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Epigenetic drugs: Correcting Nature's mistakes

France: Transplant surgeons perform outstanding feats

Simultaneous surgical successes open new perspectives for multiple transplants

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Born in 1957 in Taher, Algeria, Professor Karim Boudjema heads hepatic surgery in Rennes University Hospital CHU, in western France.

He trained at the Strasbourg CHU, internationally renowned for its Research Institute for Digestive System Cancers (IRCAD) founded by Professor Jacques Marescaux.

In 2007, Prof. Boudjema participated in a three organs transplant (heart, lung, liver) for a young girl suffering cystic fibrosis.

He is the only surgeon in France able to conduct ex vivo transplant surgery, which is one of his team's specialities. Another, more common procedure, is the auxiliary liver transplant, in which half a healthy liver is transplanted onto a damaged liver area. After a few months, the damaged area becomes healthy and the organ rebuilds itself. This procedure, a world's first, was conducted a few years ago.

Report: Annick Chapoy

Three exceptional transplant procedures successfully occurred in France within one month as 2012 neared its end. Two were on cancer patients; the third involved the simultaneous transplant of five organs of the digestive system.

At the CHU (University hospital) or Rennes (western France) the head of the biliary-hepatology department Professor Karim Boudjema performed ex vivo surgery on a 64-year-old woman suffering liver cancer. The tumour being quite large (60% of the liver), the liver had to be removed from the abdominal cavity, refrigerated and placed under extra-corporeal blood circulation. First, the damaged organ had to be removed, with a sectioning of arteries and veins while the patient was connected to a blood circulation device outside her body. Then the work was centred outside the body and the cancerous area of the organ was removed. Finally, the organ could be re-transplanted.

The whole procedure took around 11 hours, involving 15 members of staff.

This was the fifth surgery of its kind in 10 years in France. Compared to some 3,000 'classical' liver cancer operations conducted in vivo, inside the body. 'In France we are the only ones able to do it because our centre has both surgery and liver transplant specialists,' Prof. Boudjema explained, adding that this type of surgery has been performed once in the United Kingdom and once in the USA.

The ex vivo technique is necessary when the tumour has invaded the arteries and the veins, which must be reconstructed, and when more time and accessibility to the damaged organ is necessary. The liver has to be extracted and refrigerated and maintained at a temperature of 4°C, to avoid asphyxia during this lengthy procedure. 'It would have been impossible to do that job, which took two and a half hours, inside the body', the professor explained.

Coincidentally, another exceptional surgical procedure took place at the same time in a public hospital

Continued on page 2

Rogue Dutch doctor prompts calls for EU early warning system

When physicians lose their licence to practice in their homeland, the EC warns that Member States should exchange that information faster and more reliably

Report: Susanne Werner

There are too many loopholes that allow bad or fraudulent physicians to beat the system. How else can doctors move from hospital to hospital throughout Europe despite their pending law suits? Only a few weeks ago a particularly crass case made the headlines: A hospital in southern Germany dismissed a Dutch neurologist without notice when it transpired that in the Netherlands the physician is facing major medical malpractice charges.

The EU Commission is working at full stretch to review the EU Directive on the recognition of professional qualifications and aims to accelerate and improve Europe-wide information exchange as soon as a physician loses his license in his home country.

Free movement of labour in the EU is not without problems: physi-

Continued on page 3

CONTENTS

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EH 6/12

Spain – France

The Cerdanya Cross-Border Hospital

Report: Dr Eduardo de la Sota

In response to the need for quality health services as well as urban development, the European Commission has supported a project to build a cross-border hospital in North Catalonia. The ERDF (development fund) contribution amounts to €18.6 million – 60% of the total cost of €31 million.

Given that this is considered a priority, the project is currently progressing despite Spanish healthcare's economic shortcuts. The new Hospital is planned to begin functioning by mid-2013.

Cerdanya's Cross-border Hospital is pioneering as Europe's first health centre to provide care for populations on both sides of a border, i.e. it will serve both the Catalan and French sides of the regions of Cerdanya and Capcir (France). The centre will significantly improve healthcare provision in this border area, which, due to its mountainous location, suffers accessibility problems. The hospital will care for a permanent population of 30,000, as well as influxes of over 100,000 more during holiday seasons. Until now, residents of Cerdanya and Capcir had no facility for acute or surgical care within their territory. Nor did they have access to obstetric care. These issues will be resolved when the 68-bed hospital opens.

Basically, the project aims to

- improve access to healthcare for people in Cerdanya and Capcir, by removing barriers

Victoriá Peralta, Cerdanya Hospital

- jointly set up a cross-border organisation to construct and manage the complex, which is designed to provide acute care to short stay patients
- integrate the two regiona healthcare systems
- establish a hospital that makes setting up a cross-border health network possible;
- ensure a special governance and management structure that respects the identity characteristics of both sides of the border
- integrate the project in the Euro-region and take account of future European issues, such as the ageing population and ageing healthcare workers, notably attracting and retaining the latter.

Project background

In 2001, the Pobres de Puigcerdà Hospital Private Foundation (FHP) and Perpignan Hospital Centre reached an emergency service and training agreement to accept French patients sent for emergency care from the Perpignan Hospital Centre.

In 2003 a key step was to launch a feasibility study for the creation of a joint cross-border hospital within the framework of the Euro-region (Agreement Protocol between the Catalan government and the Regional Council of Languedoc-Roussillon signed in January in Perpignan) and included in the European project INTERREG III.

2004 and 2005 were devoted to technical Committee meetings. A key advance was the Constitution of the Cerdanya Cross-Border Hospital Private Foundation (July 2006). The Cerdanya Cross-Border Hospital Private Foundation is responsible for sponsoring, monitoring and promoting the project.

Challenges

The aging population, lack of professionals, financial management, harmonisation of policies of the different administrations, coordinating the different countries and parties involved, ensuring that the project's ideological strength takes precedence over political agendas and, finally, ensuring that the true beneficiaries of this project, i.e. the general population and healthcare professionals, embrace the project, are all difficulties to be faced.

Current situation

Dr Victoriá Peralta, Director-designate of the Cerdanya Hospital, predicts that it will begin functioning by mid-2013. An ambulatory centre has already opened, thus advancing the Cerdanya region's healthcare network.

France: Transplant surgeons perform outstanding feats

Continued from page 1

in Marseille, South of France, on a woman patient with bone cancer (sarcoma) localised in the hip, which was reconstructed using part of the patient's thigh bone. 'Only a handful of such procedures have been performed in the world', the hospital management stated.

It was the only solution available for this patient to eradicate the cancerous lesion. 'The success of the procedure proves that it's possible, in certain cases, to treat patients efficiently who up to now could only be offered palliative treatment', and '…at this point, the patient who is in her fifties, shows no complication', the head of AP-HM (Assistance Publique-Hopitaux de Marseille) announced.

The surgery lasted for more than 12 hours. Initially, it was necessary to remove more than 50% of the pelvic bone and retrieve a part of the thighbone. Then the missing part of the pelvic bone was reconstructed, using the removed thighbone section and a prosthesis. The nerves and vessels could all be preserved.

Meanwhile, in mid-December in Paris, surgical teams at the Beaujon (AP-HP) public hospital successfully managed a very rare simultaneous transplant of five organs, on a 26-year-old patient suffering muscular dystrophy of the alimentary canal. The teams of Professor Jacques Belghiti and Professor Yves Panis managed simultaneously to transplant the liver, pancreas, stomach, duodenum and small intestine.

During that highly complex operation, four surgeons, four anaesthetists and one intensivist, took turns in the operating theatre over a period of 12 hours. All the digestive medicine departments also participated in the surgical feat.

The young man was suffering from a rare congenital disease identified when he was eight years old, which led to a damage of alimentary canal muscles preventing him from feeding himself normally. Helped by his family, he had survived up to now through parenteral nutrition, but for some time that feeding had become impossible due to a thrombosis of the venous axis. To overcome such a major obstacle, radiologists in Prof. Vilgrain's department and anaesthetists and intensivists in Prof. Paugam's department, installed a catheter directly into the vena cava inferior, to enable an intestinal transplant that had become of vital importance. To allow oral alimentation, this transplant case had to include the stomach and duodenum. Since there was hepatic damage because of long-term parenteral feeding, a concomitant liver transplant appeared preferable. Considering the multiplicity of transplants, the surgical team made the decision to conduct a single joint operation of the whole alimentary canal.

Multiple organs removed and replaced

The operation meant a removal of stomach, the duodenal pancreatic block, liver and small intestine, while leaving the spleen to improve the immunological tolerance of a transplant carrying high risks of rejection.

The organ retrievals were carried out by the Beaujon surgeons from a brain dead person more than 400 kilometres away. The organs were then transported to Paris in less than three hours and the length of the cold ischaemia was four and a half hours.

The transplant process began with the liver in the usual manner and the revascularisation of the alimentary canal and pancreas. The continuity of digestive function was provided through an anastomosis with the stomach, the extremity of the small intestine being put in ostomy, for a length of more than four metres.

The patient recovered well from the surgery and parenteral feeding could be resumed after 48 hours. Soon afterwards, he wished to be fed orally.

The success of such an operation opens new perspectives in the field of multiple transplants in adult patients, according to Mrs Mireille Faugère, AP-HP general manager, who congratulated all the medical teams over their spectacular feat.

The nose knows

Dutch dog demonstrates his talent for sniffing out C. difficile

Cliff, a two-year-old beagle, has recently demonstrated his talent for detecting Clostridium difficile according to doctors at the Vrije University Medical Centre (VUMC) in Amsterdam. 'A dog's nose is 300 times more sensitive than a human's, and in the case of well-trained dogs their sense of smell can be 500-600 times better than a human's', explains Hotsche Luik, professional dog trainer at the Scent Detection Research Academy in Amsterdam. 'The dogs use their noses in the same way that we humans use our eyes.' This ability benefits patients in the Amsterdam hospital as Cliff sniffs for C. difficle during regular ward rounds with his trainer Hotsche. Patients' stool samples are not needed. The dog can identify an infected person from a distance, even if they are lying under a duvet.

Cliff's biggest advantage is his speed. Whilst a result from a stool sample taken to detect the pathogen takes more than three days, the dog can detect an infected person shortly after entering a patient's room. Thus, by isolating an infected patient earlier, valuable time can be saved in the avoidance of infection transfer from human to human.

C. difficile does not usually present a danger for healthy people. However if, for instance, antibiotics affect the healthy gut flora, bacteria can spread undisturbed. Older patients in particular can then develop symptoms such as fever, nausea and diarrhoea, the latter being very hard to distinguish from ordinary diarrhoea, although one distinctive feature is the smell associated with C. difficile.

Cliff was prepared for his new task through conditioning. Based purely on the smell of the bacterium, perhaps picked up in the air from a wooden stick, some fabric, or even if it had been sealed in a plastic container, out in the woods Cliff showed his strengths. 'After two months, we tested his sense of smell based on 50 positive and 50 negative stool samples. He detected all positive samples and 47 out of 50 negative samples accurately. The sensitivity was therefore 100%, which makes it much higher than that of laboratory tests,' said Dr Marije Bomers, infection specialist at the VUMC and head of the study, which was published in the British Medical Journal*.

Cliff also achieved comparatively good results during his first ward rounds six months later. He detected 25 out of 30 infected patients and correctly identified 265 out of 270 negative control subjects.

'The idea,' said Dr Bomers, 'holds great potential, but more research has to be done first to see whether this concept actually works.'

For now, there is hope is that conditioning dogs like Cliff might prove to be an effective and cost efficient screening procedure for C. difficile. in hospitals, with the added positive psychological effect that the presence of animals has been shown to have on in-patients.

* http://www.bmj.com/content/345/bmj.e7396

Russian cancer research team gains international funding

Report: Olga Ostrovskaya

The international research project 'The Definition of new types of tumours containing potential mutations sensitivity to drugs' has begun in Petrov Research Institute of Oncology in St Petersburg, the oldest Russian oncology institute. The project, funded by the international biopharmaceutical company AstraZeneca Pharmaceuticals, is Russia's first experience of this kind of cooperation in fundamental science between a pharmaceutical company and a scientific research institute.

The main aim of the project is to search for new 'targets' for effective chemotherapy, under lead researcher Professor Evgenij Imjanitov, Head of the institute's Tumour Growth Biology Department. The biopharmaceutical company has allocated about $500,000 and the Research Institute of Oncology has donated Europe's largest collection of tumours (about 1million samples). Researchers have to choose the most common types of malignant formations (about 28 tumours) and examine them for the presence of gene mutation targets.

The diagnostic value of genetic damage in tumours has become obvious to scientists only in this century. The most striking example is the detection of mutations in the epidermal growth factor receptor: tumour cells, which have the mutation, have a unique sensitivity to target drugs.

'Unfortunately,' the professor observes, 'mutations of the gene of epidermal growth factor receptor were so far found only in lung cancer, and systematic studies of other tumours have not been carried out yet. Besides, there are about 60 genes similar in its structure in the group, and they may also get mutations, which are the potential targets for therapy. Finally, researchers should remember that the spectrum of mutations in different countries has regional characteristics: patients are unlike the gene pool, and therefore the search for targets is relevant to each individual country.

Evgeny N Imyanitov heads the Tumour Growth Biology Department at N.N. Petrov Institute of Oncology; the Medical Genetics Department at St Petersburg Paediatric Medical Academy, and Professor at the Oncology Department, Medical Academy for Postgraduate Studies. He graduated from I.P. Pavlov Medical School in 1989, gained his PhD from N.N. Petrov Institute of Oncology in 1992, and the IARC Fellowship for post-doctoral training in the Max Planck Institute of Biochemistry in Munich. In 1996 he established his research group at the St Petersburg institute to focus on translational aspects of cancer science – making a substantial contribution in hereditary cancer syndromes. His team also studies basic aspects of cancer pathogenesis (investigations of molecular features of bilateral breast cancer).

Rogue Dutch doctor prompts calls for EU early warning system

Continued from page 1

cians – just like members of any other profession – can work in any EU country. However, the supervision and administration infrastructures are not prepared to deal with professional mobility, not on the national and much less on the European level.

In the case at hand the physician had met all formal requirements to work as a locum doctor in Germany: he had a valid medical license as well as a specialist physician license issued by a competent body in North-Rhine Westphalia.

Equipped with these documents he freelanced at several hospitals in different German States. Nobody knew, or suspected, that he was facing charges in the Netherlands. Even when, in 2011, he had to return his license in the Netherlands, his then-employer only checked whether the submitted documents were indeed valid. No information on the pending law suit ever made it across the border.

Meanwhile, in the Netherlands, the case received high publicity. Dutch media called the 67-year-old neurologist 'Dr Frankenstein'. The police investigation file lists concrete evidence of offences: between 1998 an 2003, as a hospital physician in the Dutch town of Enschede, the accused allegedly misdiagnosed almost 200 patients as having Alzheimer's or Parkinson's diseases, or multiple sclerosis, and prescribed strong medication. Nine patients died and thirteen underwent brain surgery based on the misdiagnoses.

Heinz Kölking

Nicolai Schäfer

In Amsterdam the case triggered one of the largest medical law suits in the Netherlands, which commenced in November 2012.

When Dutch journalists discovered the physician in the southern German town of Heilbronn neither authorities nor the hospital management were aware of the charges. The hospital immediately ordered a review of 443 patient records and, in early February 2012, external experts concluded that no German patients were harmed by the Dutch physician's actions.

Shortage of physicians puts hospitals under pressure

Has Germany's shortage of physicians reached a point where hospitals are quick to hire foreign locum doctors without thoroughly screening the applicants? About every second hospital there needs 'itinerant physicians', who work on a freelance basis for a few weeks or months.

What needs to be done at the European level to sufficiently protect patients? The case of the Dutch physician in a German hospital sounded the alarm bells in Brussels. Claudia Guske, Press and Media Officer at the EU Commission, says Directive 2005/36/EC on the recognition of professional qualifications will be amended to include an 'early warning system'. The newly introduced article 56a requires the competent authorities in a Member State to inform all other Member States as well as the Commission when the license of a physician, a specialist physician or any other member of a healthcare profession is revoked.

The notice is supposed to be disseminated within three days, confirms the office of Dr Peter Liese MEP. Experts welcome this initiative as an important first step to increase patient safety in Europe. Professor Frank Ulrich Montgomery, head of German Medical Association, is happy to hear that, in future, the Member States can proactively warn one another. Hans-Joachim Freese, Media Officer of the Marburger Bund, the German association of hospital doctors, calls the introduction of such an early warning system a 'vital step'.

Germany's federal structure – another obstacle

As far as Germany is concerned, the government needs to review the country's federal structure to ensure that notifications reach the competent authority. Nicolai Schäfer, Director of the Bundesverband deutscher Honorarärzte (German association of locum doctors), points out major gaps in the fragmented administrative structure in Germany. 'The German physicians' associations at State level, which were founded in the last century, are not prepared to handle the phenomenon of locum physicians,' he said, adding: 'The recent events involving the Dutch physician are shocking but they are in no way related to locum doctors as such.'

Indeed, the Dutch neurologist remained undetected because he did not register with the competent physicians' association in the State of Baden-Württemberg. The president of that body, Dr Ulrich Clever, now urges hospitals to require their applicants to submit a current registration certificate of the competent physicians' association. But what can a piece of paper prove? Definitely not the quality of a physician.

Hospitals need to screen applicants more thoroughly

Heinz Kölking, president of the European Association of Hospital Managers (EAHM), passes the ball to the hospital managers. They, Kölking stresses, need to screen their staff with utmost care taking into account professional qualification, experience and social skills – no matter whether the physicians apply for a permanent or a temporary position and whether they are from Germany or abroad. The EAHM President recommends that the hospitals 'develop and implement standardised procedures with defined criteria and steps.' The criteria must be designed in a way that formal qualifications of a foreign applicant can be evaluated. 'But we lack information,' Heinz Kölking concedes. He plans to put the issue on the agenda of his association.

Nicolai Schäfer, who represents the locum doctors, goes even further. His organisation suggests the introduction of a certificate for locum doctors where, in the certification process, documents as well as references will be reviewed and supplemented by an Internet search. He hopes that such a certificate will help hospitals to screen their applicants better.

Germany's White List

A large survey for leading German health insurers has resulted in a hospital evaluation portal that enables patients to compare and choose a doctor and treatment or care centre very quickly

Report: Dr Jörg Raach

Thanks to compulsory health insurance in Germany no citizen is without insurance cover. A mere eleven percent of the population are privately insured. Nevertheless, over the past decade the number of statutory health insurers has decreased significantly, mostly by way of mergers and acquisitions, and politically desired.

Today, large and powerful insurance companies shape German healthcare. Several of these major insurers commissioned repeat surveys of their members to get a clearer picture of customer satisfaction with the medical services provided – and to distinguish themselves from the competition. Between November 2011 and October 2012, two big players, AOK and Barmer GEK, surveyed about one million patients right after their hospital stay; 450,000 insured responded. The scientifically designed short questionnaire contained 15 questions regarding satisfaction with medical and care services and with the organisation of the hospital. Finally, the patients were asked whether they would recommend the facility.

The results were integrated into the so-called 'Weisse Liste' (White List), an online portal created in 2008 by the not-for-profit and privately funded Bertelsmann Foundation and the umbrella associations of all major patient and consumer organisations. This portal allows patients in Germany to compare healthcare institutions and supports their search for a suitable hospital, physician or care facility.

Announcing survey results in Berlin

Survey results

In general, the patients were satisfied with the care they received: 82 percent of the surveyed would recommend their hospital; 83 percent were satisfied with the medical care and 82 percent were satisfied with the nursing care. At 79 percent, the satisfaction with hospital organisation and service was slightly lower. However, patients did notice significant differences between hospitals. 'Two thirds of the facilities mentioned by the patients receive a positive rating of 80+ percent. The rest is lagging. 2.4 percent were rated below 70 percent, meaning they are recommended much less', Jürgen Graalmann, Chairman of the Board of AOK Bundesverband explained, summing up the results when the survey was presented at a Berlin press conference. He also pointed out that younger patients tend to be more critical than older ones: while about 84 percent of the 60-80-year-old patients were prepared to recommend their institution, among the 20-40-year-olds the rate was only 75 percent.

No 'soft' data

The significance of patient experience is confirmed by a study headed by Felix Greaves, whose results were published in the February 2012 issue of 'Archives for Internal Medicine' *(Associations Between Web-Based Patient Ratings and Objective Measures of Hospital Quality)*. 'According to this study the patient evaluations of British hospitals correspond to a large extent with objective quality assurance results. For example, patients' perception of a hospital's cleanliness and the rate of infections with dangerous pathogens in this hospital, correlate.

Thus, the argument that data derived from scientifically sound patient experience surveys are merely 'soft' data is clearly debunked,' Gerd Billen, head of the umbrella association of the consumer protection organisations, said at the conference.

Online portals drive quality improvements

Patient evaluations are not only integrated into the hospital portal 'Weisse Liste' they are also an important feature of the websites maintained by the participating health insurers. A consumer-oriented glossary with 5,000 healthcare terms was created and today complements the information on the hospitals' service portfolio and quality *(www.aok.de/krankenhausnavigator, www.krankenhausnavi.barmer-gek.de)*.

German hospitals are required by law to report quality assurance data covering services areas and quality indicators with the aim to offer a transparent view of the quality of care. Service areas are, for example, breast cancer surgery and cardiac catheter interventions; quality indicators encompass inter alia the frequency of complications or the scanning time in X-ray imaging.

These data provide an important foundation for the hospitals' internal quality assurance and are complemented by quality assurance data developed by the AOK scientific institute. Thus information on severe and high risk pathologies with a high prevalence is routinely available; it includes data on the treatment procedures used and on standardised 30 days, 90 days and one year mortality rates, no matter whether the patient died in the hospital where he or she received initial treatment, in a different hospital or after discharge.

The data show which surgical interventions resulted in severe complications during standardised intervals or where repeat interventions were required, even when the follow-up is performed in a different hospital than that were the initial intervention was performed. Since the health insurers collect these data routinely no additional administrative effort is required. Thus the quality of medical services is quantifiable and made transparent on the AOK hospital portal: tree symbols indicate the quality of outcomes.

'When surgery is required and can be scheduled the patient and referring physician should chose a quality-tested hospital,' recommends Jürgen Graalmann, Chairman of the Board of AOK Bundesverband, underlining that the evaluation portals by the health insurers offer an important and easy to use decision-making tool.

The key to cost cutting: Stepping in where competitive markets don't deliver

Transparency and benchmarking

Interview: Michael Reiter

Premier is a provider-owned performance improvement alliance of 2,700 hospitals and 90,000-plus non-acute care providers. Late last year, at the German Hospital Procurement Congress (Beschaffungskongress) in Berlin, we met with Durral R Gilbert, President of the US firm Premier Supply Chain Services, who was presenting cost-cutting strategies that reach far beyond reducing consumables and equipment prices – strategies that might also help hospitals in Europe.

'Lending has loosened a bit in the US over the past year, after a very difficult situation in the preceding two years,' Durral Gilbert observed, when asked about the US hospital financing situation. 'However, debts have to be serviced, which is where the issue of liquidity comes in. In the context of reimbursement cuts, American hospitals face the challenge of cutting cost and optimising profitability and cash flow.

How is Premier's alliance positioned to help hospitals and health systems?

Gilbert: 'At Premier, we understand that the issue reaches well beyond procurement. We focus on two major concerns. One is driving out unnecessary cost; this is not just about supply chain cost, but includes eliminating any unnecessary waste, inefficiencies and human capital costs, such as benefits. The second focus is on increasing quality of care. For a long time, the belief was that achievements such as reducing length of stay, minimising complications and hospital-acquired infections, as well as improving mortality rates, were impossible in the context of cost savings. Premier and our alliance of hospitals have demonstrated, at a national level, that improved quality can indeed help cut cost by, for example, reducing readmissions.

How was this has achieved?

'Transparency is a core aspect in this context. It requires being able to compare one's financial and clinical performance to that of peers – hospitals that are similar or which are located in the same region, to identify influences by geography.

'Reducing supply chain cost is another key aspect. Direct sourcing helps cut excessive cost by taking links out of the supply chain. For example, in lieu of specifications that manufacturers come up with, we have clinicians in our member hospitals who define specifications exactly for the gloves, isolation gowns, etcetera, that they require. Premier then sources products that meet the demand of the hospitals. We cut out the intermediaries that add unnecessary cost to the supply chain.

'Savings can exceed 30 to 40 percent on commodity items. You'd think margins would have already been whittled out for those kinds of products, but this has not been the case. We provide transparency regarding real cost of products and of getting them to each hospital.'

Asked for more information about Premier's benchmarking strategy, he said, 'Selected member hospitals provide us with blinded patient-level data. We are able to capture information on length of stay for specific ICD-9 and DRG codes, with and without complications. We benchmark this information across hospitals. In combination with the cost on the supply side, we can look at the total cost of a procedure.

'Over-utilisation of imaging, for example, is a big cost driver, as are lab analyses and pharmaceuticals. Information on utilisation of all these products helps hospitals figure out where they stand and what potentials for reductions in consumption are.

What is the influence of differing payment models?

'There may be a great diversity of payers in the US – national and regional payers, federal payers, and private pay – but there is a noticeable trend towards standardisation of models in the context of reform. Premier is involved with the evolving accountable care delivery models, which will also drive change.

Why does the USA pay a higher price for equipment than Europeans?

'For one, there is a deeply ingrained system of reps over here, who all take their margins, and there is an added cost associated with increased advertising addressing end customers – the consumers.

'The standard of living is higher in many regions of our country, and device manufacturers have seemed to feel that US care providers can afford to pay higher prices. Things may be changing. While broadening patient coverage, the Affordable Care Act is putting cost pressure on providers and manufacturers. But whereas providers have endured billions in reimbursement cuts and more, some manufacturers are attempting to pass on the newly introduced medical device tax – a Federal Excise tax addressing classes II and III devices, as well as pharmaceuticals – to hospitals.

'Premier has been a leader throughout the design and implementation of this tax in working aggressively to protect our members from having this tax passed on to them. This tax is the responsibility of the manufacturers. 'Healthcare reform rests on the principle of shared sacrifice - hospitals are not responsible for absorbing this tax, simple and plain.'

Can Americans learn from Europe and/or vice versa?

'Innovation in care will be required regardless, and the US may be a leader in that respect, which in turn may drive costs up. However, players on both sides can learn about the values of a free market. Premier strongly believes in a highly competitive market for goods and services in the healthcare segment; in niches where we perceive excess margins that are not eliminated by the market, we'll go in and eliminate those excess margins through direct sourcing – stoking the fire of competitiveness. 'There are some very good models in Europe for patient care, reimbursement and for patient empowerment. In the US, not many citizens own their health yet, while in Europe many will bike to pursue a healthy diet. Improvements in lifestyle could help prevent disease – it will be exciting to see how the US and Europe will learn from each other's models.


Photograph: MR

Speaking at the German Procurement Congress late 2012 – **Durral R Gilbert** President of supply chain services with Premier, a USA-based provider-owned performance improvement alliance of 2,700 hospitals and 90,000-plus non-acute care sites. A graduate from the University of North Carolina at Chapel Hill, where he was inducted into the prestigious Order of the Golden Fleece, and Duke University's Fuqua School of Business, where was selected for the distinction of Executive Fellow, his present role involves overseeing the company's core supply chain operations, as well as Premier's emerging services businesses of specialty pharmacy, pharmacy benefit management, and direct sourcing.

