features of patient


'Commander' Gero Strauss

comfort, right down to the provision of excerpts from the patient file and an input medium for the surgeon.

The KLS Martin Group is jointly developing new lighting concepts and their integration into the assistance systems and ergonomics of the surgical cockpit.

To increase safety, surgical quality and ergonomics for the surgeon, Ergosurg and Karl Storz are working on mechatronic assistance systems.

The IRDC was among 365 winners of a *Selected Landmark 2011* prize, an annual award in the initiative 'Germany – Land of Ideas' (Patron: The Federal President partnered by Deutsche Bank). 'The creation of the operating theatre of the next but one generation furthers research into new technologies,' said Michael Erfurt of Deutsche Bank. 'The IRDC has created a unique project, which serves as a worldwide example.'

At Leipzig, Leonard McCoy would certainly not have to wait until 2264 to develop his neurosurgical techniques.

Dysglycaemia

Greater glucose control in the ICU is critical for every patient

Dysglycaemia is a new term in critical care that recognises the vital importance for glucose monitoring of patients in the intensive care unit (ICU). Beyond the clinical consensus over this word for grouping critically ill patients with hyperglycaemia, hypoglycaemia or high blood sugar, there is no broad agreement on how best to manage these patients.

Report: *John Brosky*

In-patient glucose control was a central discussion at the 2011 International Hospital Diabetes Meeting in Barcelona this November. There is little controversy in the clash of clinical opinion. Instead, debate centres on how conservative or aggressively patients should be treated to maintain acceptable glucose levels and the quality of evidence for determining the right approach.

Even when clinicians encounter diabetes in the ICU, a condition that clearly indicates a need for careful attention, there is not agreement on how to best manage these vulnerable patients, according to Ingrid Mühlhauser MD, from the University of Hamburg in Germany, who presented 'The Future of Guidelines for In-Hospital Care' and then moderated a session dedicated to clinical management of diabetes in the hospital.

Most hospitals have some kind of guidance for the management of diabetes, she told *European Hospital*, but the effectiveness and efficiency of guidelines are poorly evaluated.

The number of guidelines continues to grow with 'a huge number of statements and recommendations dealing with diabetes care,' she said. Yet the overall quality of guidelines is low as they are often not evidence-based, the conclusions on identical topics are often at variance, and even where specific hospital guidelines are available, adherence to and the use of these is low.

The critical importance of managing blood sugar levels for all patients in ICU, and not just diabetics, was first revealed in 2001 by Greet Van den Berghe in a study at the University Hospital Gasthuisber in Leuven, Belgium, which showed intensive insulin therapy reduced morbidity and mortality among critically ill patients.

A key speaker at the Barcelona congress, Van den Berghe has emerged as a world authority in diabetes care, though his initial findings have not been confirmed despite a decade of follow up studies. However, raising awareness of the critical role of glucose among ICU patients directly inspired more than 2,400 published articles and opened the wide debate on patients, protocols and the appropriate technologies to apply.

To set the scene for discussion in Barcelona, Jean-Charles Preiser MD,


Ingrid Mühlhauser


Jean-Charles Preiser

from Erasme University Hospital in Brussels, Belgium, described the state-of-the-science in his presentation 'Impact of In-Hospital Dysglycaemia,' and then expanded the review of in-hospital diabetes technologies by including a wider patient population in a presentation on glucometrics, 'Measuring Blood Glucose Levels in the Hospital'.

The current consensus is to keep blood glucose as constant as possible for ICU patients to avoid conditions summarised as dysglycaemia, to avoid hyper- and hypoglycaemia and high glucose variability, he explained.

There is no difference between diabetic and non-diabetic populations because any ICU patient is vulnerable to stress-related hyperglycaemia, which he described as 'a rapid response to metabolic stress induced by inflammatory mediators, which are sky-high during critical illness whether the patient has experienced a cardiovascular or stroke event, surgery, trauma, infection, or any kind of fever. 'Clearly controlling glycaemia is a priority, and we need better tools to have a closer monitoring of blood glucose,' Dr Preiser said.

Current practice calls for blood level checks six times daily in the ICU, '… more frequent than it was 10 years before, but we need continuous monitoring, or near-continuous monitoring,' he said.

Resistance to insulin, a reflection of the effects of inflammatory mediators, is changing from hour to hour, he said. 'So it's difficult to have a satisfactory insulin infusion rate without taking into account the changes in insulin resistance.'

