# EUROPEAN HOSPITAL

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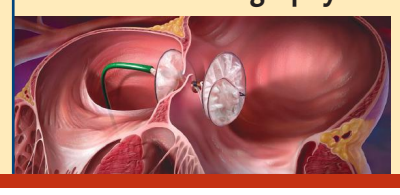



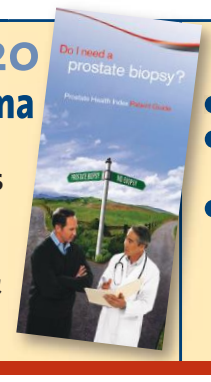





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## Pancreatic cancer

### TeloVac enters Phase III trial

**United Kingdom** - The Phase III randomised clinical trial of TeloVac has begun, involving 1,000 patients with pancreatic cancer and 53 hospitals. This study is comparing combination Gemcitabine and Capecitabine therapy with concurrent and sequential immunotherapy using the telomerase vaccine GV1001. Results are expected in 2012 and, should the vaccine prove to be a success, it may be available to treat advanced pancreatic cancer by the end of 2013.

Telomerase is a ribonucleoprotein enzyme that is involved in the DNA replication of the cell cycle. The enzyme is over-expressed in most human cancers, including 90% of advanced pancreatic cancer patients and therefore is a natural therapeutic target in the treatment of cancer, as explained by the Professorial Hepatopancreatobiliary Unit at the Royal Liverpool University Hospital. Led by Professors **John Neoptolemos** and **Robert Sutton**, this is the largest national centre for pancreatic diseases in this country, seeing about 1,300 patients annually.

'The over-expression of Telomerase enables the cancer cells to overcome mortality and therefore be a major contributing factor to progression of cancer. Telomerase is one of the body's own proteins and therefore not recognised or attacked by the immune response. The GV1001 vaccine targets the over-expressed telomerase by enabling the immune response to recognise the enzyme and illicit an immune response against it. As telomerase is over expressed in majority of cancers and plays a leading role in the mortality of cancer cells, GV1001 could in future become a common cancer vaccine.'

Dr Jay Sangjae Kim, founder of GemVax, the Korean firm that is developing the TeloVac vaccine, said: 'We strongly believe this has the potential to overcome the limits of other current cancer vaccines and become part of the standard of care not only for pancreatic cancer but for various other types of cancers. In other words, a truly universal vaccine will be available in the near future.' KAEL-GemVax is reported to be planning a lung cancer trial of the vaccine later this year.

The TeloVac trial is funded by the charity Cancer Research UK, which stresses that the vaccine is not a cure but, if it works, might prolong life.

# France: The country's first 'saviour sibling' is a 'double-hope baby'

The birth, in France, of its first baby to be conceived by artificial insemination on top of the selection of an embryo based on its blood, has sent new flames into the hot parliamentary debate over the reform of bioethics law. The child's deliberate embryonic selection rested on it not having the gene for beta thalasaemia, and its birth potential to help cure beta-thalasaemia suffered by two older siblings. Theoretically, the use of 'saviour siblings' has been allowed since 2006, when the 2004 Bioethics Law and associated decrees was passed. The USA has utilised this for about ten years, but such a birth is rare in Europe – and, depending on the results of a current debate, might become even rarer in France. *Annick Chapoy* reports from Paris

Umut-Talha – a name meaning 'our hope' in Turkish – entered life this February in Clamart, south-west of Paris. He weighed 3.65kg and was pronounced 'very healthy'. His birth resulted from in vitro fertilisation after a double pre-implant genetic diagnosis that enabled doctors to choose an embryo that would not carry the disorder beta-thalasaemia, and whose blood and tissue would be compatible with that of his brother and sister. This type of technique was legalised in France with the Bioethics Law of 2004, but is still the source of great controversy in the public.

It is the first successful birth resulting from this type of pregnancy in the country. The practice is legal in numerous other European countries, including Spain and Belgium where, in 2005, the first two 'medicine babies' in Europe were born. The first birth of this type took place in the USA in 2000.

France's first so-called 'saviour sibling' was born to parents of Turkish origin and he was conceived under circumstances that would have been unthinkable only a generation ago. Umut Talha's parents had approached the hospital in Clamart just over a year ago. They had a serious problem – their two youngsters were both afflicted with the inherited blood disorder beta thalasaemia, which requires monthly blood transfusions. The parents knew the hospital was one of only three in France that was developing a treatment for their children's illness.

An embryo was screened and genetically selected from an original group of 12 embryos. It was chosen to ensure it did not carry the Beta thalasaemia gene and also due to its compatibility with the sick siblings. Besides selecting an offspring that would be spared from the disorder, the parents hoped their future baby could also become a donor of the right kind of treatment cells.

Born disorder-free, the baby's cells also proved compatible with his two-year-old sister. Doctors feel confident that she will be cured with the cells from his discarded umbilical cord, and her monthly blood transfusions will be discontinued.

A Professor at the Faculty of Medicine, University Paris XI, René Frydman also heads the Department of Gynaecology and Obstetrics at Antoine Beclere Hospital, Clamart, France, where the first 'donor baby' in France was born. Prof. Frydman counts biomedical ethics among his interests. His work in this sphere has 'led to many invitations by religious authorities of the Vatican, Jerusalem and of the Reform Church to debate the moral issues created by the use of the techniques of artificial procreation'. He has also been an active participant in the preparation on the law on bioethics.

The family have since returned to their home in southern France, but plan to return to Clamart to undergo the same procedure to cure their other child, Umut's four-year-old brother.

Following his birth, French newspapers spread 'Medicine baby' headlines across their pages. However, **Professor René Frydman**, a fertility pioneer and the 'medical father' of the first


*continued on page 2*


# Nurses need annual physical and psychological fitness tests

**England** – 'Wheelchairs receive better care than nurses'; they need annual physical and psychological tests to ensure they can cope with job demands. The subject, discussed this April during the Annual Congress of the Royal College of Nursing, followed the publication (11/2010) of the Government's *NHS Health and Wellbeing Report* (pub: 11/10), an independent review led by occupational health expert Steve Boorman that found that the National Health Service (NHS), Europe's biggest employer (1.4 million personnel), suffered a far higher number of staff sickness days off (10.7 days per annum – and higher in Scotland and Wales) than the private sector (6.4 days), and advised that the health service needed to do more to improve the health of staff.

At the time, a spokesperson for UNISON, Britain's biggest public sector trade union, pointed out that the comparison was unfair, because the work carried out in the healthcare sector is far more stressful than in the public sector.

Airing the problem, delegates at the RCN congress suggested the introduction of an annual physical and psychological assessment for all [NHS] staff, as stress among nurses is of 'rising concern', according to Claire Topham-Brown. Some RCN members, she said, had reported becoming ill due to taking no breaks, insufficient staffing levels and also being expected to work late. 'One activist observed that we take better care of wheelchairs than we do of staff. Bizarre but true,' she added. 'We now risk assess everything monthly, weekly and sometimes daily. But, when do we ever assess that vital, delicate and most valuable part of the machine – you and me?'

Karen Webb, RCN director of England's eastern region, suggested that testing and support was even more important given the expansion in nurses in training in recent years, which could lead to an increase in those that are unsuitable for a career in nursing. 'It's about making sure people have the right attributes.'

However, Douglas Lockhart, from Scotland, warned that such an assessment could be used as a stick with which to beat staff. In addition, another nurse expressed concern about the viability of annual assessments, bearing in mind that such assessments would take valuable time and cost money out of already over-stretched budgets and NHS cutbacks.

Staff sickness costs the NHS £1.7 billion annually.

contents


# EUROPEAN HOSPITAL
## Reader Survey

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For new EH registrations, tell us more about your work, so that we can plan future publications with your needs in mind. Please put a cross ☒ in the relevant boxes.

**1. SPECIFY THE TYPE OF INSTITUTION IN WHICH YOU WORK**

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☐ Up to 150 ☐ 151-500 ☐ 501-1000 ☐ more than 1000

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In which department do you work?

| | | |
|---|---|---|
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| Are you in charge of your department's budget? | ☐ Yes | ☐ No |
| **How much influence do you have on purchasing decisions?** | | |
| I can only present an opinion | ☐ Yes | ☐ No |
| I tell the purchasing department what we need | ☐ Yes | ☐ No |
| I can purchase from manufacturers directly | ☐ Yes | ☐ No |
| **Do you consider that your equipment is** | | |
| out-dated | ☐ Yes | ☐ No |
| relatively modern | ☐ Yes | ☐ No |
| state-of-the-art | ☐ Yes | ☐ No |
| Do you use/buy second-hand equipment? | ☐ Yes | ☐ No |
| 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 |
| Is your department involved with telemedicine in the community? | ☐ Yes | ☐ No |
| Do you consider your department is under-staffed? | ☐ Yes | ☐ No |
| 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 2/11



# How green is your hospital?


Mandana Banedj-Schafii

**Sometimes small efforts can have a big effect. In a pilot project, a team at the University of Heidelberg is studying what are the real energy guzzlers in hospitals and what cost savings can actually be achieved by simple energy saving measures**

Mandana Banedj-Schafii Dr.-Ing., Managing Director of consulting firm Mandamehr, holds a 14-day course on healthcare facility management for students taking the Masters Degree course 'International Health' at the Institute of Public Health, University of Heidelberg. With sustainability close to her heart, last year the expert devoted one day to the course day 'Green Hospital', an initiative inspired by employees at the Institute of Public Health who wanted their own workplace to be environmentally friendlier. Initially they had reduced the amount of paper used and changed from white to recycled paper. Moreover, the introduction of multimedia conferences led to reduced travel – saving on time, costs and $CO_2$ emissions.

Since then, Dr Banedj-Schafii has been an advisor on the energy savings project at the University and University Hospital of Heidelberg. The pilot phase will conclude shortly. The long-term objective is to extend the findings and strategies implemented for environmental and climate protection to the entire organisation.

'The sustainability approach goes far beyond the environmental friendliness of a building,' Dr. Banedj-Schafii points out. 'It comprises the entire life cycle of an object. This extends from planning to design, building, use of the building and, finally, demolition and recycling. Obviously, the opportunity to participate actively in the planning phase of a 'green' project right from the start is not always given. Many people believe therefore that they have no leeway to create a greener working environment, because they can't change the building shell or existing electricity contracts. However, each and every one of us can still contribute towards sustainability.' In fact, every kilowatt hour of electricity not used means half a kilo less of climate-damaging carbon dioxide ($CO_2$).

From the beginning, the integration of several partners was important to the project's success. For example, to document the concrete benefit of measures from a financial aspect, the Green Institute team depended, first and foremost, on help from the hospital's technology department. 'We required concrete data to enable us to compare the energy consumption before and after the introduction of the energy-saving measures. Up to that point there had been no available data, or a feel for how much energy each individual employee consumes.'

Five working groups dealing with different aspects of sustainability over the coming months were set up to achieve a more structured organisation. Whilst working group I (object/building analyses) collated data on the buildings and determined sample buildings and rooms for later measurements, working group II (equipment analyses) assessed the exact data for all energy consuming devices to determine their consumption levels. It turned out that most electricity was being used by PCs, laptops and printers. 'We found that only very few users made use of the energy-saving mode of their computers,' Dr Banedj-Schafii points out.

Working group III (users' behaviour) developed ideas on how to draw employees' attention to energy saving, and enforced a switch to the energy-saving mode for all PCs and laptops in the Institute.

Working group IV (organisation/ management) dealt with all types of resources, from the distribution of staff in rooms to the acquisition, maintenance and repair of equipment.

Working group V (PR/politics) dealt with communication and data transfer.

All this ensured that important tips on energy saving were passed on efficiently during the monthly institute meetings.

Although there are no conclusive before and after results from the pilot project as yet, based on data already collated the team could look at different scenarios that show the effects of a small investment (scenario 1), such as power strips, and a larger investment (scenario 2), such as the acquisition of new equipment.

The expected savings are 44% for scenario 1 and up to 55% for scenario 2. Therefore, with a small investment of around €280 the institute could save around €3,800 and 14,520kg of $CO_2$ over three years. 'This may not seem like much from an economic aspect,' says Dr Banedj-Schafii, 'but, when you work this out across all institutes at the university and the university hospital, it is actually quite a large amount.'

*Dr Mandana Banedj-Schafii will speak about the Green Institute Project on 23 May, 2011 at WÜMEK congress in Würzburg, Germany*

# KIMES 2011

## Watching a medical industry shift into top gear


Korea has a large, diverse and vibrant medical device manufacturing industry, which has boomed in recent decades due to the rapid growth of the country's economy. The scale of its medical industry was very evident at the 27th Korea International Medical and Hospital Equipment Show (KIMES) held at the Convention and Exhibition Centre (COEX) in March. Noticeably bigger this year than in previous years, the event has grown along with the development of South Korea's medical industry, to become a world class trade fair.

Along with 1,045 firms from 32 countries, 453 Korean manufacturers exhibited their wares.

Speaking at the opening of the show, **Choong Jun Kim**, president and CEO, Korea E & Ex, the organisers of KIMES, noted that the event is an important gauge of the direction the medical technology industry is taking. 'It is valuable to see the evolution of leading high tech products, eco-friendly products and other diverse solutions along with the convergence of IT and medical technology.'

Indeed, this was a complete healthcare show, in that the range of exhibits included everything from drugs and oriental medicine to medical devices and hospital accommodation.

The country's own medical industry has developed from a focus on disease treatment to the enlargement of its medical services and healthcare quality, expanding its level to that of an advanced country. Korea also has a great opportunity to expand outwards by, for example, increasing exports, product diversification and focusing knowledge on intensive high-tech medical equipment based on IT. Portable diagnostic devices were exhibited, for example, which provide time and cost reductions, and a digital diagnostic system to enable remote consultations.

As one of the industries that could drive the Korea economy in the future, to stimulate growth in this sector, the Korean government provides a blue print for political and financial support of the medical industry. Among government and other bodies supporting the show were the Ministry of Health, Welfare and Family Affairs, Seoul Metropolitan Government and the Korea Food & Drug Administration (KFDA), the Korea Trade Investment Promotion Agency, Korea Health Industry Development Institute and several other healthcare related associations.

*Details: www.kimes.kr*

*continued from page 1*

French test-tube baby in 1982, oversaw Umut's case, said he preferred the term 'double-hope baby'.

'Medicine baby is a media term invented by people who are against this kind of procedure,' said Prof. Frydman. In English-speaking countries, the terms 'donor baby' and 'saviour sibling' have been widely used in the media.

Umut certainly presents a double hope for his parents: the hope of having a new, healthy baby, and the hope of curing one of their sick children.

However, other scientists, religious groups and parents beg to differ. The issue of saviour babies has raised complex ethical debates, and renewed fears of a move towards 'designer babies', or babies whose traits – e.g. intelligence, eye-colour and height – have been predetermined.

Thus, Umut's birth has raised questions among medical, political as well as religious circles in France. **Christine Boutin**, President of the Christian-Democratic party, denounced an 'instrumentalisation of the human being, conceived in the sole purpose of being used', while the head of the Bishop's Conference said he was 'totally opposed to a procedure by which somebody is being used exclusively to serve somebody else'.

The timing of Umut's birth was also significantly timely – just as the very law that allows for cases such as this to be revised. Observers say that the existing legislation guiding biotechnology in France might be tightened and restrict research in certain fields, including stem cells.

The country's standing bioethics law allows for cases like Umut's. In fact, the government has earmarked €800,000 per year for Clamart to practice and develop the procedure.

Nonetheless, Prof. Frydman and colleagues say a lot more needs to be done, complaining of endless hurdles to launch further research and access funds. They regret that France has started a decade after the USA and that the government is still reluctant to give them full backing.

# Identifying risk, averting risk

**The introduction of comprehensive risk management to a hospital is challenging. Although initiating quality and safety processes is often easy, the structural changes in a microcosmic hospital are harder to crack. However, successfully integrated risk management can represent a decisive, competitive advantage in the healthcare market. How can risk management be improved quickly and what kind of measures will ensure that employees really do change their attitude and behaviour?**


Tobias Möhlmann

'If you want to establish integrated risk management in a hospital, a good start is taking a look beyond the rim of your teacup, at other industries,' Dr Tobias Möhlmann, Associate Principal, Co-head of the McKinsey Hospital Institute, McKinsey & Company, advises. 'One industry sector where the business model is almost completely based around the subject of risk management is the financial sector. There are two dimensions to this: measuring instruments in the form of rating agencies, which capture and evaluate risks, and a branch culture that is aimed at recognising risks, assessing them and finally making decisions based on those risks.'

However, the 2007 financial crisis proved that even supposed experts can overlook existential risks. The fatal economic effects of the banking crash also affected perceptions in other industry sectors. 'Risk management' is increasingly a focus for hospital administrators.

## A question of business culture

In terms of measuring tools, Dr Möhlmann believes hospitals are already in a good position. A range of quality and safety systems, such as operating theatre checklists, Critical Incident Reporting Systems (CIRS), interdisciplinary case conferences, or patient tags, along with electronic patient files, are already in place. If anything, deep-rooted cultural barriers, which are widespread in hospitals, are a more likely reason for failure in the implementation of new measures. 'Instead of evidence-based medicine, it's often a case of eminence-based medicine. You know, for instance, that your doctor colleague should not be wearing a tie by the patient's bedside to prevent wound infections, but you are too afraid to mention it.'

A McKinsey survey on the risk culture in hospitals confirmed this impression across all groups. Two basic problems were found: Fewer than 70% of all staff (ranging from board members to auxiliary nurses) abide by existing risk systems in their respective hospitals, or even understand the importance of the risks.

To explain the result, Dr Möhlmann says: 'When you think about hospital risks you often only think about medical risks and patient safety. However, when you look at the hospital as a whole, there are a number of other factors, such as regulatory risks, financial risks, or reputation risks, which are all interdependent but have to be managed in different ways. Current quality and safety systems in hospitals promote documenting and delegating responsibility, instead of fast reactions and decisions. Frequently they are also much too detailed and complex, so they run the risk of being ignored by senior management.'

## Creating transparency

So do you break the spell? There are three essential elements for successful establishment of risk management which are decisive. Initially, it's all about creating transparency, which means risks must be identified in detail, i.e. via employee surveys or interviews. On the basis of this data analysis, risks should then be prioritised according to their likely occurrence and effects. This allows the development of strategies to avoid those top risks, and/or damage limitation if they do indeed occur. 'The key of transparency, however, is breaking down the barriers between the responsible staff units and the Board. If the problem is not being addressed at management level there is no opportunity to implement measures in the other direction – this is a typical top-down problem,' he points out.

## Effective processes

The second key element of risk management is organisation and process. It is therefore advisable to assign some one to each individual risk. Structures should be determined in such a way that a potential risk, or risk event that has already occurred, are identified in time and reacted to respectively. 'The most important thing is to create a base to learn from mistakes, i.e. through comprehensive implementation of anonymous CIRS. Of course, the best thing would be not just to talk about events once they have occurred, but also to broach the issue of near-miss situations,' he advises.

## Creating a risk culture

Dr Möhlmann emphasises the third essential issue – the culture. Are employees informed of potential risks and containment measures? Are they aware of the risks and do they address them? Do they feel personally responsible and are they likely to react to impending risk events appropriately? Are they motivated to avoid and contain risks? 'Risk management is often viewed as a bureaucratic burden by many employees as they lack the understanding of the necessity of these measures. Accordingly, they are then only carried out half-heartedly.'

He is sure that staff will only change their behaviour when they understand the expected changes and when these make sense to them. The important issue here is to focus on a few selected, clearly defined changes of attitude. It is also very important for well respected, senior staff to act as role models: 'If the sister in the operating theatre does not wear a face mask then the staff members she oversees will assume there is no need to do so. However, if they feel well supported by the formal, organisational structure, i.e. if there are regular face mask controls in the theatre, they will feel more empowered to talk to their direct superior about the importance of wearing the mask. If you are sure of your facts, you are more likely to express your opinion.'

## The 128th Congress of the German Society of Surgery

### 3-6 May, Munich, Germany

*Healing between Rationality and Humanity* – that's the slogan for this year's German Society of Surgery Congress. Indeed, healing is intentionally central to the planned discussions. 'If healing is the objective, and rationality is the way, humanity as the oldest pillar of medicine that represents the origin of all surgical activity,' explained Professor Axel Haverich, the 2011 Congress President. It is, he added, 'the most powerful bond around our multidisciplinary, surgical competence, which is now represented by our 10 specialist associations. We, as surgeons, perceive healing as a form of art that is used exclusively for the benefit of patients, each and every one of whom is hoping to be healed.'


Prof A Haverich

The programme will present several innovations. 'By reducing the number of specialist sessions, room has been created for the joint discussion of interdisciplinary topics in the field of surgery in Germany,' he said, thus providing the opportunity for sessions in which to work jointly through the topics of surgical infections, transplantations of cells, tissue and organs, surgical intensive care medicine and emergency care/catastrophe management.'

*Congress details: http://chirurgie2011.de*

# Human organ donations

## Maltese acceptance is notably high

**You often need the vision of a hypermetropic eagle to find Malta on the world map – even its name fills more space than the representation of the island itself. And yet, in the Eurobarometer 2010 survey, among the recent European Union Member States, the Maltese showed an unusually high level of consent (72%) to organ donation and 77% are willing to donate their own organs, making us a beacon in southern Europe, *Moira Mizzi* reports**


The Mater Dei Hospital

The therapeutic use of human body parts, including the donation and transplantation of organs, is a process by which an individual wilfully and generously donates an organ or tissues to another individual without expecting any financial or other gain, thus giving that person an opportunity to live a healthy life. In living donation, the donor donates an organ (usually a kidney) to a member of the same family, or even a complete stranger, although the latter is not frequently performed in Malta. In deceased donation, the organ donor is a patient admitted to Intensive Care suffering a severe catastrophic brain event that eventually leads to brain death (as certified by the ITU team and neurologists according to established clinical criteria). These cadaveric donors are typically victims of road traffic accidents, a fall from heights and brain haemorrhages.

Organ transplantation has been successful in treating serious health conditions since 1954; in fact, it is now the most cost-effective treatment for end-stage renal failure and the only available treatment for end-stage failure of organs such as the heart, lungs and liver.

Locally, we perform about 30 pmp kidney transplants annually, half from living donors and the other half from cadaveric donors. Non-heart beating organ donations are not carried out in Malta. The Intensive Care Unit at Mater Dei Hospital treats around 1,100 patients per year and has an average mortality of 18-20%. The deceased organ donation rate is 22.5 pmp/year, which is above the EU average of 18 pmp.