Ambulatory surgery

A leading expert reveals ways for hospitals to tackle more out-patient procedures

Report: Bettina Döbereiner

Massive and increasing cost pressure urges many hospitals to look for alternatives to expensive in-patient surgery. Ambulatory (or out- or day-patient) surgery centres associated with the hospital may be an option because these spin-offs promise significant savings in terms of beds, staff and valuable operating theatre time. Professor Michael Möllmann of St. Franziskus Hospital in Münster, Germany, is a renowned expert on the future-oriented design and operation of ambulatory surgery centres.

'A hospital looking to offer day surgery services should consider a separate and lean organisation, which requires less staff that can be efficiently deployed,' he points out, adding that, ideally the day surgery centre is a purpose-built, single-storey construction that is physically attached to the hospital. He recommends a circular or semi-circular building where a minimum number of staff can cover a maximum number of tasks and where the waiting, preparation, examination and recovery areas can be monitored from the centrally located admission area.

No matter what building shape is chosen, short distances are imperative: 'The distance from the admission area to the operating theatre (OT) table must never exceed 10 metres, so the patient can cover it without assistance and quickly,' he recommends. In many hospitals, he notes, it takes ten minutes from the patient admission area to the OT. In the time staff spends 'en route', four to five additional patients could have been treated. 'This adds up to an annual loss of several hundred thousand Euros,' Professor Möllmann estimates. Moreover he recommends OTs with two tables, to ensure transition times between interventions of five minutes maximum. 'With transition times of 30 or 40 minutes, ambulatory interventions are no longer profitable as only the mere OT time is being reimbursed.'

A successful day surgery centre also needs intelligent management. Professor Möllmann recommends workflow-oriented theatre planning as well as a fixed schedule with only one type of surgical procedure per day, to reduce transition efforts. The surgeon stays in theatre between procedures and no valuable time is lost.

Anaesthesiology preparation for day surgery patients remains a crucial open issue, the professor points out. In Germany, prior to an intervention the surgeon assigns the patient to one of three groups in line with the classification of the American Society of Anaesthesiologists (ASA). Only patients in group 3 (ASA III) need to come for a pre-operative anaesthesia consultation; patients in the two other groups simply show up just before the surgery. 'This procedure frequently leads to the difficult situation that a patient scheduled for surgery needs a more in-depth assessment and the anaesthesiologist is forced to decide whether to call off the intervention or turn a blind eye,' Prof. Möllmann points out.

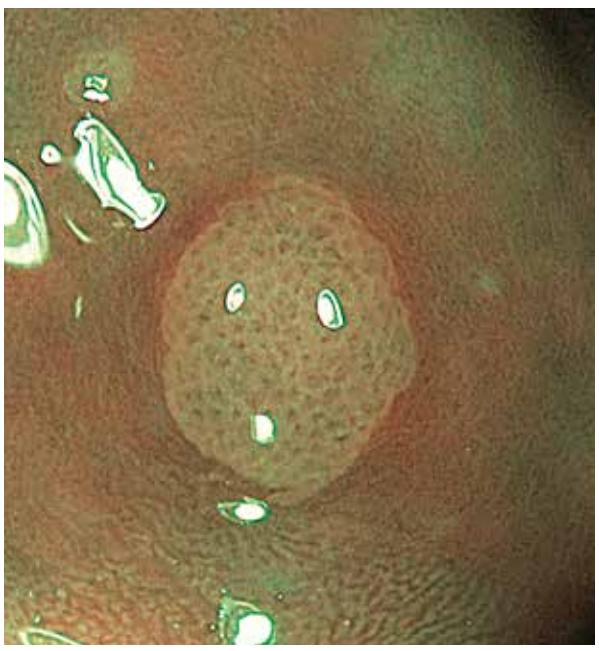
A promising approach, Professor Möllmann explains, is a risk assessment and a pre-medication screening by telephone before the surgery, as developed by Professors Guy Ludbrook and Cliff Grant at the University of Adelaide, Australia. The surgeon forwards the relevant patient data to a call centre, which contacts the patient. The study so far indicates that the data quality provided by that telephone screening is comparable to that provided by conventional methods. Thus the surgeon has sound data on which to base a decision whether the patient needs to come for a pre-operative consultation or not.

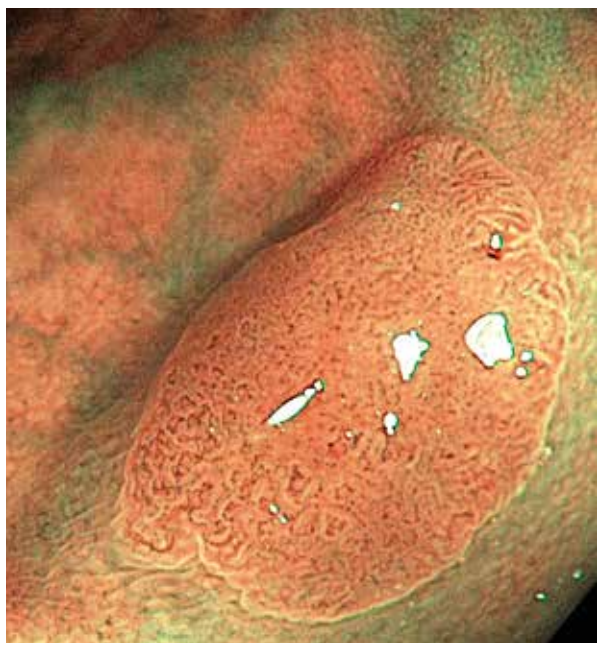
Continued on page 6

Professor Michael Möllmann, specialist in ambulatory surgery, studied medicine at the Westphalian Wilhelm University of Münster, Germany. From 1984 to 1993 he worked at the Anaesthesiology and Intensive Care Department, at Münster University Hospital before his roles as Assistant Professor in Anaesthesiology at Wilhelm University and Head of the Department of Anaesthesiology and Intensive Care at the St. Franziskus Hospital Münster, of which has also became Medical Director in 2007.
The hospital has operated a dedicated associated ambulatory centre since 2001. Around 11,000 surgical procedures have been conducted in day surgery, mostly involving ophthalmology, minimally invasive gynaecology, ENT and paediatrics.

Colorectal cancer screening

Aiming to raise safety and lower costs: The new NBI-based endoscopic classification (NICE)





Evis Exera III NBI images in "Near Focus Mode" of a sessile hyperplastic versus adenomatous polyp

Colon cancer remains the second most common cause of cancer-related death in the Western world with 450,000 citizens in Europe newly diagnosed and 230,000 deaths annually *(Source: Globalscan 2008)*. A rise to 90% in the five-year survival rate is seen if cancer is detected by endoscopic diagnosis and treated early enough.

Well known precursors for colon cancer are the adenomatous polyps that arise from the glandular structure of the colonic wall and differ from normal or hyperplastic tissue because they grow continuously and very likely develop dysplastic changes later on, eventually leading to invasive colonic cancer. The primary goal of any screening colonoscopy is therefore to detect and remove those adenomas.

Diagnosis and costs

Current clinical practice in colonoscopy is to detect and remove any polyp regardless whether harmless (hyperplastic) or adenomatous. The endoscopist is obliged to leave the final diagnosis of the polyp nature to a pathologist. Depending on number, size and sometimes with regards to national guidelines also depending on the details of the histopathology of the adenomas, the endoscopist will then define the surveillance interval: three or sometimes five or ten years if only diminutive hyperplastic lesions were detected. The economic downside of that well-established concept is the huge cost associated with the histopathological workup of retrieved polyps – particularly to evaluate diminutive polyps that are almost all benign anyway.

Given that over 14 million colonoscopies are performed annually in the USA, and assuming that 44% of them find at least one diminutive polyp, Kessler et al. *(Endoscopy 2011; 43(8): 683-691, DOI: 10.1055/s-0030-1256381)* have estimated that the cost for evaluation exceed US$1 billion annually in the USA – 'a conservative estimate that does not consider related costs such as the specimen container, pathologist time and endoscopist time to follow up on the pathology report,' the authors state.

Cost-savings via optical diagnosis

Recent advancements in endoscopic imaging such as Narrow Band Imaging (NBI) to improve visualisation of vessels, and High Definition (HD) imaging combined with dual focus for close up observation, encourage endoscopists worldwide in their attempts to change the state of care for diminutive polyps towards endoscopic optical diagnosis of the polyp nature, eventually allowing them to skip the costly pathologic analysis and discard all discovered and retrieved diminutive polyps.

Obviously such an approach can only work if a common, simple classification system for differentiation between adenomas and hyperplastic lesions is at hand. Therefore, recently an international group of renowned endoscopy experts suggested the so-called NBI International Colorectal Endoscopic (NICE) classification for assessment of small colorectal polyps *(Hewett et al., Gastroenterology, Volume 143, Issue 3, September 2012, Pages 599-607.)* This classification is based on the observation of three major criteria using NBI in close-up view:

1. Colour: light vs. browner relative to background
2. Vessels: None, or isolated, lacy vessels coursing across the lesion vs. brown vessels surrounding white structures
3. Surface pattern: Dark or white spots of uniform size or homogeneous absence of pattern vs. oval, tubular or branched white structures surrounded by vessels.

The former alternatives suggest a hyperplastic, the latter an adenomatous polyp.

Hepatogastroenterology expert and university professor **Thierry Ponchon MD** studied medicine at Lyon University and today heads the specialist department at the E. Herriot Hospital in Lyon, France. From 2001-2003 he served as President of SFED, the French Society of Digestive Endoscopy and has been President of the Society's research and development commission since 1999. He also continues as the SFED's International Secretary and is President of the organisation's commission on hygiene and public health (since 2003). He has been Chairman of the Research Committee of the European Society of Digestive Endoscopy since 2001, of which he is also a member of the committees for education and guidelines. Prof. Ponchon is also a Member of the French National Society of Gastroenterology, and of the French Foundation of Digestive Oncology, where he is a member of the Scientific Committee. Given his standing in gastroenterology, endoscopy and lithotripsy, Prof. Ponchon additionally serves as a member of American, German, Brazilian and other international societies and scientific committees. Since 2000, he has been on the International Advisory Board of Digestive *Endoscopy* (Japan) and also has co-edited the journal *Endoscopy* since 2002. From 2004 he has also been a member of the International Editorial Board of *Gastrointestinal Endoscopy* (USA).

Is optical diagnosis safe?

As stated previously, current guidelines do not allow endoscopists to completely rely on optical diagnosis of polyps. In the USA, to change the state of care the American Association of Endoscopists (ASGE) has issued a PIVI (Preservation and Incorporation of Valuable Endoscopic Innovations) *(Gastrointestinal Endoscopy, Volume 73, No. 3: 2011)* on real-time endoscopic assessment of the histology of diminutive colorectal polyps. For colorectal polyps <=5 mm in size to be resected and discarded without pathologic assessment, endoscopic technology should provide at least 90% agreement in the assignment of post-polypectomy surveillance intervals when compared to decisions based on pathology assessment of all identified polyps. 'The PIVI is intended to guide technology developers and clinical investigators toward the design and testing of technologies that address these important clinical needs in diminutive polyp management,' the ASGE explains in the rationale for this PIVI: 'Once endoscopic technologies meet an established PIVI threshold, those technologies are appropriate to be incorporated into clinical practice…'

What we need to make it happen

Some years ago, a first publication in the United Kingdom *(Ignajatovic et. al. The Lancet Oncology, Volume 10, Issue 12, Pages 1171 - 1178, December 2009)* already showed that optical diagnosis of small colorectal polyps during routine colonoscopy is feasible with 98% agreement between optical diagnosis and histopathology for screening intervals (British Guidelines) and 95% (US multi-society guidelines).

As for NICE, several studies are underway to collect further evidence that the classification can be safely used in a discard and resect regime using the latest high-tech endoscopes (EVIS EXERA III, Olympus Europa Holding GmbH).

However, providing clinical evidence is just the first step towards spreading the concept and eventually changing the state of care. Endoscopists will need extensive training on NICE, guidelines for colonoscopic examination and the histopathologic follow up will need revision, as will reimbursement schemes – changes such as those already established in Japan, where NBI-based optical diagnosis with zoom endoscopes already enjoys reimbursement.

Adequate collection and preservation of images is another issue to be covered and secured, particularly for medico-legal reasons.

Ambulatory surgery

Continued from page 5

Data collected during the screening are on the anaesthesiologist's desk before the patient arrives on the surgery day. Since 'the physician already knows quite a bit about the patient, which significantly increases patient safety,' Prof. Möllmann considers introducing such a system in Münster. 'We are currently conducting a study to develop an algorithm for our patients,' he explains. However, the interview will be conducted by care staff and will not replace premedication. It is much more designed as a pre-check 'to give us an idea of the patient we will be seeing'.

The professor expects initial study results to be available in spring 2013.

A new LED brings man

Specialist lighting firm ACEM reports that Soled 15 its new LED light 'contains all the advantages of the LED technology and is suitable for multi-purpose uses thanks to its flexibility, offering excellent light intensity; an IR-free light beam; colour temperature (CCT) of 4.900°K; colour rendering index (CRI) of 95, and low power consumption.'

The device also promises a long life. 'The high technological level combined with the use of high-powered LEDs allow Soled 15 to have a very linear yield and a negligible performance decay for its entire life duration,' the company explains. 'Thanks to the high efficiency achieved, Soled 15 has a light intensity of 65.000 lux and low power consumption (22W). The

Brussels – 19 March 2013

The 33rd International Symposium on Intensive Care and Emergency Medicine

Belgium – Last year, the annual ISICEM event attracted almost 6,000 participants from 101 countries. Its chairman, Professor Jean-Louis Vincent, from the Intensive Care Medicine Department in Erasme University Hospital, Brussels, offered EH a few reasons for its continuing success

'The ISICEM is the largest meeting in this field in the world; the three major meetings are those of the Society of Critical Care Medicine (SCCM) at around 4,000 participants, the European Society of Critical Care Medicine (ESICM) at around 5,000 and we are at almost 6,000,' he explained. 'Of course, other meetings are larger, for example, the American Thoracic Society (ATS) meeting, but this includes all pulmonologists, and doesn't just focus on critical care.'

Has the financial crisis caused a decrease in participants?

Jean-Louis Vincent: 'Meetings in general are seeing some decline in numbers. This is not only the financial crisis but also the development of internet-based education programmes and other factors related to improved communication platforms and data transmission. However, for the ISICEM, a slight decline in participants from European countries (some European countries in particular) has been compensated by an increase in the number of participants coming from further away, for example, North America, China and the Far East, so the number of participants is actually quite stable, and the meeting is becoming even more international. This has always been a particularly attractive aspect of our meeting because the opportunity to exchange ideas with colleagues right around the globe is an important means of promoting and expanding critical care medicine.'


© Pawel Szczepanski / Shutterstock.com

Has the Square Centre in downtown Brussels become too small for this event?

'Yes, the Square can accommodate about 3,500-4,000 participants – and we always have more than that number.

Even with renting other rooms in the vicinity and constructing a tent to provide more room, and careful estimations of how many people are likely to attend which sessions, sometimes there is still only standing room. But, people like to be in the centre of the city, so we will stay here.'

Why do you choose to remain in Brussels?

'First, it's my home city, so I'm a little biased, of course! But, apart from that, it's such an attractive town, with easy access by train, plane or road, which is really important; there's also good accommodation and restaurants, famous chocolates and beer, a friendly atmosphere… I could go on. People just love Brussels. Yes, the weather in March is very unpredictable, but we chose March because there are not too many other meetings at this time of year and March has become synonymous with the ISICEM, so we couldn't change it! Anyway, if the weather is fine, people have extra-special memories of their four days, and if the weather is bad, the participants stay in the conference rooms and we have better discussions!'

Do the same participants come, year after year?

'Yes and no - those who can come every year, do so - some participants are very proud to state that they have attended the ISICEM every year for x number of years. However, in some centres, people come only every other year, so that other department colleagues also get to attend.

'You can't shut down an intensive care unit for a few days as you can an out-patient clinic for example. In many cases, about half the ICU doctors remain at work in the hospital while the other half comes to Brussels.'

How vital is industry support?

'Industry support is essential and, for many meetings, this has become a big issue. With budget cuts, exhibitions are shrinking everywhere but, at our meeting, we have actually seen support increase every year, not only in terms of the number of companies, but also total financial support. This is because of the "top-down" approach in which companies choose just the very few most important meetings to maximise cost-effectiveness - and the Brussels meeting is at the top of their list.'

Briefly, what's the secret of the ISICEM's continuing success?

'I believe one of the most important positive aspects is that the ISICEM is fully independent - we are not part of a scientific society that needs to follow a fixed ethos and please all its members; we can operate free from internal politics and just focus on looking for top quality speakers from around the globe.

Finally, the ISICEM is now in its 33rd year - when will it end?

Personally, I'd like to continue until we reach our Golden Anniversary – the 50th ISICEM, but others will take over. After all, it would be a shame to stop this winning formula!'

Jean-Louis Vincent MD PhD, Professor of Intensive Care at the Université Libre de Bruxelles and Head of the Department of Intensive Care at Erasme Hospital in Brussels, is also Secretary General of the World Federation of Societies of Intensive and Critical Care Medicine and President of the Belgian Society of Intensive Care. He is author or co-author of more than 800 peer-reviewed publications, about 90 books and more than 800 original abstracts. He is editor-in-chief of *Critical Care, Current Opinion in Critical Care,* and *ICU Management* and on the Editorial Boards of more than 30 journals. He has received many awards for his work, including the prestigious Belgian scientific award of the FRS-FNRS (Prix Scientifique Joseph Maisin-Sciences biomédicales cliniques).

lamp that y choices

LEDs layout gives a visual comfort and produces a uniform, homogeneous and shadowless light.'

The light is easy-to-move and has an easy-to-grip and removable handle for sterilisation.

An I-Sense series touch panel controls all lamp functions, including intensity, parts selection (SEL) to choose single parts of the light beam and activation of the desired LEDs in a sequential way according to needs, and also a brightness increase (BOOST), used to obtain a maximum light intensity in case of a wide light field. This approximate 10% increase deactivates automatically after five minutes.

The lamp comes for ceiling, wall and trolley mounting.

Details: www.acem.it

Ventilator-associated pneumonia

Draining respiratory secretions using endotracheal tubes with subglottic suction can reduce VAP

Interview: Bettina Döbereiner

The use of endotracheal tubes with a dorsal lumen to allow drainage of respiratory secretions is currently not common in Germany, although two meta-analyses from the USA and Canada have already demonstrated that this special technique can reduce ventilator-associated pneumonia (VAP) by 45-50%. The Department of Anaesthesiology and Operative Intensive Care Medicine at Berlin's Charité University of Medicine had introduced the endotracheal tubes (ET) with subglottic suction in 2011 at their all-in-all three university campuses. Christine Geffers PhD, senior physician at the Charité Institute of Hygiene and Environmental Medicine, spoke with our correspondent about the drainage technique for respiratory secretions.

Asked why these special tubes were introduced to intensive care at Charité, Dr Geffers explained that, having read about an official USA recommendation, the hospital's anaesthetists and intensive care specialists discussed the device's introduction during a meeting regarding about possible improvements in medical devices. 'We were immediately convinced by the system and findings of the first meta-analysis from 2005, which was then available and confirmed a reduction in VAPs of up to 50%. In the US, these special tubes that drain respiratory secretions collecting under the glottis over time during mechanical ventilation, have been officially recommended for a while (CDC and Healthcare Infection Control Advisory Committee 2003 recommendations). However, in Germany we have no official national recommendation yet; the last recommendation from the responsible Commission for Hospital Hygiene and Infection Prevention (KRINKO) was published in 2000 – but most studies on these tubes were not published until later.

Dr Christine Geffers studied medicine at the Free University Berlin, and then became a resident at the Institute of Pathology at Moabit Hospital in Berlin for two years. In 1996 she became a research associate at the Institute of Hygiene and Environmental Medicine at the Free University Berlin (now Charité University Medicine Berlin).

Since qualifying as a Hygiene and Environmental Medicine specialist, including a 12-month residency on the intensive care ward at the Clinic for Anaesthesiology and Intensive Care at the DRK Hospitals Westend in Berlin, she has been a consultant at the Institute of Hygiene at the Charité since 2001.
In 2003/2004, Dr Geffers worked for Professor Barry Farr at the University of Virginia, USA, with a scholarship from the Walter-Marget Association for the Promotion of Infectology.

'When introduced in 2011, we opted for an ET, which differs from conventional tubes in two ways. On the one hand it has this special aspiration function, which works via a small opening above the cuff to which a tube is attached, which aspirates the respiratory secretions of the prone patient. The secretions can either be drained manually via a syringe or, as recommended for clinical practice, with a vacuum pump that aspirates the secretions permanently or intermittently. The other difference is that the ETs we use are equipped with a very thin cuff material. The finer the material of this cuff the better it adapts to the trachea and the fewer secretions get into the lower airways.'

Use of the micro-thin cuff has not been backed up in studies to the same extent as the benefit of subglottic suction, he noted, but is convinced its use does no harm.

Indications for use

'The most common indication for intubation is a general anaesthetic during surgery. All patients who are likely to require mechanical ventilation for more than 24 hours after surgery are fitted with ETs with subglottic suction. On the intensive care ward, all patients who need to be ventilated are fitted with this type of system because we can assume they will need to be ventilated over a longer period of time. They often then also receive tracheal cannulas, and in this case, we also use special cannulas with subglottic suction and a thin cuff.

Feedback

'In the beginning some people were a bit critical because the vacuum pumps make very loud slurping noises, considering that we try to make an intensive care ward stay as comfortable as possible, i.e. with as little noise as possible and with pleasant lighting. The level of noise is a distinct disadvantage, but not significant enough to outweigh the advantages.

Disadvantages? 'There are studies which, with the help of endoscopic examinations after mechanical ventilation using these tubes, have found that the suction may cause damage to the mucous membrane in the trachea. However, it isn't clear whether the pressure of the cuff caused this, or the suction itself. In any case, we haven't been able to observe any remarkable damage to the mucous membrane, although we did not explicitly look for it.

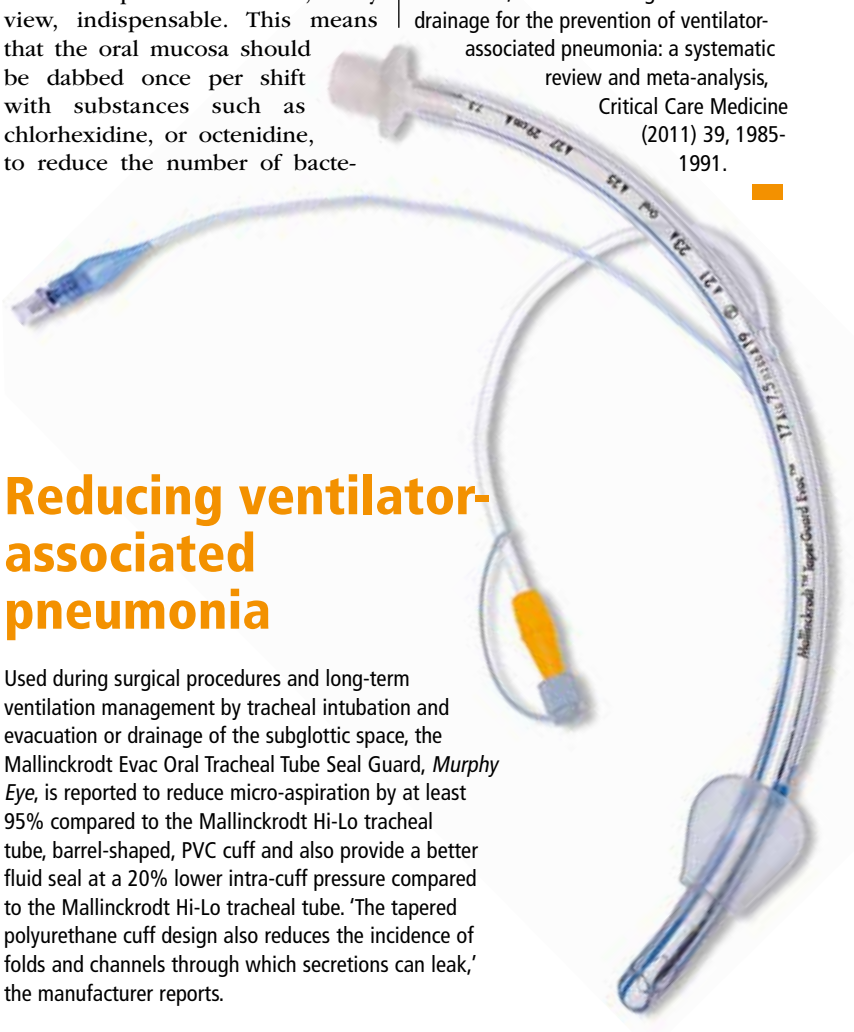
A further meta-analysis, from 2011, has now arrived alongside the one mentioned earlier. Whilst the first analysis evaluated five randomised, clinical studies (with 896 patients) the second study evaluated 13 (with 2,442 patients). This analysis also confirmed a reduction potential for VAP of 45%. Asked whether she has been able to observe the respective effects on the wards, Dr Geffers said that she does not believe that the pneumonia rates under real-life conditions are actually halved. 'However, I do expect to see an effect just based on the theory. But regardless of that, the combination with other methods is very important to effectively reduce the pneumonia rate.

'Apart from the earliest possible extubation, regular mouth hygiene with antiseptic substances is, in my view, indispensable. This means that the oral mucosa should be dabbed once per shift with substances such as chlorhexidine, or octenidine, to reduce the number of bacterial pathogens to start with. There are studies that confirm an up to 50% reduction of VAPs through appropriate mouth hygiene. I'm convinced that the combination of good mouth hygiene and subglottic suction with a micro-thin cuff can significantly lower the number of pathogens and therefore the risk of VAP for the respective intensive care patients.

Meta-Analyses
Dezfulian, Cameron et al., Subglottic secretion drainage for preventing ventilator-associated pneumonia: a meta-analysis, The American Journal of Medicine (2005) 118, 11-18.

Muscedere, John et al. Subglottic secretion drainage for the prevention of ventilator-associated pneumonia: a systematic review and meta-analysis, Critical Care Medicine (2011) 39, 1985-1991.

Reducing ventilator-associated pneumonia



Used during surgical procedures and long-term ventilation management by tracheal intubation and evacuation or drainage of the subglottic space, the Mallinckrodt Evac Oral Tracheal Tube Seal Guard, *Murphy Eye*, is reported to reduce micro-aspiration by at least 95% compared to the Mallinckrodt Hi-Lo tracheal tube, barrel-shaped, PVC cuff and also provide a better fluid seal at a 20% lower intra-cuff pressure compared to the Mallinckrodt Hi-Lo tracheal tube. 'The tapered polyurethane cuff design also reduces the incidence of folds and channels through which secretions can leak,' the manufacturer reports.

Traumatic brain injury

The Lund Concept: Although still controversial, there is a convergence of guidelines regarding TBI treatment

Report: Brigitte Dinkloh

Traumatic brain injury (TBI) is the main cause of accidental death in Europe and all highly developed countries, accounting for around 40% of all accidental mortality. Often, such injuries also cause permanent invalidity. Road traffic accidents are the most common cause by far. Around 20-30% of patients with severe TBI have intracranial bleeding or impression fractures that necessitate neurosurgical intervention. More than 70% of patients with traumatic brain injuries can be treated conservatively, which why intensive care plays a key role in TBI treatment. To understand TBI treatment it is important to know that primary and secondary brain damage can be differentiated. During the development of a delayed secondary injury the post-traumatic cerebral underperfusion of the tissue (ischaemia) plays a decisive role. The cerebral perfusion pressure (CPP), defined as mean arterial pressure (MAP) minus intracranial pressure (ICP), together with cerebral vascular resistance are the physiological variables that control cerebral blood flow (CBF) and metabolic supply. Therefore, there is a close link between CPP and ischaemia.