Dr Preiser pointed out that up to five devices used for continuous monitoring of type I diabetes at home have been adapted for the ICU, and are currently undergoing evaluation and validation ahead of approval for wider use. A first concern is a quality assessment of glucose meters used for monitoring that were originally designed for diabetics and not critically ill patients, he said.

Finally, new algorithms need development and testing to adapt insulin rates to maintain normal levels better.

A niche with no lobby

Interventional radiology in the diabetic foot

Italy is a front runner in diabetic foot revascularisation. Among the country's pioneers is Professor Roberto Gandini (right), at the Diagnostic Imaging and Interventional Radiology Department, University of Tor Vergata in Rome, who has developed and improved new technical options in peripheral vascular disease intervention, a technique that now saves about 92% of patients from major amputations due to critical limb ischemia. However, during an interview with *Karoline Laarmann*, the professor pointed to one big problem: 'Thwarted by turf battles and the medical industry, the new techniques cannot find their way into larger clinical practice despite the fact that they could save half of at-risk limbs from amputation'

At the Tor Vergata Hospital in Rome, Professor Roberto Gandini and team have performed more than 2,600 revascularisations since 1999.

During this minimally invasive procedure a vascular introducer is first positioned to perform a preliminary angiographic study and then followed by recanalisation of long segments of the chronically occluded vessels using a combination of coronary guide wires and low-profile balloons. Thus the arteries are opened by two to four millimetres to enable sufficient blood flow through the foot.

The risk of complications is decreased in this less invasive procedure than seen in bypass surgery. It can also be used to treat very distal arterial obstructions.

In May 2010, Prof. Gandini's team published a five-year follow up study about the long-term outcomes of 510 diabetic patients with critical limb ischemia and an active foot ulcer or gangrene (*Diabetes Care,* May 2010 vol. 33 no. 5 977-982). All probands involved were candidates for a major amputation. The report showed that in 70% of the patients the limb could be saved and > 60 % of patients had healed wounds with smaller ulcers and less coronary artery disease. These patients had lower rates of dialysis treatment and required less emergency room care. Only 15 % of patients received a major amputation.

In Prof. Gandini's opinion: 'For successful treatment of impaired circulation in diabetic feet, instruments must have special features. The arterial occlusions are often very hard and long. Therefore, the balloon must be longer than usual and must sustain high pressure. Currently they are on the market but with delay. However, for some reason manufacturers have no interest in this dedicated device. Instead, they try to push us in the direction of stents.

'If, on the one hand, stents offer the right initial results and longer vessel patency in respect of the balloon but, on the other, in the case of recurrence or complications the device could preclude or make vessel re-treatment harder, in my opinion in this sense the use of stents is very limited. I only use guide wires and balloons. The industrial target should go further than only increasing the revascularisation instruments portfolio. The goals must be education, support and training for old/new interventionalists to increase the number, skills and comprehension of anatomical complexity, but mainly push to create a dedicated multidisciplinary foot care group.'

The professor also points to a lack of awareness of IR in diabetic foot treatment in other medical disciplines. 'The field of revascularisation in diabetic feet is a scope for different specialties, as there are interventional radiologists, cardiologists and vascular surgeons. While vascular surgeons currently do not have appropriate skills in these procedures, cardiologists still have a coronary approach in a vascular region characterised by completely different technical/anatomical aspects. Cardiologists believe they can work in the small vessels similarly to the coronary arteries, but the anatomical situation is totally different. In the coronary arteries you have to cross an occlusion of three centimetres length, while in the limb you have to open up vessels from 20-30 cm. You have to work much more aggressively here to be successful.'

However, he emphasises that who performs the revascularisation is not the issue; what matters is that it is performed in the right way. The interventional radiologist is currently the best clinical partner for foot care diabetologists, he believes, and a close relationship between diabetologist and radiologist therefore plays a key role: 'The development of a new professional role in diabetology, with physicians dedicated particularly to foot care management would be auspicious; this ultra-specialist is a main decision maker for the treatment of foot pathology. Today's diabetologist should not only be a clinician in charge of clinical management, follow-up and ulcer care, but also a mix of orthopaedic specialists and surgeon. The best results in foot care originate from shared activity of a team composed of a technically skilled endovascular operator and an expert diabetologist.'

In the USA, Prof. Gandini concludes, interventional radiologists have already lost functional responsibility for artery treatment, passing this role to other specialists. In around 20 articles published in an issue of the American *Journal of Vascular and Interventional Radiology*, only one or two wrote about endovascular treatment and fewer than this specifically on distal artery revascularisation. He hopes that 'the same thing is not going to happen in Europe'.

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