The Maltese attitude to organ donation is very positive: it is perceived as a noble act of altruism and generosity to help those in need, and is something positive that comes out of the death of a loved one. Malta has a donor card system, but final consent for deceased organ donation is given by next of kin. In fact, the consent form gives the choice to select only certain organs to be donated. The same selflessness is manifested on the part of live donors, with relatives and friends of the chronically ill showing a remarkable willingness to donate their kidneys to improve another's life.

After consent for donation, the donor and his or her organs are characterised using questionnaires about the donor's lifestyle, as well as relevant blood and radiological investigations. Tissue typing to match the donor to the appropriate recipient is usually done abroad. In Malta, a kidney transplant programme is provided by a team of three local transplant surgeons. Additionally, we have performed a number of heart transplants, as well as corneal transplants (the latter considered tissue transplantation, as the cornea is not a complete organ). All other donated organs that are not transplantable for patients in Malta are offered to other countries. In fact, since we do not have a liver transplant programme, Livers are usually sent abroad, particularly to Italy, while all Maltese patients requiring a liver transplant receive treatment in the United Kingdom.

In Malta, organ donation and transplantation activities are based in the same acute general hospital, Mater Dei Hospital, thus providing more visibility in the management of organ donations and transplants, although it can create a problem with anonymity.

No words can describe feelings when someone dear is lost, especially if suddenly and of relatively young age. And yet, in the midst of such tragedy, many families still find the strength to think of others in need and donate something precious to them, to renew a life and prevent another family from losing someone. Ironically, in such selflessness many families find peace and healing.

It would be wise to think of the life we could leave behind when the bell also tolls for us. Likewise, we would be making the decision ourselves, thus making this easier for our loved ones and also leaving behind a legacy of love, selflessness and hope.

*Special thanks to D. Carmel Abela MD and Tony Bugeja, from the ITU Department at Mater Dei Hospital for their help in the preparation of this article*

# ROLE OF

*Rapid technological progress and the changed working patterns of surgeons have greatly increased the demand of simulated training in the United Kingdom, notes **Professor Mike Larvin**, Director of RCS Education at the Royal College of Surgeons in London, where a new Education and Simulation Centre is incorporating state-of-the-art education and training facilities in response to those changes*

"Simulation training in surgery is becoming increasingly sophisticated and, as time for surgeons to learn has been reduced by working time regulations, this now forms a key role in the development of practical skills.

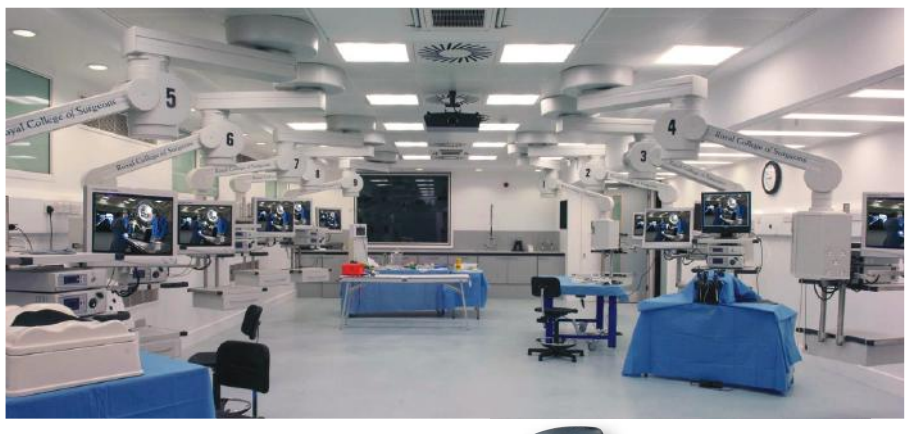
The recently completed Education and Simulation Centre at the Royal College of Surgeons' London headquarters houses state-of-the-art education and training facilities, and offers a wide range of courses for surgeons and the wider surgical team. The new facilities include a cadaveric anatomy centre, clinical skills unit, team skills training theatre and seminar and lecture theatres.

Courses aimed at early years' trainees are generic, but become more specific as they progress. Courses for trainees and consultants cover all nine surgical specialties, with many also aimed at sub-specialist interests. More recently RCS Education has developed courses that support the wider surgical team as well as other medical specialties, in recognition of increased multidisciplinary care of patients.

Surgeons attending our courses are able to learn and practice new skills, refresh existing skills or prepare for examinations in a safe, controlled environment with the support of expert surgical faculty and other specialists as required. All courses are carefully quality assured, whether delivered at the College and at our UK regional centres. A range of simulation techniques are incorporated into training courses, from simple plastic models on which trainees can practice stitching, to performing surgery for the first time using donated cadaver tissues, or learning about teamwork and leadership in our state-of-the-art operating theatre suite.

The introduction of fresh frozen training to the UK has greatly enhanced procedural simulation, providing a close match to the anatomical structure of living patients when dissecting or handling tissues. This allows trainees to use the latest technology to practice and develop their operative skills. Embalmed material can be used, but the process renders the tissues stiff and so less lifelike for training.

The College's Wolfson Surgical Skills Centre is the UK's largest cadaveric dissection facility, and is equipped to use either 'Soft fix' embalmed or fresh frozen cadaveric material to simulate specific operations. The centre has nine specially designed anatomy dissecting tables to accommodate



# Surgical staplers

**Mechanical suturing tools are an indispensable part of modern surgery. Gastro-intestinal surgery as well as minimally invasive surgeries, would be unthinkable without this technology, a growing sub-market in an ever-growing industry, possibly driven by the patient's benefit, writes *Holger Zorn***


SOURCE: COVIDIEN

**Covidien's Tri-Staple Technology provides Endo GIA reloads across a broader range of tissue thickness, thereby simplifying the cartridge selection process**

The idea to use something to stitch wounds together is probably as old as surgery itself. In ancient Egypt, around 2000 BC, ants were placed on wound edges. When their mandibles penetrated the patient's skin, their body was detached, leaving the head with mandibles in the patient's tissue. Thus, the first surgical clip was a bio-product.

In 1921, Hungarian surgeon Aladar von Petz enhanced the first surgical sewing machine, invented in 1907 for gastrointestinal procedures by his compatriot Huemer Hueltl. Petz built the 'Petz', manufactured by Aesculap in Tuttlingen for over 80 years. 'I designed the gastro-intestinal suturing instrument in 1920, while working as an assistant professor,' he wrote (Dig. Surg. 2002;19:393-9). 'The idea stemmed from the surgeon's need to open the digestive tract with its highly contaminated lumen, thereby risking consequent peritonitis with its associated increase in mortality.' Thus he gave the reason for surgical stapling that is still valid today.

The Petz apparatus had to be filled each time with staples by a nurse. Today's devices are mostly preloaded disposables. This progress is based on a 1960s Russian invention from Moscow's Scientific Research Institute for Experimental Surgery. In the USA, Leon C Hirsch bought the patents, founded the United States Surgical Cooperation and manufactured those staplers under the AutoSuture brand – today part of Covidien.

Surgical staplers can be divided into four groups: linear 180° and 90° instruments, circular and endoscopic. The staple line may be straight, curved or circular – depending of the type of anastomosis (field of resection). The staples are mostly made of titanium, due to less immune reaction and, being non-ferrous, MRI compatibility.

At Covidien, **Dirkjan Doyen**, Marketing Director for Endo Stapling Europe, explained: 'Linear staplers have applications in abdominal, gynaecological, paediatric and thoracic surgery for resection, transection and creation of anastomosis. Circular staplers have applications throughout the alimentary tract, to create end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries. Staplers designed for laparoscopic use are longer and thinner than those for open surgery and can be rotated and articulated.'


COURTESY OF 3M MEDICA

**Skin stapler in use**

Skin closure is another important application for staplers, often called tackers. If the cosmetic result is of secondary importance, they are often used as a quick alternative to conventional skin suture. Such staplers are suitable for lacerations as well as surgical procedures closure. In contrast to surgical staplers, skin tackers are mostly made of plastic and their staples are made of stainless steel, because they will not remain in the skin and will removed later.

Staplers consist of a handle/grip in different shapes, forms and sizes, depending on their functionality, and are loaded or pre-loaded with staple cartridges. These cartridges contain two or more staple rows. Between these rows, a knife blade is mounted to enable cutting and stapling (mechanical suturing) in one step. When the stapler is correctly placed, targeted tissue is positioned within the stapler jaws and then the firing sequence takes place. Staples are fired and formed and closed during the firing process. Simultaneously, the knife blade cuts through the tissue to separate it, the staples at both sides of the cutting line penetrate the tissue and are formed. Thus, the wound edges are compressed and stapled (sutured) and the small blood vessels are also closed during the stapling process.

**Enhanced products** to optimise efficiencies and compression during open surgery were recently launched by Ethicon Endo Surgery (EES). The Linear Cutter 55/75, for example, employs a novel 3-D staple technology that produces angled, parallel staple legs that overlap, unlike traditional surgical staples. Six staple rows, instead of four, combined with selectable staple heights, in one cartridge provide superior haemostasis.

**The market** for surgical staplers is very sensitive. On the one hand the number of uses is increasing; on the other, competition is tough. A variety of manufacturers from the Far East is trying to break the existing duopoly. Also, some hospital service providers offer refurbishing and re-sterilisation of originally single-use devices, but they give no warranty to the hospital – probably why there are few reliable figures.

In 2007, MedMarket Diligence, LLC, the California-based publisher of medical technology market and assessment

# SIMULATION IN SURGICAL TRAINING

up to 36 participants.

The room incorporates state of the art audio visual facilities with each dissecting table provided with a mounted screen for close-up viewing of procedures, and permits live demonstration links to other lecture areas throughout the building or externally. In addition, there are two smaller demonstration rooms ideally suited for courses teaching procedures on smaller organs, such as Head and Neck Anatomy.

Our Clinical Skills Unit provides a flexible space that can be utilised for skills based training (for example suturing technique) in a laboratory environment and minimally invasive (keyhole) surgery skills using the integrated laparoscopic equipment supplied through boom arms able to recreate the entire range of simulation techniques. Laparoscopic procedures require different technical skills and dexterity to open surgery, and the Clinical Skills Unit is equipped to provide a realistic training environment to learn and develop both essential skillsets.

The Team Skills Training Theatre comprises a functioning operating theatre, recovery area and debriefing room and simulation can now be extended to the wider surgical team, including anaesthetists, radiologists, physicians, cardiologists and theatre nurses. All activity can be recorded and debrief techniques employed to monitor behaviour and team interaction. The theatre is equipped with the latest SimMan wireless 3G mannequin, with multi-angle video capture offering simulation training and creating numerous opportunities to develop and teach teamwork skills.

The clinical skills unit and team skills training theatre can be combined to simulate critical incidents and major disaster scenarios, such as road traffic accidents and life-threatening anaesthetic or surgical complications can be set up while experts observe and provide feedback to the theatre team.

The Education and Simulation Centre has a team of highly trained surgical resource technicians to provide technical advice and expertise and support the setting up and running of courses and events.

*Course details: RCS Educatio.*
*Phone: +44 (0)20 7869 6300*
*Email: education@rcseng.ac.uk*
*Website: www.rcseng.ac.uk/education*

reports, analysed the European wound closure market: The proportion of staplers is $151,000,000 and represents 45% of the total market volume. Patrick Driscoll, the company's founder, predicts $248 million in 2013 – a compound annual growth rate of 1.2% *(Source: MedMarket Diligence, LLC, Report #S180 'Worldwide Surgical Sealants, Glues, Wound Closure and Anti-Adhesion Markets, 2008-2015', pub: October 2010)*. In contrast, independent suppliers of supplemental products for both large stapler manufacturers estimate the annual market volume to €300,000,000 in Germany alone.

**Patient's benefit** in one indication is currently under evaluation by the randomised, controlled multi-centre DISPACT trial to compare surgical stapling versus hand-sewn sutures as the closing technique after resection of the left pancreas. The study aims to determine which operative technique results in the lowest risk for one of the most common complications – pancreatic fistula. Both of these surgical operations remove the diseased section of the pancreas, the pancreatic tail. This partial organ resection can be carried out with a traditional scalpel and closed with a hand suture, or performed in one step with a stapler.

In the study, the Ethicon TL60 was used, a linear stapler that delivers two staggered rows of titanium staples for a 60mm long suture and which may be reloaded three times for a total of four firings.

Markus K Diener MD, study coordinator at Heidelberg university hospital, said: 'Both techniques are frequently used, standard surgical techniques. However, until now it hasn't been clearly shown which of these techniques has the lowest risk for the occurrence of pancreatic fistula.'

With 450 patients in 21 centres throughout Europe, enrolment was completed in June 2010. 'We are very busy preparing results of the primary endpoint pancreatic fistula, which will be ready for presentation shortly,' Dr Diener confirmed. EH will stay tuned to answer the question of whether a benefit for patients can be proved – whether a win-win situation exists.

# Facing the eye of the storm


Peter Biberthaler

**Be prepared for catastrophe management in trauma surgery**

**Major disasters and natural catastrophes occur all the time – but in most cases we are only aware of them as images in the news on our TV screens or in the newspapers. Fortunately, most European hospitals are confronted with such major events only occasionally. It is all the more important to be well prepared 'just in case' -- a sufficient reason for trauma surgery and catastrophe management to be key topics at the forthcoming German Surgery Congress in Munich (3-6 May 2011)**

Burns, fractures or contusions are part of daily routine for **Professor Peter Biberthaler**, Director of the Trauma Surgery Clinic at the University Hospital rechts der Isar in Munich. As an expert in polytrauma research and a representative of the German Society for Trauma Surgery, the professor is to present a lecture at the German Surgery Congress in May.

Prof. Biberthaler well understands what is important when many severely injured patients must be treated all at once following a large-scale incident: 'Efficient medical care starts with the organisation of transport at the incident site. The ambulance service or fire brigade initially assess the severity grade of injuries to ensure optimum allocation of patients to hospitals in the vicinity.

'In Germany the rescue coordination centres have catastrophe plans that strictly govern which patients should be admitted to which hospital, so they can ensure no more than 10 severely injured patients are being taken to, and treated at, any one hospital providing maximum care, thereby also keeping traffic routes free. Moreover, we work in 30 – 40 minute transport intervals when polytraumatised patients are taken to A&E.'

Regular training is important, to ensure every move is perfectly executed during an emergency. Large-scale events – say, a bomb in a sports stadium or airport, with over 100 severely injured and 500 with minor injuries – are customised according to local safety conditions and re-enacted for this purpose. 'Simulating such catastrophe scenarios is extremely complex, but also irreplaceable for successful emergency care,' explains Prof. Biberthaler, 'because a later evaluation will show where possible error sources and problems occur.'

Technological innovations will also help to improve safety and catastrophe management even further. Researchers in many locations are working on early warning systems, such as automated computer video evaluations, where cameras capture the speed of movement and density of people per square metre to ensure early warning in case of danger.

Trauma surgery itself is also developing rapidly, he points out. 'Since findings from materials technology and biomechanics have been integrated into this field, and because we've been giving biology more consideration during our operative procedures, we've been achieving increasingly improved results in the case of highly complex injuries.'

## Scanning

Recent, large-scale studies have also proved what many trauma surgeons already suspected – the early use of CT scanning, as part of resuscitation room management, increases patients' survival chances significantly because bleeds and fractures can be quickly identified.

The numerous technological and medical advances have also increased the need for trauma surgery services: 'Trauma surgeons are usually very dedicated to their field of expertise,' the professor points out. 'There are many colleagues for whom not just high-tech, but 'high-touch', meaning the human aspect of their medical work, is very important, and therefore they voluntarily travel across the world to help the victims of catastrophes, with great personal commitment.'

Another event discussion of intense interest focuses on interdisciplinary emergency admissions. Whilst many German hospitals still operate subject-specific emergency admission departments specialising in the treatment of specific problems, large interdisciplinary emergency admission departments, open to emergencies of any kind, are already established elsewhere, e.g. the USA. 'We can only be successful in emergency medicine on an interdisciplinary basis,' Prof. Biberthaler believes. 'As trauma surgeons we are specialised in the treatment of injuries of any kind, but we still also need the help of specialists in vascular surgery, plastic surgery or neurosurgery.'

Because 75% of patients in an emergency department are trauma surgery cases, dual team leadership has proved beneficial – meaning, in the context of this interdisciplinary concept, a trauma surgeon as department head supported by a specialist in internal medicine, for example. 'Although there are some concerns about the interdisciplinary approach regarding the necessary training concepts, I still think this is the future of emergency medicine,' Prof. Biberthaler concludes.

# Widescreen in the operating theatre

**State-of-the-art operating theatres are shifting from X-rays to the display of images on monitors. The variety of different picture sources is also increasing, ranging from boom and endoscopy cameras to C-arms or PACS (Picture Archiving and Communication) systems. Thus the trend is to use an image management system to display the various surgical images on just one monitor**

The new RadiForce surgical monitor series, made by EIZO, is specially designed to integrate a variety of video inputs. Within the monitors, the configurable gamma function ensures optimal display of images from various applications. The Picture-in-Picture and Picture-and-Picture functions even make it possible to display several picture sources on one monitor simultaneously, and the video output on the EIZO monitors can transfer the picture signal to other monitors in the operating theatre. The signal can also be transmitted to an archival system: either into the PACS database as a compressed video via a video grabber, or directly to a DVD recorder.

In cooperation with Ondal Industrietechnik GmbH, EIZO provides prewired carrying systems (Monitor Carrying Systems), precisely attuned to EIZO's monitors and image management systems. Prior to delivery, the carrying systems are connected to the monitor components to simplify subsequent fittings significantly. EIZO monitors can then be interchanged in the monitor carrying system simply by plug-and-play, and no longer have to be extensively wired up on site.

The RadiForce LS560W is a large 56-inch widescreen monitor with a resolution of 3840 × 2160 pixels – the equivalent of four full HD televisions or six conventional medical monitors. This new colour monitor can easily replace conventional greyscale monitors thanks to its 1200:1 contrast ratio, brightness of 450 cd/m² and 176° horizontal and vertical viewing angles. The ISS system (Internal Stability System) automatically stabilises the brightness over the monitor's entire lifetime, and a correction feature ensures uniform brightness across the whole screen. The monitor can be tailored quickly and effortlessly to different applications using its five integrated and calibrated look-up tables. Together with EIZO's Large Monitor Manager (LMM56800) different video sources can be flexibly arranged and displayed on the large display screen.

Accessories, such as the Transmission DVI Link (TDL3600), allow picture data to be transferred in digital image quality from any video source to any monitor in the operating theatre. If a signal needs to be routed along the ceiling to the ceiling suspension, or from an external room to the operating theatre, it is even possible to bridge this digital transmission path as far away as 36 metres without degradation.

The monitors are available with a waterproof glass panel protector for safe and clean integration in the theatre. In addition, their clean lines and smooth surfaces enable easy cleaning and disinfection and, of course, they are all resistant to medical cleaning and disinfection agents.

EIZO surgical monitors meet the EN 60601 medical safety standard, with the ability to connect an additional ground cable, making it possible to install the monitors in patient environments.

The picture quality of all EIZO monitors used for radiology and in operating theatres can be monitored and, if necessary, corrected for DICOM or CIE using calibration and quality assurance software developed by the company.



# The Confocal Laser

**A new technique to aid the early detection and diagnosis of inflammatory bowel disease has been developed by UK and German researchers. *Mark Nicholls* reports**


Alastair Watson

The Confocal Laser Endomicroscope (CLE) contains a powerful microscope that allows clinicians to view bacteria in the intestine that are thought to trigger bowel diseases such as Crohn's and ulcerative colitis.

**Professor Alastair Watson**, at the University of East Anglia (UEA), who led the work in partnership with researchers in Mainz, said: 'Bacteria within the wall of the gut are already believed to play an important role in the development of inflammatory bowel disease and we now have a powerful new tool for viewing this bacteria during routine colonoscopy. This new technique will allow the rapid identification of patients at risk, or in the early stages of this common but distressing group of diseases.'

The causes of Crohn's disease and ulcerative colitis are still not completely understood but bacteria within the mucous membrane of the gut are thought to play a role. The current method of taking biopsies prevents observation of the bacteria's exact location and of the way it interacts with the mucous membrane.

The new endomicroscopy technique, which uses a fluorescent dye to highlight the bacteria, allows these exact processes to be viewed at a sub-cellular level during routine colonoscopy.

Collaboration on the new technique has been between the UEA and Johannes Gutenberg University and funded by the Wellcome Trust.

In an earlier study, Professor Ralf Kiesslich, from Mainz, co-ordinated research that found it was possible to find precancerous tissue in

# When the heart gives up...

## Congress focuses on cardiac insufficiency

This April the 77th Annual Meeting of the German Cardiac Society (DGK) presented over 300 events with 1,800 speakers, covering the entire spectrum of cardiovascular diseases, from fundamental research to clinical routine. **Professor Gerd Hasenfuss**, Director of the Department of Cardiology and Pulmonology and Chair of the Heart Research Centre in Gottingen, particularly requested a focus on cardiac insufficiency and regeneration.


Gerd Hasenfuss

Cardiac insufficiency, one of the most common cardiovascular diseases, often occurs after myocardial infarction. Impaired diastolic as well as systolic function not only lead to severe limitations in ability, but also to increased mortality rates. Around 50% of cardiac insufficiency patients die from arrhythmia, rather than cardiac pump dysfunction.

What can be done to help these patients? 'In recent years, an important finding is that, rather than going easy on themselves, the affected patients should optimise their cardiac function through physical exercise,' Prof. Gerd Hasenfuss advised. 'Endurance training is an important building block to improve the disorder.

'There are also many new technological developments in the field of pacemakers and pumping systems. During the advanced stage of the disease, it's now possible to implant miniature pumps as an alternative to heart transplants. This is particularly suitable for older patients who, in view of the scarcity of donor organs, don't make it onto the transplant registers.

'In addition to surgical procedures, catheter procedures are also becoming increasingly important, for example to treat defects of the mitral valve, where the valve can no longer prevent blood in the ventricles from flowing back into the atrium. Patients in the final stage of the disease often also suffer impaired kidney function. Although there are not many treatment options available yet, it's very important to customise treatment individually if kidney problems are also present.

### Cardiac regeneration

Prof. Hasenfuss: 'Basically, this term refers to the use of stem cells to replace scar tissue with new heart muscle tissue for the restitution of cardiac function. Although, in this sense, cardiac regeneration can not yet be carried out on a patient, it's already possible to grow new heart tissue *in vitro*. However, in order to grow heart muscle cells from other body cells in the future, the suitable stem cells need to be identified.

'There are already some studies where bone marrow stem cells were used for patients with myocardial infarctions, which led to a partial improvement of cardiac function,' he added. 'However, these studies have also shown that bone marrow cells actually do not grow and develop into heart muscle cells in the tissue. Therefore, at the Heart Centre in Gottingen, we are trying to identify other stem cells that could develop into heart muscle cells. It's already possible to change hair cells into cardiac muscle cells, but this requires viruses to feed the genetic material into the cells. Moreover, you must ensure that these cells do not grow into tumours.