There are currently very different views about the level of the necessary cerebral perfusion pressure. The guidelines from the European Brain Injury Consortium (EBIC) and the American Association of Neurological Surgeons (AANS) recommend a CPP targeted treatment as ischaemia and hypoxia (lack of adequate oxygen supply) of the brain are considered to be main factors of post-traumatic brain swelling. For a long time this was the accepted treatment approach. However, the high mortality rate of this treatment made Dr Per-Olof Grände and his neurosurgical colleague Dr Carl-Henrik Nordström, at the University Hospital in Lund, look for an alternative.

The alternative he developed is based on the basal physiology for brain volume and brain circulation. The main objective is to prevent an increase in intracranial pressure (ICP) and thus improve the perfusion and oxygenation of the injured brain areas. Unlike the conventional guidelines, with their meta-analytical approach, Per-Olof Grände's team did not want to accept high blood pressure in the brain: 'The American guidelines even recommend the administration of catecholamines to increase blood pressure in the brain, but with the Lund Concept we do the opposite. We administer antihypertensive treatment to lower the blood pressure, because we assume that an increase in blood pressure goes hand in hand with increased cerebral oedema,' Dr Grände pointed out.

The most important parts of the concept were proven in animal research and clinical studies. In the first study in the early 1990s, 45 patients were treated according to the new concept. Result: Mortality for severe TBI was lowered from 40 to below 15%.

Other studies also confirm a better clinical outcome for patients. However, the Lund Concept still remains controversial, mainly because most studies were not randomised. 'Only one study from China, published in 2010, was carried out using a control group. This study also showed a tendency similar to the other studies,' he said.

Meanwhile, according to Dr Grände both approaches have converged somewhat. Whilst the conventional guidelines originally recommended a CPP minimum of 70 mm Hg, they have since been changed because of the bad outcome for patients. 'The US guidelines from 2007 give almost the same recommendations with regards to CPP as we do with the Lund Concept,' he explained. Therefore, nowadays there is a clear convergence with the Lund Concept not only regarding CPP but also for many other aspects of TBI treatment.'

Professor Per-Olof Grände gained his MSc in technical science in 1969, PhD in circulatory physiology in 1979, and graduated as a medical doctor in 1981, from Lund University, Sweden. In 1986 he became a specialist in anaesthesia and intensive care and in 2002, took the role of Professor for Anaesthesia and Intensive Care at Lund University Hospital. His research has focused on circulatory physiology, head trauma and sepsis, while his circulatory physiology study has concentrated on control systems of the peripheral circulation and particularly mechanisms controlling transvascular fluid exchange. An important part of his research has dealt with the Lund Concept to treat severe brain trauma.

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SPECIAL ISSUE FOR THE EUROPEAN CONGRESS OF RADIOLOGY

VIENNA • AUSTRIA • 7-11 MARCH 2013

Hybrid imaging: PET/MR climbs the diagnostic ladder

Experts across Europe believe the combination is beginning to demonstrate its broad potential as a hybrid imaging tool

Report: Mark Nicholls

Whilst PET/CT remains the gold standard in hybrid imaging at this stage, PET/MR has shown great promise for imaging of head and neck cancers, prostate and breast imaging and, over the last two years, radiologists have recognised its value and potential as a diagnostic tool.

However, evolution has not been pain-free for those pioneering its development. During the PET/MR: *A marriage made in heaven or hell?* New Horizons session (ECR 2012, 9 March. NH8. 8-10 a.m.) when the latest position on PET/MR will be presented, it will also serve to underline only too well that the journey has not been easy.

Professor Osman Ratib, Chairman of the Department of Medical Imaging and Information Sciences and Head of the Division of Nuclear Medicine at the University Hospital of Geneva, Switzerland, is among the speakers. His department was the first in Europe (2010) to have whole body PET/MR.

With questions over whether such technology will replace, or complement, PET/CT, he said that the session would offer a clinical perspective on this new hybrid modality. 'We know there are problems; that's why we have the 'heaven and hell' scenario. It can be hell in terms of protocols and the logistics of putting two complex modalities together, but can be heaven by having all the answers in one study.

'In some areas, we have demonstrated it has really improved the quality of the diagnostic process by having those two modalities perfectly aligned and perfectly superimposable.'

Professor Ratib said one area where they were particularly challenged was how to protocol the studies with the standardisation and complexity of MR protocols in this context 'uncharted territory'.

His team had to be creative about how to protocol to obtain high quality MRI swiftly in 3-D for the whole body, select specific MRI sequences to apply and how to optimise and standardise the protocols.

However, he said, 'We are now reaching the stage of 'heaven'. After a year of struggling with protocols and with the help of radiology experts of different subspecialties of our department, we have identified and optimised most of the protocols for clinical routine – particularly in head and neck imaging, because we think that is where a PET/MR has a great impact.'

The same applies for prostate and breast imaging, though they continue to work to improve protocols for paediatric cases.

During the ECR session, Professor Ratib will speak specifically about PET/MR in oncology where he believes it has major potential. 'PET has new tracers; MRI has new protocols like diffusion-weighted imaging, which shows tissue density and has a very good correlation with tumour versus non-tumour tissue. Having both is having the best of both worlds.

'The future is in multi-parametric diagnostic criteria, which will combine things you see on PET with the different behaviour in functional MRI. Having those two together we believe brings more diagnostic accuracy and more diagnostic confidence and that is something that is very important clinically. We saw a clear improvement with PET/CT when the reports became more conclusive and we are seeing the same with PET/MR.'

Patients benefit from having one study instead of two and more conclusive diagnostic results, which will lead to better treatment as well as the reduction of radiation exposure with MRI.

The future

Professor Ratib believes this lies in the coupling of the two rapidly evolving technologies - a quantum leap in PET with fully-digital detectors compatible with the MRI magnetic field and new MRI imaging protocols and multi-transmit detection – combined with the development of new tracers.

With PET/CT and PET/MR now more widely available, the development of biomarkers and tracers that was slow because of limited access to machines, he said, has suddenly accelerated and seen the availability of specific tracers for specific cancers, and also specific biological receptors.

One final wish for Professor Ratib is that this hybrid technology will breach a gulf in radiology and instead of having a radiologist and nuclear medicine physician there will soon be training and certification of hybrid physicians who have capability in both areas.

Professor Osman Ratib is Chairman of the Department of Medical Imaging and Information Sciences and Head of the Division of Nuclear Medicine at the University Hospital of Geneva. Previously, he was Professor and Vice-Chairman of the Department of Radiology at the University of California Los Angeles (UCLA). His clinical activities and areas of expertise include cardiovascular MR, CT and PET/CT imaging. Prof. Ratib is active in medical imaging research in Europe and is a member of several societies of computed radiology and telemedicine and the former President of the EuroPACS society. He has pioneered several innovative projects including the first whole-body PET/MRI unit in Europe.

Cardiac imaging

PET/MR: The opportunities are almost unlimited

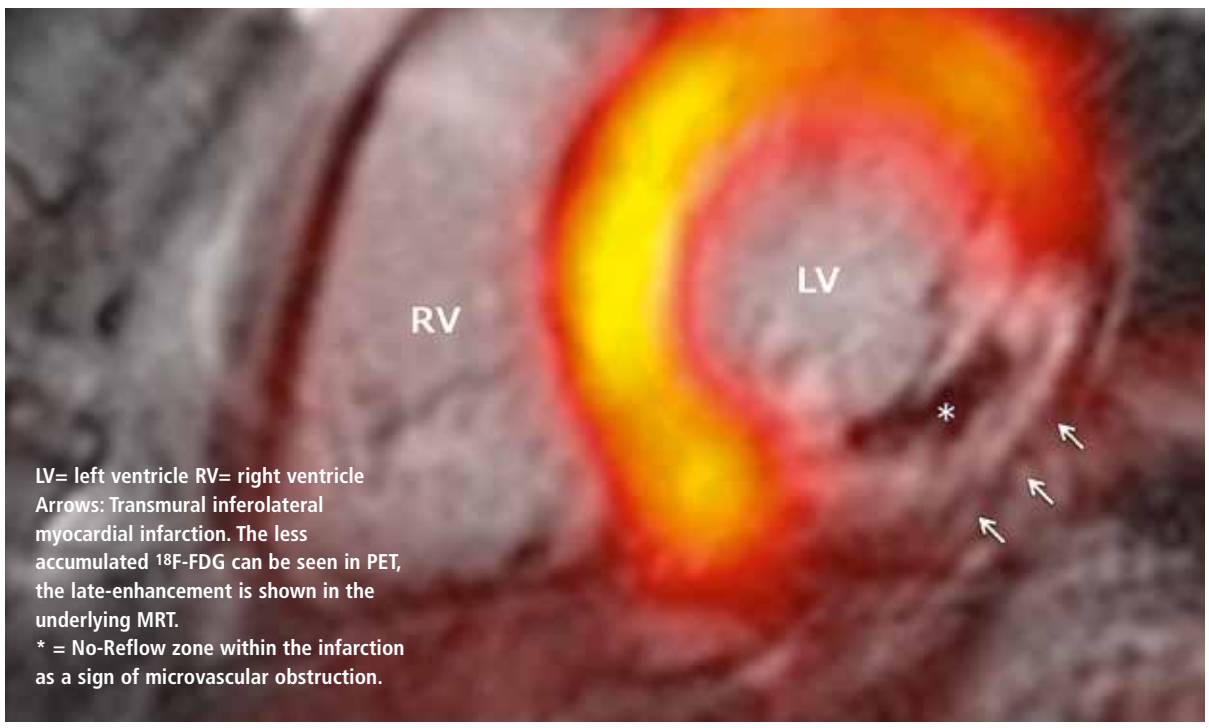
MRI has become the gold standard for many indications in cardiac imaging, apart from imaging the coronary arteries. For function and morphology assessment, MRI is the leading technology. A further advance into as yet unknown territory is myocardial imaging aided by one of the first integrated 3-Tesla PET/MR systems currently used at the Institute of Radiology, Essen University Hospital, Germany.

Last year, the Essen team published the world's first case report on PET/MR cardiac imaging in the renowned journal Heart. Opportunities for cardiovascular imaging are nowhere near being fully known and explored, enthused Felix Nensa, a member of Essen's Cardiovascular Imaging Working Group. 'MRI has the advantage that it lets us assess the individual anatomic compartments and different soft tissues much better than CT. The heart is not simply positioned in an axial transverse but in a quite complex position in the body. With the help of localisers, we position the MRI scanner along the anatomic axis, rather than the body axis, and we can also determine many different axes, planes and contrasts,' he said, explaining some MRI advantages over CT. An MRI examination initially starts with a standard protocol that provides an overview over the heart and surrounding areas. This is followed by different, specific heart protocols, and often includes an assessment of the heart function, i.e. moving heart imaging.

Myocardial Infarction: How T-2 weighted sequences and late enhancement can provide information on the point in time when an infarction occurred

'If the heart function measurements, such as 3-D volume reconstruction or four-chamber view, result in conspicuous findings we perform further diagnostic evaluations with T-2 weighted sequences. As fat is suppressed in these examinations and water becomes more visible, this is a particularly good way of visualising oedema within the myocardial wall (tissue classification). Increased build-up of water in the tissue is clear evidence of an acute infarction or inflammatory heart disease.'

Myocardial blood-flow is assessed with a dynamic contrast-enhanced perfusion examination. This is followed by one of the most important sequences of the cardiac examination: Around ten minutes after the perfusion with contrast media, it is possible to detect the so-called late enhancement – bright areas that result from the contrast media accumulating in certain parts of the myocardium. This is clear evidence of perished myocardial tissue, which could have been caused by an acute infarction or a chronic scar. 'This sequence is incredibly sensitive and anatomically of a very high resolution, therefore also making very small scars in the myocardium visible. But we can only determine how long the tissue has been dead by assessing it in combination with the T-2 sequence. Only once an oedema is also visible in late enhancement can we be sure that it is an acute infarction; however, if no oedema is visible in this location it is an older scar, Felix Nensa explained. This is important because it impacts the treatment and the chance of a cure.



LV= left ventricle RV= right ventricle
Arrows: Transmural inferolateral myocardial infarction. The less accumulated ^{18}F-FDG can be seen in PET, the late-enhancement is shown in the underlying MRT.
* = No-Reflow zone within the infarction as a sign of microvascular obstruction.

Tricking cardiac metabolism with glucose

Many of the examinations described can also be carried out with procedures used in nuclear medicine; in this context, PET images have a significantly higher resolution than, for instance, those from myocardial scintigraphy. The basis of PET scanning is the imaging of the metabolism, which is also utilised for PET/MR scanning: Under normal circumstances the heart specifically metabolises fatty acids; however, if it is exposed to a real 'glucose shock', with the patient taking 75 grams of glucose, the heart changes its metabolism to sugar. 'This is helpful to assess infarctions. In a healthy patient, the radio-labelled glucose 'glows' homogenously in the left ventricle; if it doesn't, then this indicates a type of pathology. The lack of glucose metabolism is an indication of dead tissue,' he pointed out.

However, there are other situations – for example, where the myocardial tissue is still intact, but no sugar or only a little sugar is being metabolised, as is the case with the so-called 'stunned myocardium'. If it was possible to open the coronary artery very soon after an infarction occurred the damaged tissue in this area might recover, which is why an oedema is normally visible on the MRI scan but no late enhancement, because the tissue has not died yet. In those cases the PET scan provides complementary information that might help to further assess the state of the jeopardised myocardium.

Radiographer Sebastian Blex plays an important role in the PET/MR on-going research projects carried out at Essen University Hospital

There are also cases where the left ventricle 'glows' very intensively. This can be an indication of a 'hibernating myocardium', characterised by chronic under-perfusion. The MRI scan shows that this area is less perfused, which may point towards a problem with heart wall motion. 'One assumes that the tissue acts auto-protectively and that a stimulus sends signals to the heart tissue to use as little oxygen as possible to stop it from dying. Normally one would also expect that less glucose is used in this area, but the opposite is actually the case. Unlike beta-oxidation during the fatty acid metabolism, anaerobic glycolysis requires almost no oxygen during the glucose metabolism.

Although researchers don't yet agree, one possible explanation may be that the myocardium switches to the lowest-impact metabolic procedure when there is little oxygen available. Assessment of vitality in under-perfused tissue is also particularly important for planning of further treatment because revascularisation of obstructed coronary arteries only makes sense if the tissue has not yet completely died, Dr Nensa explained.

Tracers as keys for metabolic information

With PET/MR, excellent anatomic resolution is combined with the metabolic information delivered by the PET. The most established tracer for the myocardium is ^{18}F-FDG, a radio-labelled glucose. For myocardial perfusion examinations radio-labelled ammoniac (^{13}N-NH_3) is commonly used. These two tracers are also the basis of purely nuclear medical PET examinations without MRI, as only the combination of the two tracers allows for a safe diagnosis.

In Europe, radio-labelled water and rubidium are less established tracers for perfusion. Rubidium has the advantage that it can be manufactured with a generator on site while its half-life is only 90 seconds. Perfusion assessment with classical MRI contrast agents suffer from contrast agents entering the intercellular spaces and remaining there for some time – an effect that is very welcome for late-enhancement but less so for perfusion, as it makes the conversion into absolute flow rate very difficult. 'In the case of a patient with three-vessel disease we are then missing the point of reference. Water, which can freely diffuse, is ideal for perfusion. However, not all tracers can be combined in one examination because they all emit the same radiation of 511 keV. When several tracers are to be combined, such as ^{18}F-FDG with a

Directly after completing his final school exams, **Felix Nensa** freelanced as a software developer for the Research Institute for the Diagnosis and Treatment of Early Lung Cancer at the Augusta Hospital in Bochum, where one of his projects included programming new diagnostic software for automated sputum cytometry. At that time he also took a distance learning degree course in IT (2000).
His medical studies at Ruhr University in Bochum (2001-2007) included two semesters spent at the University of Strasbourg in France. During this period he continued work at the Augusta Institute and, in 2008, began his dissertation – Comparison of spirometry and body plethysmography as detection methods for bronchial constriction in an unspecific provocation test with methacholine.
In 2011, Nensa became a registrar at the Institute for Diagnostic and Interventional Radiology and Neuroradiology at Essen University Hospital and manages research projects on PET/MR, Cardio-MRI and DCE-MRI.

perfusion tracer, the nuclear team carries out an overlay, meaning that an image with a certain tracer and a certain intensity is over-framed by a tracer with a markedly higher intensity.

On the trail of cardiac insufficiency

Further, very promising tracers are C-11-hydroxyephedrine (^{11}C-HED) and iodine-marked MIBG (^{124}I-MIBG), which act as a nor-/adrenaline analogues, taking the neurotransmitter's place, i.e. in the heart's sympathetic nervous system. With these tracers the regrowth of synaptic connections between the heart and the nervous system can be verified in patients with heart transplants.

A further important area of application for nor-/adrenaline analogues is cardiac insufficiency. As more and more people survive cardiac infarctions these days there is an increasing number of patients with heart failure because of reduced cardiac output due to areas of myocardial scarring. Left ventricular ejection fraction, which is reduced in the case of cardiac insufficiency, is an important parameter for the assessment of cardiac performance. 'The big advantage of PET/MR is the fact that it not only allows us to determine the left ventricular ejection fraction but also the sympathetic innervation, which is usually also compromised. We can now visualise this with the PET/MR,' the radiologist explained. ^{123}I-MIBG has been used for single-photon emission computed tomography (SPECT) for some time, although so far without good anatomic reference –which is now possible through PET/MR.

Inflammatory changes and tumorous diseases

In future, PET/MR scanning is also likely to play an important role in the diagnosis of cardiac inflammatory changes and tumorous diseases. Myocarditis, an inflammatory disease affecting the myocardium and most often found in young people as a result of protracted flu, is very dangerous. So far, inflammation of the myocardium has only been possible to confirm via biopsy, which, although highly specific, is not particularly sensitive, meaning that an inflammation can only be pathologically confirmed if the tissue has been sampled in exactly the right location. If the myocardium is completely switched to fatty acid metabolism, therefore becoming 'silent' for the ^{18}F-FDG tracer, it is possible to confirm that there is an inflammation in those places where glucose accumulates, as inflammatory cells are not capable of a fatty acid metabolism and only able to perform glucose metabolism.

This means that an ^{18}F-FDG scan after one day of Atkins diet makes it possible to distinguish between inflammatory cells and normal cells. The same applies to tumorous diseases of the heart. Tumour cells also metabolise sugar to a great extent. This even makes it possible to distinguish between benign and malignant tumours. It also enables detection and treatment of diseases that are hard to diagnose, such as cardiac sarcoidosis, at an early stage. 'It's specifically the combination of both procedures that is so promising and where there are almost unlimited opportunities for cardiovascular imaging,' he noted.

Essen benefits from good interdisciplinary co-operation, along with input from Siemens

Presently, the Essen team is entering considerable uncharted territory and the relevance of their results is not always obvious and clear. However, in many cases, the response to certain treatments can already be assessed with more ease.

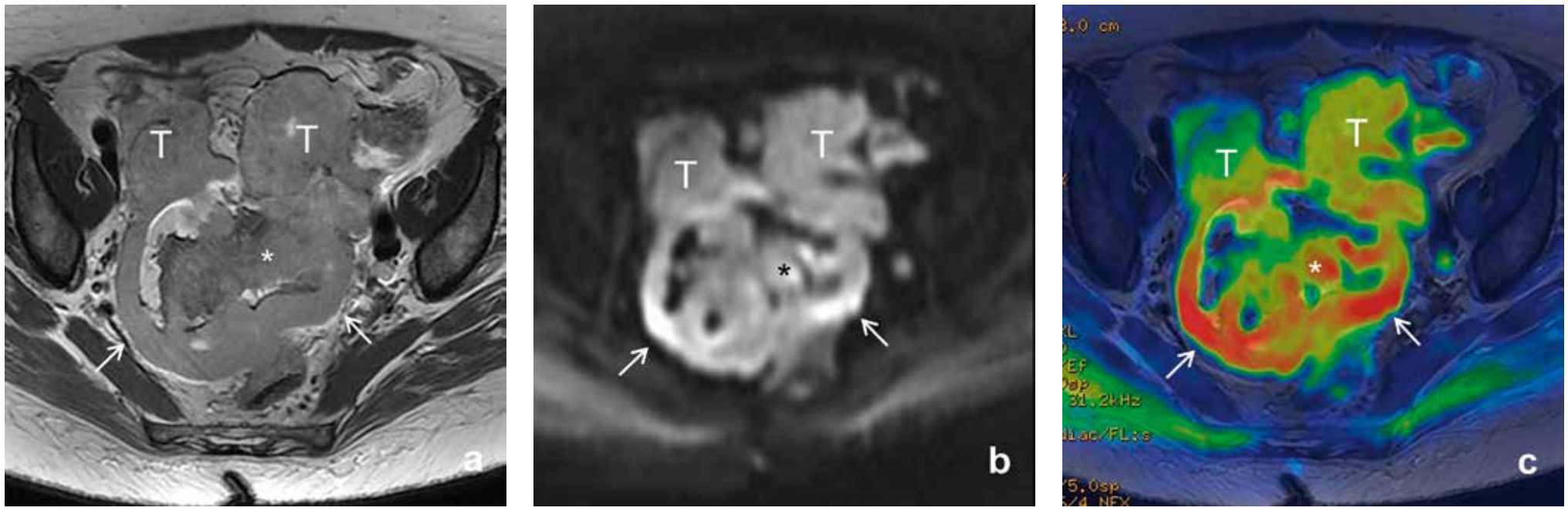
Essen's traditionally close cooperation between radiology and nuclear medicine on the one hand and device manufacturer Siemens on the other hand greatly facilitates the clinical evaluation of that complex technology. 'We've come a long way and are now in the process of implementing the first, concrete studies,' Nensa revealed.

Only with clear clinical indications the project PET/MR will become truly established and economically viable. As a reference centre for Siemens the Essen team are among the first to clinically evaluate newly developed technology. On the other hand, Siemens are also happy to listen to experiences and suggestions from Nensa and his colleagues. 'This exchange is extremely important for both sides; it's give and take – we have the very latest technology at our disposal and deliver the latest findings about it. Both sides have the same objective: to advance technology even further to ultimately improve patient care,' the radiologist is happy to report.

In the control room at the institute where all incoming information from the PET/MR equipment is supervised

The importance of MRI for gynaecological malignancies

Hedvig Hricak, Chair of the Radiology Department at the Memorial Sloan-Kettering Cancer Center, New York, USA, describes emerging applications and potential trends in gynaecological cancer treatment described at the 15th International Symposium *Crossing Barriers*



High-grade serous papillary adenocarcinoma of the ovary. Axial T2W FRFSE (a), DW (b) and fused images (T2WI +DWI) (c) at 3-Tesla demonstrate bilateral solid adnexal masses (T in a, b and c), peritoneal deposits outlining the pelvis (arrows in a, b and c) and serosal deposits along the sigmoid serosa (* in a, b and c). The latter are better appreciated on DW and fused images.

Combining technological advances, new clinical management paradigms and discoveries from epidemiology and biology has been and remains the hallmark of our specialty. The presentations at the 15th International Symposium, Crossing Barriers, are in keeping with this tradition and show how our profession continues to elevate the quality of clinical care by applying increasingly powerful imaging techniques to clinically relevant questions.

MRI has become integral to the diagnosis and management of patients with gynaecological malignancies, as it provides exquisite anatomical detail and allows quantitative, multiparametric functional assessment of tumours. Adding functional sequences – such as dynamic contrast-enhanced MRI (DCE-MRI), diffusion-weighted MRI (DW-MRI) and most recently Intravoxel incoherent motion (IVIM) MR imaging – to conventional MRI, has been found to be particularly helpful for lesion characterisation, assessment of tumour response to treatment and differentiating post-treatment changes from tumour recurrence.

The emerging hybrid imaging modality PET/MR has the capacity to combine anatomical detail with an even richer supply of functional and metabolic information and will fundamentally change the way we evaluate gynaecological cancer patients. Its application in the laboratory as well as the clinic will aid drug discovery and enable the delivery of substantially more individualised cancer care. The value of PET/MR will be further enhanced by the advent of clinical hyperpolarised MRSI (HP-MRSI). Clinical HP-MRSI can increase the MR signal 10,000–100,000-fold, allowing imaging of nuclei other than 1H with unprecedented sensitivity and speed. Thus, it not only can identify the location and quantity of a targeted hyperpolarised agent, but can also identify the agent's downstream enzymatic products, elucidating an entire chain of metabolic events in vivo. Multiple hyperpolarised substances can be injected and examined simultaneously, enabling multiple metabolic pathways to be probed in the same imaging session. With clinical HP-MRSI, imaging is crossing a threshold into a new level of real-time, quantitative assessment of tumour biology that will open up unprecedented opportunities for developing powerful predictive, prognostic and early response biomarkers for cancer management.

HP-MRSI, conventional MRI, and PET have different, yet complementary strengths. In the future, combined PET/MR/HP-MRSI will allow results from the various imaging approaches to be precisely correlated – providing new insights into cancer biology and increasing the value of imaging biomarkers in both drug development and clinical care.

MRI's role in gynaecological oncology

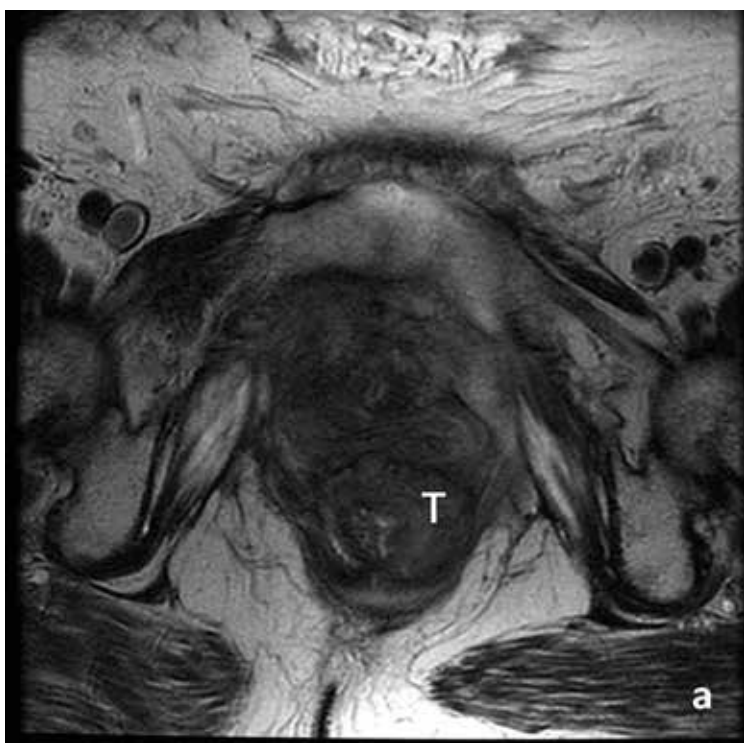
MRI has become integral to the diagnosis and management of patients with gynaecological malignancies as it combines exquisite anatomical detail with functional, multiparametric and quantitative assessment of tumour burden and its response to treatment. Techniques such as dynamic contrast-enhanced MRI (DCE-MRI) and diffusion-weighted MRI (DW-MRI) enable the radiologist to move from morphological to functional assessment of gynaecological malignancies.

In patients with endometrial cancer, MRI plays an important role in pre-operative evaluation and surgical planning: Not only does it allow non-invasive assessment of important prognostic factors such as depth of myometrial invasion, cervical stroma invasion, presence of peritoneal implants and lymphadenopathy, but through the use of functional imaging techniques, such as DW-MRI and DCE-MRI, it can also provide insights into tumour aggressiveness and micro-environment.