'Stem cell research not only provides us with the opportunity for regeneration but also helps with research into the causes of diseases, so that new drugs can be developed.

'Another study in our centre deals with leaks in calcium storage. Calcium is the intracellular transmitter substance that activates the heart muscle cell. The storage mechanism, as we've discovered in our clinic, leaks in patients with cardiac insufficiency. The respective drugs to repair these leaks are currently being clinically trialled.'

### Imaging research

'The main question here is how to detect heart problems on an intact organism without a catheter and with as little radiation exposure as possible,' the professor explained. 'In my view, the way forward is MRI scanning. We are carrying out a large research project in Gottingen into the use of real-time MRI, in cooperation with the Max-Planck-Institute.

'We can already generate a high time resolution of 50-100 images per second, which means we can generate all images during just one heart cycle. Heart wall motion abnormalities, perfusion or the movement of different parts of the heart become much more visible,' said Prof. Hasenfuss, adding: 'The long term objective is to carry out angiographies and interventions with the help of the MRI scanner. This would be particularly interesting for the ablation of arrhythmias. We hope to be able to detect instantly whether disrupting the electrical circuit has been successful with the help of MRI. This procedure should be ready to use in about five years.'

*Interview: Karoline Laarmann*

# Heart replica ready for human tests

**The French firm Carmat intends to begin testing its artificial heart in humans by the end of 2011 and, by mid-2013, the company hopes the technology will enter European and US markets. *Annick Chapoy* reports from Paris**

A little over three decades after the world's first human heart transplant (HT), Carmat's life-size artificial heart, a mix of animal tissue, titanium and missile technology that perfectly replicate a human heart, might save the lives of thousands.

The new heart is covered in specially treated tissue to avoid rejection by the body's immune system and particularly the formation of blood clots. Thanks to the latest electronic sensor technology used in guided missiles, the heart also can respond instantly to changes in blood pressure and flow, and adapt the heart beat rate accordingly. 'If you showed the electrocardiogram to a cardiologist he would say, *That's a human heart*, Well no, it isn't. It's a prosthesis,' says its creator, **Professor Alain Carpentier**, the renowned French surgeon-scientist, from the Pompidou European Hospital in Paris.

The professor has worked on the prototype in the utmost secrecy for more than 15 years, initially in conjunction with laboratories at Matra, a French engineering firm which merged into EADS (European Defence and Aerospace company) in 2000. EADS is the parent company of the passenger jet maker Airbus.

The commercialisation of the entirely artificial heart is the realisation of a life-long dream for Alain Carpentier, and the headstone of a career that made him the most famous cardiologist in France.

The design of the Carmat artificial heart, protected by 10 global patents, offers numerous advantages over existing alternatives from rival laboratories in the USA or Asia.

A world authority in artificial heart valves, Prof. Carpentier used his expertise to overcome the problem of blood clots – the main stumbling block in other attempts to build an artificial heart. He managed this by using specially sterilised 'bioprosthetic' pig cartilage and by replicating the exact same blood flow – or haemodynamics – of the human heart that reduce blood clot risks.

'The aim of this heart is to allow patients to go from an impossible life – where they can do just a few steps from bed to armchair – to a normal social life. They will even be able to run - although naturally not a marathon,' he predicts. A renewed hope and quality of life for hundreds of thousands of patients suffering in the aftermath of a massive heart attack, or with late-stage heart failure, and those for whom standard drug therapy, ventricular assistance or heart transplant have failed or are not possible.

The Carmat heart is designed for much greater durability than earlier devices, with a projected lifetime of about five years, or 230 million heart beats. Weighing around one kilogram, the only external part of the man-made organ is its battery, which has a five-hour charge life.

Prof. Carpentier said the new heart is necessary, given the chronic shortage of heart donors and growing heart patient waiting lists. 'I couldn't stand seeing young, active people dying aged 40 from massive heart attacks,' he said. Heart disease is among the world's biggest killers, claiming 17 million lives per year (some 100 000 deaths per year in Europe and North America alone).

The prototype has cost about €55 million and already the groundbreaking organ has been successfully implanted in calves.

The first clinical trial will involve implanting the hearts into patients and monitoring them for 180 days to measure short-term safety and efficiency; the second trial should include 22 patients including six from the first trial, to test for longer term use. The cost of the operation is expected to be roughly equivalent to that of a HT, but follow-up care, which adds up to €50, 000 per year for patients with transplanted human hearts, will be significantly reduced as the artificial hearts are expected to require fewer doctor visits, re-hospitalisations, and drugs.

The artificial heart developed by Carmat, has been financed by Truffle Capital, a venture capital firm, which holds almost 32% of the equity. EADS holds almost 30%. Carmat has also received €33 million in subsidies from a French government innovation fund.

# Endomicroscope

patients with inflammatory bowel disease much more easily by using the CLE.

Professor Watson said: 'We found that bacteria took very well to the fluorescent dye and it became very bright and that the CLE could diagnose and identify infection in the wall of the intestine. We also found that bacteria were much more common in patients with ulcerative colitis and Crohn's disease.'

The latest study on the technique found that, among the 163 patients, those with Crohn's disease or ulcerative colitis were far more likely to have bacteria within the wall of their gut than those with healthy intestines. 'We found the bacteria were patchy,' Prof. Watson added, 'but if there are no bacteria we know there is no infection.'

An advantage for patients is that they receive results straight away, rather than having to await the results of a biopsy, or undergo unnecessary biopsy.

However, whilst the advantages from the equipment for clinicians and patients are clear, the researchers acknowledge that there are also drawbacks, notably cost. The CLE can cost between three and four times the price of a standard colonoscope. Professor Watson, who is also a gastroenterologist at the Norfolk and Norwich University Hospital, acknowledged that the machine was still 'taking its time to find its place' in clinical practice and that no cost effectiveness studies on it had been published in major journals. 'This study shows proof of principal. There is no question that it works but is it really worth the money?' he questioned, adding that there are training costs for endoscopists who are having to become pathologists and recognise what they are seeing with the CLE.

A next step for the researchers, he said, is to identify further applications for the CLE.

# A route planner shows virtual bone anatomy

## Surgical navigation aided by intra-operative 3-D imaging

**Intra-operative three-dimensional imaging in bone surgery kills two birds with one stone. The 3-D sets of data generated via a C-arm are not only used as control scans to check the correct positioning of implants and the reposition of fractures, but are also extremely suitable for direct navigation during a surgical invention**


Paul Alfred Grützner

Repairing and screwing together damaged bones and joints is a precision job. X-ray images provide a fast, simple method for visual control. But often the 2-D imaging achieved through conventional X-rays is not good enough to check the correct fixation of bone fragments. Since 2001, 3-D imaging carried out with the help of a C-arm has also been used for particularly critical orthopaedic interventions, generating X-ray images from all perspectives and assembling them into an overall image. The rate of complications caused by the wrong positioning of bones or implants is significantly minimised by using this procedure.

One of the first to use this technology – initially developed and marketed by Siemens Healthcare – was **Professor Paul Alfred Grützner**, Medical Director of the BG Clinic Ludwigshafen, Germany, and Director of the Clinic for Trauma Surgery and Orthopaedics. Since 2001 he has worked with the Siemens C-arm *ARCADIS Orbic 3D*.

The data sets generated by the 3-D image enhancer not only flow into the image processing workstation via a joint interface but can also integrate into the BrainLab-navigation system if required, delivering additional information on the position of implants. 'Similar to an in-car navigation system, the system shows the planned route and positioning information,' Prof. Grützner explained. 'Reference markers on the bones and instruments are used as a GPS and an infrared camera that receives the signals from the GPS serves as the satellite. This results in a virtual map of the bone anatomy, which the surgeon can use for orientation.'

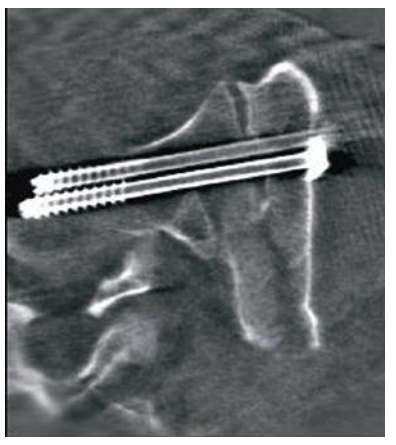
Nowadays the use of 3-D scans for navigational purposes makes up 14.3% of all scans at the BG Clinic Ludwigshafen. 'Unlike pre-operative CT images, the system can directly visualise any change in anatomical structure caused by the fixing of a fracture,' the professor pointed out. 'A further advantage, compared to CT imaging, is that the combination of image and instrument position via reference markers happens automatically rather than manually. Previously, this type of registration was only possible under difficult conditions or not possible at all.'

The 3-D technology gives images spatial depth and visualises anatomical structures free from superimpositions. Therefore, surgical 3-D navigation is frequently used in the treatment of pelvic injuries, because this type of intervention involves a very complex bone structure surrounded by a lot of soft tissue. 'There are many nerve roots and organs in the posterior pelvis that must not be injured during the positioning of plates and screws under any circumstance,' he said. Surgical 3-D navigation has also proved useful to spot drilling into bones in joints affected by blood deprivation (Osteochondrosis dissecans) or benign bone tumours (Osteoid osteoma).

Studies have shown that the radiation dose, compared to conventional X-raying, is vastly reduced with this procedure because the exposure time is shorter and only one 3-D scan is needed to carry out the entire positioning of the implants, while the navigation camera follows the position of the bones in real-time.

'However, there are,' he said, 'limitations to the possible application of this procedure, as in the case of very small bones, which cannot be labelled with reference markers because these are too big or, in the case of too many individual bone parts, where registration and referencing is also difficult,' he explained.

The professor also sees a need for improvements to the procedure for the imaging of soft tissues and optimum planning of surgical access. The size of the image section achievable with the X-ray camera and C-arm also needs improving, he believes. Currently, the CT image is still superior to the 3-D image enhancer when it comes to surface area and volume – but the first prototypes with larger X-ray cameras are already undergoing experimental trials. The last evolutionary step in intra-operative 3-D imaging has not yet been reached.



# Catheter-based valve surgery

**Transcatheter valve implants (TAVI) have encouraged a new group of patients. Previously inoperable, they may now receive adequate treatment. Some centres report a success rate close to the conventional open surgical procedure. Naturally, the long-term outcome is still unclear. *Holger Zorn* reports**

A significant increase in the number of heart valve operations was reported at the 40th Annual Meeting of the German Society for Thoracic and Cardiovascular (DGTHG) in February this year. 25,127 isolated cardiac valve operations were carried out in 2010, compared with 23,556 in 2009 – an increase of 6.7%. However, a closer look presents a different picture. Aortic valve surgery has been performed less frequently over the last three years (pic. 1). The reason is a huge increase in catheter-based interventions, as reported in EH 6/2010.

11,582 of all aortic valve procedures were conventional operations to replace the valve, which functions as a semi-lunar valve between the left ventricle and the aorta, either with an alloplastic or biological implant. There were also over 3,600 catheter-based aortic valve implantations, where a pre-fold heart valve prosthesis is introduced via femoral arteries and aorta, or apex into the defective aortic valve, pushed them aside, unfolded and fixed (pic. 2). 'The clear advantage is that it is less stressful for the patient than surgery. However, we recommend this method so far only for patients over 75 years old, who also have severe concomitant diseases,' said **Professor Friedrich Wilhelm Mohr**, president of the DGTHG, 'because mortality for conventional aortic valve surgery depends on the age and health status between 1-3%. In catheter-based implants, also used for younger, healthier patients, mortality rates up to 7% are observed.'

At the meeting, scientific discussion confirmed his view. Several presentations dealing with TAVI showed a wide range of special applications. **Moritz Seiffert MD**, from Hamburg University Heart Centre, reported a series of 10 patients with a mean age of 80.1±6.7 years and a logistic EuroScore of 36.3±24.5% who presented with significant xenograft degeneration 13.3±6.2 years after aortic (n=8), mitral (n=1), and combined aortic and mitral (n=1) valve replacement. Edwards Sapien prostheses were implanted valve-in-valve in aortic (n=9) and mitral (n=2) positions through a transapical access. The valve function, described in NYHA stages, was improved from 3.1±0.3 before intervention to 2.1±0.3 at 30-day follow-up. Six out of these 10 patients were doing well with adequate valve-in-valve function in a follow-up range of 30-707 days. Dr Seiffert confirms this technology is 'a promising treatment option in high-risk surgical patients', but adds: 'Adequate patient selection is crucial to the success of this procedure. With satisfactory short-term follow-up, long-term clinical and haemodynamic data have to be awaited to thoroughly evaluate this approach.'

**Semih Buz MD**, from the German Heart Centre Berlin, showed data of 280 patients aged 79±8 years and a mean logistic EuroScore of 39±19%, treated since April 2008 with the Edwards Sapien valve via transapical access. 17 patients were in cardiogenic shock, 55 had previous cardiac surgery. Combined planned additional procedures were performed in 42 patients including simultaneous coronary stenting in 30 cases. The procedure was technically successful in 99.6%; the 30-day survival was 95.4% for the whole group. But that's not yet the whole truth, Buz drew attention to learning curve: 'The log EuroScore was 38±20% for the first 100 cases, 42±19% for the second 100 cases, and 35±18% for the last 80 cases. The 30-day mortality for both the first and second 100 cases was 6.0%. It dropped to 1.3% for the last 80 patients.' Considering the high risk profile of the patients, this result is comparable with conventional aortic valve replacement.

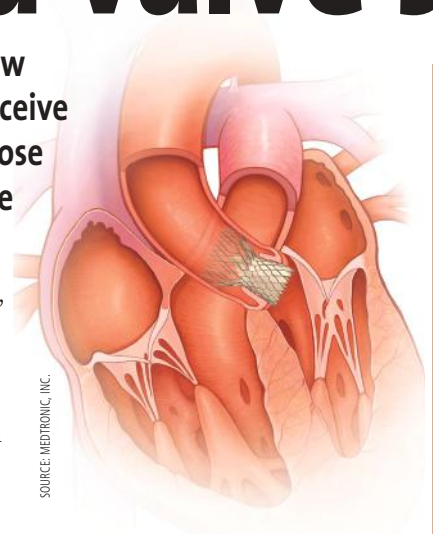
**Markus Krane MD**, from the German Heart Centre Munich, focused on the quality of life of those patients, measured by using the standardised Short Form 36 Health Survey questionnaire (SF-36) at baseline and one-year follow-up. 'We performed a prospective analysis of 68 patients who underwent TAVI with either the Medtronic CoreValve or Edwards Sapien device', he explained: 'There were significant improvements for physical functioning (baseline: 35.3±2.8 vs. one-year follow-up: 45.0; p≤0.001), bodily pain (59.5±3.7 vs. 66.7±3.2; p≤0.05), general health (46.6±1.8 vs. 54.6±2.8, p≤0.01) and vitality (35.0±2.6 vs. 47.6±2.3; p≤0.001). No significant improvement could be detected for social-functioning (75.6±3.3 vs. 76.1±3.3; p=0.85) and role-emotional (67.4±5.9 vs. 66.4±5.8; p=0.75).'

At the same institution, **Sabine Bleiziffer MD** compared the survival of 382 patients referred for TAVI, of whom 12 died on the waiting list, 229 underwent transarterial or transapical TAVI, 64 conventional aortic valve replacement (AVR), and 77 conservative treatment: 'Medically treated patients had worse one-year survival outcomes than TAVI or AVR treated patients', she demonstrated (pic. 3). 'The benefit of TAVI and AVR over medical treatment emerged only at 6-month follow-up,' she concluded. 'There was no significant survival difference between TAVI and SAVR patients.'

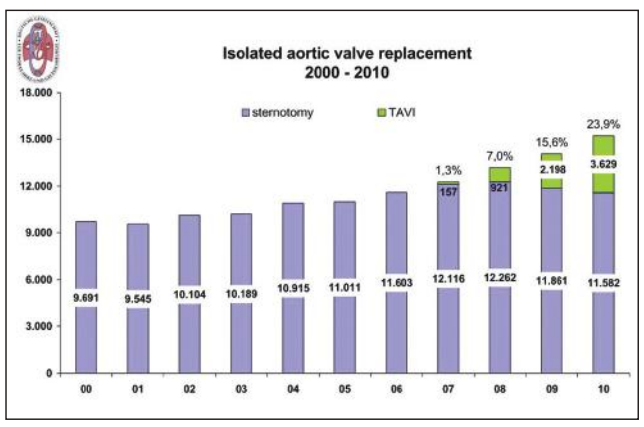
Looking at Dr Bleiziffer's data again reveals another fact: Only 62% of the patients referred for TAVI could receive this procedure. One reason is seen in the high co-morbidity of these patients. To broaden the physicians' arsenal, a further step was taken by Medtronic. The firm received the CE Mark for the CoreValve System to be delivered via a novel approach that would allow access through the subclavian artery located beneath the collar bone. Consequently, thousands more aortic stenosis patients in Europe may be eligible to receive catheter-based aortic valve implantation. 'Today, a significant subset of patients is underserved because of limitations of the femoral access. If the femoral arteries are too small, stenosed, or show severe tortuosity, the femoral sheath cannot be advanced. In addition, previous peripheral artery bypass grafting or stent implantation precludes transfemoral valve implantation. The subclavian approach will give us expanded access to care for these patients. It allows us to perform the retrograde transarterial procedure analogous to the established transfemoral approach, with the same equipment and technique. Furthermore, it might be advantageous, in terms of exact valve placement, due to a shorter distance from the arterial access to the valve. Still, this hypothesis has to be proved with growing experience,' Dr Bleiziffer pointed out.

With this background, Prof. Mohr, one of the pioneers in minimally invasive cardiac surgery, predicts 30,000 aortic valve procedures in Germany in 2013, although the ideal product is not yet developed. 'These valves must crimped, which damages the endothelium and the material.' There will also be changes to the form, when the new valve is pressed into the native. 'Seventy percent of the catheter valves have 1-3 paravalvular leaks,' the professor said. In conventional procedures, such a leak – a small opening between the aorta and the left ventricle around the outside of the valve – occurs in just one percent.

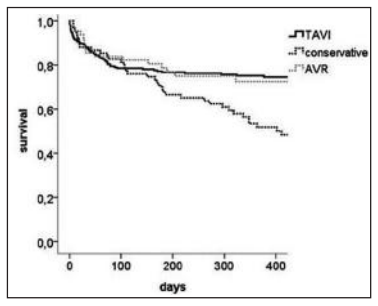
A next-generation technology is also on the horizon: The St. Jude Medical transcatheter valve is designed to resolve the limitations seen with the first generation products, making transcatheter valve deployment and retrieval easier for clinicians. Additional details pertaining to the clinical trial have not been publicly disclosed at this time.


SOURCE: MEDTRONIC, INC.

A catheter-based introduced aortic valve is expanded in its final position




Number of conventional and interventional isolated aortic valve procedures in Germany. Interventions performed in cardiology specialist practices are not included. Prof. Mohr: 'There is vandalism. There are cardiologists who come to the surgeon and say 'Make the standby for my intervention, otherwise you will not receive any patients of mine.' (Source: DGTHG)




Survival of 382 patients referred for TAVI and, due to various limitations, treated either surgically, interventionally or conservatively. Source: German Heart Centre Munich

**EuroScore** stands for **Euro**pean **S**ystem for **C**ardiac **O**perative **R**isk **E**valuation, developed with nearly 20,000 consecutive patients from 128 hospitals in eight European countries and established in 1998. The logistic EuroScore predicts the individual risk of death of a patient undergoing cardiac surgery, related to his patient, cardiac and operation related pre-operative risk factors.

**NYHA** stands for **N**ew **Y**ork **H**eart **A**ssociation, the original publisher of a simple classification for cardiac insufficiency. There are four stages:

**NYHA I** - No symptoms and no limitation in ordinary physical activity

**NYHA II** - Mild symptoms and slight limitation during ordinary activity

**NYHA III** - Marked limitation in activity due to symptoms, even during low activity. Comfortable only at rest

**NYHA IV** - Severe limitations. Experiences symptoms even while at rest. Mostly bed-bound patients.

# Tele-echocardiography identifies healthy though aged donor hearts

**A team of Italian cardiologists are expanding the age range of organs available for heart transplantation, *Mark Nicholls* reports**

A Pisa-based team has established the Adonhers (Aged Donor Heart Rescue by Stress Echo) protocol and is using second-opinion stress tele-echocardiography to assess the condition of the heart from older donors. A key aspect of this was to raise the donor cut-off age limit from 55 to 65 years, where the stress echo screening on the candidate donor showed as normal.

**Dr Tonino Bombardini** at the Department of Echocardiography and Medical Informatics, Institute of Clinical Physiology, National Research Council, Pisa, explained: 'Age-related high prevalence of asymptomatic coronary artery disease and cardiomyopathy severely limit the feasibility of this approach unless a functional screening of the candidate donor heart is performed.

'Pharmacological stress echo is inexpensive and allows a simultaneous evaluation of inducible ischemia and contractile reserve of the left ventricle. It's therefore possible to unmask prognostically meaningful occult coronary artery disease or cardiomyopathy.' However, he stressed the importance of having the donor heart assessed by an experienced operator, who may not always be available at the donor centre. Obtaining that expert's opinion can be possible by using telecardiology. 'A second opinion of digitally transferred images of stress echo results could solve the technical variability in selection of aged donor hearts for heart transplantation,' he said.

Under the Adonhers protocol, when the Transplant Coordination Centre identifies a marginal aged donor, the cardiologist at that location performs rest echocardiography and when that shows as normal, a stress echo. From there, he logs into the Adonhers website, which automatically transfers the reports and images to a central server in Pisa, where, once alerted, the Core Echo Lab Cardiologist interprets the tele-echocardiograms, offers the second opinion and decides whether to proceed with the donation. 'When done, the second opinion report is sent to the transplant coordination centre and, if the marginal heart is eligible for transplant, it is proposed to the cardiac transplant surgeon,' said Dr Bombardini.

Italy, like the US and other European countries, is short of donor hearts. About 300 heart transplants (HTs) are performed annually, but 700 patients are on the HT waiting list, with a 10% yearly death rate and a mean 2.5 years waiting list before a transplant.

With around 1,250 consensual donors annually, 270 of whom are aged 55-65 years, Dr Bombardini says recruitment of even a third of the dismissed donor pool would make a significant impact on the current donor shortage.

The International Society of Heart and Lung Transplantation (ISHLT) guidelines for the care of HT recipients recently recommended that donor hearts over 55 years should only be used if the survival benefit of an HT for a recipient unequivocally exceeds the decrement in early HT survival due to transplantation of a heart with limited myocardial reserves.

'The stress echo-driven selection of hearts may be a possible approach to resolving the mismatch between organ supply and demand,' Dr Bombardini pointed out.


Tonino Bombardini

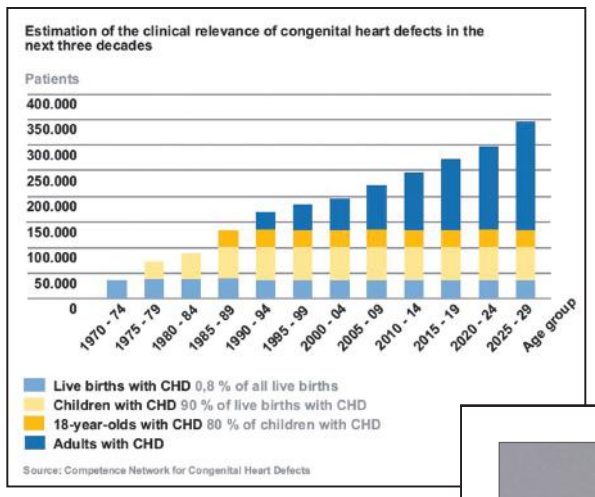
The Adonhers Project is approved by the Ethical Committee of the Emilia-Romagna Region and Tuscany Region, and has recently been accepted, endorsed and funded by the Italian Health Ministry.

As Scientific Coordinator of the Project, Dr Bombardini said results so far have been significant: 'From 51 marginal candidate donors, the team found 23 eligible hearts with normal findings. Of these, 19 eligible hearts were uneventfully transplanted in marginal emergency recipients. The recipients' one-year survival rate was similar to standard younger donor heart (not selected by stress echo) recipients' one-year survival.'

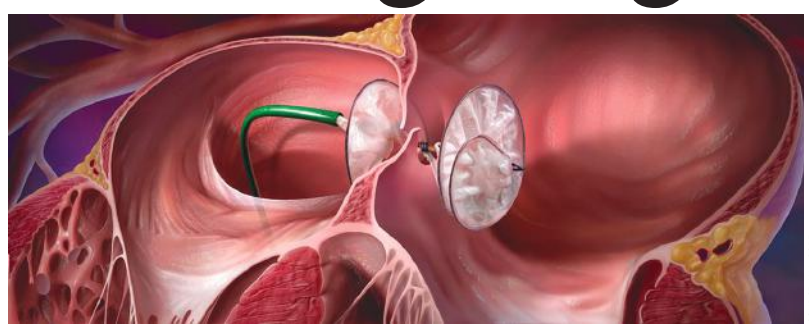
However, he stressed that further experience is needed in the use of 'marginal donors' before exact guidelines can be established with more liberal use of stress echo for donor selection. However, the protocol is now set to be expanded from Pisa across all Italian centres and potentially to other European centres.

The methodology and pilot study results are to be presented at the American Society of Echocardiography meeting in June and have been submitted for presentation at the annual ESC Congress 2011 this August in Paris.

# Born with heart defect but living longer




**Adults with congenital heart failure (CHD) are a growing special subset of patients with specific needs; most need lifelong care, but in adulthood many fail to receive it, *Holger Zorn* reports**



SOURCE: W L GORE

An atrial septal occluder, the HELEX system, in its target position before the two membranes on either side of the wall meet and disengage from the device

Up to 90% of children with CHD reach youth and adulthood due to progress in diagnostics and therapies in recent decades. Between 200,000 and 300,000 young children, adolescents and adults live with CHD in Germany alone. Highly complicated cardiac defects can be treated surgically with very good results. Interventional cardiac catheterisation techniques have progressed greatly and, by merging paediatric cardiac surgery and cardiology, the life expectancy of CHD newborns and young children has increased.

Atrial septal defect, the second most frequent cardiac problem, is now predominantly treated by intervention, introducing by catheter a two-piece umbrella-like ePTFE membrane prosthesis.

The rare hypoplastic left heart syndrome (HLHS) is fatal without surgery. In the early 80s, a triple surgical intervention strategy was developed – the Norwood, Glenn and Fontan procedure – usually performed at ages 1-6 days, 3-6 month and 2-4 years. Today, the treated survivors are in their mid-20s, with life-time prognosis unknown.

Since all three procedures are very distressing, a new hybrid strategy has been developed, as Professor Felix Berger at the German Heart Center in Berlin, explains: 'With the hybrid approach to HLHS, instead of the traditional Norwood I operation we can operate without the need for total circulatory arrest under deep hypothermia, which leads to a significant minimisation of the first surgical step. The complicated comprehensive step II can be postponed to later in life. Although the second step means a major surgical procedure, it's combined with a significant volume unloading of the heart in one major procedure, since the Glenn anastomosis will be simultaneously established. We all hope that this new strategy will not only improve survival but also bring significant improvement of the entire outcome – for example, neurodevelopment, ability index, exercise capacity.'

## Lifelong care needs

Wiebke Lesch from the German Competence Network for Congenital Heart Defects surveyed 1,372 children, teenagers and young adults with CHD regarding their CHD knowledge and information needs. 52.3% responded, 174 of them were children aged 10-13, and 147 teenagers aged 14-17. Only 33.9% of the children and 44.9% of teenagers could define their CHD. 59.8% of children and 35.4% of teenagers stated that the doctor only talks to their parents. Consequently, only 40.8% of the children and 41.5% of teenagers reported that they fully understand the explanations of their doctor. 'Young CHD patients have major gaps in their knowledge about their condition,' Dr Lesch notes. 'This may have harmful consequences.'

To address this problem, the German Federal Ministry of Education and Research awarded €16 million to a 10-year research project by the German Competence Network, which has established a National Register for CHDs, to provide a basis from scientists and clinicians can assess present CHD levels, carry out epidemiologic studies concerning quality of life and psychosocial aspects, evaluate current studies and exchange knowledge, and produce relevant information for patients and the public.

CARDIOLOGY

# Neurocardiology

## Treatment options for atrial fibrillation to prevent a stroke

Neurocardiology – especially atrial fibrillation (AF) – was the key topic during a press conference held during the 55th Annual Congress of the Germany Society for Clinical Neurophysiology and Functional Imaging (DGKN) this March. For good reason: Worldwide, there are around six million AF sufferers – and it is one of the most common causes of stroke because this cardiac irregularity can result in development of blood clots that move from heart to brain, obstructing blood vessels there. **Professor Bernd Ringelstein**, Director of the Clinic and Polyclinic for Neurology at Munster University Hospital and the Congress President, described the significance of AF, the prevention of strokes and newly available treatment options


Rainer Dziewas


Bernd Ringelstein

'Atrial fibrillation not only causes a quarter of all strokes, but also leads to a particularly severe form of cerebral infarction,' explained Prof. Bernd Ringelstein. 'On the one hand this makes it very dangerous but, on the other, early diagnosis and treatment of atrial fibrillation also makes it particularly preventable.'

70% of all strokes can be averted through drug treatment. Anticoagulants ensure that blood clotting is prevented and thus no thrombus can develop in the heart. Unfortunately, this treatment is a double-edged sword – anticoagulants, such as Marcumar, can also lead to a higher risk of bleeding. 'On average, a patient with atrial fibrillation has a risk of about 5% a year of suffering a stroke, compared to a just under 1% risk of bleeding caused by anticoagulants. Thus many patients, and doctors, have reservations about treatment with Marcumar,' he pointed out.

However, most recently there has been considerable progress in developing anticoagulants. Three new drugs, which directly affect the clotting system and have fewer side effects, are close to licensing: *Dabigatran*, *Rivaroxaban* and *Apixaban*. Dabigatran has already been licensed in the US and Canada to treat atrial fibrillation and many European countries are expected to follow this year.

### Intermittent AF is particularly dangerous

A further problem involved in the risk of stroke through cardiac arrhythmia is intermittent (paroxysmal) AF. Whilst chronic AF can be detected easily by taking a patient's pulse, intermittently occurring forms of AF are more likely to remain undetected because they may occur when a patient sleeps and therefore remain unnoticed. According to estimates, around 50% of all strokes for which the causes remain unclear are likely to have occurred due to intermittent AF, Prof. Ringelstein said. The new anticoagulant substances also could be used for preventive treatment in those cases.

Several hospitals, including the University Hospital of Munster, are currently cooperating with Medtronic in carrying out a TRACK-AF study into the detection of this silent type of AF. This involves a small intervention to implant a diagnosis chip under the patient's skin, which then monitors cardiac function over a three-year period. The data is fed to a server for evaluation via the internet, using a detector held by the patient close to the implanted chip for three minutes daily. The chip costs €2,000. 'The device helps us to better understand silent atrial fibrillation and to determine the precise number of affected patients to ensure they receive suitable preventive treatment as early as possible,' Prof. Ringelstein explained.

Currently, the only promising alternative to the diagnosis chip is a seven-day ECG to detect this insidious problem. 'But here the success rate is only around 20%,' he added. 'The chip may also indirectly provide confirmation as to whether, for instance, a seven-day ECG should be extended to a 14-day ECG examination.'

### Dysphagia after stroke

Along with atrial fibrillation, the event also focused on dysphagia, one of the most common effects of stroke. Up to 50% of all stroke patients have problems swallowing during the two-week acute phase. Apart from obvious symptoms, such as hemiparalysis or speech problems, these dysphagias are much harder to diagnose. 'The clinical examination to detect dysphagia is very imprecise and around half of the affected patients remain undetected. Next to dehydration and malnutrition, this can lead to further, significant complications such as aspiration pneumonia,' said Professor Rainer Dziewas, head of the neurological intensive care unit at the Clinic and Polyclinic for Neurology at Munster University Hospital. 'That's why, at this stage, we need additional diagnostic tools, which have only very recently become available.'

The use of video-endoscopic procedures makes precise diagnosis of the type of disturbance present and its severity. Dysphagia scores allow a systematic categorisation and standardised conclusions.

The fact that the examination can be carried out directly at the patient's bedside brings a significant advantage.

Apart from adapting the consistency of nutrition or a complete avoidance of oral food intake by fitting a stomach catheter, there are now innovative treatments available for dysphagia. These are based on research findings showing that dysphagia develops centrally in the brain. Therefore, stimulation of certain brain areas leads to an improved ability to swallow.

Pharyngeal electrical stimulation, a procedure developed in England, by Professor Shaheen Hamdy and his research team (pub: 2011), involves sending light electric impulses to the throat via a catheter. The method has already shown promising results.

Another procedure, transcranial direct current stimulation, is currently on trial in a clinical study at Munster University Hospital by the working group 'Neurogenic Dysphagia', led by Prof. Dziewas. This involves stimulating the patient's brain via two electrodes fitted to the patient's head. The procedure has already proved itself as a treatment for paralysis caused by stroke.



ORTHOPAEDICS AND TRAUMATOLOGY

# The 12th EFORT Congress

***'No European orthopaedist should pass up this opportunity.' Prof. Wolfhart Puhl***


The 12th EFORT Congress, celebrating the 20th year of the European Federation of National Associations of Orthopaedics and Traumatology, aims to update knowledge of any specialty or subspecialty involving the diagnosis and management of bone and joint problems. The event will draw experts from over 30 European countries, and also benefit from specific contributions from Nordic countries.


Wolfhart Puhl

According to EFORT's Past President, specialist orthopaedic surgeon **Professor Wolfhart Puhl** burning issues will include rapid rehabilitation and quality control in joint replacements, as well as initial steps towards an even broader, interprofessional approach to working with patients. Also, presentations will range from new advances in endoprosthetics to innovations in cyphoplasty and the management of fractures in the elderly. Three highly topical issues in the plenary sessions will be cell therapy, particularly PRP (Platelet Rich Plasma) therapy in bone healing; the sensible application of registers (logs) to improve therapy in clinical practice, and fast-track treatment and rehabilitation in orthopaedic surgery.

'The enormous advances in imaging will certainly provide exciting subject areas,' said **Professor Pierre Hoffmeyer**, Vice President of the EFORT Foundation, Chairman of the Scientific Committee and President of the Swiss Society of Orthopaedic Surgery and Traumatology (SSOT). 'This field, in turn, drives development in micro-invasive surgery techniques. The congress will also cover new technology for surgical therapy of the spinal column and, not least, the big problems facing an aging and increasingly osteoporotic society, where orthopaedist and traumatologists are called upon to engage not only in therapy but also in prevention.'

EFORT acts as an advisor to European and national institutions in central future issues inter alia with the policy symposium on muscular skeletal diseases and active aging in the EU. Professor Puhl: '**David Marsh**, from University College London, will present evidence that if intensive rehabilitation management following osteoporotic fractures is begun immediately after a fracture, it reduces expenses, despite its costliness. The multi-morbid patients involved need a fast and appropriate operation, immediate physiotherapeutic activation and suitable pharmacotherapies, or will otherwise quickly become cases for costly nursing care. That can be prevented if care-givers mobilise them the day after the intervention, talk to them and motivate them to engage in mental activities.'

A special highlight, the Speciality Session on water sport injuries and shoulder problems, will present cutting edge methods that might soon become standard in general traumatology. 'We will demonstrate some of the exciting surgery performed by European orthopaedic sports traumatologists, perfected to meet the needs of professional athletes to return to training and competition as soon as possible.' explained **Dr Mike Carmont**, Consultant Orthopaedic Surgeon from Preston, UK. 'We'll present recent achievements in minimally invasive surgery and arthroscopy as well as the most effective methods of rehabilitation and new approaches, like platelet rich plasma therapy (PRP), which may improve healing and shorten rehabilitation time.'

**Education – CRC, ICs and ExMExs**

'CRC stands for Comprehensive Review Course and is being provided for the third time,' explained Prof. Hoffmeyer. The one-day CRC covers the entire material in European and national examinations for medical specialists. The ICs (Instructional Courses) are numerous and give generalists a chance to learn from experts. Finally, ExMEx (Experts-Meet-Experts) sessions involve top experts briefing specialists on new advances. Then there are the 'Difficult and Complex Cases' discussions. They are interactive and therefore quite lively. They give participants a chance to present their own cases.'

An entirely new feature is the Poster Cinema where participants can sit and relax to watch the accepted posters on the screen.

As EFORT co-founder Professor Puhl said, this is 'a precious platform that showcases the entire diversity of opinions throughout Europe and helps bring them into balance to improve quality'.

*Details: www.efort.org*

INTENSIVE CARE

# Hemolung speeds COPD patient recovery


Frank Bonin

This March, Heinz-Dieter Hilgers arrived for his once-monthly check-up at Ruhrlandklinik in Essen. Last June, his situation was far less relaxed. Suffering chronic obstructive pulmonary disease (COPD) for almost two years, he had been listed for a lung transplant since April 2009. During his wait for an organ, his illness increased. From February 2010 he received oxygen therapy. From May, it was non-invasive ventilation. Nothing helped. 'Taking a shower took me an hour. Even eating was an effort,', he said.

In June, he was transferred to Ruhrlandklinik Essen, a specialised thoracic centre in North-Rhine Westphalia. 'He had an infection-induced exacerbation and came to us with an arterial carbon dioxide pressure of 90 mmHg, more than twice the normal value, and he developed a pneumothorax,' explained ICU head **Frank Bonin MD**. Antibiotic treatment began and continuous non-invasive ventilation was established. There was no clinical improvement. 'I couldn't remove the ventilation mask for twenty seconds,' the patient recalls. Just days later, extracorporeal carbon dioxide removal was performed using the Hemolung Respiratory Assist System, a new lung support device developed by ALung Technologies of Pittsburgh, PA, USA (see EH 1/2011 page 7-8).

The patient's breathing soon became far easier – a respiratory rate reduced from 35-40 breath/min down to just under 10 breath/min; the required minimum frequency of 16 breath/min was not tolerated by the increasingly active patient. 'The first day, we couldn't interrupt the mask ventilation,' recalled Dr Bonin. 'Up to the third day, we could stop three to four times for up to 15 minutes at a time. By the fourth day, we could stop for 30-60 minutes and, on the fifth day, the pause was 16 hours.' The next day, the patient's lung function had almost recovered, with an arterial carbon dioxide less than 50 mmHg. The Hemolung treatment was stopped.

H-D Hilgers is one of 12 patients currently included in an ongoing feasibility trial in Germany. 'I'm very excited about this result,' Dr Bonin said. 'Using the Hemolung we saw a very quick recovery. The device is as simple as a haemodialysis and was easily inserted – just the right choice for such an acute situation.'

While receiving Hemolung therapy the patient's transplant listing was upgraded to 'high urgent'. Four weeks later, sitting with other patients, nurses and physicians at McDonald's, an organ donor was found. Meanwhile, this patient celebrated his 50th birthday. 'Last week-end,' he said happily, 'I took my bike out of the garage for a first cruise.'

*Report: Holger Zorn*

# The best of both worlds

## Mobility meets performance in a new hybrid

Innovative mobile C-arm solutions by Nuremberg-based Ziehm Imaging are quickly conquering interventional radiology. At this year's European Congress of Radiology in Vienna, **Martin Herzmann**, Director of Global Marketing at Ziehm Imaging, met with EH correspondent *Karoline Laarmann* to discuss developments. 'Due to the excellent image quality provided by our flat panel technology,' he explained, 'the C-arm solutions have become an attractive option beyond the surgical department'


Martin Herzmann

Deeply rooted in surgery, the mobile C-arm manufacturer Ziehm Imaging is entering interventional radiology. Indeed, one of the highlights at this year's ECR was the firm's new hybrid C-arm solution Vision RFD. 'Hybrid in this context describes the fusion of surgery and imaging as well as the interdisciplinary cooperation of physicians in the operating theatre,' Martin Herzmann, Director of Global Marketing at Ziehm Imaging explained. Its presentation at the ECR, he added, is due to the fact that the C-arm is an X-ray based imaging solution for the operating

theatre, and the radiologist has a say in purchasing. 'Our flat panel technology offers superior image quality, which enables radiologists to perform minimally invasive procedures themselves. This high-end product by far surpasses the possibilities of conventional standard orthopaedic surgery. It is in the Champions' League of surgery: cardiac and vascular interventions.'

Whilst high-quality imaging in the operating theatre was previously the exclusive domain of fixed installations, the new generation of mobile C-arms offers comparable image quality and distortion-free resolution in more than 16,000 grey scales. In addition, the hybrid solution is easier to handle. A synchronised interface links the C-arm with the contrast agent injector so that the surgeon can trigger imaging and contrast agent injection with a pedal.

The product combines the mobility and low investment costs of a C-arm with the high performance of a fixed installation, Martin Herzmann points out. 'Here, performance refers above all to generator performance. Whilst in older generation C-arms the cooling system frequently failed, the new liquid cooling system, hidden in the C-arm, ensures uninterrupted operation of the system and avoids overheating.'

Housing the generator in a separate room is no longer necessary – a positive effect in terms of radiation dose, he adds. 'To achieve high-quality imaging you have to continuously provide high performance, which is the generator's task. However, this increases a patient's radiation exposure. If a split-block generator transfers high voltage to the C-arm, voltage builds up and diminishes slowly. Our mono block generator, on the other hand, offers much more precise and shorter image pulses. Moreover, our product uses the so-called Object Detected Dose Control, which means the square image detector recognises the anatomical image in the field of view and positions itself accordingly.'

The new hybrid edition, he says, completes the Ziehm Imaging product portfolio for the time being.

On top of the new high-end solution for the operating theatre, Ziehm Imaging also offers a purpose-designed C-arm for disaster relief and military use. Ziehm Solo Portable is an extremely small unit that can be dismantled for transportation. This highly mobile product does not require a separate monitor cart and is delivered as a modular 'out of the box' system. Until recently, this model was produced exclusively for the German Armed Forces, but is now is also available to civilian disaster relief organisations.

Convincing innovation combined with German engineering is in demand worldwide. The Ziehm Imaging product portfolio is available through a network of 75 distributors in 70 countries. Today, the company generates one third of its turnover in Germany, one third in the US and a third in the rest of the world, Brazil, Russia, the Near East and Scandinavia being important markets. Ziehm Imaging is well positioned to continue Germany's success story, Martin Herzmann says, confidently predicting a bright future.

# Maxi value in a mini machine

## MRI scanner targets specific anatomical needs

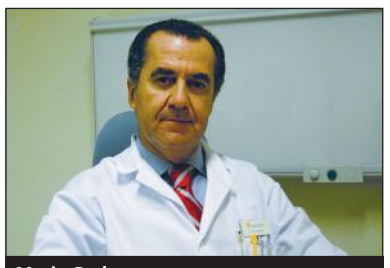
At first glance you think it's a futuristic washing machine, or maybe an oversized designer amplifier. Actually, you are looking at GE's *Optima* MR430s*. This is not only a real eye-catcher because of its exceptionally compact design (ever, for an MR scanner) but also due to the system's truly smart function and performance. Enabling musculoskeletal imaging of only an arm or leg, the device not only saves space but also helps to remove the anxiety and discomfort often associated with full-body MR systems. *Karoline Laarmann* reports

GE's Optima MR430s scans a hand

The Optima MR430s, GE's extremity MR scanner, moves from an overall picture to a more detailed diagnostic view of pathologies of formal and functional defects in bones, joints, muscles and tendons.

Comfortably seated on a chair, the patient puts his or her arm, leg or just wrist or ankle, into the 21cm diameter tube of the small 1.5 Tesla MR magnet. The Optima MR430s machine is so small in size that it only needs 10m² of space – i.e. 60 % less than a whole body scanner – and can pass through a standard door, which makes installation far easier and that means in almost any medical or clinical environment.

For users, the system's compactness presents greater mobility, accessibility and convenience, as confirmed by **Dr Mario Padron**, head of the radiology department at Clinica CEMTRO in Madrid, Spain, who

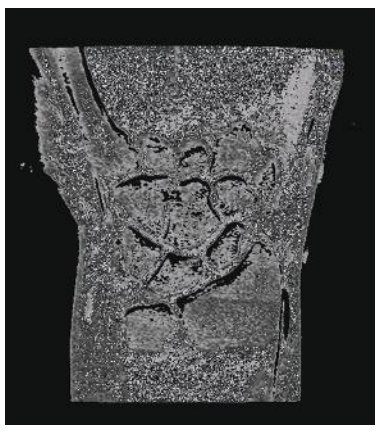


Mario Padron

is also chairman for the European Society of Musculoskeletal Radiology (ESSR) Sports Subcommittee. A year and a half ago he acquired the high-tech extremity MR scanner from the American MR provider ONI Medical Systems, Inc., which was subsequently acquired by GE Healthcare and re-branding as Optima MR430s. Since then, Dr Padron has used this scanner daily, now examining some 24 patients per day, many of them professional or amateur sportsman of all kinds.