In patients with cervical cancer, MRI is the preferred imaging modality for evaluating primary disease, as it can determine tumour location (exophytic or endocervical) and size as well as invasion of the parametria, pelvic side-wall or adjacent organs, and lymph nodes with greater accuracy than clinical examination. Additionally, quantitative DCE-MRI and DW-MRI parameters serve as predictive biomarkers of response to chemo-radiotherapy, thus allowing for individualised tailoring of patients' treatment.

In patients with ovarian cancer, MRI is a problem-solving modality. There is growing evidence that DW-MRI allows more accurate mapping of the extent of peritoneal disease than does CT.

MRI plays an important role in patients with recurrent ovarian cancer by assessing the resectability of



Recurrent cervical cancer in a patient prior to pelvic exenteration. Axial T2W FRFSE (a) and fused axial PET/MR (T2W FRFSE +PET) image (b) demonstrate recurrent tumour invading the rectum (T in a, b). The second focus of recurrence posterior to and invading the pubic bone (arrow in b) is better appreciated on fused PET/MR images.

Born in Zagreb, in former Yugoslavia, **Professor Hedvig Hricak** MD PhD Dr (hc) studied medicine at the University of Zagreb and in the Karolinska Institute in Sweden. Today, she chairs the Department of Radiology in New York's Memorial Sloan-Kettering Cancer Center, and is professor of radiology at Cornell University Medical College and radiologist at Memorial Hospital in New York.
In 2010, she presided over the RSNA, and her professional awards include the Marie Curie prize from the Society of Women in Radiology and the Beclere-Medal from the International Society of Radiology.
Prof. Hricak's clinical activities include diagnostic radiology and oncological imaging of urogenital tracts.

solitary pelvic recurrences.

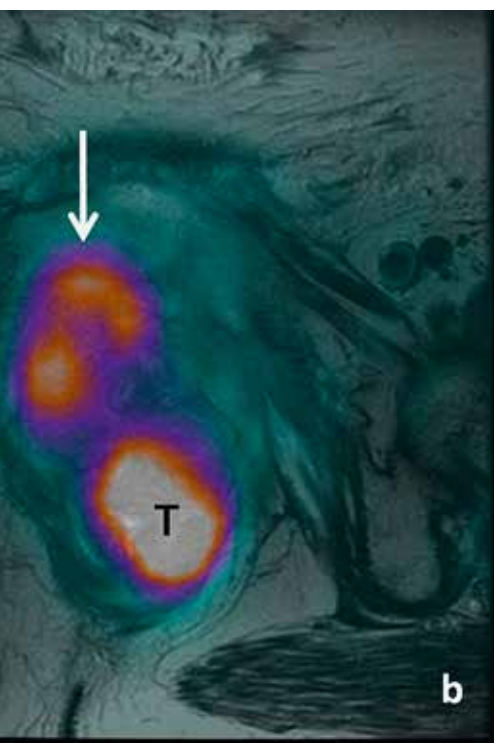
MRI can help to plan and tailor the pelvic exenterative procedure by accurately depicting local tumour extent and invasion of adjacent organs in patients with treatment-resistant or recurrent gynaecological cancer.

The gold standard

CT is still the gold standard for evaluating disease extent in patients with ovarian cancer, whereas PET/CT is routinely used to evaluate distant metastatic disease (including lymph nodes) in patients with primary and recurrent gynaecological malignancies. The maximum standardised uptake value (SUVmax) – a quantitative parameter derived from PET/CT – serves as a prognostic biomarker in patients with primary cervical cancer as well as in patients with recurrent ovarian cancer.

MRI's role in chemo-radiotherapy planning and monitoring

MRI plays a central role in planning chemo-radiotherapy and monitoring the response to such therapy in patients with advanced cervical cancer. DCE-MRI parameters reflecting heterogeneous tumour perfusion and subtle tumour volume changes early during chemo-radiotherapy are independent and better predictors of tumour recurrence and poor survival than are clinical prognostic factors. Preliminary data also demonstrate that the apparent diffusion coefficient (a parameter derived from DW-MRI) may serve as a predictive biomarker and has the potential to allow early assessment of response to chemo-radiotherapy.



The benefit of a higher magnetic field

MRI is the most sensitive technique for delineating small lesions due to its superb soft tissue resolution. A higher magnetic field strength improves image quality (due to an increased signal to noise ratio) and enables more effective use of functional techniques such as DW-MRI and DCE-MRI as well as more detailed metabolic imaging with MR spectroscopy.

Will PET/MR give additional clinical information?

This is a very new and exciting area of clinical research. The preliminary reports suggest that PET/MR may provide additional information for tumour staging and thus may influence patient management. In the future, with the development of new, targeted radiotracers, PET/MR will supply powerful biomarkers for multiple purposes.

Future roles

PET/MR, which has the capacity to capture an unprecedented diversity of functional and metabolic parameters in the context of exquisite anatomical detail, will change the way we evaluate gynaecological cancer patients and will greatly aid in drug discovery and the delivery of individualised clinical care.

Radiogenomics will provide the ability to match MR imaging traits with genomic information, furthering the development of prognostic and predictive imaging biomarkers.

Imaging (by MRI and or PET/MR) will be central to the way we design future clinical trials, as a more adaptive trial design is urgently needed.

The use of molecular imaging techniques, including HP-MRSI, will allow the development of more powerful predictive biomarkers, particularly for treatment selection and response assessment. Intra-operative molecular imaging will likely facilitate more complete tumour resection.

The development of sensitive molecular imaging biomarkers for ovarian cancer may enable repeat molecular imaging to substitute for preventative oophorectomy in high-risk patients by allowing detection of the disease before symptoms arise.

By courtesy of the Richard III Society

Richard III – modern imaging transforms a historical image

Mark Nicholls discovers how a CT scan at a British hospital played a critical role in identifying the long-lost remains of a 15th Century English king

For many centuries, the image of the English monarch King Richard III was that created by playwright William Shakespeare, who depicted the last Plantagenet King of England as an evil, hunch-backed murderer. That image endured virtually unchallenged over the centuries – primarily because of a lack of any contemporary paintings of the monarch, or the recovery of his remains.

The remarkable discovery of a skeleton a few months ago on the lost site of a forgotten church beneath a car park in Leicestershire, in the heart of England, was to change all that.

In February, DNA analysis confirmed the bones to be those of King Richard III, who is known to have been killed at the Battle of Bosworth on 22 August 1485.

It was modern hospital imaging technology that was to throw an added dimension on the remains and also help experts recreate his facial features. A team from the radiology department at Leicester Royal Infirmary scanned the bones using post mortem CT scanning protocols, similar to a normal clinical scan, to produce detailed images of the bones.

The unit has had a research interest and expertise in post mortem CT scanning for several years, so was well placed to offer the skills needed by archaeologists to unravel the mysteries surrounding Richard III's remains.

Claire Robinson, lead forensic radiographer at University Hospital Leicester carried out the scan with Professor of Radiology Bruno Morgan and Home Office pathologist Professor Guy Rutty and his team from the East Midlands Forensic Pathology Unit.

The bones were initially laid out on the scanner as close as possible to the anatomical position in which they were found. After the initial analysis of the images, a further scan of the bones was taken, using a bespoke polystyrene template to better position them, in order to reconstruct the images to make a 'virtual' three-dimensional model.

Professor Morgan said that as well as conducting a standard clinical scan using hi-res bone protocols, the University of Leicester team also used micro-CT to conduct a long but very high resolution scan of the skull. This was used to create the 3-D print used by the team at Dundee University to help reconstruct the facial features of the dead king (see above).

After his death, Tudor historians, as well as Shakespeare, portrayed Richard III as a villainous monarch with a curved spine who was rumoured to have murdered his brother's young sons in the Tower of London. He was eventually challenged by Henry Tudor (later Henry VII) and killed at Bosworth after only two years on the throne and given a hurried burial beneath the church of Greyfriars in the centre of Leicester city, in a clumsily cut grave with sloping sides and too short for the body, forcing the head forward. Greyfriars church was demolished in the 16th Century and its exact location was forgotten. However, a team of enthusiasts and historians managed to trace the likely area – and, crucially, after painstaking genealogical research, they found a 17th generation descendant of Richard's sister with whose DNA they could compare any remains. Joy Ibsen, from Canada, died several years ago but her son, Michael, who now works as a furniture maker in London, provided a sample.

The Leicester scans show that the skeleton's spine was indeed curved, a condition known as scoliosis, but there was no trace of a withered arm or other abnormalities described in the more extreme historical characterisations of the king.

Professor Morgan said: 'Richard III's bones were scanned three times and while it was relatively straightforward when compared to difficult clinical cases, there was the constant care needed because of the

From left: Claire Robinson, radiographer and advanced forensic practitioner, observing osteo-archeologist Dr Jo Appleby laying out the royal bones, watched by Dr Mike Biggs, pathologist from the EMFPU team.
Far right: Toshiba's Aquillon 64-multislice helped to extract secrets held in Richard's hand and arm bones for over 500 years

A resurrected king: Using the skull dimensions, the mouth width could be determined precisely by the position of the teeth; the little bump on the outer orbit is the outer corner of the eye, which also guided the reconstruction of the King's features

age, delicacy and importance of the remains.

'For us, one of the key elements was in trying to work out just how crooked he was. There is no doubt that the skeleton had scoliosis, but it was a case of working out just how bad it would have been and how easily it would have been to hide it.

'It has been a great opportunity to be involved in the project and learn a little more about Richard III's scoliosis and about the man himself. He did have scoliosis, though it was not as exaggerated as Shakespeare made out, but it was not made up.

'The big advantage of the scanning is it means that once the bones go back into the earth again, we have still got a very accurate facsimile of his bones, we have a permanent record for people to use for research in the future, especially as the CT images are being used to make a full 3-D print of the skeleton at the University of Loughborough.'

With University of Leicester osteo-archaeologist Jo Appleby and Piers Mitchell, anthropologist at the University of Cambridge and consultant paediatric orthopaedic surgeon for Peterborough and Stamford Hospitals NHS Foundation Trust, who have studied the skeleton's scoliosis, Professor Morgan will help produce a scientific paper looking particularly at how bad the scoliosis of Richard III would have been. He said that the Richard III project has been invaluable in promoting the role of the post mortem imaging team at Leicester and its capabilities. Post-mortem CT (PMCT) is becoming an option as a minimally invasive alternative to post-mortem examination. Leicester has become an established centre in PMCT, developing post mortem coronary imaging techniques and running a number of courses designed to introduce professionals to the use of computed tomography (CT) in the investigation of sudden death.

The bones are of a man in his late 20s or early 30s and have been carbon dated to 1455-1540. Richard was 32 years old when he died in battle. The skeleton had suffered 10 injuries, including eight to the skull, at around the time of death.

Dr Appleby said: 'The CT scans of the bones, carried out at Leicester Royal Infirmary by the Radiology Imaging Unit have been a crucial part of the investigations. The three-dimensional images of the skeleton that have been produced have played a central role in our interpretation of the injuries. In addition, the CT scans mean that we will have a full record of the skeleton even after the bones are reburied.'

While the CT scan provided a permanent 3-D record of the bones which cannot be obtained by other means, enabling images and models to be reproduced, minimising any potential damage that could be caused by repeated handling of the fragile bones and facilitating further analysis and comparisons after the bones are interred, the Leicester CT scans were also critical in helping build up an image of the much-maligned monarch's facial features.

When it came to reconstructing Richard III's face, the Dundee team used CT scans and photographs of the skull, which they ran through a computer programme. Caroline Wilkinson, Dundee University's professor of craniofacial identification, said clues from the skull were used to reconstruct features while a specific formula enabled researchers to predict what the soft nose would look like from the underlying bone and the shape of the brow.

'The width of the mouth can be determined exactly by the position of the teeth,' Professor Wilkinson explained. 'The little bump on the outer orbit is where the outer corner of the eye is. We can use these anatomical standards to help us rebuild the face.'

Over the centuries, some scholars sought to re-evaluate Richard III's brief reign and highlight his good work, such as reforming the English legal system. That debate is set to continue. But with the bones scanned and confirmed as the remains of King Richard III, planning is now under way for a formal reburial of a long-lost English monarch.

Improving X-ray technology

A new technique being pioneered in a UK hospital aims to help orthopaedic surgeons with spine and hip surgery

The Image Overlay Template Alignment (IOTA), now being used at Leicester Hospitals, improves on current X-ray technology and helps increase the accuracy of complex surgery, such as spinal fixation following a car crash.

Gareth Robinson, a senior radiographer at Leicester's Hospitals, who invented the technique, said: 'Currently, our very skilled surgeons use X-ray images to help guide operations, together with their knowledge of the body and their eyesight. However, X-rays can be difficult to interpret because their exact magnification is unknown and there is little information on the X-ray to suggest depth. In other words, they're rather two-dimensional. My technique uses laser lights and templates that can be laid over x-ray images to help surgeons make even more accurate surgical decisions."

Thus surgeons gain more information about precise angles at which pins and other prosthetics need to be placed and the system reveals parts of the implants or shapes of the bones into which the implants are to be inserted, which are normally hidden to X-rays and the human eye.

Accurate measurements would confirm lengths of screws and other implants to be fitted. These can be cross-checked with the surgeon's initial calculations.

Manangement In Radiology

Finding that perfect match

Advice from an 'old hand' for juniors wanting to work in a department where they fit in and which also suits their personal hopes and ambitions

The professor giving sound advice at the Junior MIR (Management in Radiology) course held in Milan in October

Report: Michael Reiter

At the end of residency physicians apply for a position in a department. More often than not, this process involves misunderstandings between the young applicant and the department's recruitment representative, as explained by Professor Yves Menu at last year's Junior MIR (Management in Radiology) course held in Milan last October. In his lecture, the chairman of the ESR Professional Organisation Committee spoke of several aspects that ought to figure prominently in this career phase.

Typically, the recruitment person is seeking someone who is ready to assume the role of a senior, someone who will attach him/herself very much to the department and the discipline. However, the applicant's self-assessment is as being someone between a junior and senior role, Prof. Menu explained.

Differing views

As an example for applicants who have finished residency, he quoted the 'Chef de Clinique Assistant' in France, which resembles a fellowship; it is a salaried university position. These physicians are expected to perform medical care as well as teaching and research activities. 'Obviously, to fill that position, the head of department requires someone who is able to diagnose and treat the patient, to train juniors and also to carry out research,' Prof. Menu pointed out. When applicants send in their documents, however, their message is 'I'd like to join your department in order to increase my knowledge'. Obviously the views from the two sides differ.

Consider key factors

There are turning points – moments that turn up in someone's life when s/he thinks a major decision should be made – on the assumption that s/he is aware of the relevant facts, skills required, within a context that includes external, family events and many more factors. Based on a firm foundation, it appears to be rather safe to go for an opportunity. 'However, someone who has just come out of residency is not endowed with the solid grounding that such a major decision would need – that point only comes perhaps two or three years later in life,' according to Prof. Menu, who adds: 'Young people should be aware of these kinds of factors and of turning points.'

Choosing a department does not mean choosing a fixed environment, he added. 'For example, if you decide in favour of a specific department in an organisation because of its modern equipment, this is not really a future-safe approach – because that equipment will be outdated at some point.' Many young physicians do not realise this, he said. 'If I were in a position to choose, I would vote in favour of a department with a lot of machines, but ones that are due to be replaced by brand-new equipment.'

Furthermore, applicants should not underestimate a department's and organisation's history, as well as the atmosphere within the team. Is the feeling compatible with his/her own way of interacting? Applicants should also analyse themselves, and never pretend to be some other person. 'Accept your weaknesses – you may be able to compensate them to some extent, but they will accompany you all your life. Therefore it's better to find a position and place where your weakness will not significantly impede your performance. For example, if you find it hard to get up early, don't join a department where you are expected to start work at seven,' he warns.

By keeping these pointers in mind, and looking beyond a department's work and equipment, applicants might avoid adaptations that might become painful – and such advice holds true beyond borders.

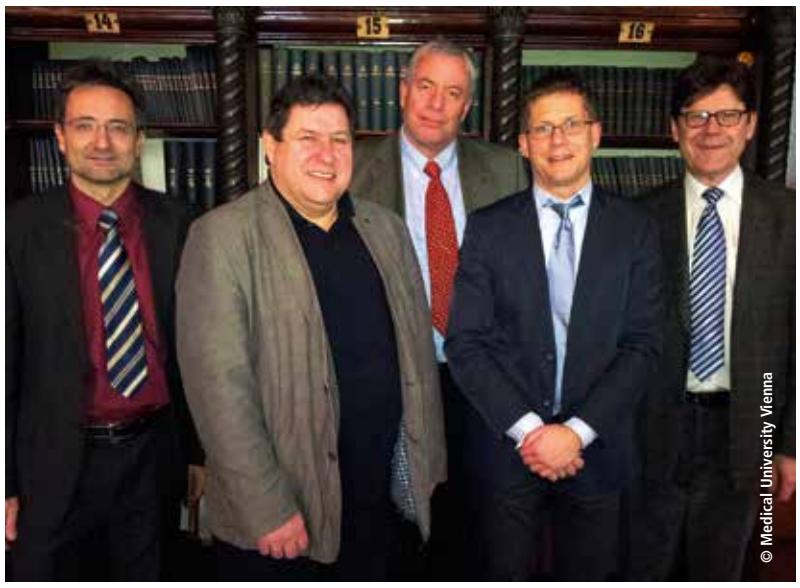
Having held key posts in several renowned French hospitals, **Professor Yves Menu** is currently Chairman of Department of Radiology at the Saint Antoine Hospital and Professor of Radiology at the University Pierre and Marie Curie (Paris VI). In 2011, he was ECR President and, within French and European Radiology Societies he is a member of the ECR Programme Committee as well as chairman of the ESR Professional Organisation Committee.

40 years of CT scanning

Report: Michael Krassnitzer

Forty years ago an article was published that would change medical practice. In the British Journal of Radiology, English electrical engineer Godfrey N Hounsfield described how he had made a patient's brain visible non-invasively by evaluating a large number of X-ray images of the skull taken from different directions. This was totally new – the birth of Computed Tomography (CT). 'It's possible that this technique opens a new chapter in X-ray diagnosis,' the engineer speculated. What an understatement. The new procedure revolutionised medicine. Two years later (1975) he was elected to the Royal Society and, in 1976, was appointed Commander of the British Empire. Three years on, he shared the Nobel Prize for Physiology or Medicine with Allan McLeod Cormack for his part in developing the diagnostic technique of X-ray computed tomography (CT). In 1981 the inventor became Sir Godfrey Hounsfield CBE FRS, following his knighthood by Queen Elizabeth ll. He died in 2004.

'Modern diagnosis of carotid artery disease, as well as diagnostic confirmation of acute stroke, is unimaginable without CT angiography these days,' Professor Christian Loewe MD, at the Department of Cardiovascular and Interventional Radiology, Radiodiagnostics Clinic, Medical University of Vienna at a 40 years of CT scanning press conference held in the Austrian Radiological Society. 'It's possible,' he pointed out, 'to visualise and quantify stenosis of the carotid arteries and occlusion in the cerebral arteries and then to plan the adequate treatment in just a few seconds of examination time, without the need for arterial puncture in the groin and with high resolution and diagnostic safety.'



From left: Prof. Reto Bale, Dr Johannes Trenkler, Prof. Gerhard Mostbeck, Prof. Christian Loewe and Prof. Werner Jaschke, President of the Austrian Society of Radiology (ÖRG)

Technological advancement has not only increased the temporal and spatial resolution of CT angiography but also significantly reduced the exposure to X-rays from CT scanning. This has also made CT angiography the method of choice to investigate aortic disease and aortoiliac occlusive disease. 'Modern endovascular treatment procedures for aortic aneurysms via vascular endoprosthesis (stent graft) would be impossible without the above mentioned advances in CT angiography,' the professor emphasised. 'The modern procedures available now also facilitate imaging of the coronary arteries and any changes within them via modern CT scanning in mere seconds.'

The high validity of this technique, particularly to exclude coronary artery disease (CHD), was confirmed in numerous national and international publications. Only for patients with a clear clinical indication for the presence of CHD does CT scanning currently not deliver added value, the Austrian radiologist pointed out.

For many years, CT scanning has also played a central role in the diagnosis, treatment planning and monitoring of cancer patients. 'Modern multi-detector CT scanners produce images of outstanding quality and resolution and deliver the relevant information that doctors require for their treatment strategies and therefore for the best possible care of cancer patients,' explained Professor Reto Bale, from the of Micro-invasive Therapy (SIP) division of the Department of Radiology, Innsbruck Medical University. 'The number of systematic diagnostic and therapeutic CT interventions in oncology has increased substantially over the last few years. A histologic examination is the gold standard of diagnostic confirmation and the basis of any oncological treatment.' Lung and bone tumours are particularly inaccessible for sonographically precise puncture and are routinely biopsied percutaneously with CT help.

CT-navigated thermal ablation procedures, such as radiofrequency ablation, microwave ablation and cryotherapy, are increasingly used to treat liver, kidney, bone and lung cancers. Combined with modern 3-D navigation systems these procedures facilitate local curative treatment of various tumours of up to 10 cm diameter and thus represent a minimally invasive addition, or alternative respectively, to surgical procedures.

As an alternative to a colonoscopy, virtual endoscopy allows a quick evaluation of the entire colon using reconstructed 2-D and 3-D images. A 'fly-thru' programme lets the radiologist see into the intestine as if he was carrying out a colonoscopy. In this way colonic polyps can be detected and examined non-invasively. Modern software also facilitates the automated 3-D reconstruction and determination of the size of lung and liver tumours. 'This allows us to recognise changes in the tissue and to more objectively assess these over time,' Prof. Bale explained, concluding his outline of CT applications in today's oncology.

Zero-Field MRI

UK research team pioneers a new type of scanning system

Scientists at Aberdeen University, Scotland, are developing Zero-Field MRI (ZF-MRI), to enable diseases to be 'seen' at an earlier stage than with standard MRI. They also suspect that ZF-MRI may reveal biomarkers that could help pharmaceutical firms to develop new drugs for neurodegenerative diseases, e.g. Parkinson's and Alzheimer's, plus cancer and osteoarthritis.

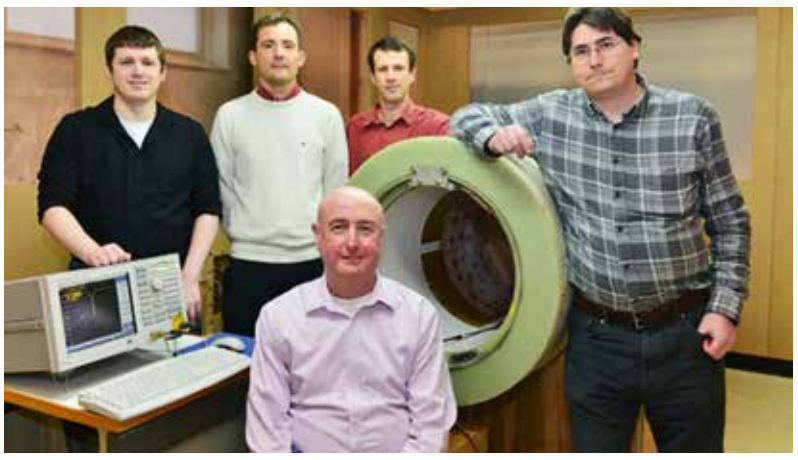
The University of Aberdeen researchers – from medical physics, radiology, neuroscience and neurology – are creating the new technology in the biomedical physics building. Aberdeen has a long record of ground-breaking scanner developments, including clinicians there being the very first, worldwide, to scan the body of a patient using MRI in 1980.

ZF-MRI is a major departure from standard MRI because it takes the magnetic field within the scanner - including the Earth's own magnetic field - very close to zero, in order to see disease-related tissue changes not revealed by conventional MRI.

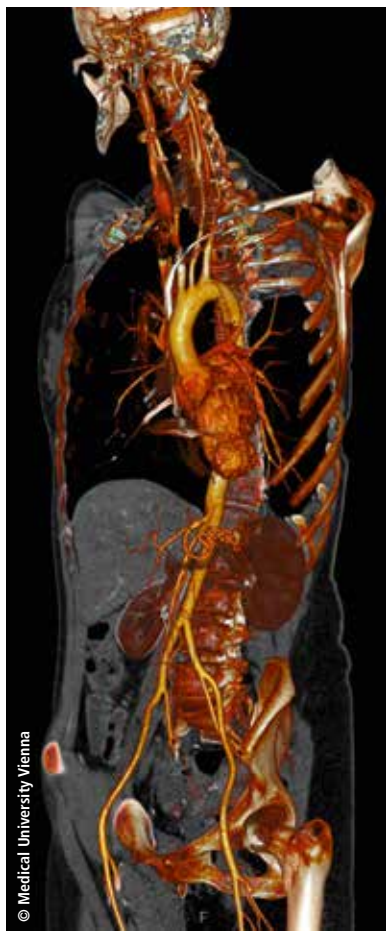
Dr Lionel Broche, a Research Fellow at the University, said: 'Right from the early days of MRI it has been known that the contrast that can be seen between normal and diseased tissue is greater at lower magnetic fields, because of the way in which molecules move around in tissues, altering the signals that are detected and used to form the detailed MRI pictures. At low magnetic fields the speed of the molecular motion is more closely matched to the frequency of the MRI signals, making the technique more sensitive to changes.

ZF-MRI should provide us with exquisite sensitivity to subtle changes in brain tissue, bringing the possibility of early diagnosis.'

ZF-MRI will be used with another MRI technique, pioneered by Professor Lurie's team, called Fast Field-Cycling MRI (FFC-MRI), which can also 'see' extra information, compared to normal MRI. Unlike conventional MRI, FFC-MRI switches rapidly between different magnetic fields - an effect rather like having 100 or more scanners with differing scanning capabilities within the one scanning machine. With the ZF-MRI technology incorporated into an FFC-MRI scanner the researchers will initially modify the FFC-MRI scanner to enable zero-field measurements. The team plans initially to use ZF-MRI to scan small objects, e.g. bottles containing protein gels to mimic normal and diseased tissues, and then, towards the study's end they hope to image patients with neurodegenerative diseases, particularly Alzheimer's and Parkinson's.



The ZF-MRI project team is led by medical physicist Professor David Lurie (centre). Their funded research will last for three years.



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CT angiography - within mere seconds CT facilitates the complete imaging of the arteries - from head to toe if needed. Thus it is possible, quickly and non-invasively (i.e. without the need for arterial puncture in the groin) to rule out or confirm arterial disease in the context of atherosclerosis and to plan treatment - also for out-patients.

Perfusion imaging: The future of CT?

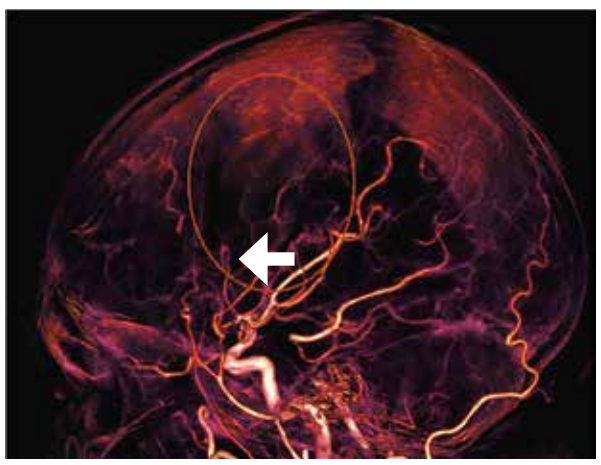
CT scanners now nicely cover morphology. The challenge is moving to CT functional imaging without frying patients

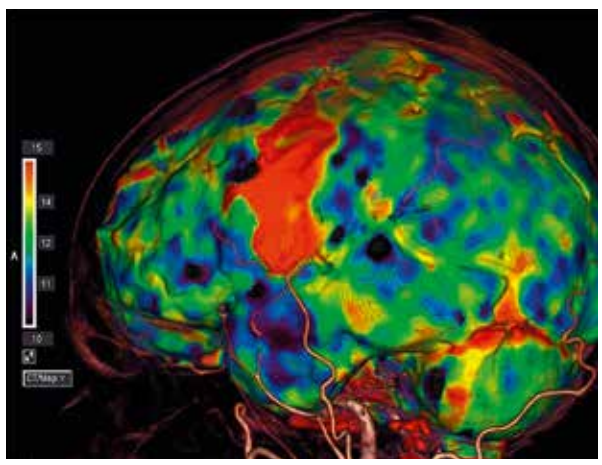
Report: John Brosky

Cardiac scanning was the driving force behind recent developments in computed tomography (CT) that saw the introduction of multi-detector imaging as well as innovations such as dual-source flash scanners and wide 320-slice detectors. The next five years will see the development of a combination of CT angiography (CTA) and CT perfusion as a one-stop shop for cardiologists, according to Professor Mathias Prokop. Radiologists will be able to offer examinations including stress tests capable of predicting the presence of ischaemia equally well as SPECT.

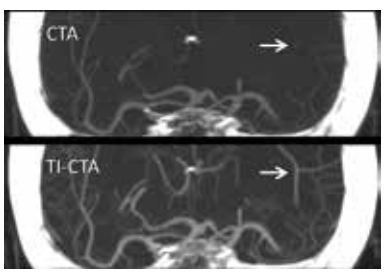
Prof. Prokop and his group at the Radboud University Medical Centre are looking further to a day when CT perfusion can offer functional diagnosis throughout the body, starting with applications in the brain but spreading to oncologic and functional imaging.

The challenge is to create good-quality perfusion scans at an acceptable radiation dose. If perfusion imaging was done using conventional settings for each time point of a perfusion series, then radiation dose would have to be multiplied with the number of scans, and thus be larger than current techniques by a factor of 20-40. Since frying patients is no option, low-dose approaches are being developed that can achieve perfusion imaging at competitive dose, but these approaches so far struggle with reduced image quality. His group sees dose and image quality as the key issues and is working on developing techniques for high-quality perfusion at acceptable dose levels. 'Widespread use of perfusion imaging is not acceptable if we can't bring down the dose,' he said. 'That's the message.'

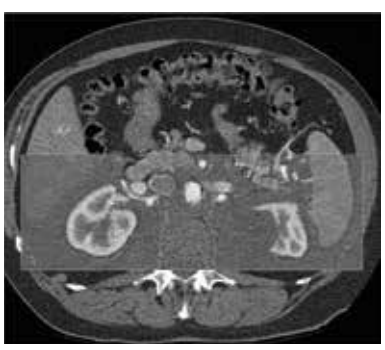




Left: High-resolution CTA derived from a CT perfusion study. Note occlusion of a side branch of the middle cerebral artery (arrow)
Right: CT perfusion map demonstrates reduced perfusion in affected territory



Comparison of CTA and timing-invariant CTA. Note the lack of collateral vessels on the left side on CTA but good filling on TI-CTA (Courtesy Ewoud Smit)



Iodine map derived from subtraction imaging demonstrates lack of contrast enhancement in a large hyper-dense cysts on the left.

So, now that the Slice Wars have settled, where are we with CT imaging?

Prof Prokop: 'Cardiac imaging used to be the driving force behind new CT developments. Today we can deliver pretty good quality imaging of cardiac morphology in almost all cases, though the technique is not completely fool proof. All the new generation scanners beyond 64-slice are capable of good-quality cardiac work. Cardiac imaging is especially simple with the scanner we use, which is a Toshiba 320-slice unit. In a fraction of patients there's a bit of a problem left with motion correction. 'GE Healthcare recently introduced a software approach to estimate the movement of the coronary arteries and use this information during image reconstruction to counteract this motion and improve sharpness and contour delineation of the coronaries. I expect this technology to spread to the other vendors who are already playing with it. Philips it was the first to publish, but hasn't yet implemented the technique in their clinical software.

'A big issue we have currently with cardiac CTA is that cardiologists tell us it's nice to know the coronary morphology, but that it is more important to know whether a stenosis is functionally relevant. This information is important for deciding whether to treat this stenosis or not. Until very recently we were not very good at answering this question because, while we could see there was a stenosis, we could not say anything about collateral vessels or whether the stenosis caused a malperfusion of the myocardium.'

Is CT really a viable modality to answer this question?

'Assessing the functional significance of a stenosis is a topic that is still under development and will remain so for the next few years, but it will get done. The current technique uses adenosine stress testing and a scan at a time point where there is the biggest difference in perfusion between normal and ischaemic myocardium. The technique has been studied, for example, at John's Hopkins and been tried out in the Core-320 multicentre trial. CT perfusion turns out to predict ischaemia similarly well as SPECT CT, but further optimisation seems warranted. In principle, the technique can be used on any modern scanner but we find it easy on our 320-slice unit because of its ability to perform snapshot imaging even at the high heart rates encountered at stress testing.

'Once the technique has matured, CT will act as a one-stop shop for patients with suspected ischaemia who now undergo a wide variety of tests ranging from bicycle stress testing to ultrasound, SPECT, MR or catheter coronary angiography. The CT workup would start with CTA to see if there are abnormalities. If there is a potentially significant stenosis, then a CT perfusion stress test will show if the stenosis is relevant and needs to be treated.'

In recent investigations you have taken CT perfusion beyond the heart. What potential do you see?

'What's coming next is dynamic perfusion imaging that consists of a series of short scans covering the target area. It can be done with most scanners with decent results, though again there is an advantage in covering an entire target, such as the brain or liver, with a wide detector that gives good signal-to-noise at a relatively low dose.

'These perfusion scans have been successfully used in stroke imaging to discriminate between infarct core and penumbra and to identify proximal vessel occlusions that would warrant intra-arterial stroke treatment. We see increasing indications in oncologic imaging: we'd like to be able to distinguish early between responders and non-responder to biologicals, the expensive but powerful new class of oncologic drugs.

'This would allow for substantial savings if treatment is stopped early and non-responders are put on alternative treatment. This appears feasible because CT perfusion is able to see an early drop in tumour perfusion in responders. Other applications of CT perfusion will include treatment planning for head and neck tumours, lungs, kidneys and tumour differentiation.

'However, the crucial factor for success is to keep radiation dose at bay while providing sufficient image quality. What we are working on now is to make sure that CT perfusion can be done without over-dosing the patient. Currently a CT perfusion of the brain scan will cause an effective radiation dose in the range of 2 or 3 mSv, which does not sound too bad. However, the local dose, for example to the eye lens, is much higher – well above 100 mGy, which is substantial.

'We are trying a couple of approaches, and while we are not there yet, results look promising. We are now acquiring such low dose images during the perfusion series that a single image is almost unusable for diagnosis. The challenge is to understand how we can retrieve relevant information from these ultra-low dose, lousy-looking images.

'One approach, for example, is a 4-D noise filter that can improve the image quality quite dramatically by using not only 2-D or 3-D information but data from the whole acquisition series. We are now already able to look at all the dynamic information: inflow and outflow of contrast via arteries and veins, and areas with delay in perfusion as an indirect sign of obstruction or other abnormalities.

'One of our team members, Ewoud Smit, has shown that a relatively simple technique that we call timing-invariant CTA is able to depict collaterals much better than conventional CTA. He has found that if you do not see collaterals on a timing-invariant CTA the outcome of a stroke patient is invariable bad. Since conventional CTA is a looking at a particular moment in time, collaterals may not yet be enhanced during the time of acquisition. Timing-invariant CTA, on the other hand, uses data from the whole 4-D series and will display vessels impendent of when contrast arrives. The result is that you cannot rely on a conventional CTA if it does not display collaterals – they might be still there but not yet enhanced, while the timing-invariant technique will always show them if they are there at all.'

You've worked in Japan with Toshiba, on phantom models relating to the ViSION Edition scanner. What's the goal?

'We have a Toshiba grant to develop a phantom that allows us to play around with the CT acquisition parameters without having to expose patients to radiation. It allows us to determine how to choose scanning and post-processing parameters to optimise the image quality. We needed models that allowed us to study the influence of each variation we are testing on the accuracy of perfusion measures, noise, spatial resolution, signal-to-noise ratios and, ultimately, visibility of small perfusion abnormalities, such as lacunar infarcts. 'The phantoms need to be organ-specific to replicate the noise that comes from real scanning. The noise in the brain is, of course, different from the chest, for example. We now have a phantom for the brain. We will probably develop such a phantom for the abdomen, and then one for the chest. Toshiba has fully embraced this approach.'

You are updating your best-selling book 'Spiral and Multi-slice Computed Tomography of the Body'. What can we expect to see?

'We hope it will come out at the end of this year. Our goal is to include the very latest information. What will be significant in the new edition is the latest technology, such as perfusion imaging, the new field for development, as well as the related subject of dual-energy and subtraction imaging for contrast-enhanced studies. We are now applying the same techniques we use to extract information from perfusion scans to subtraction imaging, another powerful tool for creating iodine maps at various time points after contrast injection. The resulting high-resolution maps look pretty cool and will probably revolutionise the way we look at contrast-enhanced studies.'

Mathias Prokop trained as a radiologist at Hanover Medical School, Germany and gained a BSc in Physics at Marburg University, Germany. From 1998 he was an Associate Professor of Radiology at the University of Vienna Medical School. He went to the Netherlands in 2002 and became Professor of Radiology at UMC Utrecht in 2004.
In 2009 he was appointed Professor of Radiology at Radboud University Nijmegen as well as Chairman of the Department of Radiology.
Dr Prokop is an expert in body imaging with a special focus on multislice CT and new imaging technologies. Over the past decade he has concentrated on chest screening using CT (cancer, cardiovascular disease, COPD) and has been a major player in the Dutch-Belgian lung cancer screening trial (NELSON).

Interventional radiology

Drawn by qualified training in interventional radiology, around 800 German-speaking specialists headed for Berlin in January to attend the Interventional Radiological Olbert Symposium (IROS) 2013

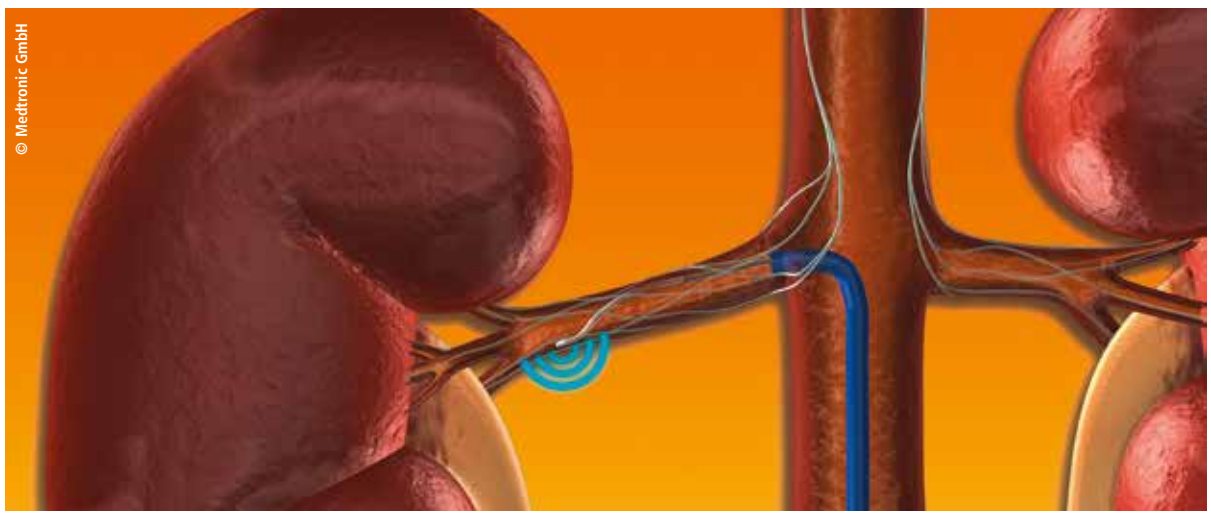
Report: Dr Jörg Raach

Since the dawn of the 1960s, interventional radiology has been a specialty within radiology that goes far beyond diagnosis; aided by imaging modalities such as CT, MRI and ultrasound, the discipline concentrates on minimally invasive treatment of chronic pain syndrome, vascular and tumorous diseases. 'The advantage of the interventional radiological method is its minimal invasiveness,' explained Thomas J Kröncke MD Priv.-Doz., Congress President of IROS 2013 and Deputy Director of the Clinic for Radiology (Campus Mitte) at Charité University Hospital, Berlin. 'Under local anaesthetic, millimetre-thin catheters are inserted into the blood vessels, or other ductal systems, to gain access to a diseased body area and to carry out the appropriate treatment.' Apart from the success rate of these less invasive procedures without scalpels the shorter recovery time is another strong argument in their favour as shorter hospital stays help to cut costs.

Helping with treatment-resistant hypertension

Around 50% of women and men in Germany aged 65+ years are known to suffer arterial hypertension. High blood pressure (BP) is among the most important risk factors for cardiovascular disease and therefore an essential determinant of the most common causes of death in adults. Therefore, correction of high BP is very important. In most cases this can be achieved via regular administration of one or several drugs. However, if a sufficient lowering of BP is not possible with medication, this is known as treatment-resistant hypertension, now believed to result from faulty signals from the kidneys, which continuously monitor BP and send the respective signals to increase or lower BP to the brain, explained Christian Scheurig-Münkler MD from the Clinic for Radiology Clinic at Charité University Hospital, Berlin, Campus Benjamin Franklin (CBF).

'If this control mechanism is disturbed, interventional radiologists can interrupt the nerves in the kidneys which transmit the faulty signal to the brain via catheter-based renal denervation. Via an incision in the groin of only a few millimetres in size the respective catheter is inserted into the renal vessels. The wall of the vessel is then heated from the inside in several locations, which makes the nerves lose their function without damaging the wall of the vessel. The faulty signal can no longer be transmitted. The treatment takes around 45–60 minutes and is now being offered all over Germany,' said Professor Dierk Vorwerk, Director of the Institute for Diagnostic and Interventional Radiology at Ingolstadt Hospital and Chairman of the German Society of Interventional Radiology.



Above: Schematic image of catheter-based renal denervation, with transmission of the faulty signal to the brain from the renal nerves being interrupted using heat

Right: Professor Josef Tacke at work in Bogenhausen Hospital during a minimally invasive intervention

'The intervention itself is low risk and the effectiveness of the procedure since its introduction in 2008 has been demonstrated in 19 studies involving 683 patients over an observation period of one to 24 months. All studies confirm a significant lowering of systolic and diastolic blood pressure. The maximum reduction in blood pressure ranged from 18mm Hg to 36mmHg (systolic) and 9mmHg to 15m Hg (diastolic),' said Professor Michael Uder, an authority on renal denervation at the University Hospital Erlangen, quoting from the new meta-analysis published by the American Society of Hypertension in 2012. At the same time it does not lead to a decrease in kidney function and has been shown to result in only few and justifiable side effects. However, patients still need to continue to take drugs to lower blood pressure. It will also be necessary to investigate whether this procedure results in a long-term lowering of high BP based on long-term studies with large patient collectives. Larger studies for medical devices prior to their admission to the market are also required (currently, unlike drugs, medical devices are often licensed based on tests involving only 100 patients). Present studies investigate whether, apart from the long-term success of the treatment, there may also be a possible benefit for other diseases such as cardiac insufficiency, cardiac arrhythmia et al.

Ensuring quality of life for diabetics and cost-cutting

Interventional radiology makes it possible to improve diabetic care significantly through early, less invasive interventions. 'With just under six million diabetes patients in Germany the costs of their care are around €6.5 billion annually. Most of those costs are caused by follow-on diseases resulting from diabetes, e.g. coronary heart disease, stroke, diabetic foot and vascular occlusion,' said Professor Petra-Maria Schumm-Draeger, internist, endocrinologist and diabetologist at the University Hospital Munich quoting from a current Robert Koch Institute study. It is these diseases that can be treated particularly effectively through interventional radiology if the intervention is carried out at an early enough stage. This has also been recognised by the International Working Group on the Diabetic Foot (IWGDF), which already includes interventional radiology procedures in its guidelines as first line, standard methods of choice.

A 50% drop in diabetic foot amputations

In the case of diabetic foot syndrome, chronic vascular changes right down to complete arterial occlusion in the legs caused by diabetes, it is possible to prevent or delay amputation through IR procedures. By inflating a tiny balloon in the affected artery (balloon-angioplasty) it is possible to re-open it. This prevents the tissue, which is now again supplied with sufficient blood, from dying, and thus a surgical intervention, including amputation, can often be avoided. In most cases the patient can leave hospital the same day or a day after the procedure. Apart from maintaining quality of life, and possibly the ability to work, this also avoids the enormous costs resulting from an amputation.

Professor Gross-Fengels, from the Department of Interventional Radiology at the Asklepios Hospital Harburg, Hamburg, explained: 'Specialist facilities have been able to lower the rate of amputation by up to 50%. This gives us hope considering that half of all patients die within the first five years of a leg amputation.'

DATES FOR YOUR DIARY

CIRSE 2013 and IROS 2014

14-18 September 2013
Barcelona, Spain
The European Congress for Interventional Radiology CIRSE.

16-18 January 2014
Salzburg, Austria
The Interventional Radiology Olbert Symposium IROS for German-speaking countries.

ForSaTum: Determi obstacles to drug d

Funding is needed, but preclinical imaging research must also gain a high confidence level, with greater efficiency and cost-effectiveness needed in fundamental research into new drugs and imaging procedures

Several obstacles hinder the establishment of new tumour therapies in Germany. Many cancer diagnosis and treatment approaches fail due to high development costs and a lack of clinical efficiency because preclinical procedures are not optimised and there can be no talk of swift clinical implementation.

Founded in 2010, with participation from Aachen and Bochum universities, Philips and some up-and-coming IT companies from North Rhine-Westphalia, the consortium ForSaTum, a German short form that roughly translates Research Satellite for an Accelerated Implementation of New Tumour Treatment Concepts, is striving to remove those obstacles. 'One major problem is that many imaging studies only result in a relatively arguable proof of principle,' explains the consortium's spokesman Professor Fabian Kiessling MD, head of the Experimental Molecular Imaging Department at Aachen University Hospital. 'Mostly the data are neither substantial nor reliable enough to allow us to rely purely on imaging.'

The fact that among some 10,000 new drugs development concepts fewer than ten make it to the clinical testing stage, and more than 80% of these go on to fail. Often, promising clinical treatment approaches are also not pursued by the industry because they were not sufficiently validated beforehand or are deemed too financially risky. The cause is a lack of efficient preclinical units for the standardised longitudinal examination of diagnostics and therapeutic agents in relevant tumour models. 'There is no suitable preclinical platform anywhere in Germany that fulfils requirements for the integration of top medical devices technology, the know-how for the development of pharmaceutical products and comprehensive data management. We have therefore made it our objective to optimise preclinical imaging research to such an extent that, firstly, it has a high confidence level and, secondly, it makes fundamental research and the development of new pharmaceutical products and imaging procedures more efficient and cost-effective,' the professor explains.

Personalised medicine

Imaging diagnostics, and particularly molecular imaging, play a central role in preclinical and clinical research because it increases the validity of preclinical studies and therefore the number of new treatment opportunities. Molecular imaging is the prerequisite for personalised medicine, which is in demand. Prof. Kiessling and the consortium are therefore proud that they have succeeded in implementing an important new development: a fully digital PET-Insert for MRI scanning. The PET scanner was miniaturised to such an extent that it can be integrated into a 3-Tesla MRI within 20 minutes, without any problems, meaning that an MRI scanner can be transformed into an PET/MR scanner at little expense, with the hybrid scanner then also working fully digitally. 'The digitisation of all stages during signal recording and

With a doctorate in internal medicine from the Ruprechts-Karls-University in Heidelberg gained in 2001, **Professor Fabian Kiessling MD** became radiology resident in the oncology department at the German Cancer Research Centre (DKFZ) and at Heidelberg University Hospital. During this period he managed various research groups, such as the Molecular Diagnostics Working Group in the Medical Physics Division of the DKFZ Radiology Department in 2003 and later headed the Helmholtz Junior Group Molecular Diagnostics.
His W3 professorship for Experimental Molecular Imaging was awarded at RWTH Aachen University in 2007 and, in May 2008, he became Chair.
He has been a Member of the Research Board of the European Society for Radiology (ESR) since 2011, and is a founder member of the European Society for Molecular and Functional Imaging in Radiology (ESMOFIR), and the current Secretary of the European Society for Molecular Imaging (ESMI). He has also been a frequent member of programme committees for the congresses of the European Society for Molecular Imaging (ESMI) and the World Molecular Imaging Society (WMIS).

MRI holds a key role in cervical cancer

Modern imaging techniques greatly enhance the treatment selection

Report: Michael Reiter

Staging of cervical cancer is clinically based on a system developed by the International Federation of Gynaecology and Obstetrics (FIGO). The staging is clinical because the majority of cases occur in developing countries where access to MRI is limited, explains gynaecological radiologist Dr Evis Sala. Clinical diagnosis is gained via a smear (pap test), clinical symptoms assessment and examination.

Although MRI has been used for evaluation of disease extent in patients with cervical cancer for the last two decades, it was 2009 before FIGO acknowledged that, where available, CT and particularly MRI could be used to evaluate the extent of disease. According to the Dr Sala this is a key step forward regarding the use of imaging as part of the evaluation of disease extent in cervical cancer. 'Imaging,' he explains, during our interview, 'plays a crucial role in the patient journey. First of all, in young patients who wish to preserve fertility, there is an operation called trachelectomy: the cervix is removed and the tumour along with it, allowing preservation of the uterus. Studies have demonstrated that this method allows affected women to preserve fertility and carry a pregnancy to term.

'Specialist surgeons capable of performing this procedure need the best information available to assess the patient's eligibility. This is where MRI comes in. In almost 100 percent of cases, it is accurate in selecting patients suitable for trachelectomy and in achieving precise planning of that procedure.

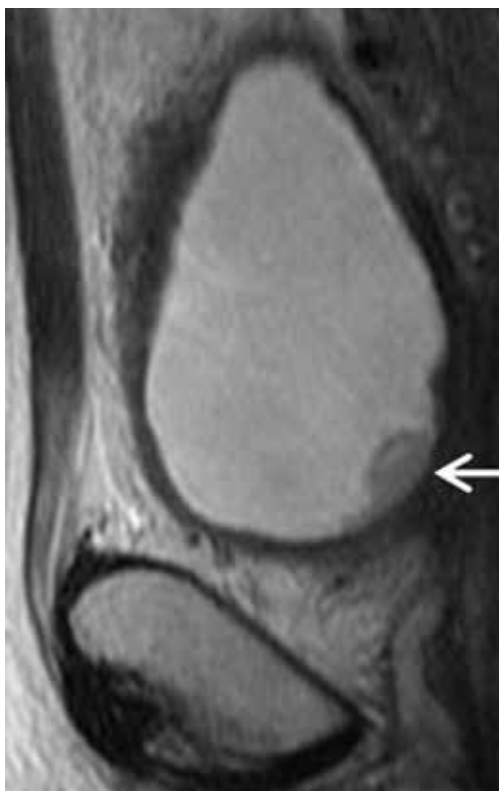
'Apart from fertility-sparing issues, triaging patients with cervical cancer is another purpose which MRI serves very well. If the tumour is small and has not spread into the adjacent parametrium, surgical removal of the uterus and adjacent tissue is performed. In cases where the tumour has spread to neighbouring tissues, radiotherapy is the appropriate option. Clinical staging has proved to be significantly inferior to MRI especially in the early stages of the disease spread to the adjacent tissues (parametrium).'

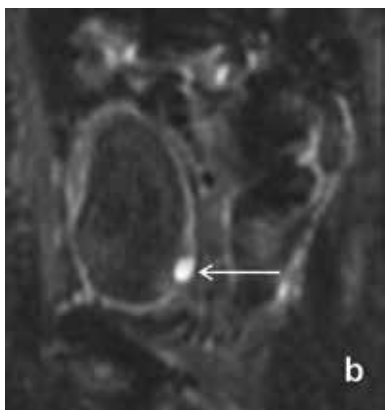
Speaking of other applications for MRI, Dr Sala pointed to the evaluation of tumour recurrence. 'MRI can map out recurrence very nicely in the pelvis and the lymph nodes. MRI can be combined with PET/CT if there is a question about distant metastases, for example, in the chest,' she added.

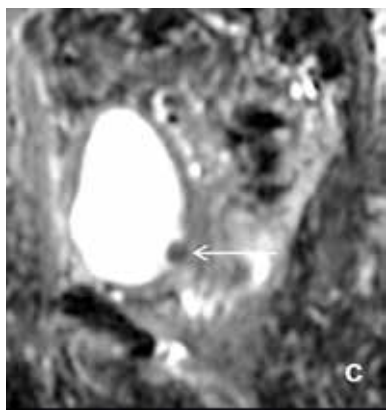
'In general, functional MRI techniques such as perfusion and diffusion MRI provide insights into tumour biology, and quantification of changes following treatment is possible. Dynamic-contrast enhanced MRI reflects tumour perfusion, whereas diffusion-weighted MRI measures water movement, which reflects on tumour cellular density and the integrity of the cellular membranes. MRI parameters, indicative of heterogeneous tumour perfusion and subtle tumour volume change early during chemo-radiotherapy, are independent and better predictors of tumour recurrence and death than clinical prognostic factors. Diffusion-weighted imaging helps predict early response to chemo-radiotherapy in patients with advanced cervical cancer. Therefore, quantitative parameters generated from functional MRI techniques, such as perfusion and diffusion MRI, may serve as prognostic and predictive biomarkers in patients with cervical cancer.'

'The key added value of MRI is in treatment selection and planning – selecting patients who wish to preserve fertility and triaging patients suitable for surgery vs. chemo and radiotherapy. Radiologists are key members of a disease management team leading to individualised treatment planning and follow-up of patients with cervical cancer.'

Following medical studies at the University of Tirana Medical School in Tirana, Albania **Dr Evis Sala** gained MPhil and PhD Degrees at the University of Cambridge, UK and took up a radiology residency at Cambridge University Hospitals. She also completed a Research Fellowship at Memorial Sloan-Kettering Cancer Centre, New York, USA, before returning to the University of Cambridge in 2005 as a University Lecturer/Honorary Consultant Radiologist. In July 2012, Dr Sala returned to Memorial Sloan-Kettering Cancer Center, to become Director of Gynaecologic Radiology. Her professional focus is on genitourinary cancer imaging; she has been awarded numerous awards and honours.







Future perspectives

One of the major future developments Dr Sala predicts is the use of hybrid imaging for cervical cancer. PET/MR combines local stag-

ined to eradicate development

processing makes for higher temporal and spatial resolution. Therefore, we achieve a significant improvement in image quality; at least first measurement results indicate this. I'm confident that this is a large gain,' he adds, 'even though the final proof is currently still the object of research.'