MRI is increasingly important in sports traumatology, he points out. 'MR is the only imaging technology that can integrate the study of soft tissue – fascia, musculature, ligaments and tendons – and bone pathology. By doing so, it gives you a very accurate insight into all anatomical structures and a fast overview about lesions. Because it works without radiation exposure it has become an important tool for diagnosis as well as follow-up checks.'

However, patients with acute sport injuries generally face a long wait before they can have an MRI examination. Due to the extremity MR scanner, Dr Padron has increased patient throughput and considerably reduced patient backlogs. In addition, patients are far more cooperative with this system, especially those who have difficulty laying still or feel claustrophobic in a whole body tube. 'The MRI room with the extremity MR scanner more looks like a normal doctor's office, with which patients feel more acquainted. Because the machine makes much less noise, they can talk with the radiologist during the examination, or hear music, or



read a book. The examination time is the same as in a whole body scanner, about 15 minutes.'

Along with sports imaging and sport traumatology, other applications for the extremity MR scanner are currently being clinically investigated, in rheumatology, for example, at the Leiden University Medical Centre, in the Netherlands.

Dr Padron believes that the introduction of dedicated MRI systems – e.g. for the extremities, breast or head – will mark the beginning of a spate of further follow-up models on the market because they are smaller and enable far more cost-effective imaging procedures in a variety of patient care settings. Given his experience with the extremity MR scanner, he is already planning the installation of a second machine in the new emergency department at Clinica CEMTRO in Madrid.

** Optima is a trademark of General Electric Company*

**The Netherlands** - In a very crowded train station, why can you immediately recognise the face of a friend? **Professor Rainer Goebel** wants to find out.

Thanks to €10 million in funding from the country's Limburg Province, the Brains Unlimited project at Maastricht University will install three high-field magnetic resonance imaging scanners that will allow Prof. Goebel to search for an answer. 'It is now known that the brain is organised in many specialised brain areas, such as the fusiform face area that responds almost only to faces,' he explained. 'But it's not yet known how the brain codes a face. For example, are there neuronal populations coding for eyes, nose, hair and mouth?'

High-field MRI scanning beyond 7-tesla (7-T) achieves functional resolution at the sub-millimetre level where, he said, his studies show neurons with similar response properties appear to spatially cluster into functional units or cortical columns.


SIEMENS

'It's my belief,' he confirmed, 'that, with a massive attempt to crack the columnar-level code in as many areas as possible, we'll ultimately reach a deeper understanding how mind emerges from simpler units in the brain.'

Another research project at Brains Unlimited will explore the structure of musicians' ears to learn why they can hear so differently from those of other

## Mega-MRI

Magnetic resonance imaging (MRI) has become so powerful it needs to be moved to a building of its own on a hospital campus.

Currently some 50 new MRI scanners at 7-tesla have been installed worldwide, an impressive increase in power from the top-of-the-line 3-T machines that can be found in advanced radiology departments, and far beyond the everyday MRI of 1.5-T used for routine clinical exams.

'These are expensive machines, but the scanner is the cheapest part,' said Professor Jürgen Hennig, of the Department of Radiology at the University Hospital Freiburg. 'You need to buy real estate to isolate the MRI, and then tons of metal sheeting to insulate the machine. Taking MRI to 7-T is not just performing more of the same examinations, it moves us into a different world,' he told colleagues during a special session at the ECR in March.

In the New Horizons Session *Quantum Leaps in MRI*, leading clinicians described the dazzling possibilities for muscular MRI that renders vivid images of the brain, or the heart, or an exquisite precision for the study of new tissue growth in knee cartilage. Yet, despite all this potential, 'there is not a killer clinical application,' acknowledged Prof. Hennig.

Pushing up the power of the magnet also creates a new world of complications, primarily for the radio frequency coils that detect the signals, according to **Luc Darrasse**, Director for MRI at the French National Research Centre.

# MRI – Aiming to crack the human brain code


UNIVERSITY MAASTRICHT


FORSCHUNGSZENTRUM JÜLICH

people. 'The ultra-high magnetic fields scanners will allow us to view the anatomy and function of the brain in vivo, with a much higher level of detail,' said Prof. Goebel, who in January 2011 received a €2.5 million grant from the European Research Council (ERC) for his study into the functional organisation of the human brain.

In funding the three new whole body scanners from Siemens Healthcare, Limburg Province hopes 'to open doors to biomedical research areas for anatomy, cardiovascular, oncology and pharmacology'.

The Limburg council also has its eye on economic development, believing an excellence centre in high-field MRI, such as Vienna recently created, can be an engine for job growth.

The project also received funding from the EU and the Municipality of Maastricht.

At Brains Unlimited, the new MRI infrastructure creates a versatile and powerful research tool with intertwined functions, according to the province council.

To be housed in a special facility at the University's Faculty of Psychology and Neurosciences, the Siemens MRIs cover a range from 3-T to 7-T to a state-of-the-art 9.4-T scanner.

Siemens manufactures the only 9.4-T MRI approved for human imaging in a hospital setting. MRIs of this scale, currently used at university centres, tend to be smaller bore scanners for animal studies, a company spokesman explained.

The 3-T scanner at the Maastricht campus will be used for routine diagnostic imaging as well as for commercial applications in MRI technology development.

*BrainVoyager*, developed by Dr Goebel, is an example of a cross-platform neuro-imaging software package for the analysis and visualisation of functional and structural MRI data sets. He also created the *Brain Tutor* 3-D application for iPhone and the *Brain Tutor High Definition* application for the iPad.

High-end research on the new high-field 7-T and 9.4-T scanners will be applied to explorations into the causes of multiple sclerosis, Alzheimer's, Parkinson's, epilepsy, and tumour growth.

*Report: John Brosky*

## Pushing the power of scanners creates a new world for imaging, but whilst high-field magnets bring new capabilities they also pose new challenges for clinicians. *John Brosky* reports

The heart, the knee and the human brain are objects too small for the enormous magnetic forces requiring a new generation of coils capable of capturing complex signals in parallel, and then next-level processing to filter the data.

Cardiac studies with high field MRI combined with contrast agents for functional imaging are coming along nicely, reported **Silvio Aime**, head of the Molecular Imaging Centre of the University of Torino.

The development of high-field MRI will come in two phases. First, functional MRI needs to pass a test using positron emission tomography (PET), the most widely used contrast agent in computed tomography (CT).

In 2010 over three million PET-CT scans were performed worldwide, making this technique the gold standard for functional imaging.

The recent introduction of PET-MRI from Philips with its Ingenuity TF, and Siemens with its Biograph mMR, will now enable MRI researchers to validate clinical applications for an alternative method.

'MRI adds to PET a number of advantages looking at soft tissues, and without any radiation,' said Prof. Aime, adding: 'There is a huge advantage with MRI to show areas of perfusion uptake and changes in vascular permeability a widely used method to classify tumours.'

'I would bet on oncology for early tumour response as an application where MRI will pay off,' predicted Prof. Hennig, adding: 'The brain is an exciting application, where we can show micro-bleeding, which CT can not. For Alzheimer's, it's much clearer with MRI where the tracer is accumulating. Beyond the brain, bones and joints are appropriate to the technology and the new MR centre in Vienna is providing spectacular images.'

In his presentation, Prof. Aime described how MRI can move beyond radioactive PET tracers in the blood with contrast agents custom designed to search for disease in the body.

Chemistry offers a brilliant array of nano carriers loaded with a binding agent that finds a specific condition and an imaging agent that 'lights up the region of interest', he said. These carriers can also be loaded with a drug to treat the condition, creating the possibility with MRI to visualise the delivery of a therapy directly to a disease site. 'This opens new fields for theranostics, therapies combined with diagnostics that will improve the treatment of patients,' Prof. Aime pointed out.

A self-described 'MRI guy,' Prof. Hennig is more enthusiastic about this second phase for high-field MRI where custom-designed MRI probes will illuminate our understanding of disease and treatment. 'First, of course, we need to validate that MRI can acquire information that is as good or even better than CT,' he said. 'Then we can switch off the PET and explore new possibilities.'

# Radiology and nuclear medicine

## Sharing an awkward waltz in Vienna

**CT-PET is the child of a forced marriage between nuclear medicine and radiology. A shared session at ECR in Vienna did little to assure there is a growing consensus between the two partners, reports *John Brosky***

The fusion of positron emission tomography (PET) with computed tomography (CT) has brought tremendous benefits to patients.

Last year, over 3.2 million CT-PET scans were performed worldwide, by combining functional images of blood perfusion in tumours and other diseased tissue from nuclear medicine with anatomical images from radiologists.

Yet, despite years of sharing this advanced technology and often working side-by-side, there remains a sharp division between these two specialised fields of medical imaging. 'Those people in nuclear medicine have really ugly images, just ink spots,' complained one radiologist.

Meanwhile experts in nuclear medicine complain that CT exams offer little more than additional information of anatomical structures to more critical data provided by nuclear agents.

At the European Congress of Radiology (ECR), for the second year in a row, the European Society of Radiology (ESR) and the European Association of Nuclear Medicine (EANM) organised a joint session to bridge the gap between their two specialties. This was a success for reviewing the achievements in both areas, but only a modest step toward reconciling the two fields, in that no collaborative project was presented.

Instead, the societies took turns putting forward their champions in an alternating and slightly artificial fashion for studies in tumour response.

**Martin O'Connell MD**, from Mater Misericordiae University Hospital in Dublin, Ireland, was put forward as the expert radiologist. In tracing the effectiveness of therapies for tumour response, 'nuclear medicine leads the way here, no question,' he said.

After reporting the effectiveness of CT-PET for determining, after just two treatment cycles, or three weeks, whether patients respond to the therapy, Dr O'Connell devoted the remainder of his presentation to a review of alternatives.

CT scans unaided by contrast agents is well established as the gold standard for Response Evaluation Criteria In Solid Tumours (RECIST), he reminded colleagues.

Tracers in the blood showing accumulations are not always reliable indicators of the disease state, he said, and there is a danger for some patients of overdoses from radioactive probes used in perfusion studies.

Diffusion weighted MRI studies, especially for whole body scans, can often outperform PET studies, he suggested, before concluding with a pointed comment suggesting that multi-disciplinary meetings are essential, urging his nuclear medicine colleagues with: 'You really need to attend the meeting.'

**Autoro Chiti MD**, with the Nuclear Medicine Unit at Humanitas Clinical Institute in Milan, gave a nod to his radiology colleagues by acknowledging that oncologists have come to trust CT exams for their reliable quantification of tumours. He then reminded the audience that RECIST standards were established in a paper from 1976, where hand measurements were used. 'Today, of course, we have sophisticated tools for measuring, but this is the heritage,' he said, adding that there remain serious limitations for RECIST in relying upon morphological measures provided by CT. 'Tumours take time to shrink, and an early measure showing no reduction risk leads to the wrong conclusion as to whether a patient is a responder or a non-responder to treatment,' he said.

CT-PET is really about the measure of the activity inside the tumour, the glucose uptake of the target lesion, which is shown by the injected nuclear agent.

CT is useful to show changes in tumour size at the end of treatment, or after six months, he said, where it is chemo-sensitivity that enables the early prediction of effectiveness of treatment. 'This gives a completely different measure with the expression of activity,' he pointed out.

As an example, Dr Chiti showed a tumour assessment after a two-cycle of chemotherapy, where the lack of change in the internal activity encouraged a change in treatment. Two further treatment cycles with the new formulation showed significant reduction of tumour activity, which, he said, 'is a predictor of the effectiveness of the changed treatment.' And yet, he added, 'the size of this targeted lesion as shown by CT did not change.

'Imaging,' he concluded, 'provides important additional information.'

The presentations by two champions of these cooperative, although clearly competitive specialties, established that the fusion of metabolic and morphological data is helping to improve diagnostic accuracy for cancer patients.

However, the joint session of the two professional societies left more questions than answers about the consensus recently established for a Multimodality Imaging Training Curriculum, which ESR President Maximilian Reiser announced would be published soon in the online journal, *Insights into Imaging*.

# The 10th United Kingdom Radiology Congress

## 6-8 June 2011, Manchester, United Kingdom

Delegates at the UKRC 2011 will examine who should deliver 21st century imaging services in the UK, when the relationship between radiologists and radiographers will be the focus of a keynote debate. The session '*This house believes that radiologists have given up enough of their professional role to radiographers*' will also see delegates vote on this issue. *Mark Nicholls* reports

**According to UKRC President Dr Erika Denton, 'The difference between radiology in the UK and the rest of Europe is that our radiographers have greater opportunities in the UK for role extension and to do what doctors have traditionally done. As well as the conventional radiographic role of acquisition of images, radiographers have the opportunity to report radiology examinations.'**

**Under changes to healthcare delivery planned by the British government, there are proposals to increase the reporting role of radiographers still further, with the Department of Health (DoH) supporting increasing the number of reporting radiographers. 'With that, there is a tension,' Dr Denton pointed out. 'Some people are of the opinion that we have now gone far enough down that road, while others feel we can extend it further. That debate will be really interesting.'**

**During other sessions, among the main speakers will be Professor James Thrall from Massachusetts General Hospital, Boston, USA, who will discuss the role of IT in optimising radiology practice; and the UK's National Clinical Director for Cancer and End of Life Care, Professor Sir Mike Richards, speaking on 'The importance of imaging within the cancer reform strategy'.**

**Dr Denton explained that an aspect of Professor Richards' discussion will look at delivering imaging earlier for patients and greater access to imaging investigations directly from primary care.**

**Professor Thrall, she said, will examine decision support technology and how it can be used to provide relevant comparative data to radiologists, such as the correct 'hit rate' by referrer on how many people have been correctly diagnosed.**

**Dr Denton, a consultant radiologist specialising in breast imaging at the Norfolk and Norwich University Hospital in the east of England and the National Clinical Director for Imaging, will present a session offering an update on imaging from the DoH perspective in light of the new government. 'The current healthcare approach,' she said, 'is moving towards decentralisation with increased local decision making as well as greater patient choice. Within that there are plans for commissioners and the new GP Consortia to commission healthcare services from any willing provider and that is likely to involve commissioning imaging services from the independent sector.'**


Erika Denton

**There is a history of commissioning imaging services from independent providers within the NHS and Dr Denton will discuss the options and opportunities within that, against a background of decreasing financial input for healthcare due to the recession and increased demand for imaging services.**

**Other sessions will include master classes, lecturers and refresher courses on neurological emergency scenarios, radiology and the Olympics 2012, issues surrounding new PACS systems, image data transfers, clinical applications of elastography and military radiology.**

**A new general interest stream will include an update on key policy messages in the UK and will provide information on what is happening in interventional radiology services, stroke imaging, aortic aneurysm screening, PET CT after the National Contract, and extensions to the NHS Breast Screening Programme.**

**Speaking ahead of the conference, Dr Denton said that UK radiology currently faces a number of issues, including the ever increasing demand for imaging and the need to turn round image requests very quickly for patients and referrers, along with workforce issues. 'We have too few radiologists and radiographers to deliver an ever-expanding service,' she pointed out. 'Workforce issues are particularly challenging for interventional radiology and pertinent with the emergence of trauma networks, which need to have interventional radiology and very rapidly accessible CT scanning.'**

**UKRC 2011 is a joint event of the British Institute of Radiology, the Society & College of Radiographers, the Institute of Physics & Engineering in Medicine and the Royal College of Radiologists.**

# The 92nd Congress of the German Röntgen Society and 6th joint congress with the Austrian Röntgen Society

## 1-4 June 2011, Hamburg, Germany

Stroke, breast cancer detection, sports medicine – the clinical programme is an impressive illustration of this year's congress theme: *Radiology is diversity*. *Florian Schneider* asked the joint congress Presidents, **Professor Bernd Hamm** (Berlin) and **Professor Walter Hruby** (Vienna) to highlight the major topics at this, the largest medical imaging event (attendance around 7,000) in the German-speaking countries

'Diversity,' said Prof. Bernd Hamm, explaining the congress theme, 'is evident on many levels – the diversity of the medical areas, from diagnostics to therapy, and also the diversity of radiological tasks, be it in a hospital or a radiologist's office. There is also the diversity of professional options, not only because radiology is well suited for part-time arrangements and is thus exceptionally family-friendly.'

'Our medical discipline,' added Prof. Walter Hruby, 'is one of the very few that can justifiably be called a whole body discipline, a discipline that looks at disease in a holistic way. It usually is able to either confirm or exclude an initial diagnosis and thus strongly influences therapy decisions as well as the course of the therapy itself.'

For Prof. Hruby, the congress itself, just like medical development, 'is a dynamic process and encompasses a wide range of topics, from neuroradiology to interventional radiology, which avoids major invasive surgery and is equal, if not superior, to traditional invasive surgery.'

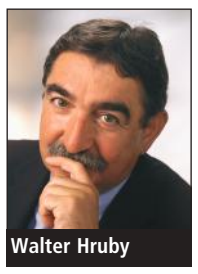
Event highlights, for Prof. Hamm: 'Within neuroradiology, we are currently debating new diagnostic options offered by higher magnet field strengths, which can improve stroke diagnostics, for example. We obtain more precise information on the areas that were affected by the stroke and on the severity of the stroke. That means imaging helps us to decide which areas we should focus on in order to preserve their function.

'Breast cancer detection is another issue: We will talk about quality assurance in mammography-based diagnostics. However, we also need to determine which method will replace X-ray mammography for screening purposes. In the medium term MRI mammography without the administration of contrast media looks rather promising.

'Radiation protection is also an ongoing debate. Forty percent of radiation exposure is generated in computed tomography. We know that and we continuously strive to reduce exposure further. We would like, for example, to reduce the dose of a cardiac CT to the level of a conventional chest X-ray image.

'Last, but not least, we chose sports medicine as a focus. We don't want to limit this issue to joints, but look at the implications of the fitness movement. For example, several studies indicate that many marathon runners experienced undetected myocardial infarctions that can, however, be seen in MRI. These athletes require specific medical care to make sure they can continue to perform their sport.'


Bernd Hamm


Walter Hruby

Prof. Hruby: 'Radiology can help the athlete to adapt the training – the physical stress – to his or her physiological make-up. Imagine you want to intensify your exercise, but had a knee problem some time ago. MRI detects minute lesions in the cartilage and allows us to decide the degree of exercise the body will tolerate. The same holds true, as Dr Hamm pointed out, for the cardiovascular system.'

Prof. Hamm: 'I'd also like to mention another major topic in the programme: tumour ablation. In this minimally invasive and image-guided therapy, tumours are destroyed with the help of heat, ice or radio waves. Tumour ablation is increasingly the therapy of choice when a tumour can't be removed surgically, or when chemotherapy is not advisable.

*Medical-technical radiology assistants (MTRAs) are increasingly interested in the Röntgen Society's annual Congress. What highlights does this year's programme provide for them?*

Prof. Hamm: 'The MTRA programme at the congress has been very successful for many years. The division of labour between the radiologist – a physician by training – and the MTRA is very important for the successful performance of an examination – above all regarding radiation protection. Our programme reflects this fact. This year, we offer session for novices and advanced MTRAs and, as usual, clinical sessions such as 'Tinnitus diagnosis and therapy', because MTRAs are not merely technically oriented, but also have received basic medical training.

Prof. Hruby: It's important for MTRAs to understand the basics of the aetiology and physiology of diseases. The MTRA training sessions at the congress combine technical knowledge, including documentation and medical knowledge. It is this fusion that makes our MTRA programme so successful.

*Finally, asked why the congress has moved from Berlin to Hamburg*, Prof. Hamm said: 'We're interested in fresh impulses – certainly regarding our medical discipline, but also regarding our environment. Hamburg is a metropolis with maritime flair and promises to be a very inspiring location. Also, in early June, we even stand a chance that the weather will be fine!

*Details: www.drg.de*

# Teheran

## Emerging as a regional centre for diagnostic and interventional expertise

It was difficult to sing along in Farsi with the Iranian musical group at the Austria Centre Vienna, a first-ever event for the European Congress of Radiology. European radiologists were far more familiar with the work of their colleagues from Teheran, who have increased their participation in the ECR yearly and who have published their works in English for seven years in the Iranian Journal of Radiology.

2011 saw a record attendance of 137 Iranian radiologists, who came in strength to participate in the special programme *ESR Meets Iran*.

European Society of Radiology President Maximilian Reiser, an honorary member of the Iranian society, opened the scientific session *Interventional Radiology: From Scratch To Innovation*, which was dedicated to interventional radiology practices in Iran. In 2010, he had travelled to Teheran to speak at the annual Iranian radiology congress.

The relationship between the two societies began in 2007, when 30 Iranian radiologists attended. The number increased to 77 in 2010.

Iran has 1,600 radiologists for a population of over 75 million people, comparable with the United Kingdom, with 1,800 radiologists for a population of 61 million.

**Abdolrasoul Sedaghat**, President of the Iranian Society, outlined the education programme across 17 medical schools dedicated to training more than 300 radiologist assistants and residency programmes at university hospitals for a new generation of radiologists.

The ESR is a key partner in the Iranian effort to build fellowship programmes and encourage the participation of visiting professors.

Today, with its increasing specialisation and expertise in radiology, hospitals in Teheran are becoming reference centres, treating patients from across the Middle East and Central Asia, he said.

By highlight interventional procedures, the Iranian Society could fast forward over questions regarding the country's diagnostic capabilities, directly to current work in this practice area.

**Hossein Ghanaati MD** pioneered interventional radiology in 1994 at the Imam Khomeini Hospital, a 2,000-bed medical centre. Initially, the procedure included percutaneous laser disc decompensation and vertebroplasty for low back indications and today has advanced to procedures for aortic stenting and neuro-interventions.

A specialist in neurovascular interventions, Dr Ghanaati also heads the Advanced Diagnostic Interventional Radiology (AIDR) group that has established cooperative exchanges with hospitals throughout the country and is a pioneering centre for stem cell transplant research.

Neuroradiologist **Kavous Firouznia MD** led an effort to develop skills for uterine artery embolisation (UAE) to treat symptomatic fibroids, which affects 70% of women by the age of 50. 'It challenged me,' he said, 'to return to earlier studies to master this procedure.' At the ECR, he contributed a paper on evaluating the outcomes of 50 patients prospectively followed after UAE for 36-108 months. He also discussed suggested methods of radiation dose reduction during UAE procedures and reported the effects of UAE on fertility and pregnancy outcomes.