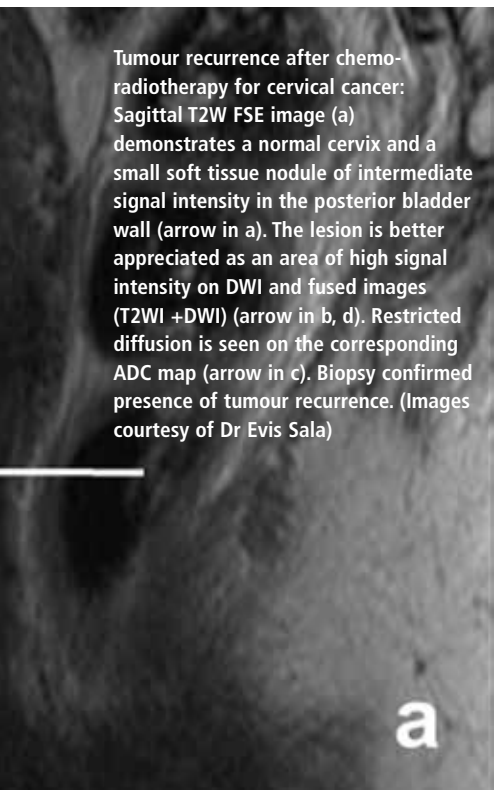
Standardisation benefits

The consortium does not only work around innovative medical devices technology. The more important step for the project as a whole is the development of a specialised animal testing platform that offers pharmacokinetic and toxicological examinations as a service, as well as supporting the testing of new treatment concepts with specific consultancy services. 'When the pharmaceutical industry wants to carry out animal testing the approval procedure takes more than six months. However, by way of a highly standardised animal testing application adapted for the needs of the consortium we can act within just a few weeks. But the time saving, the shortening of the developmental pipeline, is only one aspect. It's also very important that all our examinations are carried out and documented according to standard operating procedures. This ensures the quality of the measurements and makes the costs of the studies easier to calculate,' the professor explains.

The fourth component of preclinical tumour research that connects the project is the development of molecular probes and diagnostics. The initial focus here was on molecular optical and ultrasound probes. Some of these probes are now so reliable that even small differences in the expression of molecular markers can be reliably captured in vivo. Thanks to all these measurements and developments the consortium has succeeded in increasing the trust in imaging in preclinical research.

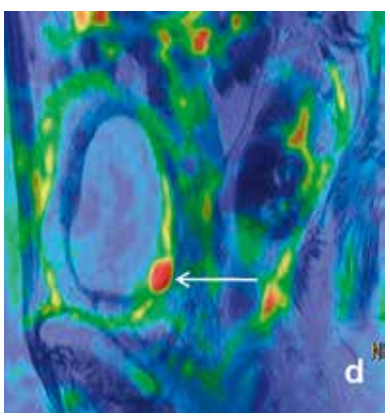
Funding

Prof. Kiessling hopes to have created a platform that facilitates the meaningful testing of drugs, contrast agents, new devices and treatment procedures and which eases the transfer and implementation of these into the hospital. Although the project is part of the interdisciplinary, integrative and inter-faculty (I3) Institute for Technology and Medicine promoted via the excellence initiative and secured from an academic perspective, it is a shame that follow-on funding for this project is currently not yet secured as the three-year term of the EU-NRW Objective 2 Programme Regional Competitive Capabilities and Employment 2007 – 2013 (EFRE) expired at the beginning of 2013. However, further suitable funding currently seems hard to envisage. 'It's very important that the consortium receives further funding,' warns Prof. Kiessling, 'particularly if the industrial partners are to stay on board and if jobs are not to be endangered.'



Tumour recurrence after chemo-radiotherapy for cervical cancer: Sagittal T2W FSE image (a) demonstrates a normal cervix and a small soft tissue nodule of intermediate signal intensity in the posterior bladder wall (arrow in a). The lesion is better appreciated as an area of high signal intensity on DWI and fused images (T2WI +DWI) (arrow in b, d). Restricted diffusion is seen on the corresponding ADC map (arrow in c). Biopsy confirmed presence of tumour recurrence. (Images courtesy of Dr Evis Sala)

ing achieved through the superb soft tissue resolution of MRI with valuable metabolic information from PET. This brings together local staging and evaluation of distant metastases, which is important for therapy planning. Individualisation of patient treatment, assisted by quantitative hybrid imaging is clearly where the future is heading.



Reaching for all corners of the globe

Mindray is quick, flexible, highly international and open to all

Interview: Daniela Zimmermann

'We want to help European customers to improve healthcare quality by providing them with high-quality innovative and cost-effective products and a very good service team and very good professional clinical support team,' David Yin of Mindray confirmed. 'There is competition everywhere, and we are so glad that increasingly European hospitals have accepted us – and also, very importantly, that they are very happy about the product, service and support. This gives us a lot of confidence. We walk very closely with the end-user and customer and medical professionals.

'We also make many very good installations in university hospitals and city-level hospitals in all of Europe. If you had asked about that about five years ago I couldn't speak of the big hospitals; but now I can – in every country. That's very important for us and for the other end-users. They can trust what our product is. A lot of university hospitals do long-term clinical trials of our product. We provide a machine and work on their requirements and import that and send our people there to work closely with the staff doctors.'

Europe differs very much from Asia or America; all the countries are different. How do you cope with the cultural differences?

'The countries have common requirements: reliability, good quality, good features – so, people like a good product. That's the same. Mindray is from China and its products are produced in China, but basically, as a first step, that product consolidates all the information from all the countries. The second step: we use local people. In every country, for each office, our general manager is local and knows the customer really well.'

Each manager in each country reports to the General Manager for Europe, he explains. 'We have six offices in Europe: the Netherlands, France, the United Kingdom, Germany, Italy and Spain. So, all the countries with the offices are our interest, along with others, such as Scandinavian countries.'

All the Scandinavian countries are not even a tenth the size of Germany or France, so, which in Europe is the most interesting for Mindray?

'Germany is the top.'

Where you have to compete against Siemens...

Not really. Our product line is different from Siemens. We have some products with little overlap. Ultrasound has very little overlap. Patient monitors – I think Siemens had this product line ten years ago but sold it to other companies. It's what big companies do; because of their structures and size they can do many things. The electronic part, like us with a patient monitor, is quite a faster moving product. In all industries, the price of electronic products is decreasing.

'Faster reactions and taking the most advantage of electronics technology, a company like us can do it very quickly. This is also important. We are quick and flexible and there's also innovation. How to make it fast is very important to us. When we understand something, we know the market needs, we can just use the new technology. For other big companies, because the product is already there, if they put out something new, that means the old product will discontinue. So, that is a painful decision. For us, everything is new. We are quite flexible, and we move faster.

'Maybe 20 or 30 years later we'll also become bigger. So then, how can we be faster? That is another question, another challenge.'

Founded in 1991 in Shenzhen, China, Mindray is now known internationally for its products that cover patient monitoring and life support, in-vitro diagnostics, medical imaging and veterinary. During Daniela Zimmermann's interview with David Yin, General Manager of Mindray Europe, he described the firm's clear strategy for Europe and beyond

What are China's strengths? In Germany, for example, Siemens' strength is absolutely high-level engineering. France and Italy are good at design. Does the strength of the Chinese, lie in electronics or engineering?

'I cannot speak generally about the Chinese, but if we talk about Mindray, we have a very strong engineering team: more than 1,600 engineers among our 7,300 employees, so we are a very big engineering team. We also consolidate resources, knowledge, from outside China. We have R&D centres in the USA and Stockholm and we consolidate all requirements. We also work very closely with our local general managers, people who have a long history in the market and the industry and know customers' needs. Therefore, they also contribute a lot. We combine everything together. We also have our own design team and win a lot of global design awards.'

Those prizes have included the internationally recognised 'red dot' design award in 2011 for the firm's HyLED operating light; the 2010 red dot award for the M7 diagnostic ultrasound system; China's iF Design Award in 2009 and, in 2006, the same for its BeneView T8 patient monitor.

So, what's missing for Mindray?

'Two things: Because it has become a global company, you need increasing numbers of local people and talented people to join the company. I think everything is related to people, because people are very important: people from China and people outside China. That is the key to being a great company; you must have a lot of excellent people all together.'

Siemens, for example, has engineers from India, China, France, America, Germany, in a multicultural team. Does Mindray also try to employ French, English or German engineers and, say, postgraduates, when they are new and fresh?

In response to this question, a Mindray representative pointed out that the Shenzhen base has grown considerably. 'You'll find our colleagues from every country, such as India, Germany, Italy and America. It is really an international company – Mindray is open to everyone.'

Peace at last for patients

Silent Scan overcomes the clunk, clunk, clunks

MRI technology has been in use for 30 years, and throughout those decades the high noise level during an examination has stressed many patients – along with being in the confined space of the tube for quite some time.

Today, almost all manufacturers produce tube openings up to 70cm in size and thus help to reduce claustrophobia – also enabling examinations of obese patients. However, noise annoyance has remained – until recently. GE Healthcare has now succeeded in removing that endless clunking sound at its very source.

'With conventional MRI systems noise levels of up to 100 dB are measured for some frequencies, which is on a par with the noise levels during rock concerts. With the Silent Scan MRI, GE has now succeeded in reducing this noise level with new sequencing technology to such an extent that apart from normal background noise resulting from the cooling of the gradients nothing else can be heard,' explains Professor Christoph Herborn, Director of MR Future Concepts at GE Healthcare.

Previous attempts to reduce noise levels during examination were mostly aimed at sealing the gantry with isolation methods instead of eliminating the noise at the source. The results were unsatisfactory. With the Silent Scan technology the T-1 and T-2 weighted examinations are now performed with noise levels comparable to those of a CT exam, i.e. very quietly.

Noise reduction at source

'MRI imaging is complex and consists of multiple parameters that define how the tissue to be examined is stimulated and how this stimulation is scanned by the MRI receiver coils. These parameters include the repetition time, flip angle and so-called echo time (TE). Through modulation of these parameters, but particularly by a significant reduction in the echo time, it has been possible to reduce the noise while the gradient is switched on and off to such an extent that the examination can now be carried out quietly. We have impacted all parameters, but the most dramatic reduction has been in the echo time, which means the sequences, and therefore the examination times, not becoming much longer than with a comparable 'loud' sequence. One example: With a T1-weighted three-dimensional frequency of the head, the examination time with a conventional MRI is around 90 seconds; with the Silent Scan it is extended by 8–10 seconds, using the same parameters and relating to the same image of the examination area,' he explains.

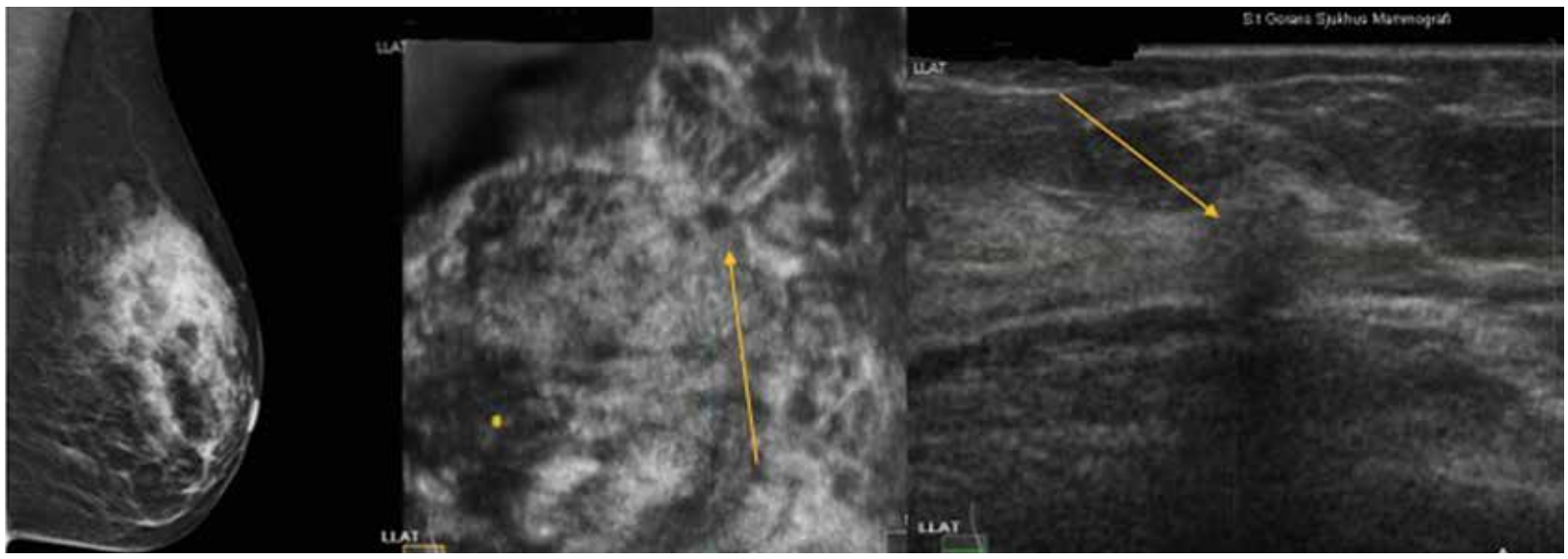
This is a dramatic development indeed, which will significantly improve patient comfort during MRI examinations – in line with the company's philosophy. Moreover, the radiologist is optimistic that further development and expansion of the Silent Scan technology to other examination sequences, such as diffusion, will more than compensate for the current, slight extension of the examination time.

Presented for the first time at the RSNA 2012, GE is currently awaiting FDA 501(k) clearance to introduce Silent Scan technology to hospitals. First study results from the USA underline positive feedback from patients – with the new system they need neither headphones nor any other ear protectors. This significantly eases communication between the doctor or other medical staff and the patient in the MR machine.

Specialist diagnostic radiologist **Professor Christoph U Herborn** MD MBA (healthcare management) joined GE Healthcare in 2011 to direct the company's MR Future Concepts business unit. Following radiology studies at the University Hospital Essen, in 2005 he joined the Clinic for Diagnostic and Interventional Radiology at the University Hospital in Hamburg-Eppendorf, where, from 2007 he undertook business administration, including the commissioning of the new building. Instrumental in the development of radiation-free whole-body MRI, the professor is one of Germany's leading experts, particularly in MRI of the cardiovascular system and gut (virtual colonoscopy).

High volume mammo centres yield high quality research

With 350,000 mammography screenings annually, Unilabs Sweden finds itself on the leading edge for research in mammography and pioneering patient education programmes. *John Brosky reports*



Unsurprisingly, prototypes for every new modality in breast imaging are found at one or another of the 23 mammography centres managed by Unilabs Sweden. In addition, as the centres perform more than 1,500 breast cancer screenings per day, it also is quite expected that research institutions are keen to conduct studies within this network, which covers half the women in Sweden.

What is unusual here is the enthusiasm and passion for this leading edge work among a very busy staff in an efficiently run private company necessarily focused on high patient through-put. Even more surprising is the company's financial support for multiple studies, the largest of which will not be finished for 10 years.

Landmark studies to be reported

The European Congress of Radiology will present a study showing a 57% higher detection rate for cancer with automatic breast ultrasound (ABUS) compared to conventional mammography will be presented. The study of 1,671 asymptomatic women with dense breast tissue was supported by Unilabs and conducted at its centre at Capio Saint Göran Hospital in Stockholm, Sweden.

Preliminary results from the 'Malmö Breast Tomosynthesis Screening Trial', reporting data on 9,000 exams of women with dense breast tissue, is now being prepared for publication. Unilabs joined the Skåne Region to sponsor this three-year study that will ultimately include 15,000 women.

'This work is a big part of our daily routine in practice,' explained Karin Leifland MD PhD, Head of Mammography for Unilabs Sweden.

One year ago, the Unilabs centre at Lund University joined the Karma study being conducted by the Karolinska Institute to identify risk factors for breast cancer among 70,000 women. Each patient who agrees to participate completes a lifestyle questionnaire, allows an assessment of her breast tissue density and undergoes a blood work up for genetic information.

According to the lead investigator, Karolinska Professor Per Hall, 'The Karma study is now recruiting almost a thousand women a week, which is a stunning figure. Without Unilabs Skåne's cooperation this could never have been possible.'

The goal of the Karma study is to create the world's best-characterised breast cancer cohort by following the patients to see who develops breast cancer over 10 years and then determine why.

There are three MRI studies underway at Unilabs centres. One follows women with a hereditary risk of breast cancer, which compares the results of conventional mammograms with ultrasound examinations and finally an MRI exam. A second MR study funded by Unilabs is for a doctoral thesis on vacuum biopsy. The third is for pre-operative diagnosed breast cancer that randomises patients with one group undergoing an MR exam to see if more cancer is detected than in the mammograms and ultrasound.

It helps that Swedish women are the nicest mammography patients in the world, Dr Leifland points out. 'When we ask them to take a biopsy for tissue samples, they say, "OK". They are really interested in participating in various studies because they know even if it may not benefit them, it may benefit their sisters.'

Pioneering Preferential RF Ablation studies

In collaboration with Capio St Göran Hospital and the Karolinska Institute, Unilabs is validating the efficacy of Preferential Radio Frequency Ablation (PRFA) in a study with three patient cohorts.

In this procedure a well-defined, solitary tumour of less than two centimetres is targeted using ultrasound so that a thin electrode can be inserted. PRFA technology induces an enzymatic destruction of the tumour by heating it for 10 minutes between 70 and 90 degrees Celsius. Surrounding fibrous and fatty tissues are left unharmed.

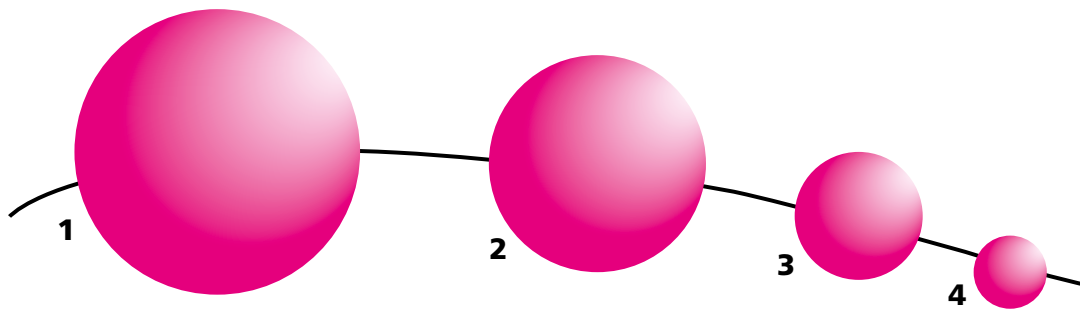
Mammography expert Karen Leifland MD PhD is head of the Unilabs SA Mammography Department at Capio St. Göran´S Hospital in Stockholm. Sweden

The first patient group are women already on the operating table. Immediately following the ablation, the tumour is surgically removed for a study of the heat-induced effects.

A second cohort of patients in this group is asked to wait three weeks before the tumour is removed surgically. The third group are much older women who cannot undergo surgery. After treatment they are followed with imaging exams to determine if the tumour has been destroyed or if the cancer returns.

'We have completed this procedure on 55 women, six of whom are in the third group, and not one has any cancer left,' said Dr Leifland. The experimental approach without surgery could never be applied to younger women, she explained. But the older patient cohort allows the group to validate the effectiveness so that with enough evidence it may someday be performed on younger women.

'If we can do this – identify women with a tumour, ask them to come back in a week, heat it up for 10 minutes and know that it is gone – that,' she declared, 'will already be a fantastic outcome.'



CROSSING CULTURAL BARRIERS TO SAVE LIVES

Immigrant children can play a key role

Unilabs also supports patient education to help the Swedish health ministry meet an ambitious goal of regularly screening 80% of women for breast cancer.

'We are at 94% participation in some areas but only at 47% in others,' explained Karin Leifland, who heads the Mammography group for Unilabs Sweden. The target group for a new campaign at Unilabs' centres is women who have immigrated to Sweden from Africa and Arab-speaking countries and who do not share the same cultural motivation to participate in screenings as Swedish women.

Where Swedish women have an incidence of breast cancer 30-40% higher than the immigrant population, an immigrant woman in Sweden is 30-40% more likely to die of breast cancer because the condition is not detected until in an advanced state. The first challenge, says Dr Leifland, is the high rate of illiteracy among the large populations of these women in urban areas.

The Unilabs Sweden team revised its invitations to come for a screening so that a seven-year-old child, who often is asked to read the letter, can tell his or her mother why she should go for a screening.

Once the woman does come for a screening she is given a key ring holding four rubber balls ranging from 24 millimetres in diameter to just 3mm. The staff explains that the largest ball is the average size of a tumour that the woman will be able to feel when palpating her breast. The next is the average size of what a doctor would feel and the third is what can be seen in a mammogram. The smallest, she is told, is the size of a tumour the Unilabs radiologists will be able to see if the woman comes for follow up visits, when they can consult her prior exams.

'Yes, it works!' Dr Leifland said, explaining it is effective with a woman who thinks that having visited once, she does not need to return the next year.

Proton therapy

Dresden will treat patients in 2014

Report: Brigitte Dinkloh

Whilst the first cancer patients are due to be treated with proton therapy in Dresden, Germany, in spring 2014, this autumn physicians and scientists will begin to work with this internationally unique research and development platform for innovative technologies in radiotherapy.

Over several days in February, the centre piece of the unit – the proton accelerator and treatment facility consisting of a gantry and nozzle – was transported in a heavy duty convoy from Belgium to the river Elbe, and then installed at the new site on the Dresden University Hospital campus.

Called OncoRay, the scientific institution is a joint enterprise organised between Carl Gustav Carus University Hospital and the medical faculty of the University of Technology, and the Helmholtz-Centre Dresden-Rossendorf (HZDR), is aiming to develop a new dimension in gentle radiotherapy: over the coming years the use of protons in cancer treatment will be further advanced with a close focus on the patient and away from commercial constraints.

The dimension of this high-tech installation from world proton therapy facilities market leader, Ion Beam Applications S.A. (IBA) of Belgium, sets benchmarks. The gantry alone, a steel construction that, once assembled, measures 13m x 11m and is rotatable by 370 degrees, weighs 110 tons. The focused proton beam travels across this steel colossus for the last few metres of its journey to the patient.

Installed at the same time at the Dresden site, the proton accelerator accelerates the particles to around two thirds of the speed of light – about 180,000km per second. To ensure the proton beam reaches the patient with the highest precision on its 50m journey from the cyclotron via the beam line and gantry, more than fifty quadrupole and dipole magnets guide it, each weighing several tons.

Set to an accuracy of a thousandth of a millimetre, the magnets ensure the correct shape and direction of the beam.

Alongside the proton acceleration facility, which is based on electromagnetic fields, the scientists at HZDR and OncoRay will test a new technology: Utilising high-energy laser beams to bring the particles up to the necessary speed, the objective is to drastically reduce the costs of the construction and maintenance of these treatment facilities in the future. This is a prerequisite to ensure all patients needing this gentle therapy will indeed be able to benefit from it. The coexistence of a conventional and a laser-based proton accelerator will be unique worldwide – the Dresden competency centre is becoming established as a reference- and crystallisation point for further research in this field.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OncoRay's Scientific Coordinator Stefan Pieck, with at Carl Gustav Carus University Hospital Board Director Professor Michael Albrecht, and OncoRay spokesman Professor Michael Baumann, with the first gantry component fitted in the proton therapy facility

Looking into the lower area of the cyclotron, one can see which way the protons travel during acceleration in the four copper tubes


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Imaging Clinical Information System

No image left behind

By creating a single interface with the patient medical record, Agfa HealthCare's ICIS can bring any type of image and linked meta-data into a patient's record to be viewed and retrieved

Interview: John Brosky

Integrated diagnosis, where multi-disciplinary teams focus on a single patient's care, can be an effective model for diagnosing illness and monitoring treatment. But it only works if every team member can access the same images at the right moment.

Using the patient medical record as the vehicle, and embedding a universal viewer called XERO inside that record, Agfa HealthCare's innovative Imaging Clinical Information System (ICIS) for the first time enables access. With sometimes surprising results.

During our interview, the President of Agfa HealthCare, Luc Thijs, explained ICIS and shared lessons learned from installations at reference centres in North America, Spain, Belgium, Russia and the United Kingdom.

This new Imaging Clinical Information System sounds as if your engineers named it. What is that and what does it do?

Luc Thijs: 'One of the biggest problems in healthcare today is bringing imaging information out of individual departments and into the mainline care process. We are solving this problem through the integration of images into electronic health record. It does not simply store images, which many others can do, but provides tools that capture meta-data and clinical information linked to those images – which very few can do. Departments outside of radiology or cardiology can now have a workflow to bring these medically relevant images into the patient record and share them with care givers.'

Are there really so many images relevant to clinicians?

'Point of care images are captured in many departments. In surgery there may be a C-arm taking X-ray images; there may be an endoscope capturing images; there may be ultrasound images. They do not make it to the patient record. Pathology is creating a lot of images, typically through a microscope. These biopsy samples and slides are stored, but the images? Where are they? There are medically relevant images in systems and devices stored in departments all over the hospital. We go into departments where we've never been before – into pneumonology, where we need to connect with endoscopes; into obstetrics and gynaecology, where there are a great deal of images being generated that have nothing to do with radiology.

Radiologists have been sharing images for years. Why is there a problem for other departments?

'Other departments don't always have the tools used in radiology, such as workflow, orders and accession numbers. With the Imaging Clinical Information System (ICIS) services platform we create an order and an accession number, capture meta data about that image and ensure the data and images themselves make it to the patient record. This becomes very important because healthcare systems not only need to store this data, they also want to retrieve it. For example, to review all images for a specific organ that has been treated in a certain way. The meta-data makes this possible.

The Cleveland Clinic is your flagship installation for ICIS. What have they learned there now that they are using the system?

'On top of all the clinical advantages discussed before, some things we've found out have little to do with the care process. Sometimes there are patients who come into the hospital who may already have a pressure wound. Having images of the patient on admission provides proof that they did not receive these wounds while being treated at your hospital. It can be a form of protection against a false charge that a patient got worse in your hospital. Is it part of a clinical care process? No. Does it save cost? Probably.

'Another example has to do with documentation. Depending on a country's reimbursement system, in certain cases if you can prove by means of an image that you performed an epidural to anaesthetise the patient, then you can receive reimbursement. Today no one does this; hospitals miss a reimbursement they earned. It is easy to take this image, and with ICIS it is easily registered, and potentially it generates revenue for the hospital.'

Finally clinicians will see everything, but do they need all this?

The time that **Luc Thijs** spent in Agfa HealthCare's Imaging Division helps to explain his passion for the firm's new ICIS system. He joined Agfa-Gevaert in 1990 and held several management roles, including Vice President of Growth Markets at Agfa HealthCare, which required him to manage the company's largest geographical area, covering Latin America, Africa and the Middle East, Asia-Pacific, Russia and the CIS states. In April 2011 he was appointed President of Agfa HealthCare and became a member of the Executive Committee of the Agfa Group.

'It always depends on the physician. In the case of integrated diagnostics, or tumour boards, a radiologist's diagnosis of a CT can benefit from a review of pathology images. This is also true in endoscopy. We'll see a trend of greater integration of diagnostics and a multi-disciplinary treatment of patients.

'What we find is that people in these departments are very excited to learn the images they create can now find their way into the patient file. And, referring physicians who send a patient to surgery, for example, can now follow this patient through images taken from the operation, through radiology images and perhaps, if there is a biopsy, he will also be able to look at pathology images together with the pathologist's report. Today this is simply not possible.

'ICIS is not just exciting for Agfa HealthCare but for hospitals. It can´t be done in a week. Hospitals want to move step-by-step because they do not know themselves, and are surprised to find how many sources of relevant images they do not find in the patient's medical record.'

Italian patients control their own diagnostic images and data

Carestream's new patient portal, MyVue, recently successfully completed its practice run in Europe at Italy's Delta Hospital in Lagosanto. European Hospital editor Brigitte Dinkloh asked Dr Giorgio Benea, Director of the hospital's Department of Diagnostic and Interventional Radiology, about staff and patients' reactions to the system

MyVue is the first portal to allow secure transmission of sensitive patient data in line with privacy regulations. After examination a patient does not need to return to hospital, but instead can await results and images at home.

Dr Giorgio Benea, radiologist at the Delta Hospital, explained that since MyVue was installed in early September last year, 455 patients have been involved and he has received direct patient feedback about the portal via a telephone survey, to which each patient is requested to respond about 20 days after admission. 'More than ninety percent of patients are very satisfied with MyVue and the reactions of doctors involved with the patient portal have also been extremely positive,' he confirmed.

Following medical and radiology studies in Ferrara, Italy, **Professor Giorgio Benea** MD worked as a registrar at the S. Anna Hospital, later heading its whole body CT and vascular and interventional radiology departments. Since 1995, he has directed the Department for Clinical, Radiological and Interventional Radiology for the Azienda USL Ferrara hospitals Argenta-Portomaggiore, Comacchio, Copparo, and Lagosanto.
A professor at the Medical and Surgical Faculty, University of Ferrara, Dr Benea is also an Italian Society of Medical Radiology (SIRM) for IT delegate.

Security encryption

'Patients who take part in the patient portal can not only view their images and read the results in any location with internet access, but also store them on their own computers and share them with whoever they wish – their physicians and specialists as well as family and friends – the data is owned by the patients,' he explained. The only important prerequisite is the safe transmission of the data to its owners without access by third parties. Carestream ensures this through its security encryption.

To use MyVue the patient is initially sent an e-mail with a temporary password that enables log-on to the portal. S/he then adds a personal password, which is only valid when combined with their personal e-mail address. If the patient wants to share his/her data with someone, s/he first sends the guest an invitation by e-mail. The guest can then log on to the system by activating a link and then view the chosen data. The owner of the images determines the length of time as well as the amount of data that s/he wants to make accessible to the guest.

Accessibility

The key benefit: Access to MyVue is possible via any browser and any type of device, be it iPad, laptop or PC. Thus the concept of a patient who can control his or her data anywhere in the world has become a reality.

The new portal not only helps to avoid repeat examinations but also provides an even bigger savings potential because neither CD nor DVD burning is necessary or hard copy printing. 'As the patient is in charge of the transmission of his images the workflow becomes more structured and effective and there's

IHE-Europe takes on the world in Istanbul

The movement for interoperability among health information devices and systems has spread across Europe reaching Turkey, which will be host to the European IHE Connectathon in Istanbul this April

Report: John Brosky

Launched 13 years ago with the first 'connectivity marathon' in France, Integrating the Healthcare Enterprise (IHE) has steadily gathered more nations and vendors in its drive across Europe to finally reach the eastern edge of the continent – Turkey.

The ambitions of the Brussels-based association IHE-Europe do not stop there. Delegations from the Middle East are expected at the 2013 event, aptly reinforcing the theme 'Connecting Where The Continents Meet.'

Reaching even further, IHE International is organising the first-ever World Summit for HIT interoperability to be held in parallel with the five-day Connectathon testing event in Istanbul. Over two days the summit offers three concurrent tracks aimed at specific levels of interest in IHE deployments from strategic planning for hospital executives to how-to sessions for IT engineers responsible for an implementation.

For the third year in a row the testing event, called Projectathon, will run concurrent to Connectathon to enable validation of cross-border patient data exchanges for the large-scale project, Smart Open Services for European Patients (epSOS). The IHE-based system came on-line in April 2012 and today counts 24 participating nations.

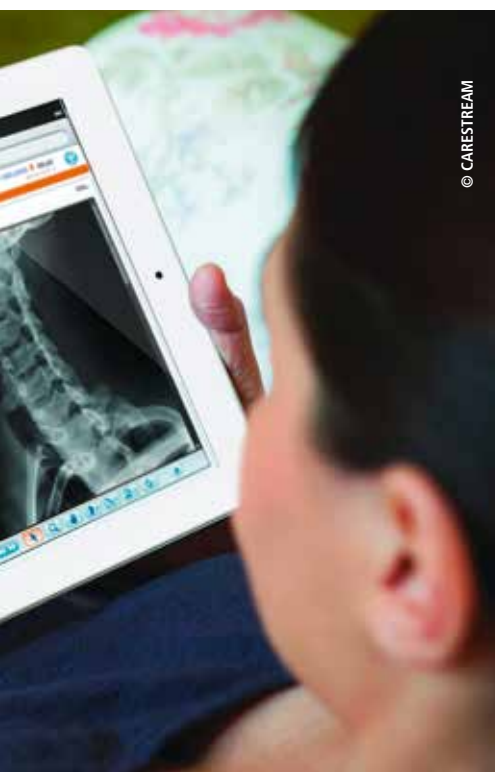
Both testing events are powered by IHE-Services, which was spun out of IHE-Europe to offer customised testing sessions and demonstrations for vendors and regional health networks.

Making available the suite of tools and simulators on the Gazelle platform that is the heart of this annual 'plug-fest' for HIT engineers is expected to accelerate the momentum toward interoperability.

The core testing activity among 300 software engineers at Connectathon shows how far IHE has grown beyond its roots in radiology to include technical frameworks and integration profiles for nine healthcare domains, including the laboratory, pharmacy and even ophthalmology.

Radiology continues to make up almost half of the tests performed at Connectathon. This year validation to the IHE Mammography integration profile will be a highlight in this large domain.

For the past two years the testing of cross-enterprise document sharing, which facilitates management of electronic health records, accounts for the greatest number of tests at Connectathon. Cross-enterprise Document Workflow (XDW) will be the hot area for testing activity this year.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less strain on staff and budgetary capacities in the imaging departments,' Dr Benea pointed out.

Although the professor cannot yet put the exact savings potential into figures, he is certain that the acquisition costs of hard- and software will have been amortised within a very short period.

The pros and cons of tablet-computers in radiology

Although not yet suitable for primary readings, tablet technology does offer potential for second opinions, sharing information with patients and clinicians, and seeking expert support, according to radiologist Dr Erik Ranschaert from the Jeroen Bosch Hospital, Den Bosch, The Netherlands

Report: Mark Nicholls

The ECR 2013 session 'Tablet computers in radiology – friend or foe?' will give speakers the opportunity to present the drawbacks and advantages of using this mobile technology in radiology. Among them, Dr Erik Ranschaert will appraise the use of tablet computers in mobile teleradiology and include aspects of the iPad in this area, looking at the evolution of mobile imaging, reasons behind tablet popularity – especially among medical professionals – and cover technical aspects, such as display, bandwidth, safety/ security and software/apps.

Dr Ranschaert emphasised: 'The main issue is that tablets are not suitable for primary readings. Although the screen quality is excellent, there are too many limiting factors: no standard DICOM calibration, limited screen size for complex examination, touch-screen only, no multitasking, limited functions of viewing software, usually no access to RIS work list and scrolling remains difficult.'

With the iPad remaining a consumer device rather than one designed for protecting sensitive patient data, issues of security and safety are also a concern, he warned, adding that hospitals need to adapt their safety policies to prevent data breaches and tablets remain vulnerable to loss or theft and patient information should never be stored on the device itself.

However, he recognises that tablet computers do have a role in radiology in general and particularly in mobile teleradiology, bringing better communication with clinicians, communication with patients and online expert consultations, but he warns they are not comparable to diagnostic screens and have no FDA approval for primary diagnosis. 'For preliminary readings, emergency readings and clinical review, iPads can be very useful to radiologists,' he believes. 'They might also improve communication between medical professionals – for instant consultation – or even between medicals and patients and facilitate expert consultations and second opinions.'

Another, very different kind of tablet in medicine: During ECR this year there will be an appraisal of the use of these flat, light, information technology tools in mobile teleradiology, and will include aspects of the iPad in this area

In terms of taking teleradiology forward they offer quicker communication and availability, emergency interpretations, though mostly for 'intra-institutional' rather than 'external' purposes.

Tablet advantages: More flexibility, less expense

He pointed out that new applications are emerging, including RadSnap, a free mobile app for cloud-based radiology that enables professional consultations for difficult cases sent via iPhone or iPad. 'This helps referring physicians and radiologists in areas of the world where they cannot afford expensive PACS software,' he pointed out.

For the radiologist, the tablet is convenient, versatile and offers enhanced flexibility both inside and outside the department, while patients can use tablets to view their own images in the hospital PACS or to seek a second opinion or specialist advice, and doctors can use tablets to explain the radiological findings.

Advantages to the hospital are that tablets are cheaper, and by facilitating quicker access to the images for both radiologists and clinicians, they help improve patient care.

Online commercial services are available where patients can upload their images for second opinions from an iPad, he said, helping them manage their own health process.

Dr Ranschaert suggests the next step for tablet computers in radiology/teleradiology is the increased power and speed of tablets, increased bandwidth for mobile viewing (greater availability of 4G network, higher bandwidths) increased resolution and even smaller pixels, automated calibration, HTML5 viewers for multi-platform compatibility and integration of IS and access to priors via PACS, cloud storage and server-side processing capabilities for image manipulation and 3-D volume rendering.

When it comes to radiology – is the tablet computer a friend or foe?

'Certainly a friend, if used correctly,' Dr Ranschaert qualified.

During the SF19 session 'Tablet-computers in radiology: friend or foe?' (11 March, 4-5.30 p.m.) other speakers will present a technical overview of tablet-computers, examine the device's radiological features and discuss reading DICOM images on the tablet.

Radiologist **Dr Erik Ranschaert** is a staff member at the Jeroen Bosch Hospital, in Den Bosch, The Netherlands and member of the ECR ICT and e-Health subcommittee. When promoting teleradiology during a Special Focus Session at ECR 2012, he presented the findings of a survey conducted with the support of the European Society of Radiology, bringing fresh insight into the professionals' reactions towards teleradiology in Europe.

The new WiF
flat-panel dig

Bringing freedom to paediatric imaging and

Success for Totoku´s LED

Japanese vendor Totoku reports that more than 3,000 units of its new i2 series displays were delivered in the second half of 2012, with 'very positive user feedback'. Although a rather high-priced model, Totoku sold the largest quantity of the greyscale display MS53i2. 'With its extremely high resolution of 15 MP the monitor is optimised for use in mammogram diagnosis,' the manufacturer explains.

This is the first model with the new LED backlighting. The successor of the CCFL technology is based on semiconductors and known from a variety of consumer products. 'The benefits are both ecological as well as of a financial and qualitative nature,' according to Marcel Herrmann, Marketing Manager at Totoku Medical displays. 'Compared to CCFL monitors, LED displays, save up to 20% electricity and have about a 30% longer life span, affecting the user's budget positively. Furthermore, the CO2 emissions decrease due to reduced energy production. Specifically, the MS55i2 display will use 15% less power than its predecessor. At the same time it almost doubles the lifetime and disposal is also much more environmentally friendly because LEDs do not contain critical elements, such as mercury.'

Because the CCFL is mounted horizontally behind the display, the LED provides a significantly higher number of light sources, which can be controlled individually, resulting in much better uniformity, the firm adds. 'The contrast ratio also increases by a quarter to 1200:1. As usual, the new models also have a five-year warranty on the backlight,' says Marcel Herrmann.

The MS55i2 also supports Independent Subpixel Driving (ISD), raising the resolution by three, thus increasing detail and image quality.

All new i2 models offer the new display port interface, enabling connection not only with DVI signals or video cards but also the latest Display Port cards from various vendors, e.g. Matrox, ATI and NVIDIA. Display Port now offers true 10-bit greyscales on a colour display and true 11-bit for greyscale products.

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JiveX Mobile

Images and clinical data are on the move

Entering the world of apps with JiveX Mobile, Visus reports that it is offering image and clinical data based on HTML 5 and adds, 'The solution runs on all mobile platforms and integrates seamlessly with HIS systems designed for mobile devices.'

While the mobile PACS viewer is currently receiving the final touches, Visus developers are confident that the solution will be well received and will prove a success, since products that give clinicians more flexibility and facilitate communication in every-day clinical work are highly sought after. Both tablet PCs and smartphones are excellently suited as a mobile desk if – and only if – the required data are quickly available, consistent throughout the hospital network and comply with the strict data privacy rules in healthcare. 'A major challenge was the development of a platform-independent system that is compatible with all current operating systems,' explained Guido Bötticher, Vice President for Sales at Visus. 'Therefore we decided to use HTML 5 for the JiveX mobile viewer: it's a programming language that all infrastructures understand well. To meet the data privacy requirements the image data are not stored locally on the device but on a web server. Working with a central data pool moreover ensures that the users access identical and up-to-date data anytime and from anywhere.'

The real-life success of a mobile viewer depends on the handling of different kinds of image and clinical data such as ECG or ultrasound images, the company points out. 'Drawing on the Visus PACS II strategy with JiveX Integrated Imaging, the mobile version masters this challenge easily. For the Visus team it was particularly important that the mobile solution goes far beyond radiology and, with its tight links to the HIS, prepares the ground for mobile electronic patient records. The open and flexible platform design allowed the creation of a HIS provider-independent solution whose architecture accommodates even highly specialised medical software systems.'

Guido Bötticher: 'We wanted to create a mobile desk that offers pretty much the same benefits as a stationary desk: the user can access as many data as possible from one system.

'Therefore,' he added, 'we were eager to link our solution with other systems. The mobile version of JiveX – like all our products – is based on an open architecture that integrates easily, flexibly and neutrally in existing hospital and provider structures.'

DATES FOR YOUR DIARY

31 May 2013
Berlin, Germany
4th Annual Scientific Symposium: Ultrahigh Field Magnetic Resonance

13-15 June 2013
Marbella, Spain
ESSR - Annual Scientific Meeting 2013 European Society of Musculoskeletal Radiology

20-21 June 2013
Milan, Italy
ESER - Annual Scientific Meeting 2013 European Society of Emergency Radiology

27-29 June 2013
Dubrovnik, Croatia
OIC 2013 - Oncologic Imaging Course

19-22 September 2013
Frankfurt a.M., Germany
ESNR - 37th Annual Meeting of the European Society of Neuroradiology

11-12 October 2013
Rome, Italy
EUSOBI 2013 - Annual Scientific Meeting of the European Society of Breast Imaging

24-26 October 2013
London, UK
ESCR 2013 Annual Scientific Meeting

Fi ultra-light gital detector

l extremity X-rays

The Pixium Portable 2430 EZ, a new WiFi ultra-light flat-panel detector, provides unlimited flexibility thanks to its multi-share, auto-detection and image storage capacity, reports manufacturer Thales. The image and diagnosis quality, with very low dose based on cesium iodide X-ray detection technology, is outstanding, the firm adds. 'The versatility and autonomy of this portable and robust detector make it ideal for paediatric imaging and, for extremity X-rays, it's the optimal complement to the larger-format 3543 EZ launched last year.'

The device can be used in a new radiography room or on a mobile cart and, Thales points out, it could prove a good solution for a retrofit. 'It can be multi-shared in various configurations: several detectors in one room, or with one detector shared by several rooms. It offers total freedom due to automatic attachment by infrared and an auto-detection feature.'

The new device complements the Thales range of detectors that cover most radiological applications, which the firm adds, '…serve as benchmarks for the majority of equipment manufacturers throughout the world.'

Fujifilm's continuing glo

New business ventures, new systems – and those include 3-D mammography

Since the Japanese firm Fujifilm, which had held a premier position worldwide for brilliant, high-resolution photographs and films, was transformed into Fujifilm Holdings Corporation, a multinational concern with almost 82,000 employees worldwide, the firm has evolved to cover a large range of technologies, ensuring the expansion of the existing business as well as formation of new business areas, such as the production of medical devices, highly functional materials and further high-tech applications.

With three core business sectors, imaging solutions, information solutions and document solutions, the corporation has achieved a constant worldwide turnover of more than €20 billion annually over the last three years. With above average R&D investments of 7-8% of group turnover, the company aims for leadership in technology in many business areas, as well as for diversification into new sectors. Over the past few years, Fujifilm has indeed demonstrated its ability to change impressively.

Medical systems

Fujifilm is a pioneer in digital diagnostics and is expanding into prevention and treatment areas. The current diverse product range within the medical systems sector offers imaging systems for diagnostics, image archiving and communication systems (PACS), imaging plate systems, digital radiography, flat panel detectors, digital mammography, dry imager, X-ray systems, X-ray film, endoscopy systems and ultrasound. The erstwhile classic revenue driver X-ray film is becoming less and less important as the trend towards digitisation is irreversible and driven particularly by cost-conscious healthcare systems that need to achieve optimum cost savings, explains Jan Döhring, who is Marketing Co-ordinator of Medical Systems Europe.

Branching into digital radiography and IT, the firm's business model has also changed from consumer goods to a more project-based business. 'Essentially, we don't need salespeople as such, but rather consultants and specialists who are aware of customers' medical equipment, are familiar with the highly complex technology and able to install and maintain it. Success can no longer be measured immediately but develops over time. This adjustment is the turning point that the company currently has to master,' he explains. However, Fuji set the course for this development at an early stage: it had one of the first web-based archiving systems as a PACS and, with a complete line-up of panel sizes, Fuji is among the leaders in digital radiography worldwide. 'This is one of Fuji's core strategies: Wherever we were market leaders in CR; we also want to be in DR. Detectors development is progressing accordingly.'

Europe's north-south divide

In Europe, Fujifilm has the largest turnover and biggest market share in the large national economies of Germany, France, Great Britain, Italy and Spain and lately also Russia. From a technology and regulatory aspect, there is now homogenisation across Europe, but there continue to be big differences regarding radiation exposure and price. The highest prices can be gained in Scandinavia, although the country's required standards are also the highest, particularly regarding radiation protection.

'The further south you go, the bigger the price divide, although the standards required are also no longer so high. Things are more difficult in Denmark, Germany, Austria and Switzerland where high standards are required whilst prices are low,' explains Jörg Müller, DR Product Manager for Medical Systems Europe. 'However, with our systems developed for the global market, the flexibility is so high that we can generally meet these different requirements.'

Jan Döhring, European Marketing Coordinator for the Medical Systems Division at Fujifilm

Jörg Müller, DR Product Manager of Medical Systems Europe at Fujifilm

On the other hand, the European market is now in the lead in many areas, particularly in mammography. This increases opportunities for Europeans to impact on new technological developments that happen in Japan regarding the modalities and, in America, for the IT sector.

This is a positive side effect of the increasing share of Europe in the overall medical turnover of Fujifilm worldwide.

New for mammo: FDR Amulet Innovality

At the ECR in Vienna, Fujifilm is presenting FDR Amulet Innovality, the third generation of the proven, fully-integrated mammography system, an X-ray machine connected to a detector.

From the start, Fujifilm took the lead when it came to dose output and readout speed and was therefore predestined for screening. Over the last few years ergonomics and workflow have been further improved with the Amulet F and Amulet S systems. With the FDR Amulet Innovality the company is introducing a completely newly developed detector, which is also based on amorphous selenium (a-Se) but has a completely different structure compared to all other detectors available. 'We have a honeycomb structure that facilitates different readout procedures. This gives us variable resolution and allows us to read mammograms more efficiently for the normal range, the 3-D range and now also for tomosynthesis,' Jörg Müller points out.

The key is totally new geometry for the 24x30cm detector. Radiation absorption is improved significantly by the new geometry and effectiveness is increased by 20% compared to the previous model, the firm reports. The detector's structure was also optimised so that noise was reduced and the signal was much clearer, further optimising the dose and display of details. 'Our new detector currently has the highest detail display and the largest modulation transfer frequency available

The new FDR Amulet Innovality supports all known volumentric methods within one device with increased sharpness, reduced dose and improved patient comfort

bal presence

Nayhmeh Eskyhi, resident in Maria Hilf's Interventional and Diagnostic Radiology Department

Christoph Müller-Leisse, Director of the Interventional and Diagnostic Radiology Department at Maria Hilf

Dr Mechthild Schulze-Hagen, collaborating gynaecology and obstetrics specialist

on the market. This means that the finest details can be sharply displayed without being affected by noise, and users can adapt an examination flexibly to each individual patient,' he explains with enthusiasm.

In addition to the new system's tomosynthesis performance the first studies in 3-D mammography in various countries have shown an up to 40% reduction in false positive results with a dose requirement comparable to that of 2-D mammography. Obviously this also cuts down the number of unnecessary biopsies, lowering patient worries.

'FDR Amulet Innovality is currently the most sensitive system available and has 20% lower dose requirement for 2-D images,' Jörg Müller confirms, 'and ten percent lower dose requirement for the tomosynthesis application compared to the previous systems.'

Fuji's 3-D mammography in practice

Maria Hilf GmbH operates two hospitals – Maria Hilf and St. Franziskus – in Mönchengladbach, north-west Germany. The healthcare company's history dates back to the 1850s, when two Catholic nuns arrived in the city from the Netherlands to care for orphans and sick people. During 150 years, the hospital grew to become an organisation in the maximum care category, partly owned by the community and highly renowned for its commitment to high quality of care and holistic orientation towards patients. Advanced technology, such as Amulet 3-D, helps support this mission. European Hospital reporters asked the hospital's leading physicians about their hospitals and experiences when working with Fuji's 3-D mammography system.

'With its 800 patient beds, Maria Hilf ranks among the major care providers in the region,' explained Professor Christoph Müller-Leisse MD. 'We support rather rare disciplines, such as pulmonology and thoracic surgery, and have dedicated centres for continence and neurourology. Our radio-oncology department is outstanding in North Rhine-Westphalia. We have a large neurology department, with a service offering that includes, e.g., thrombus extractions. For cases such as acute strokes we cooperate with specialists in the field. We have general surgery, emergency surgery, and trauma departments.

'In addition, we carry out a large number of interventions, many of them image guided with the support of CT. Quite a number of cases are referred to us from a visceral practice with which we collaborate. Percutaneous interventions are part of our portfolio. Interventional radiology is a focus of Maria Hilf.'

What about working with the 3-D mammography equipment?

'Based on her work with the Amulet 3D from Fuji, Dr Mechthild Schulze-Hagen and I are currently carrying out an ROC – Receiver Operating Characteristic – analysis comparing 3-D to 2-D … something that hasn't been done yet. ROCs are diagnostic confidence rankings associated with the diagnostic categories of BI-RADS – the Breast Imaging-Reporting and Data System devised by the American College of Radiology. In this context, this new approach will compare 2-D and 3-D mammography regarding, for example, scar detection, which is not part of the ACR approach, as well as micro-calcifications.

'Each year, I read about 12,000 mammographies with a screening background. In addition, we have worked on 500 patient cases from a curative, non-screening background, using Fuji's Amulet 3-D since May 2012, and we detected 11 carcinomas. We analysed this non-screening group of patients, and have been able to demonstrate that there are a number of significant benefits of 3-D over 2-D. Carcinomas that form along lactation ducts are an illustration in point. These carcinomas manifest themselves through calcifications that are hard to discern in 2-D. Calcifications formed alongside ducts are relevant indicators for malignity.

Are there additional benefits from Amulet 3-D mammography?

Dr Schulze-Hagen: 'The technology helps reduce false positive, but also false negative diagnoses. I'll explain on the basis of oil cysts: these cysts, which have no pathogenic relevance, lead to calcifications over the long term. In 2-D there is sometimes no way of telling apart emerging oil cysts from carcinomas that form in scarred regions. In 3-D, physicians can differentiate cysts on the surface from carcinomas that are growing into surrounding tissue. And for breasts that have had surgery, 3-D also has significant advantages; in these cases, duct structures may be interwoven and highly complex, producing unclear results in ultrasound. MRI may be an option; but 3-D mammography can help resolve suspected recurrences conveniently.

How does this mammography compare with tomosynthesis?

Dr Nayhmeh Eskyhi: 'In 3-D mammography, the summation effect of 2-D images is resolved in 3-D, which makes dense tissue more transparent. 3-D serves for routine initial image acquisition. For subsequent diagnostic steps, or in follow-ups tomosynthesis is used for precise measurements. We should keep in mind that tomosynthesis comes with an exposure which is significantly higher compared with the dose from Amulet 3-D.'

ECR at a glance

The European Congress of Radiology organisers want to strengthen interactivity with the audience, so is offering many chances for direct communication between attendees and the speakers as well as even longer discussions

The second innovation in 2013 is that 'multidisciplinary' activity will be even more in focus than in former congresses.

Here we present a brief overview relating to sessions that provide much in this way, particularly the three in the **Managing patients with cancer** group, which emphasize the increasing importance of multidisciplinary cooperation in cancer diagnosis and treatment. Sharing their expertise, radiologists, surgeons, hepatologists and oncologists lead the sessions, selecting colorectal liver metastases, hepatocellular and cholangiocarcinoma as central themes:

Thursday, 7 March, 16:00–17:30, Entrance Level, Room E2
MS 3: Colorectal liver metastases
Session Objectives:
1. To learn about the prognostic factors of colorectal liver metastases.
2. To become familiar with the most common therapeutic strategies.
3. To understand the role of the multidisciplinary team in patients with colorectal liver metastases.

Friday, 8 March, 08:30–10:00, Entrance Level, Room F1
MS 4: Hepatocellular carcinoma
Session Objectives:
1. To learn the current management of HCC as laid out in scientific guidelines.
2. To identify those areas of uncertainty, where multidisciplinary teams are needed most.
3. To understand the basis of personalised care for HCC patients and the need for multidisciplinary teams.

Saturday, 9 March, 16:00–17:30, Entrance Level, Room E2
MS 11: Cholangiocarcinoma
Session Objectives:
1. To learn about state-of-the-art diagnosis of cholangiocarcinoma.
2. To understand the value of surgical and systemic strategies in therapy.
3. To appreciate image-guided interventional treatment.

Last year the mini-courses 'The Beauty of Basic Knowledge' were successfully introduced. Their number has doubled in 2013.

These events will cover themes in the field of head-and-neck radiology as well as musculoskeletal radiology.