*Report: John Brosky*

# Think thin, go big

## Ready for the future with the Thin Client PACS

**To meet the high demands of today's radiological environment, a PACS must provide far more than archiving, controlling and distribution of electronic data. Post processing and upgradable network structuring capabilities are just as important to guarantee efficient workflow. The Visage Thin Client looks like a smart solution indeed**


Hubertus Gloger

The Nuremberg Radiography Institute in Germany has been working with the web-based Visage PACS since 2004. Before its move to Berlin, Visage was based nearby and using the Institute to test its products in actual working conditions. There, the radiology team has worked for 18 months with the new Visage7-Thin Client 3-D PACS for diagnosis and post processing, which can be seamlessly integrated with the existing, preceding PACS version.

### Visage7 - Thin Client 3D PACS at a glance

**Universal viewer**: One thin client application for reading everything from plain film to cardiac CT.

**Native Thin Slice and 3-D Processing**: Seamlessly integrated multi-planar reformatting, volume rendering, and volumetric analysis.

**Advanced clinical applications**: CT/MR angiography, cardiac CT, neuroradiology, oncology, nuclear medicine, etc.

**Distributed workflow and archiving**: Instant, unified remote access to multiple locations without replicating data.

**Native Windows and Mac Client**: Windows and Mac users seamlessly integrated into a single workflow and IT platform.

**Scalability made easy**: Distributed thin client architecture makes it easy to add more modalities, users and locations.

The system is a thin-client solution, in which data processing and administration is done by a central server. Images can be streamed to any workstation in seconds via a client-server model, without the need to replicate data. Each potential new workstation is simply equipped with a new client access without having to change existing IT structure.

The Institute runs nine fully-digitised Institutes in other locations, which supply five hospitals with a full range of tomography diagnostics. Thus, telemedical diagnosis services are run daily through the internal radiology network: 'The Visage PACS allows staff direct access to all images inclusive of thin slice data, regardless of where the images were generated. So there's no long wait caused by the need to upload images,' explains **Dr Hubertus Gloger**, specialist for diagnostic radiology at the Nuremberg Radiology Institute. 'A third of our colleagues in our multi-site organisation are specialist radiologists who are always virtually available for a first or second diagnosis. If a cardiac MRI scan is carried out in Bayreuth, but the respective specialist happens to be in Nuremberg that day, he still has access to the data, so the diagnosis can be carried out on the same day.'

However, sometimes, Dr Gloger points out, a particularly complicated case is thought about long after leaving work. 'When you suddenly have a brainwave, it's reassuring to know that images can be quickly checked again in your home office via the client server system. The system also enables you to call up images on the laptop when you are with colleagues to get some more personal advice on difficult cases.'

The close cooperation and intensive exchange with colleagues at the institute, as well as doctors and regional hospitals, generates an annual 2.5 terabytes of data, presenting the need for high performance and resources need. The Visage PACS ensures that this flood of data can be tackled without problems. Making the workflow even more seamless, the additional acquisition of the Thin Client visualisation solution, instead of specialised workstations, was a decision in favour of a consequent standardisation of hard- and software components.

Whilst the implementation was quite technically seamless, finer details still need to be honed. Individual support during the implementation of the visualisation solution was therefore of great importance, says Dr Gloger. 'When we started working with the Client, we realised after four weeks that we needed additional settings and tool palettes, particularly for the diagnosis of PET-CT images and for oncological imaging. Soon after, we contacted the service department about this and these additional settings were sent to our system.'

The visualisation procedures are mainly utilised for multiplanar reformatting and 3-D reconstructions, such as for Cardio-CT. MIP and vascular visualisation are also well covered by this solution. Other additional features, e.g. animations, are also of great use, Dr Gloger says. 'We carry out open MRI, which makes it possible to visualise cardiac motion, such as the pumping function of the heart.' And, he adds: 'These graphic motion images are also ideal for the purposes of demonstration, whether for a specialist medical audience or the patient, who gains a deeper medical understanding.'

# Contrast enhanced tumour studies

## Ultrasound advances where CT and MRI are challenged

**Medical imaging has recently advanced so rapidly that it should halt. Applying more power to computed tomography (CT) and magnetic resonance imaging (MRI) scanners is becoming too dangerous for patients and healthcare workers. Magnets for the next-generation MRIs are so powerful that they must be moved to a separate building on hospital campuses, while CT radiation levels have risen to alarming rates. Studies have also indicated a limit to diagnoses based on what we can see. Where do we go from here? *John Brosky* reports**

Attention is turning to the disease mechanisms that are invisible to the human eye but can be illuminated by injecting chemical agents into the blood. Even when using low-power CT, simple glucose charged with a radioactive isotope can reveal a high activity of blood flow that signals the growth of a tumour. The opposite condition, a reduction in blood flow to a known tumour site, can indicate necrosis showing that a therapy is effective in killing the tumour.

Advances in dynamic contrast-enhanced (DCE) imaging was the focus for a special session this year's ECR, with presentations devoted to developments in CT, MRI, and the newest modality to enter this highly specialised field – ultrasound.

**Jana Votrubová MD**, with Na Homolce Hospital in Prague, described techniques for DCE-CT with a focus on the unique advantages of perfusion studies of the blood-rich liver using radioactive fludeoxyglucose (FDG).

Imaging techniques make it possible for radiologists to study the entire liver, she reported, but studies have increasingly shown the emphasis on quantifying the visible changes to the tumour's diameter and volume using widely accepted criteria for Response Evaluation Criteria In Solid Tumours (RECIST) 'are useless'.

Instead, a study of perfusion illuminated by the FDG agent reveals more valued information about the response of a tumour to treatment.

Due to her concerns for the high levels of radiation with CT for patients undergoing serial studies of tumour response, Dr Votrubová said she is turning increasingly to diffusion-weighted imaging using MRI.

**Anwar Padhani**, from Mount Vernon Hospital in Middlesex, United Kingdom, presented developments in DCE-MRI, but cautioned there are limitations for this modality that challenge radiologists to ask whether they can confidently answer key questions as to whether a tumour has changed or whether a treatment is effective.

MRI does not captured an image of light but far more complex electromagnetic signals that need to be processed and can be affected by what he called 'confounding factors'.

The drug used for the treatment might be creating phenomena revealed by MRI, such as temporary effects of increasing blood flow or arterial tension. These phenomena are assessed by software that depends upon assumptions of values. Dr Padhani encouraged colleagues to 'know the software parameters encoded in the black box from vendors', to be certain the defined values are appropriate with imaging objectives and the clinical questions being asked.

After the complexity and uncertain success presented by the previous speakers, there was refreshing simplicity and encouraging confidence in the description of DCE for ultrasound from **Luigi Solbiati**, from the Busto Arsizio General Hospital in Varese, Italy.

There is only one injected contrast agent for ultrasound, an easy to understand product called SonoVue from Bracco, with micro bubbles that suddenly illuminate blood flow when exposed to the sonic waves of ultrasound. This simple technique of physics provides a very high temporal resolution, very high spatial resolution, he reported. 'It is fast and reliable, provides an immediate assessment and is very safe for the patient.'

It is also significantly less expensive than exams performed by the more complex CT or MRI scanners.

In fact, with a sensitivity for measuring lesions in millimetres, contrast enhanced ultrasound (CEUS) has been shown to outperform CT and CT-PET.

This quantitative measure enables the assessment of changes to a tumour following radiofrequency ablation, allowing the interventionalist to decide immediately whether to re-treat a patient while the patient is still on the operating table.

A limitation of CEUS is that the exams can only be applied to specific organs, he said, adding that a new possibility for CEUS is the delivery of therapeutics using microbubbles that can be designed to carry both a marker for a disease and a drug to treat the disease.

Acknowledging that changes to a tumour size do not always indicate the effectiveness of a chemotherapy treatment, Dr Solbiati highlighted a new pan-European study that is extracting from raw data of ultrasound signals to determine whether patients are responding to chemotherapy.

At the Radiology Society of North America (RSNA) meeting, a multicentre study conducted in France showed how two ultrasound parameters accurately predicted after just 30 days whether a chemotherapy treatment was effective.

The significance of this conclusion, to be validated in the wider European study, is that a €200 exam can decide whether a €50,000 treatment should be stopped, continued or increased, he said.

Currently, the exam is limited to centres equipped with ultrasound scanners from Toshiba Medical Systems – the only company to provide raw data from its signals for analysis by the French team, led by Nathalie Lassau, from the Institute Gustave Roussy in Paris.

# Contrast-induced nephropathy

**Contrast induced nephropathy (CIN) is widely recognised as a potentially serious complication of contrast media use – a risk that increases with a patient's age and decreased renal function. *Mark Nicholls* reports**


Remy Geenen

The rise in referrals of older patients for diagnostic and interventional procedures that use contrast media includes many people aged over 60 who also suffer renal impairment - a group at significant risk of developing CIN.

The risks factors, contrast media safety, wider issues surrounding CIN and how to avoid CIN, were the subject of a refresher course session at the ECR in March. Taking part was radiologist **Dr Remy Geenen** a private practitioner who works at Medisch Centrum, a large, non-university teaching hospital in Alkmaar, the Netherlands. Dr Geenen focuses on abdominal and cardiac radiology, and has a specific interest in contrast media.

At the ECR session he discussed the pharmacology of contrast media, the pathogenesis of CIN, iso- vs. low osmolar CM and hydration with NCL vs. NaHCO3. 'The pathophysiology of CIN is complex and not well understood,' he explained. 'Basically, an imbalance between vasodilatation and vasoconstriction takes place inside the kidney after intra-arterial or intravenous CM administration.

'Furthermore, increased oxygen demand of tubular cells due to increased re-absorption of sodium and water is a second mechanism, leading to transient medullar ischaemia. Patients who develop CIN have a significantly higher chance of serious or adverse events such as stroke or myocardial infarction. There is also a higher risk of death, especially in the short-term.'

A key first step toward prevention is to identify patients at risk and they are primarily those with kidney problems, or older patients.

Dr Geenen explained that the CIN incidence in healthy patients with normally functioning kidneys is as low as 1-2%. For those with any severe kidney disease this increases up to 50%. 'Knowledge of the patient's medical record and recent basic kidney function is mandatory. High-risk patients should receive prevention. Two major questions in CIN prevention are whether iso-osmolar CM causes significantly less CIN than low-osmolar CM and whether hydration schedules with NaHCO3 give significantly less CIN than hydration schedules with NaCl 0.9%.'

Evidence for the standard use of iso-osmolar contrast media for CIN prevention in radiological procedures is limited, he said. Five randomised, controlled trials regarding intravenous administration showed conflicting results - three showed no significant difference in CIN incidence; one favoured comparing low-osmolar agent and one favoured the iso-osmolar agent.

For NaHCO3 versus NaCl, Dr Geenen said, of the 12 RCTs performed, seven favoured NaHCO3, with five showing no significant difference in CIN incidence. 'Pre- and post-hydration with NaHCO3 is therefore at least equal to NaCl.'

Radiologists can take certain steps to avoid or reduce the CIN risk, he advised. Calculating the patient's estimated Glomerular Filtration Rate (eGFR) is important – if less than 60, the radiologist should act promptly with pre- and post-hydration.

However, whilst Dr Geenen remains content that contrast agents are as safe as radiologists wish them to be, and usually only 10-15% of patients are at increased CIN risk, he said it is crucial that preventive measures be taken in high-risk patients.



# NEW HI VISION Ascendus digital ultrasound

Launched in Europe at this year's ECR in Vienna, the HI VISION Ascendus joins Hitachi's ultrasound systems series that include the HI VISION Preirus and HI VISION Avius.

The new ultrasound system includes expert modalities such as Hitachi Real-time Tissue Elastography (HI-RTE) to image tissue stiffness, and dynamic Contrast Harmonic Imaging (dCHI) technology to enhance the visualisation of tissue microvasculature after injection of an ultrasound contrast agent. Hitachi adds that the system also supports new leading edge technologies and is the world's first to be able to display 4-D Real-time Tissue Elastography images, where volume data is captured in real-time and the tissue stiffness information is transformed into images by high-speed signal processing.

The Ascendus also offers tools for interventional specialists: Hitachi Real-time Virtual Sonography (HI RVS) for displaying CT or MRI images in real-time alongside ultrasound slices; Real-time Bi-Plane imaging (RTBi); and support for dedicated biopsy, intra-operative and laparoscopic transducers.

'With its completely new ultrasound transducer circuitry, the HI VISION Ascendus provides the highest definition image quality,' Hitachi adds. 'The image processing unit is driven by the Ultrasound Broadband Engine 2nd Generation (Ultra BE II) – which greatly increases the processing speed – facilitating the development of sophisticated image processing and new application functionality. Through the combination of Ultra BE II and highly sensitive, wide bandwidth probes, Hitachi achieves images of precision and clarity.'

# Sharing radiological data

## ‘Don’t throw anything away. Utilise what you have!’


Ulf Andersson

When thinking about sharing radiological data within a multi-site center or even within a region, the initial question that arises always sounds the same: How should we cross-link all the data from the existing PACS solutions without going bankrupt? Because drawing a line and installing new systems all over the site in most of the cases is simply not affordable. On the other hand, the communication between the systems from different vendors is sub-optimal which can make the image exchange quite bumpy.

With its SuperPACS architecture Carestream Health claimed to overcome this problem by building a kind of roof that brings together all PACS systems by creating a global worklist. Doing so the barriers between the single solutions vanished and a seamless data exchange can take place. “Our motto is: Do not throw anything away – utilize what you have”, said Ulf Andersson, Director of Marketing & Business Development North Europe Region during this years´ ECR. Following this way the Carestream of course is XDS (Cross Data Sharing) compliant, a technology that functions like a traditional library (registry and book shelfs)

“XDS is a IHE standard to share data across large enterprises, with special regard to the distribution of stored data. Our new strategy makes it possible literally to start a query and get the information about where the required data can be found. It tells you: The CT data from patient x is located in site y and the X-ray from the private practitioner can be found on platform z,” Andersson describes the process that normally would end just by finding the data. “And this where the SuperPACS architecture comes in, because it is the logic continuation of this process. Our technology gives the user not only the information about where the data is but can move it through the SuperPACS very fast across the enterprise. Depending on the demands, this happens via tunneling which enables a user to query data from any node and have data automatically routed from any location to this node, via smart routing that ensures that images are automatically retrieved from the best available location and routed via the optimal way or with streaming technology that is seamlessly activated when required.”, Andersson adds.

Utilizing existing data is also the buzzword regarding cloud computing offered in eHealth Managed Services by the company. Andersson: “Here again the driver behind the technology is cost effectiveness. In former times the decision for a new PACS or RIS was connected to a huge investment. Today, hospitals buy services tailor made for their individual requirements. At the beginning, there was a lot of skepticism because of data security etc. But now we feel that hospitals change their attitude and learn to trust cloud concepts. The advantages of expanding or reducing services are in the forefront. Consequently the principle is transferred to clinical applications like 3D-rendering. Instead of buying a software, hospitals buy a 3D-rendering function for application and only pay for what they use. The idea of this service of course goes far beyond a simple financing model – it is a business strategy.”

And another innovation perfectly fits into this strategy: At the moment Carestream Health rolls out its new RIS which is a completely web based solution and therefore a totally new approach that might start a small revolution in the radiology department.

4-D elastography images are displayed in real-time

# The IFCC WorldLab and EuromedLab Congress

## A once every three years event

'Three years is a long time in the world of research. The amount of information on offer quickly grows quite enormously,' says **Professor Rudolf Tauber**, joint head of this year's WorldLab congress with **Professor Harald Renz.** Thus, one organisational challenge was to channel current trends and developments and present participants with an informative, comprehensive overview. How was this achieved?

During the congress in Berlin (15-19 May), four distinct topics will be discussed in great detail during the daily plenary sessions: Molecular tumour markers, clinical and diagnostic immunology, neurodegenerative diseases as well as new methods and procedures in laboratory medicine, Prof. Tauber explained. 'With molecular tumour markers, the focus is on the early diagnosis of malignant tumours. New findings in molecular biology – key words epigenetic tumour markers and micro RNA – give cause for hope that we'll be able to develop new screening parameters in the future which will make diagnosis possible at the very early stages of diseases.'

Autoimmune diseases will be the main topic in the field of clinical and diagnostic immunology. 'Early detection is also a key word here – the earlier treatment can begin, the better the results. Other hot topics are individualised therapy and reprogramming of wrong immune responses – both areas where intensive research is currently being carried out.'

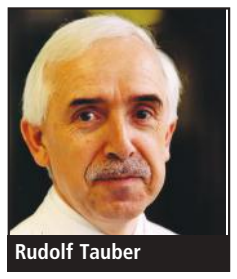
Intensive discussion will also focus on one of the big challenges in coming decades -- neurodegenerative diseases. 'The objective is not only to develop new treatments – such as for Alzheimer's – but also to research new biomarkers for diagnostics to facilitate early detection and monitoring of the effectiveness of treatment.'

**New methods and procedures**

Next generation sequencing enables the sequencing of the entire genome within hours. 'Procedures such as this, which are currently finding their way into research and development, will allow us to analyse genetic risk factors for diseases, or groups of diseases, for the individual patient in the near future. Next generation sequencing will take diagnostics as well as prevention to a completely new level, the consequences of which we cannot yet quite grasp in its entirety. It will form the basis of customised treatment procedures, which in return could revolutionise the entire world of healthcare. Analytical procedures such as mass spectrometry and the decoding of the proteome, i.e. the entirety of all proteins, as well as of the metabolome, i.e. the entirety of all metabolites, are also vital. The scientific programme and the large industry exhibition at the IFCC WorldLab Congress will give an outstanding overview over all new developments.'

**Laboratory medicine's clinical impact**

'Laboratory medicine and its related disciplines provide around 60% of the information decisive for a diagnosis. With the increase in the identification of pathomechanisms and increased understanding of the genetic causes of diseases, laboratory medicine will become increasingly important for the field of prevention. The same goes for therapy: In the future we will be better able to monitor the use of certain drugs as to their benefit for the individual patient. The entire field of personalised medicine would not be possible without laboratory medicine.'


Rudolf Tauber


Harald Renz

**Future challenges**

'Scientific activity must be extended – what we need is an active and committed science that aims to understand the molecular causes of diseases. Monitoring the clinical benefit of all new procedures and new biomarkers will play an essential role. Therefore, we must check how new procedures and parameters can be integrated into in- and out-patient care. And finally, we must also intensify training of academic and non-academic staff. The challenges that go hand in hand with the introduction of new technologies can only be mastered through consolidation of training.'

*Interview: Meike Lerner*


## The International Liver Congress 2011

Over 8,000 international clinicians and scientists travelled to Berlin in March to attend the International Liver Congress 2011, hosted by The European Association for the Study of the Liver (EASL), to hear the latest research, perspectives and treatments in hepatology.

These included a modelling study (Deuffic-Burban S et al) that looked at current treatment practices and available epidemiological data across a number of EU countries (including Belgium, France, Germany, Italy, Spain and the UK), and showed that based on current practice HCV-related (hepatitis C infection) morbidity and mortality will be reduced by 10 % from 2012 – 2021. In addition, the incidence of cirrhosis will be reduced by 16 %.

Based on these forecasts, experts conclude that the development and implementation of ambitious policy strategies to ensure effective access to diagnosis and treatment alongside the availability of new therapies, such as proteases inhibitors, could have a major impact in further reducing HCV-related mortality in the future.

Beyond, the first clinical study investigating the use of the AKIN criteria (Acute Kidney Injury Network) in cirrhosis has shown significant benefits that potentially could change future diagnosis, according to results from a Spanish study (Fagundes C et al).

AKIN criteria consider renal failure as an increase in serum creatinine ≤ 0.3 ml/dL compared to baseline within 48 hours. Out of 300 patients admitted to hospital for complications of cirrhosis 29 % developed renal failure according to AKIN criteria. Three-month survival of these patients was 38 %, compared to 87 % of patients who did not develop renal failure. Because liver disease is associated with a high mortality due to renal failure, more sensitive tests like AKIN help to identify patients at risk of renal failure or death earlier. Due to the results, AKIN criteria have the potential to replace current screening and diagnosis criteria in hospitalised cirrhotic patients.

Furthermore, according to results from two other new studies presented, there are options for clinicians to expand the pool of liver grafts for use in liver disease patients. The UK retrospective study (Jassem W et al) analysed liver transplant donation after cardiac death between May 2001 and October 2010. 186 DCD allografts were transplanted and included 19 paediatric recipients. Overall the study found positive outcomes of transplant, with an overall patient survival of 89.9%, 85.6 % and 83.6 % at one, three and five years respectively.

The second Italian Liver Match cohort study (Angelico M et al) evaluated the survival of liver grafts from hepatitis B core antibody positive (HBcAb+ve) donors in recipients with hepatitis, by analysing data from 1,477 adult liver transplantations from June 2007 to May 2009. Of these, 1,237 were HBcAb negative and 240 HBcAb positive donors, with unadjusted two-year graft survival of 80 and 69 % respectively.

The two-year study found HBcAb positive donor grafts survive better when allocated to HBsAg positive recipients, but have worse outcomes when given to all categories of HBsAg negative recipients, regardless of their HBcAb/HBsAb status. In addition, as graft loss was unrelated to hepatitis HBV recurrence it is unlikely that this is due to insufficient HBV prophylaxis.

*2012 International Liver Congress: 18-22 April, Barcelona, Spain.*

EASL | THE INTERNATIONAL LIVER CONGRESS™ 2011
46th ANNUAL MEETING OF THE EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER

# Pharmacogenetics

## Researchers focus on customised medication for patient groups

In the first month of 2011, the Centre for Pharmacogenetics and Pharmacogeno-mics at the Paracelsus Pri-vate Medical University in Salzburg, Austria, officially opened its doors. Why have pharmacogenetics and pharmacogenomics so increasingly important in medical research? We asked the head of the new research centre, **Professor Markus Paulmichl**

'There isn't one drug that helps all patients,' said Professor Paulmichl. 'One group of patients may respond to a drug as desired. However, the next group might feel no effect whatsoever, and the third group may end up with complications. This obviously makes one wonder whether this may have something to do with the individual genetic make-up. Therefore we examine whether the said patient groups have mutations in those genes involved in the absorption, distribution and metabolisation of drugs in the body.

'For example, the liver enzyme CYP2D6 required for the metabolism of xenobiotics metabolises around 20% of drugs used in Europe. In six to eight percent of Caucasian Europeans this enzyme works insufficiently and they can expect side effects. Around 4% of Europeans have an excessive function so that the drugs are metabolised too fast and don't amount to a therapeutic concentration. These are significant figures.'

Asked about the research projects currently being undertaken at the centre, he said: 'At the beginning of pharmacogenetic research the emphasis was on metabolising enzymes. However, we focus on those structures responsible for the absorption and distribution of drugs. This is a new field to which great importance should be attached. One of our central areas of research is the blood/brain barrier. There are pathological changes in the brain that we'd like to be able to control pharmacologically. However, the blood/brain barrier ensures that many substances in the blood do not get into the brain. A second area of research is the bronchial epithelium, because some drugs are applied to the lung via inhalers, as in asthma treatment, and the target cells are not directly at the surface. The genetic make-up obviously also has an impact here.'

So, is pharmacogenetics a step in the direction of personalised medicine? 'The development is definitely heading towards the direction of a strong segmentation of the patient pool.'

Wouldn't such segmentation lead to higher costs? 'Overall, we could put a black zero under the line for healthcare. Clinical studies could be carried out on a smaller scale because they are no longer expected to cover the effects in the entire population on a broad scale. This could result in significant savings in the development costs for new drugs. A lot of money could also be saved through the reduction of side effects. If you project the data from the USA, then we spend around €100 million on the treatment of side effects from medication – in the Salzburg region alone. This is a considerable sum. But the money saved in the process will have to be invested in diagnosis. However, the discussion shouldn't always be reduced to talking about costs. The advantage for patients is evident: They are given the drugs with the least side effects.

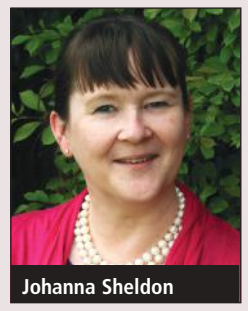
What possible obstacles do you foresee? 'It will make things more complex for clinicians. One problem is likely to be the training and advanced training of doctors who have not had to become involved in pharmacogenetics, so far. They will have to be convinced of the advantages that this new approach results in for the patients.

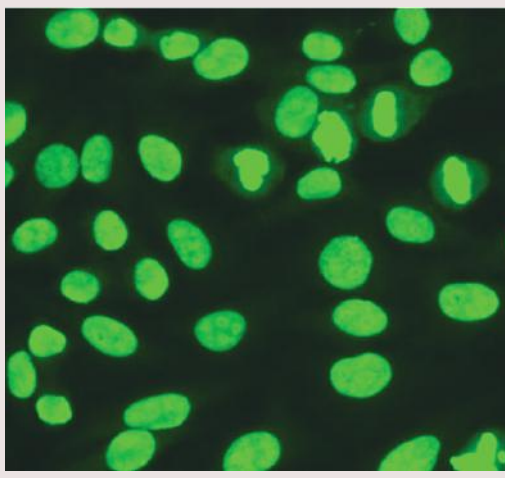
*Report: Michael Krassnitzer*

# From friend

## Autoantibody testing as an important diagnostic tool in autoimmune disease

**It's a war against a perceived enemy that is not – autoimmune disease like rheumatoid arthritis, lupus erythematosus or multiple sclerosis, occur when the immune system attacks normal tissue components. Characteristic of those disease patterns are autoantibodies in the blood, which the immune system produces to attack its own organism. The detection and quantification of those disease-specific autoantigens are an important test in the diagnosis and management of a variety of autoimmune diseases, as Dr Joanna Sheldon*, Director Protein Reference Unit, Department of Cellular and Molecular Medicine at St. George's University of London, UK, well knows. We asked her to explain how laboratory testing can discover those autoantibodies and what challenges the tests present**


Johanna Sheldon


Anti nuclear antibodies – homogeneous pattern

Dr. Sheldon: Tests, any test, should be used to help the physician include or exclude a diagnosis, monitor a disease or assess a patient's prognosis. Autoantibody measurements are most useful as part of the diagnostic panel for disease, for example, antibodies to components of cell nuclei are part of the diagnostic criteria for systemic lupus erythematosus. Autoantibodies are generally less useful in monitoring disease progression or assessing prognosis.

***In recent years, what technical leaps have autoantibody tests taken?***

The major development has been the introduction of automated methods for autoantibody detection and measurements. Some labs are moving from manual indirect immunofluorescence methods to automated ELISA or even multiplex based assays. Unfortunately, in many situations these have made the analysis easier with less need for technical skill, but have not improved the diagnostic value of the tests. Some companies are even trying to develop bedside assays for autoantibodies!

# to foe

***What are the weak spots of those autoimmune serology tests?***

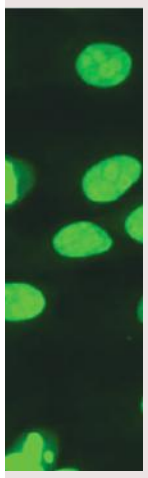
There are many weak spots and they can all be summarised by the word variability. Variability in the target antigens, variability in the antibodies in the patients' samples, variation in methods, variation in the detection systems and poor standardisation. Each contributes to high variation in autoimmune serology testing and no-one knows what the right answer is.

***Why are standardisations so difficult to realise?***

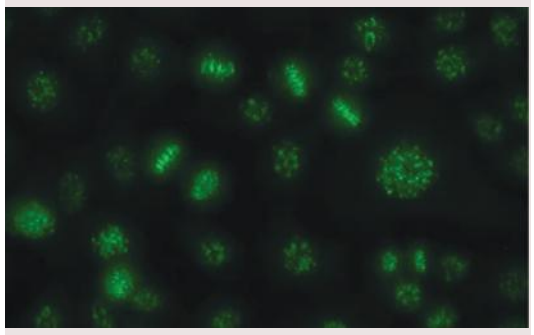
The difficulties also come down to variability. There are many components of an autoantibody test that need to be defined and it will not be easy. Every manufacturer of autoantibody tests believes they are doing the tests in the correct way and getting the correct result, but it's just not possible that they are all correct. It's likely that we will need to define more clearly the antigens to be, the standards for the assay and the detection systems used. All these elements present problems and this process will take time and considerable effort. We also need all the diagnostic companies making autoimmune kits to participate in this important process.

***What must be overcome to change the analytical problems?***

There are many hurdles – and I can't imagine a quick result. We need to start somewhere and recently a collaborative project between the IFCC and IRMM has started on the harmonisation of autoantibody testing. We have identified five quantitative autoantibody tests where there is an importance in the 'concentration' of the autoantibody. We have some materials that we are evaluating for their potential as 'harmonisation samples'. There are considerable processes to go through; these materials need initial testing, stabilisation, purifying, more testing and then, hopefully, bottling, value assignment and distribution. However, this is a gross over-simplification of exactly what needs to be done.



If we are successful, we need the diagnostic companies to perceive that this is an important and valuable development and to consider it sufficiently important possibly to change their methods to harmonise them using these materials. If we do achieve this, the work will not stop. There will be a continual process of re-evaluation of the materials and investigations of whether the introduction has reduced variability in autoimmune testing. We may then need to look at harmonisation of the autoantigens and maybe even the methods….I think this is a life time work!



Anti nuclear antibodies - speckled pattern

** As an international expert and speaker at the IFCC WorldLab session 'From Bench to Bedside in Autoimmunity', Prof. Sheldon will discuss: 'The many challenges of autoantibody testing' on 16 May at the 2011 IFCC WorldLab meeting in Berlin, Germany.*

# Artificial pancreas

Two small randomised trials published on bmj.com suggest that closed loop insulin delivery (also referred to as an artificial pancreas) may improve overnight blood glucose control and reduce the risk of nocturnal hypoglycaemia in adults with type 1 diabetes.

The closed loop insulin delivery system automatically computes insulin dose according to glucose levels detected by a sensor. Previous studies have shown that this system is effective in children and adolescents, but its effectiveness in adults is unknown.

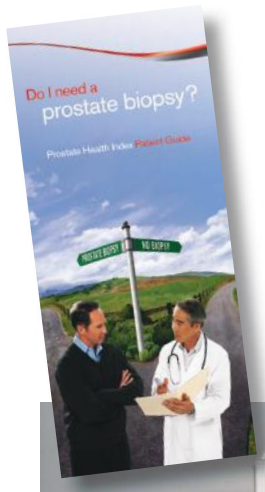
A research team led by **Roman Hovorka**, Principal Research Associate at the Institute of Metabolic Science, University of Cambridge, Addenbrooke's Hospital, has carried out two studies to compare the safety and efficacy of overnight closed loop insulin delivery with conventional insulin pump therapy in 24 type 1 adult diabetics, aged 18-65, who had used insulin pump therapy for at least three months.

In the first study, 12 participants were twice monitored overnight after consuming a medium-size meal (60 g carbohydrate) at 7pm: they were randomly assigned to use either closed loop delivery of insulin or conventional insulin pump therapy and then, on a night one to three weeks later, they used the other delivery method. In the second study, the other 12 participants were twice monitored overnight (using one or other of the two insulin delivery methods) after consuming a larger meal (100 g carbohydrate) at 8.30pm, accompanied by alcohol.

The time spent with blood glucose levels in the target range increased by up to 28% during overnight closed loop insulin delivery. Closed loop delivery also lowered glucose variability overnight and significantly reduced the hyperglycaemic period.

The authors conclude that their findings provide further evidence that overnight closed loop delivery can operate safely, effectively, and consistently across different age groups, insulin sensitivities and lifestyle conditions. They add that the closed loop system '… may in future allow more flexible lifestyles in conjunction with improved glycaemic control for people with type 1 diabetes'.

# A novel prostate disease marker and index show increased clinical accuracy




**The role of prostate-specific antigen (PSA) in prostate cancer detection continued to command attention at during the annual congress of the European Association of Urology (EAU) in March**

The likelihood of being diagnosed with prostate cancer in later life is highly dependent on the PSA level at the initial screening. However, according to a study published in *Cancer* (*J Natl Cancer Inst 2003;95(12):868-78*), approximately half of cancers detected are found to be indolent. Many patients have therefore undergone an invasive procedure. In the same study and another (*Arch Pathol Lab Med* 2004;128(5):557-60) it is estimated that the annual number of negative biopsies is around 750,000 in the US alone. Further, the European Randomised Study of Screening for Prostate Cancer (ERSPC) in its March 2009 report indicated that 75.9% of the men who underwent a biopsy for an elevated PSA value had a false positive.

In a recent article in the *European Journal of Cancer*, the ERSPC, referring to the findings of its side studies, indicated that the benefits of screening could be significantly increased by the introduction of new biomarkers, such as PSA isoforms.

At two of the Congress's scientific review sessions, leading urologists presented a series of abstracts that delivered encouraging findings on the accuracy of the new prostate disease marker and the Prostate Health Index (*phi*)† and the correlation with prostate cancer aggressiveness, later confirmed by biopsy and pathological examination.

The new marker from Beckman Coulter, named *Access Hybritech p2PSA*†, measures an isoform of free PSA*. The new Prostate Health Index (*phi*) is derived by combining the results of three automated blood tests – PSA, free PSA and the new p2PSA. This is now available in Europe. When *phi* is installed, the analyser automatically calculates and reports the Prostate Health Index results and helps better determine if a man should be recommended for prostate biopsy.

These new observational studies presented at EAU looked at the isoform p2PSA and *phi* to see if, in a clinical setting, it might significantly improve the accuracy of total and free PSA in predicting the presence of prostate cancer and in correlating cancer aggressiveness.

As **Massimo Lazzeri, MD PhD**, of Milan's San Raffaele Hospital, explained: 'From our clinical, observational studies, the markers** and *phi* levels do correlate with aggressive cancers that can be separately confirmed by biopsy and pathological examination in patients who underwent radical prostatectomy. The development of more specific markers will be significant in helping us make better prostate biopsy decisions and, ultimately, improve our clinical decision-making for patients with prostate cancer.'

Dr Lazzeri and his colleague Luciano Nava MD will also present their clinical results at the American Urology Association conference in Washington, D.C. in May.

Based in California, USA, Beckman Coulter, Inc., develops, manufactures and markets products that simplify, automate and innovate complex biomedical tests. More than a quarter of a million Beckman Coulter systems operate in laboratories around the world, supplying critical information to improve patient health and reduce care costs. Recurring revenue, consisting of consumable supplies (including reagent test kits), service and operating-type lease payments, represents about 80% of the company's 2010 revenue of $3.7 billion.

**[-2]proPSA molecule  **p2PSA and %p2PSA*

*†Not available in the United States*


NEW

# Four automated immunosuppressant drug tests on one integrated system

**Following *CE mark* registration to sell a fully-automated Mycophenolic acid (MPAT) test for use on the *Dimension* integrated chemistry systems*, Siemens Healthcare Diagnostics has become the first to offer the consolidation of four fully-automated immunosuppressant drug (ISD) tests – Mycophenolic acid, Cyclosporine, Tacrolimus and Sirolimus – used to monitor organ transplant patients. The tests can be run simultaneously with routine chemistry tests on the Dimension system and enable more comprehensive care for transplant patients.**

**David Hickey**, CEO of the Chemistry, Immunoassay, Automation and IT Business Unit at Siemens Healthcare Diagnostics, explained: 'These are four of the most commonly prescribed immunosuppressants used by physicians to prevent organ transplant rejection. Physicians continue to use multi-drug regimens to treat transplant patients, making it important for us to give customers the option to consolidate all of these tests on one instrument platform of their choice.'

Because there are no manual sample pre-treatment steps required for any ISD tests performed on the Dimension systems, including the new MPAT test, clinical laboratories can be more efficient and reduce the potential for errors that may be caused by extensive handling of patient samples, the firm points out, adding: Laboratories also save time by performing ISD tests alongside other routine chemistry tests, all on one integrated instrument. This helps streamline ISD testing workflow and improve efficiencies with transplant patient management.

Outside the USA, Siemens also offers the consolidation of Mycophenolic acid, Cyclosporine, Tacrolimus and Sirolimus ISD drug tests on the V-Twin and Viva-E drug testing systems. In addition, a Cyclosporine test is offered on the company's ADVIA Centaur immunoassay systems and Dimension Vista intelligent lab systems. 'Siemens intends to continue developing up-to-date drug tests to help monitor drug levels in transplant patients and is currently developing a Tacrolimus assay for use on the ADVIA Centaur immunoassay systems,' the company reports.

** The new Dimension MPAT test is under FDA review and is not available for sale in the USA.*

# Cytomegalovirus test approved

## The Roche Cytomegalovirus (CMV) test is now commercially available in Europe

**CMV viral load testing helps physicians manage immunocompromised patients at risk of CMV disease, including those who have undergone solid organ and stem cell transplantation. 'This standardised, fully automated test monitors CMV infections using an easy-to-operate system capable of delivering accurate and reliable results to clinicians so that they can make critical treatment decisions.**

**The test is designed for use on Roche's fully automated COBAS AmpliPrep/COBAS TaqMan System.**

NEW

# A two-step biomarker approach for prostate cancer

## Swiss researchers in Zurich and St Gallen have defined new biomarkers in patients' blood that indicate the presence of prostate cancer. *Jane McDougall* reports

Prostate cancer is the most frequently diagnosed cancer in males in developed countries and the sixth leading cause of cancer death worldwide. One reason for the increase in diagnosis is the widespread uptake of the prostate-specific antigen (PSA) test, capable of detecting slow growing cancers that might otherwise go undetected. Although PSA is the current standard biomarker to detect early prostate cancer, its lack of sensitivity and specificity leads to considerable over diagnosis and sometimes unnecessary treatment, making its effectiveness in systematic screening controversial.

A recent PNAS publication from Switzerland describes a new two-stage strategy corresponding to specific cancer-causing genetic mutations and the underlying disruption of signalling pathways to guide the discovery of novel serum biomarkers in application to prostate cancer.

The loss of tumour suppression leads to increased cell proliferation due to the loss of apoptosis (programmed cell death). Inactivation of the phosphatase and tensin homologue gene (*PTEN*) occurs in many cancers, especially glioblastoma, endometrial cancer and prostate cancer, and expression is reduced in other cancers, e.g. lung and breast. Up to 70% of men with prostate cancer have lost one copy of the *PTEN* gene. The Swiss researchers therefore considered it a good potential target for specific prostate cancer biomarkers. A well characterised consequence of *PTEN* inactivation is the constitutive aberrant activation of the phosphoinositide 3-kinase (PI3K) signalling pathway, a key regulator of numerous cellular processes in biology.

The first step was in an animal model, based on the supposition that PTEN loss will disrupt specific signalling pathway-activation pathways and the resulting changes in the surface and secreted proteins of the affected tissue (prostate) should be detectable as discrete biomarker in the serum. By comparing the serum of genetically modified mice, in which *PTEN* had been inactivated with wild-type controls, the researchers identified 126 different proteins. These became candidate biomarkers based on three criteria: PTEN dependency, prostate specificity and detectability in serum.

The second phase of the study examined tissue and serum samples, collected between 2004 and 2007, in men with prostate cancer or clinically confirmed benign prostatic hyperplasia (BPH). Using the information obtained from the mouse experiment, enrichment techniques were used to detect the glycosylated biomarkers specific to *PTEN* inactivation in both serum and prostate tissue. Building predictive models for the discrimination between normal and aberrant *PTEN* status, the group could identify a serum signature of four proteins that could correctly predict 78% of cases belonging to patients having aberrant or normal PTEN status with a sensitivity of 79.2% and specificity of 76.7%, and distinguish between prostate cancer and BPH. When used together with PSA, the resulting sensitivity was 85% with a specificity of 79%. This suggests these biomarkers are potentially suited for screening tests by reducing false-positives and therefore avoiding anxiety and biopsies in men who have an elevated PSA, but not cancer.

With further biomarkers it was also possible to draw conclusions about the progression rate of the cancer and therefore the best treatment options from other patterns of markers.

Such biomarkers have an important role to play in the development of personalised medicine and the authors feel that this method of biomarker discovery will be equally successful applied to other types of tumours.

NEW

# Hitachi's all-in-one data management system

A mix of hardware, software and services, the *Hitachi Clinical Repository* (HCR) system draws together all patient data from many information sources, thus providing quicker and better use of records. As **Mark Clark** at Hitachi Data Systems, explained: 'HCR basically provides the infrastructure to put together both clinical and non-clinical data into a centralised, non-proprietary-repository to provide an overall and longitudinal view of the patient information'

Mark Clark

Today's problem is not lack of data but the lack of being able to use it meaningfully, i.e. bringing everything together and, more so, using the meta data that provides information about certain items such as size and dimension, modality used, publishing date, author etc. Such metadata are usually stored in a static, proprietary format that is inaccessible to other applications – and they therefore remain unutilised. Thus, creating a central, integrated metadata repository of patient data is integral to optimising the use of patient data. 'HCR is adding patient metadata to image and non-image data to restore the long-term value to this most critical class of data. It displays all relevant data in a single, longitudinal record – regardless of in which information system the data resides,' Mark Clark explained.

The system enables the user to start a query through all the available data in an easy, accessible format and access information quickly, despite the volume stored. Additionally, streaming makes the data distribution very efficient.

Hitachi Data Systems provides a complete data transformation service that captures appropriate data from the many information sources within an enterprise and then indexes that data along with its file system, application and customer metadata. The data is then made available to external sources through the platform's API architecture.

Business rules, privacy and security requirements, quality and audit assessments, governance and workflow processes can all be applied against the indexed data for further improvements to patient care.

Hitachi points out that additional HCR benefits are many, including:

- Indexing and sophisticated metadata analysis of more than 50 different document extensions and 400 multi-purpose internet mail extensions (MIME) types, their content and possible different levels of information, provides unprecedented interoperability.
- A significant reduction in waste, operational and maintenance costs, whilst improving access to data and increasing efficiency.
- Metadata indexing improves the organisation, accessibility, discoverability and long-term value of data.
- Physical adoption and utilisation of a single longitudinal patient record through EHR and portal solutions enables enterprise adoption and utilisation of EHR solutions.

'All data can be stored in the PACS, or directly from the modality into the repository,' Mark Clark pointed out, adding: 'It also can, of course, first be stored in the PACS for a certain time and then removed to HCR for long-term storage. This depends of a hospital's individual need.'

All in all, this all-in-one solution aims to improve the physician's access to patient information, ultimately to improve clinical decisions.

## The 9th International Med-e-Tel

6-8 APRIL 2011 MedeTel LUXEMBOURG BY ISFTEH

**Belgium** – The 3-day Med-e-Tel congress on e-Health, telemedicine and health ICT, drew over 300 international participants this April, when the organiser, International Society for Telemedicine & eHealth (ISfTeH) in Zurich, also held its annual general meeting.

The ISfTeH unites national organisations for telemedicine and eHealth, encouraging knowledge and experience exchange and promoting IT use in healthcare. The society also has good links with the WHO, International Telecommunication Union, and the EC. In all, 44 subject-specific partner organisations are associated.

- The congress programme provided technical and scientific lectures, contributions from medical practice and solution-orientated presentations from the IT industry. Discussions included:
- The state of telemonitoring, telecardiology and mobile health solutions
- The stage of development of telematics in nursing
- Healthcare providers as innovation drivers for better healthcare organisation
- Telemedicine as an aid in prevention

27 exhibitors from 12 countries showed products and gave the opportunity for an intensive exchange with specialist eHealth providers.

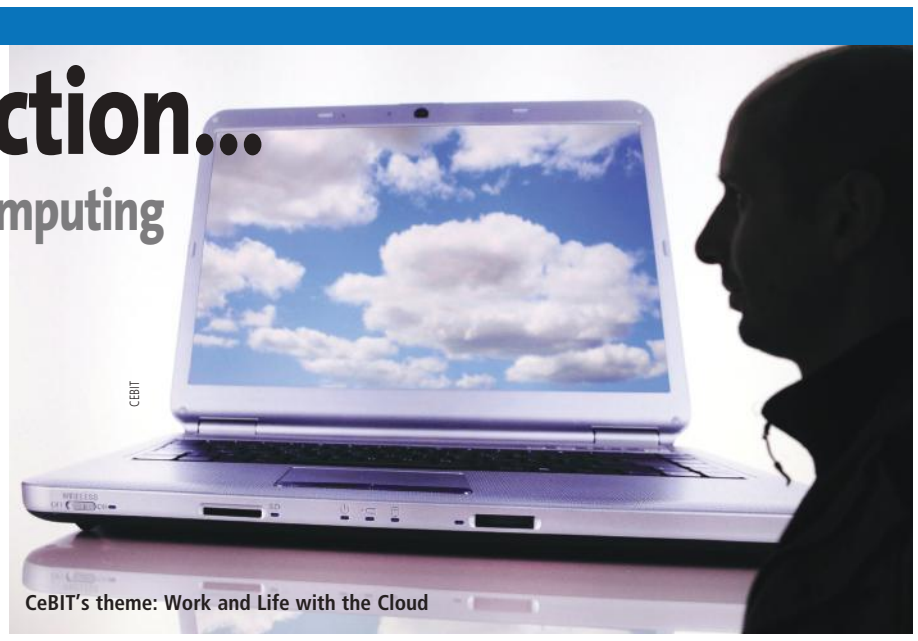
Med-e-Tel is recommended for healthcare experts wanting to look beyond the sometimes narrow, national view on telematics and eHealth topics. Make a date: 10th Med-e-Tel – April 2012.

*Details: www.medetel.eu and www.isft.net*

# Floating in *your* direction...

## Clouds lighten the horizon for hospital computing

**The new cloud hovering over the IT industry bodes pleasant and sunny business weather. Reason enough for the organisers of CeBIT 2011, the large international IT event held in Hanover, Germany, this March, to make 'cloud computing' the keynote theme, dubbed 'Work and Life with the Cloud'. *Walter F Schäfer* questions what cloud computing is and what promise it might hold for healthcare providers**



CeBIT's theme: Work and Life with the Cloud

The fluffy metaphor 'cloud' designates an indeed groundbreaking technological concept that begins with the assumption that the user should not have to store IT infrastructures and applications physically. Instead, server capacities, software solutions and entire system landscapes are made virtually accessible via the internet. The user decides, on a case by case basis, which services he or she needs.

How real is the virtual cloud?

In the beginning was the word – that is, the word of expert analysts. In 2013, according to the market research, analysis and consulting firm International Data Corporation (IDC),10% of the worldwide IT spend will go to cloud computing; for Germany that percentile threshold will be reached in 2015.

Currently, large companies and public bodies are considered the most likely users of cloud computing. Thus at CeBIT, most leading IT providers showcased pilot projects – attracting many visitors because the virtual cloud promises real technological change.

A special cloud computing exhibition, jointly organised by the German high-tech industry association BITKOM and the German Federal Ministry of Economics and Technology, demonstrated the new technology's trend status.

Large firms that require an extensive range of IT infrastructures and software packages look to cloud computing to facilitate sales and customer management, resource planning and content management.

What are its advantages? Cloud computing, which uses the potential of the internet, has resulted from the increasing number of applications and the trend towards mobile IT. Its core concept – virtual IT – does away with the physical availability of IT computing power, infrastructure, storage media and applications. Instead, a dynamic IT landscape is provided, which the user can enter as and when needed. This creates an entirely new – and for the user beneficial – cost structure. For the first time, longer-term IT costs can be calculated precisely on the basis of leasing contracts. Without hard- and software on site, costly maintenance also becomes history.

Is cloud computing already used in healthcare IT? According to analysts and IT experts, healthcare is an area that could profit from cloud computing. The fact that applications, computing power, storage capacities and network infrastructure are resources available on demand opens attractive financial perspectives. Healthcare facilities pay only for services they actually use. Overcapacities and related costs are no longer an issue – interesting for an industry under permanent cost pressures.

However, concrete applications are rare, since no one wants to be the first to step into any potential trap cloud computing might contain.

Many new technologies provoke many questions. The same holds true for cloud computing, as soon as this technology-based theory began to hit the hard ground of application-based reality. Currently, a host of promising industry initiatives and research projects are trying to answer those issues, knowing that cloud computing could only realise its potential when the ground is well prepared.

Above all the users, e.g. large firms and healthcare, need binding and reliable information before they can implement cloud computing – for example, regarding the legal framework and implications of the new technological approach, and to standards in terms of sensitive (patient) data.

Healthcare is a particularly demanding environment for cloud computing – and thus offers the opportunity to trigger the answers to crucial questions.



# TeraRecon's intuition Cloud enters Europe


Robert Taylor

**The global software provider TeraRecon is recognised for strong clinical applications containing advanced image processing and 3-D visualisation for CT, MRI and PET. Since May 2010, this Silicon Valley company (Frost & Sullivan's 2010 'Company of the Year Award' winner, for European Advanced Visualisation Applications) has been expanding its core business into cloud computing services via the internet. Just in time for the 23rd European Congress of Radiology in Vienna, the firm's *iNtuition CLOUD European Datacentre* in Frankfurt, Germany, went online. Over 600 users have already signed up for a free account. Reason enough for EH reporter *Karoline Laarmann* to meet with TeraRecon President and CEO Robert Taylor PhD, to unearth more information about the firm's commitment to web-based technology and its future application services**

'We don't sell prefab equipment boxes to our healthcare professionals customers,' emphasised Dr Robert Taylor. 'Cloud computing is just one of our solutions that broadens the radiologist's workplace outside the walls of a hospital. In addition, it is very flexible. If, for example, you are a very low volume customer, you can still access the full service, at the level that meets your needs. You can use it 10 times a month, or a year, and just pay for what you've used. By this means, you don't have to invest, for example, in setting up a prohibitive 3-D-deployment in your hospital. The other positive thing is that cloud computing relieves the burden on internal IT services. If the server is not in the hospital, the hospital IT department doesn't have to take care of it.'

***What decided you to bring this offering to Europe?***

'Firstly, it is because of the strong growth we have had and the future potential we anticipate in Europe. We witness a vibrant community of countries here, investing in healthcare technologies, in contrast to the US, which is currently in a kind of near-paralysis because of the complete review of its healthcare legislation and funding structure. In addition, we already offered cloud services to European users connected to data centres further away. So we wanted to improve their access to local support, ensuring them of optimal performance.

'Another idea behind this build-up is that, in contrast to traditional cloud models where there are usually many server rooms in different places, we decided that in the medical field it is of great importance to be point specific about where sensitive data is stored. Usually, the concept of cloud computing is that the company worries about the hardware and the customer only worries about having access to software through their web browser. When you buy a book at Amazon, you do not care where their server stands. But you do care, when it's about patient data. Our European data centre is located in Frankfurt's financial district, where it shares the same special security features as the resident banks.'

***Why is your cloud service free?***

'There is still a lot of uncertainty about web-based technologies and confidential data – *How does it work? Where is my data? What happens to it?* None of these questions have come into the picture before. To create awareness of its benefits we made access to the cloud hosting platform completely free for a limited time. That philosophy is quite uncommon in the medical industry because companies tend to sell everything under very strict controls and medical regulations sometimes necessitate that; but we are keen to try and create something different. When customers see the potential of cloud computing we can talk about how to make them feel comfortable about their concerns regarding the technology. So then the other side of the process starts. We are expecting to uncover problem areas in the next 12 months and work on the solutions with our customers, to a point in the future where cloud computing can probably be integrated into their clinical practice.'

***What is the potential of this technology?***

'There are two exciting aspects: First, this software is phenomenally useful for research. For example, if you run a clinical trial to test a drug, you typically define standard protocols for how to acquire the data and how it should be interpreted. Using our advanced visualisation tools and our cloud hosting platforms, we can bring the data to the cloud from all remote sites and converge all data results in one place that is fully accessible through the internet. The other thing is that the technology has tremendous value to improve the way physicians communicate. They could share references with each other and send patients to each other to be interpreted. So this is a very interesting model for a social network of individual physicians.'

*Link: To sign up for a free evaluation account, visit terarecon.com/cloud*

# Dell's Mobile Clinical Computing solution

## Initial results from a large European trial demonstrate values for clinical use in hospitals

**Preliminary results from a large, ongoing study involving medical staff in 11 hospitals in six European countries indicate that Dell's *Mobile Clinical Computing* (MCC) system has made the use of applications easier for doctors and nurses, significantly increased efficiency in IT management and raised IT acceptance in the hospitals involved. EH reporter *Walter F Schäfer* asked Hans Solgaard, EMEA Healthcare & Life Sciences Programme Manager at Dell, and Volker Welte, IT Architect at Systemtechnik SRH Dienstleistungen GmbH, about the study results and their implications**

'Dell, with Intel and partners involved in the MCC solution, commissioned a large-scale trial programme that enabled us to comprehensively assess the practical application of MCC in a clinical environment,' explained Hans Solgaard. 'Ignetica Ltd. was appointed to monitor the study as an independent entity, analyse the results and formulate conclusions resulting from the different sections of the project.'

The pilot projects began in October 2009, with the last concluded in August 2010. 'The MCC was carried out and overseen by Dell Services consultants in Belgium, Germany, England, France, the Netherlands and Spain, in a total of ten pilot hospitals,' he added.

### MCC features

The solution opens up new ways of accessing information systems and, along with optimised access to applications, it facilitates a seamless transfer of active sessions from one workstation to another – all within a secure environment. The user sessions are carried out on central servers instead of local PCs, so that they are made available on all machines that can be set up for MCC.

'With the help of this functionality, mobile users can access their systems and data via any MCC-compatible machine, without any problems, whilst non-mobile users can interrupt their sessions at jointly used PCs at any time, and later continue them simply by hitting a button or inserting a chip card. With the MCC solution, there is no need for the user to keep logging on – a function particularly helpful to hospital staff,' Hans Solgaard pointed out.

Asked why the SRH Kurpfalzkrankenhaus in Heidelberg participated in the Dell study, Volker Welte recounted: 'In the past we realised that the use of existing applications by doctors and nurses was impaired by time-consuming handling. As one of the pilot hospitals participating in the Mobile Clinical Computing study, we wanted to increase our chances of optimising our existing IT infrastructure and IT management and to improve the acceptance of IT solutions among our staff. We had experienced limitations in the use of the existing IT infrastructure in day-to-day hospital life. Either the PCs were being used by someone else or calling up required programmes took too long.'

'There were also complaints about the time it took to log on to the system. This led to a situation in which a lot of information was being written on paper, and only fed in to the system later, when the opportunity arose. This was a time consuming process.'

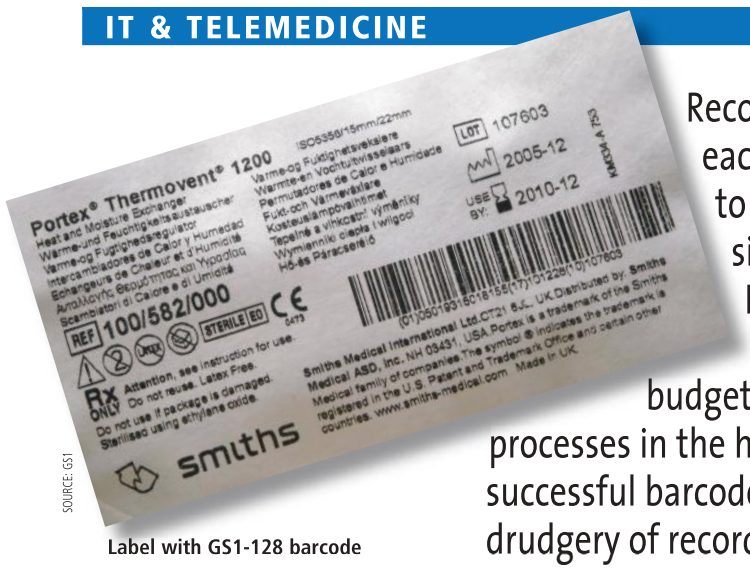
Five doctors and 30 nurses in the hospital's neurological department participated in the study. Using MCC, the convergence of all applications on one terminal server and the introduction of a fully virtualised environment resulted in faster, easier and more secure access to all the applications, Volker Welte pointed out. 'Using a smart card and card reader, each log-on becomes much faster. Doctors and nurses quickly get to where they need to be on the system without further ado, which has found a lot of favour among the staff.'

Speaking of other important advantages, he noted that the centralised installation of applications on a terminal server and the virtual MCC environment significantly simplifies the distribution and administration of tasks – and data security increases. 'Troubleshooting can be structurally improved,' he added, 'because we can now look into the actual error sources and don't just need to patch.'

Hans Solgaard

What conclusions has he drawn from the implementation of MCC? 'Through the standardisation of log-in procedures and the respective fast availability of data, doctors and nurses can save much time. The users are very pleased and acceptance of IT increases. As for those of us who work in IT, we've been able to prove that IT really exists for the benefit of the user.'

What are the future perspectives for the MCC Virtual Client Solution? 'We are very pleased with the positive MCC pilot project results in the participating hospitals and are now proceeding with a wider roll-out of MCC,' Hans Solgaard confirmed.



SOURCE: GS1

Label with GS1-128 barcode

Recording individual materials used for each patient is laborious but essential to meet health insurers' requirements since the introduction of Diagnosis Related Groups (DRGs), as well as for procurement, inventory and budgets control, planning and internal processes in the hospital. *Bettina Bartz* reports on a successful barcode system that has transformed the drudgery of recording materials usage at Heidelberg University Hospital

# Barcode system transforms nurses' workload

At Germany's Heidelberg University Hospital nurses manually listed all items used, from syringes to screws and so on – sometimes a defeating task that resulted in the hospital having no transparency for some costs. For repeat orders, patient labels were attached to internal order forms and forwarded to Purchasing, which initiated the order and posted it to the patient's case number. However, whenever a package contains a larger number of products than, say syringes and catheters, products are not labelled individually. The box label was then affixed to the order form, although all the contents had not been used for the patient. Additionally, several materials are used per patient and measure. This, she points out, can involve over 50 different products, e.g. during surgery.

To overcome problems with recording materials use, **Tobias Schneider**, in Heidelberg University Hospital's management department, introduced delivery barcode scanning of packaging, a system that has resulted in materials being recorded as soon as their use for a patient.

Initially, the hospital entered the material master data, including the unique GTIN (Global Trade Item Number), in the database of the merchandise management system, using SAP software (both the merchandise management system and the HIS are SAP modules). The staff records all activities for each patient in work lists. Medical products used for each measure can also be recorded by going from the measure in the work list to a materials list. When the barcode is scanned, the product is automatically included in the materials list, the system taking the data linked to the GTIN encrypted in the barcode from a database. With the material now listed, the next material can be scanned and recorded and so on, automatically recording products – according to Tobias Schneider, providing nurses with a truly user-friendly system.

He and his team went one step further. When scanning, they check the success of each individual material recording operation. Has all the material data been entered correctly? Are there problems with the vendor or supplier information? Is the GTIN contained in the material master data? Is the barcode clearly legible? What is the onsite staff doing while scanning? Thanks to a sophisticated fault management system he can answer all these questions. The system automatically stores every scan operation centrally. Using this database the management staff can evaluate the success of the scanning project and reduce the number of faulty scan operations.

In addition, nothing in the documentation is lost, because if no product information from the database is available when a barcode is scanned, the team can research that information and enter it retroactively.

Currently, 600 scan operations occur daily in various hospital wards, e.g. vascular surgery, endoscopy and urology. In the medium term that number is scheduled to rise to around 5,000 per day.

## Different barcode types

Another important need at the hospital for precise patient-related billing concerns product labelling. Around 90% of materials used have a barcode, and 75% of these are unique. Thus, at least three in four products can be recorded unambiguously by using the barcode. Most products have the EAN barcode from GS1. Others either have none or only an internal barcode, which enables no unique assignment. With these products a staff member must assign the correct information to each product. Despite a high level of automation, often this needs painstaking care.

However, from the users' experience, Tobias Schneider can say: 'Scanning is fast and efficient only when the barcode is located in the correct place, the packaging contains no more than one barcode, and ideally the product is labelled or even has a barcode directly on its individual packaging.' In this he shares the opinion of other hospitals – they have to rely on the vendors to decide which barcodes appear on the packaging and how. A number of hospitals have expressed their needs for product labelling to suppliers, at joint road show meetings in 2010, for example. There, the EK-UNICO and hospital purchasing syndicates organised within the German Association of Purchasing Institutions in the Healthcare Sector (BVBG), favoured medical products being identified unambiguously by means of GTIN at various packaging levels. In addition, packages should, as far as possible, only have one clearly legible EAN barcode and the master data for the products should be transferred electronically using GS1 standards.

A wide range of applications exist for the GS1 standards in hospitals. In addition to recording material usage for more efficient DRG calculation chosen by Heidelberg University Hospital, they can be employed, for example, to record patients more easily and manage their care more effectively. Further barcode information, e.g. batch number or serial number and expiry date, can be used to guarantee automatic control of expiry dates. Storage of the batch number or serial number is helpful for patient documentation, permitting the batch to be tracked and for possible call-backs. The data identifier system of the GS1-128 barcode and of the GS1 DataMatrix permits data such as batch number and expiry date to be read out unambiguously.

What is useful for hospitals should not be detrimental for vendors. They also profit from their products labelled with standardised barcodes. In addition to the classical EAN code, GS1 offers two further barcodes tailored to the special features of the healthcare sector: the GS1-128 barcode and the 2D code GS1 DataMatrix.

Users can encrypt master and movement data in the GS1-128 barcode. The GS1-128 symbols offer a high level of security and delimit the data contents presented there from non-standardised barcode applications.

The GS1 DataMatrix can encrypt a large amount of information in a very small space. The GTIN (Global Trade Item Number), for example, can fit on print areas of less than 25 sq. mm and consequently label very small products. Due to its technical configuration, the GS1 DataMatrix is suitable for direct labelling of components or, e.g. surgical instruments. Product authentication at various levels of the supply chain permits unambiguous traceability. Thus, product counterfeiting can be reduced and call-backs can be organised more efficiently and effectively.

The standards are developed by practitioners from pharmaceutical and medical devices firms and hospitals in regular ideas exchanges at an international level.

## Little effort, great benefit

At Heidelberg University Hospital the effort and costs of setting up automatic materials recording were kept within limits. On top of existing IT systems, the hospital purchased one or two computers and new camera scanners that are USB-capable and compatible with every computer. The data processing is designed so that processes can be freely selected by users, who can decide whether they scan a material immediately on use, or later. Every sector – e.g. care or the OP area – can decide according to needs.

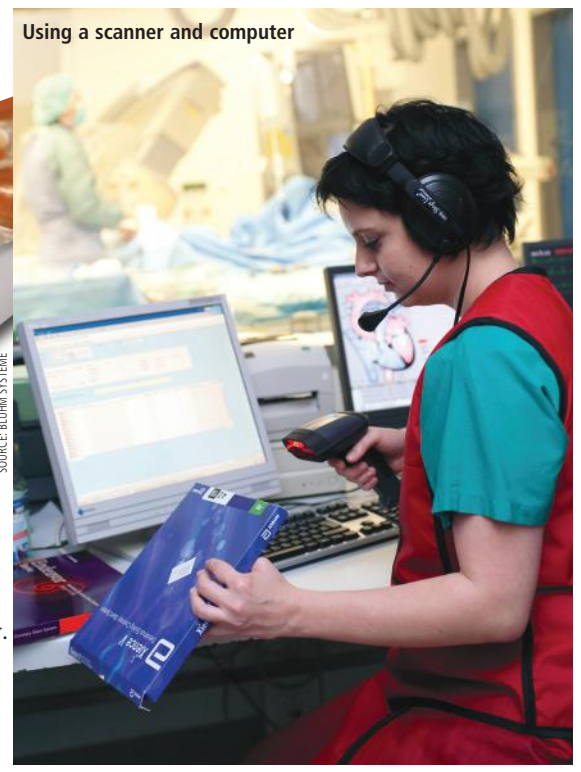
Initially sceptical, ward staff is now thrilled by the speed and potential of scanning. Despite at first involving more effort because all materials used for a patient are recorded in this way, they are now also intrigued by additional options. The new transparency makes transactions such as orders and budget management easier for the nurses. Hospital management profits from the precise overview of materials consumed, not only in billing health insurers, budget control and procurement, but also in having more leeway in negotiations with health insurers.

Other hospitals have already looked into barcode scanning and tested it in practice. EAN barcodes applied by the vendor achieved time savings of up to 86% for patient-related consumption recording at the Heart Centre Bad Krozingen. In a project in the logistics and document centre at the St.-Marien-Hospital in Bonn, for example, scanning materials enabled a total saving of 472 working hours when extrapolated over the year.

'Although as yet we can't put a figure on the money and time saved by scanning, we feel the benefits every day in our procedures, and this despite a quarter of our materials not yet adequately labelled,' Tobias Schneider pointed out. 'Therefore, one further important aim is to work with our suppliers to achieve optimum product labelling.'


SOURCE: BLUHM SYSTEME

Drugs package with GS1 DataMatrix


SOURCE: HEIDELBERG UNIVERSITY HOSPITAL

Using a scanner and computer

**EUROPEAN HOSPITAL**

EUROPEAN HOSPITAL Publisher,
Theodor-Althoff-Str. 45,
45133 Essen, Germany
Phone: +49 (0)201 87 126 850
Fax: +49 (0)201 87 126 864
E-mail: info@european-hospital.com

**www.european-hospital.com**

**Editor-in-Chief** Brenda Marsh
**Art Director** Mary Pargeter
**Managing Editor** Meike Lerner
**Editor** Karoline Laarmann
**Production & Distribution** Janka Hoppe
**Russian Supplement** Sergey Bezrukov, Fibrotex GmbH, Fischerstr. 1, 40477 Düsseldorf Phone: +49 211 550 49 70, E-mail: fibrotex@gmx.net
**Executive Director** Daniela Zimmermann
**Founded by** Heinz-Jürgen Witzke

**Correspondents**
**Austria:** Michael Kraßnitzer, Christian Pruszinsky.
**France:** John Brosky, Annick Chapoy, Jane MacDougall.
**Germany:** Anja Behringer, Annette Bus, Bettina Döbereiner, Karl Eberius, Guido Gebhardt, Walter Schäfer, Holger Zorn.
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**Russia:** Olga Ostrovskaya.
**Spain:** Eduardo de la Sota.
**Switzerland:** Barbara Steinberg, Dr. André Weissen.
**USA:** Kerry Heacox, i.t. Communications.

**UK editorial address**
55 Wey Meadows, Weybridge, Surrey KT13 8XY

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

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**Representatives**
**China & Hongkong:** Gavin Hua, Sun China Media Co., Ltd, Room 802, 15th Building, BinJiang Residential Quarter, Dongyuan Road, Futian District, Shenzhen, Guangdong, China, Code: 518031
Phone: +86-0755-81 324 036
E-mail: gh@european-hospital.com

**France, Italy, Spain:** Eric Jund, 2264 Chemin de Sainte Colombe, 06140 Vence, France
Phone: +33 493 58 77 43
E-mail: ejund@b2bportales.com

**GB, Scandinavia, BeNeLux, France:** Simon Kramer, Willem Alexander Plantsoen 25, 2991 NA Barendrecht
Phone:/Fax +31 180 6200 20
E-mail: sk@european-hospital.com

**Israel:** Hannah Wizer, International Media Dep. of El-Ron Adv. & PR Co., Ltd., 7, Leteris street, Tel-Aviv 64166, Israel
Phone: +972-3-6 955 367
E-mail: hw@european-hospital.com

**South Korea:** CH Park, Far East Marketing Inc, Room 103-1011, Brown Stone, 1330, Baekseok-dong, Ilsan-ku, Goyang-si, Gyunggi-do, Korea 410-360
Phone: +82 2 730 1234
E-mail: ch@european-hospital.com

**USA & Canada:** Hanna Politis, Media International, 8508 Plum Creek Drive, Gaitherburg, MD 20882, USA
Phone: +1 301 86 96 610
E-mail: hp@european-hospital.com