Thursday, 7 March, 12:30–13:30, first Level
MC 25A: Musculoskeletal Imaging: Trauma. Room P
MC 24A: Head and Neck: A taste of the oral cavity and salivary glands. Room N/O

Friday, 8 March, 12:30–13:30, first Level
MC 25B Musculoskeletal Imaging: Degenerative disorders. Room P
MC 24B Head and Neck: Main pipelines of the neck: pharynx and larynx. Room Q

Saturday, 9 March, 16:00–17:30, First Level
MC 25C: Musculoskeletal Imaging: Inflammatory/infectious disorders
MC 24C: Head and Neck: Main pipelines of the neck: pharynx and larynx. Room N/O

Sunday, 10 March, 12:30–13:30, first Level
MC 25D: Musculoskeletal Imaging: Neoplastic/nonneoplastic lesions. Room P
MC 24D: Head and Neck: The suprahyoid neck: anatomy and diagnostic algorithm of the neck mass. Room Q

Monday, 11 March, 12:30–13:30, first Level
MC 25E: Musculoskeletal Imaging: Metabolic/endocrine disease. Room
MC 24 E: Head and Neck: Temporal bone: so beautiful, yet so complicated. Room N/O

Also worth mentioning is the Foundation course 'Neuroimaging'. According to its theme 'All you need to know about neuroimaging in 18 easy lessons', this will answer most questions:

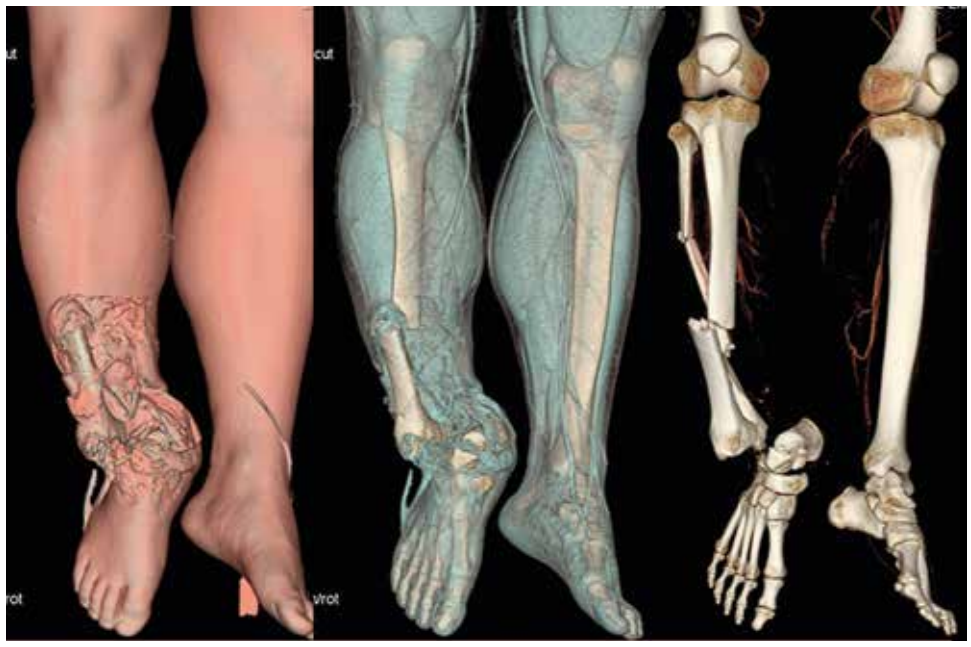
Friday, 8 March, 08:30–10:00, Entrance Level, Room E2
08:30 – 10:00 The orbit, the petrous bone and the sella.
10:30 – 12:00 Paediatric
14:00 – 15:30 Trauma and vascularity
16:00 – 17:30 Infection and inflammation

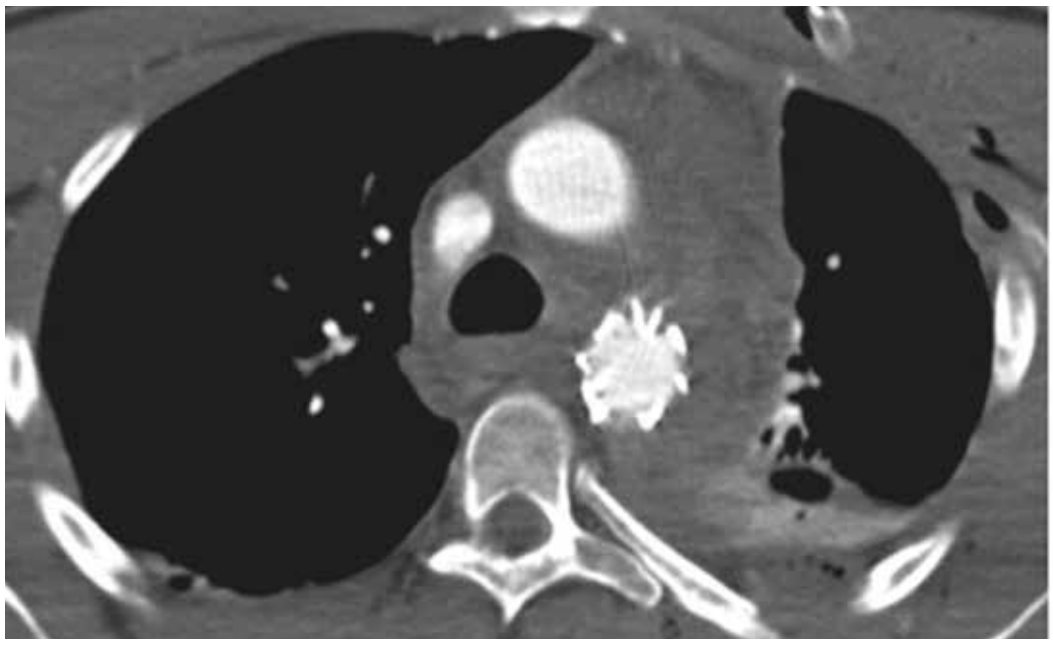
Saturday, 9 March, 16:00–17:30, Entrance Level, Room E2
08:30 – 10:00 Metabolic and neurodegenerative disorders
10:30 – 12:00 Tumours and phacomatosis

The scientific highlights of ECR at least will be the categorical courses, 'Never without Arteries', 'Urogenital Imaging' and 'Oncologic Imaging', all providing participants with the latest results and innovative techniques in the related areas.

The importance and exciting potential of cardiac imaging might be seen separately. One of the last sessions at ECR 2013, but surely one the highlights is the following:

Monday,11 March, 14:00 – 15:30, Lower Level, Room D1
SS 1803 Cardiac imaging: Into the future





Polytrauma imaging

To be effective, guidelines, protocols and algorithms are essential

Polytrauma images of the damaged lower limbs of a nineteen-year-old patient following a subway accident. Left: Whole-body computed tomography (WBCT), a 3-D VRT reconstruction for soft tissue, bone, artery. Right: haemodynamically stable, with TAA completely excluded

Report: Brigitte Dinkloh

Professor Ulrich Linsenmaier, a leading expert in emergency radiology, has highlighted the need for clinicians to read image data rapidly in an emergency department if they are to help improve clinical outcomes for polytrauma patients.

Whilst he acknowledges that the volume image reading (VIR) approach advocated by his Munich group may be somewhat controversial, he believes that reading large, whole-body CT data directly on the console, prior to the arrival of reformatted images on the PACS, dramatically speeds up diagnosis.

Professor Linsenmaier, who heads the Institute of Diagnostic and Interventional Radiology at Munich Hospital KMPP and is an associate professor at Munich's Ludwig-Maximilians-University, will present his views to the ECR 2013 Special Focus Session Imaging in Intensive Care Patients*.

Among other points, he will emphasise the importance of having clear guidelines, protocols and algorithms in place to ensure effective and safe imaging of polytrauma patients. He believes having such a structure available to the emergency department – along with the necessary imaging – will help speed up diagnosis, reduce complications and improve outcomes for the most severely injured patients.

Additionally, Professor Linsenmaier, who also presides over the European Society of Emergency Radiology (ESER), will focus specifically on polytrauma imaging, highlighting radiological diagnosis of polytrauma patients in his lecture covering logistics about radiologic management, scan protocols, imaging guidelines and patient care and follow-up imaging while being treated in intensive care units.

Professor Ulrich Linsenmaier is Head of the Institute of Diagnostic and Interventional Radiology in Munich Hospital and Associate Professor at Ludwig-Maximilians University, Munich. He is also President of the European Society of Emergency Radiology (ESER) and has carried out extensive research on the benefits of CT scans for seriously injured patients as well as techniques for imaging polytrauma cases.

Speaking to European Hospital ahead of the conference, he said there are a number of key factors to consider to successfully set up an emergency radiology department to treat polytrauma patients. The first step, he explained, is triaging patients for the emergency department treatment (ED), following Advanced Trauma Life Support (ATLS)-based entry criteria to securely establish whether the patient has polytrauma. 'Next, you need clear algorithms for early clinical treatment in the emergency room with radiology being part of the ED team. Good communication between radiology, anaesthesiology, emergency medicine and surgery is essential.'

A third step is to use ultrasound for Focused Abdominal Sonography for Trauma (FAST). Professor Linsenmaier and his team having defined a modified FAST version, which they prefer to use – it also quickly views the heart and bilateral pleural spaces for haemorrhage. FAST is a critical step in how quickly a patient can undergo CT, and whether they are triaged directly from the emergency room to the operating theatre.

He stressed that the radiologist on-site in the emergency room must have specific emergency radiology knowledge; the technologist running the CT scanner should be familiar with performing whole body scans in polytrauma; and there needs to be a pre-programme protocol, specifically designated to whole body CT.

Of his firm belief in the VIR concept having particular value in this context, he further points out: 'Today's whole body CT produces a large number of images, with which it's difficult to work, so my group recommends VIR - volume image reading – where we start reading the data before the images arrive in the PACS. This is new, even a little controversial, but an interesting concept that speeds up radiology because we can read the images right away when the data is available on the CT console. We don't wait until every reformatted image is in the PACs, we instead start VI reading the raw data immediately from the console and this speeds up the diagnosis.'

With a limited role for conventional radiography in this context, the professor recommends having the availability of 'a modern, very fast scanner, capable of handling large scan volumes and ensuring integration of all modalities' for successful polytrauma imaging.

The key learning points from the ECR session, he said, will be how to apply modern emergency radiology in a clinical priority-oriented concept. Adopting such processes will speed up diagnosis, he added, reduce the complication rate and improve the outcome for the patient.

The professor's Munich team has conducted research on the influence of whole body CT in polytrauma on patient outcomes. 'We showed that applying whole body CT in patients with polytrauma, significantly improves survival,' Professor Linsenmaier confirmed (The Lancet. 2008).

As for the latest developments, he believes many advances have already been made with today's scanners in assessing vascular and head and neck injuries with the option, for example, to perform a CT angiography of the supra-aortic arteries to rule out vascular injury.

The ECR session will also examine point-of-care versus diagnostic ultrasound in the intensive care unit. Professor Linsenmaier is keen that advances in polytrauma imaging are not only available in major centres but that the knowledge, teaching and training cascades down to rural areas to improve diagnosis in polytrauma in less specialised radiology departments.

* Friday, 8 March. 4-5.30 p.m. SF 7c: Imaging in intensive care patients.

A new forum founded at ARCHIS 2013

The Joint German military/ civil medicine forum CAMIN

Report: Michael Reiter

There are long-standing ties between military and civil medicine in Germany: physicians practicing military medicine receive their professional grounding in civil institutions, explained Michael Zallet MD, head surgeon at the Central Army Hospital, Koblenz, speaking at the ARCHIS 2013 congress. The country's five military hospitals are teaching hospitals of academic organizations, with an active exchange between research and education. This collaboration could be broadened by instituting research clusters, possibly integrating NATO interests. 'An international context for this kind of collaboration of military and civil medicine would be viable for disciplines such as traumatology and, for example issues such as severe haemorrhages and loss of hearing,' he suggested. The Central Army Hospital, Koblenz, is driving these kinds of approaches.

With increased activities outside the country, acting in UN and NATO missions with international collaboration, the number of emergency surgery cases in the German army has expanded. 'This has lead to an increase in specialised know-how, which our combined visceral-trauma surgeons, for example, now wish to exchange with civil medics,' said Dr Christoph Veit, President of DGWMP – the German Society of Military Medicine. 'In particular, we can provide highly specialised expertise regarding the practice of first-line trauma surgery in contexts where resources are limited … such as, for civil practice, in remote areas.'

For quite some time, Germany's five army hospitals have been treating civilians. Today, up to 70% of patients do not have a military background. This has helped these hospitals to function financially, and to ensure a broader portfolio of medical cases. Some 600 military physicians serve around 60,000 in-patients annually

Until today, competence from the military side had been present in civil medical societies at the level of organs, Dr Zallet pointed out.

During the congress DGWMP and DGAV, the German Society for Visceral Surgery, jointly founded a working group. CAMIN (Chirurgischer Arbeitskreis Militär- und Notfallchirurgie – Surgery Working Group in Military and Trauma Surgery) will provide a platform for know-how exchange in trauma surgery to foster outcomes both in military and civil medical routine. 'This creates cross-sectional visibility for military medicine concerns, and allows us to bring in our expertise, which is of great research interest to civil colleagues, e. g. in the case of post-traumatic stress disorders,' the head surgeon said.

Photograph: MR

Organised by the German Society of Military Medicine (DGWMP), the 20th ARCHIS gathering in Koblenz/Germany, last January, welcomed 270 attendees

'CAMIN is only the beginning of an expanded interchange of expertise between military and civil medicine, aiming at joint research activities,' Dr Veit concluded. All surgeons are invited to participate; congresses such as ARCHIS and DGAV, as well as visiting physician schemes will provide platforms.

Implantable cardiac devices

Evaluating the efficiency of centralised cardiac monitoring

Patients with cardiac implantable electric devices (CIED) need on-going and lifelong follow-ups. Due to the growing number of CIEDs, the demand for follow-up visits is increasing rapidly and already pushing clinics to maximum capacities. Inconsequential, non-actionable visits are of particular nuisance to both physicians and patients. Today, follow-ups can be done remotely through remote cardiac monitoring, which eases clinical routine and allows patients to obtain treatment as soon as needed, further leading to safer and more efficient patient management.

Clinical studies like TRUST (2010: Varma et al., Circulation 2010 and Circ Arrhythm Electrophysiol); COMPAS (Mabo P. et al., Eur Heart J 2012), REFORM and ECOST have proved that remote monitoring is a safe and effective tool in assessing the patient's medical status. Studies have also demonstrated that satisfaction with remote monitoring is very high among both patients and physicians. 'Biotronik Home Monitoring is regarded as the most user-friendly system because it does not require any patient interaction in order to obtain data,' the manufacturer reports. 'Instead it delivers alerts to the clinic in an easy-to-assess traffic light system.'

The claim that Home Monitoring reduces in-office follow-up visits is supported by several independent randomised controlled trials for both pacemakers and ICD's (implantable cardioverter defibrillators) and has also been confirmed by observational study data. In 2009, the Biotronik Home Monitoring system received specific FDA and TüV approval for its ability to replace in-office visits safely, and to detect health issues and device-related issues earlier, allowing for timely medical intervention, the company reports.

Time and cost reduction for clinics

Home Monitoring cuts the number of in-office visits by around 50%. The RCT's for Home Monitoring consistently report a reduction in in-office follow-ups as follows: 45% (TRUST), 55% (COMPAS), 63% (REFORM).

In addition, routine remote follow-ups can be carried out in a third of the time needed for conventional clinical follow-ups. Fewer in-office follow-ups also result in reduced patient travel time and costs, and reduced patient waiting times (Charles et al., 2007).

Recently the MoniC (Model Project Monitor Centre) study has evaluated the efficiency gains in clinics using Biotronik's system, the company reports. 'Results of the study showed that centralised Biotronik Home Monitoring is reliable, beneficial and efficient: basic screening and communication of relevant arrhythmic and technical events required a total of 1.1 minutes of a physician's time and 30 minutes of a trained nurse's time each day per 100 patients monitored by the centre.'

Left: Modern remote cardiac monitoring reassures patients, enabling them to obtain treatment as soon as needed and stay at home when it is not

Right: Studies show that basic screening and communication of relevant arrhythmic and technical events required only 1.1 minutes of a physician's time per 100 patients monitored

'MoniC underlines the all-around positive impact of Biotronik Home Monitoring has every day in our study clinics,' commented Christoph Böhmer, the company's International President. 'This trial clearly demonstrates the large potential for efficiency gains and therapy improvements, which are important parameters for healthcare decision makers. It's a clear win-win for both patients and physicians, no matter what size the clinic.'

Radial access to the heart is favoured

Report: John Brosky

Twenty years after introducing radial access for cardiac interventions, EuroIntervention has published a consensus document favouring this shorter route to the heart when performed by experienced practitioners.

Compared to the more widely used femoral access to place coronary stents, radial access has been shown to cause fewer complications at the vascular access site, lower hospital stays and reduce costs.

The consensus was developed by a panel appointed by the European Association of Percutaneous Cardiovascular Interventions (EAPCI), which included pioneers of radial angioplasty and experts nominated by the European Society of Cardiology.

For coronary angiography and percutaneous interventions (PCI) the consensus is that radial access is feasible as the default approach in routine practice, in stable and unstable patients, including for ST-elevation myocardial infarction (STEMI) patients.

The experts cite the recent Radial Versus Femoral Randomised Investigation in ST-Segment Elevation Acute Coronary Syndrome (RIFLE study) that concludes unambiguously that radial access in patients with ST-segment elevation acute coronary syndrome is associated with significant clinical benefits, in terms of both lower morbidity and cardiac mortality.

The endorsement is conditioned by recommendations for appropriate skills levels and insistence that operators should also demonstrate proficiency in the femoral approach.

The panel recommends an annual procedure volume of more than 80 transradial cases, which they find correlates with a significant reduction in access failure, sheath insertion time and procedure time. The length of these procedures is the sole downside described by the panel for radial access, as it increases the risk of exposure to radiation for the patient as well as the team.

Austria's cardiovascular research

AIT's device Mobil-O-Graph enables arterial stiffness measurements over a 24-hour period

Report: Michael Krassnitzer

Arterial stiffness of the central human blood vessels leads to increased work for the heart and damages microstructures in the organs. However, measuring blood vessel elasticity inside the body is not that easy. The established method – a minimally invasive procedure – is mainly used in a scientific setting and only rarely used outside the hospital. However, an Austrian research institution has developed a mobile device that facilitates measurements of arterial stiffness over a 24-hour period.

'Measuring the stiffness of the vessels allows a better assessment of the cardiovascular risk and improves the ability to monitor the effects of treatment,' explains Dr Siegfried Wassertheurer, Deputy Head at the Department of Health & Environment at the Austrian Institute of Technology (AIT).

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In their current treatment guidelines both the European Society of Hypertension and Cardiology (ESH and ESC respectively) refer to the use of pulse wave analysis (PWA) to determine central haemodynamics. Pulse wave speed, pulse wave reflection and data on central blood pressure deliver information about the stiffness of the arteries because pathologies lead to characteristic changes in the dynamics of the pulse waves. 'When the vessels become stiff, meaning calcified, the speed at which the pulse waves spread through the body is significantly higher,' Dr Wassertheurer points out.

For the measurement of arterial stiffness inside the body, conventional blood pressure measuring on the brachial artery alone does not suffice. Peripheral pulse curves differ in form, speed and amplitude very clearly from central pulse curves. The AIT has therefore developed mathematical algorithms that make it possible to determine the aortic pulse curve from the peripheral pulse curve measured on the upper arm. These were integrated into a conventional, mobile blood pressure measuring device, which continuously measures a patient's blood pressure over a 24-hour period. 'This combination of 24-hour measurement and algorithms facilitates a focused diagnosis of the state of the aortic vessels, ' he says.

Via a cuff attached to the upper arm, the Mobil-O-Graph initially measures peripheral blood pressure in two measurement cycles and then, indirectly, measures the internal blood pressure and therefore the state of the aortic vessels. Developed in collaboration with the Department of Cardiology at Wels-Grieskirchen Hospital (Upper Austria) and the German blood pressure measuring equipment manufacturer I.E.M., the AIT device is already licensed in Europe, the USA, Canada and South America and a license for use in Japan is currently in the pipeline.

More than 1,000 of these devices are currently used worldwide, mainly in hospitals and some surgeries. The cost of acquisition is currently around €5,000. 'We are working on making the devices smaller and simpler still, so that costs will continue to fall, making mass production feasible in a few years' time,' Dr Wassertheurer predicts.

'In the past, the thinking was that high blood pressure leads to stiff arteries. However, it seems to be the other way round,' says Thomas Weber PD MD, head of the Hypertension Out-patient Clinic at Wels-Grieskirchen Hospital, explaining the medical importance of arterial stiffness. 'With every heartbeat, the large vessels are stretched, which, over the years, causes enormous mechanical strain. The elastin in the media degenerates and is replaced by the stiffer collagen, which makes the large arteries stiffer.' This increases strain on the heart while the circulation also worsens, and it also damages the small blood vessels in the brain and kidneys, he points out. 'Therefore it's important to carry out screening at an early stage, to diagnose damage to the heart, brain and kidneys and, through consistent treatment, avoid anything worse.'


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Born in Graz, Austria (1972), **Dr Siegfried Wassertheurer** studied Business Information Technology at the Vienna University of Technology and wrote his doctoral thesis on cardiovascular modelling and simulation. In 2000 he joined the Biomedical Systems Unit in the Department of Health & Environment at the Austrian Institute of Technology (AIT), where he is Deputy Head. This is Austria's largest extramural research institution (formerly known as the Austrian Research Centre).

Disambiguation

A new system might help to analyse unstructured clinical documentation, such as lab/pathology results, thus tapping a wealth of hidden information

Report: Michael Reiter

Electronic patient records (EPRs) may harbour a host of clinically useful data, which could bring benefits from the analysis of correlations between symptoms, treatments, and outcomes. The shortlisting of candidates for enrolment in clinical trials would be another potential option.

However, a major obstacle to the extraction of this valuable information from freeform notes has been word-sense disambiguation. The identification of intended meanings in words may now have become possible, computer scientists explained at the 2012 American Medical Informatics Association's (AMIA) annual symposium in Chicago.

The work on the new disambiguating of words system described was launched at the MIT Computer Science and Artificial Intelligence Laboratory (CSAIL) by Dr Anna Rumshisky and Master's student Rachel Chasin, in the Clinical Decision Making Group headed by Prof. Peter Szolovits. At the time, Dr Rumshisky was a postdoctoral associate; today, she is an Assistant Professor at the Department of Computer Science, University of Massachusetts/Lowell, USA.

Asked about the current situation regarding EPRs and options to extract information – particularly lab and pathology results – for research and routine, Dr Rumshisky summed up: 'Compared to the general domain text, information extraction from unstructured clinical data has been lagging behind, and the main obstacle has been the absence of annotated data for training supervised machine learning systems. This situation is partly due to privacy restrictions on the clinical text.

Anna Rumshisky PhD studied Computer Science at Brandeis University until 2009. As an Assistant Professor at the Department of Computer Science at University of Massachusetts, Lowell and research affiliate at the Clinical Decision Making group at the Computer Science and Artificial Intelligence Laboratory at MIT, her primary research area is natural language processing (NLP), with applications in clinical informatics, computational lexical semantics, as well as digital humanities and social science. Her work focuses on the development of data-informed unsupervised learning methods and on leveraging existing resources and information-harvesting techniques to overcome the knowledge acquisition bottleneck.

'However, over the past six years several large de-identified sets of clinical records have been annotated for different linguistic information, and several community-wide information extraction challenges have pushed the state of the art forward.

These have been organised under the aegis of the Informatics for Integrating Biology and Bedside (i2b2) project and led in large part by the Clinical Decision Making group, with the lead organiser Dr Ozlem Uzuner, a research affiliate and former postdoctoral fellow in the Clinical Decision Making group, currently an assistant professor at SUNY Albany.

Blocked structuring/standardisation and potential approaches

'The annotated data covers document-level diagnosis extraction, text-level annotations of clinical problems, tests, and treatments/interventions, as well as relations between them, extraction of medications, and dosages, and a few other information extraction tasks. Last year, we ran a challenge on extraction of temporal relations between clinically relevant events, and another annotation effort is under way this year. Importantly, we make the annotated data available to the community for training and testing the automated systems.'

'Information extraction from clinical text is challenging for a number of reasons. Typically, clinical text is written for experts by experts, and uses shorthand characterised by highly non-standard syntax, which is, at the same time, brimming with abbreviations and acronyms not well documented in any knowledge resources. The most prominent semantic resource used for clinical text processing is the Unified Medical Language System (UMLS), which has not been designed with text processing in mind, and therefore is often not directly useful.

'As far as disambiguation of undocumented acronyms is concerned, for example, creating annotated data would entail (1) devising a sense inventory and (2) annotating a corpus of text for every single ambiguous word. Since this is too labour intensive and therefore expensive, our goal has been to develop unsupervised learning methods to accomplish the same tasks.'

Solution paths

'We tried several disambiguation methods that do not involve supervised machine learning. The first set of methods used the UMLS to attempt to disambiguate words. For the reasons mentioned (UMLS is not structured appropriately as a linguistic resource) the results were not very impressive. We then decided to adopt a modification of an unsupervised bottom-up probabilistic graphical modelling technique, called topic modelling, which has been used with some success in the general domain.

'Topic models – in particular, we used Latent Dirichlet Allocation and Hierarchical Dirichlet Process – assume that each document was generated from a succession of topics the writer meant to discuss. In turn, each topic generates a set of terms. Topic modelling uses correlations among terms as they are used in a large corpus to suggest what might be the likely succession of topics, and learns probabilities for both topics and the terms they generate. This probabilistic model then permits identification of common topics in this domain, and subsequent recognition of discussions of that topic in future documents.

'The twist that we've adopted from the general domain is to treat each occurrence of the target ambiguous word as a separate document, and to associate the induced hidden topics with the senses of the ambiguous word, which in turn will be associated with the linguistic features characterising each example.

'Tested on 50 annotated targets, our best results are 85.6% accuracy on targets with two senses, and 66.3% accuracy over all targets combined.

'We are currently developing a generalised model that integrates more sophisticated linguistic features characterising each ambiguous example, specifically, context features based on syntactic parses and UMLS mapping of context words. We are also trying to apply similar ideas to predictive modelling based on retrospective clinical data, in particular using unsupervised topic modelling methods on narrative patient records for outcome prediction and risk stratification for different patient populations.'

Patient data transfer and healthcare policy-making

Now central to most medical and policy-making discussions, cross-border healthcare, telemedicine and e-health are a top priority on the EU's healthcare agenda, and most Member States are working to develop viable systems in this field

Report: Moira Mizzi

During a recent presentation at the EMMIT conference in Malta, Dr Mario Ciampi, researcher into software architecture for e-health at the Istituto di Calcolo e Reti ad Alte Prestazioni (ICAR) in Naples, gave an account of Italian efforts to introduce e-health on a national level. This member state is working on three main e-Health initiatives: e-prescription, online sick notes and medical reports, aiming to collect and store relevant data in repositories and harmonise communication between the parties involved. In fact, most of the regional administrations have started a series of initiatives to set up Electronic Health Record (EHR) systems. However, unfortunately each region is setting up its own system, adopting heterogeneous architectural and technological set-ups and thus not only is progress uneven overall but interoperability is also hindered.

In his capacity as a researcher at the National Research Council of Italy (CNR), of which his institute is part, Dr Ciampi also talked about projects, coordinated by Dr Giuseppe De Pietro, which were launched in an attempt to set up a functional e-health system at a national level. The first, InFSE, a joint project between the Research Centre and the Presidency of the Council of Ministers of Italy, ran from May 2009 to October 2010 and aimed at setting up the technological infrastructure of EHRs. This infrastructure includes an Access Interface, found both at local and regional nodes. This allows interactions between the local domain and the infrastructure and provides all necessary functions to search for, obtain or publish a health document. It also includes a Federated Index Registry, made up of the regional registries, a Document Manager that allows storage and retrieval of documents by an authorised user, a Hierarchical Event Manager, able to notify clinical events, and an Access Policy Manager, which deals with authentication, identification and authorisation mechanisms.

This InFSE architectural model has also been outlined in detail in guidelines that have been incorporated in the 'Guidelines on Electronic Health Record, produced by the Italian Health Ministry.

OpenInFSE success

The OpenInFSE project followed suite, aimed at the setting up of an operational infrastructure to support the interoperability of EHR in the context of the Public System Connectivity. Three regions, namely Piedmont, Campania and Calabria, were involved in this project, which not only worked at implementing and sharing InFSE components with Web Services Technology but also at integrating these components with regional EHR systems and it experimented with the interchange of healthcare documents between the three regions involved.

The setup of the OpenInFSE project laid the groundwork for the IPSE project, which involved a greater number of regions and provinces in the Italian peninsula and experimented with the exchange of patient summaries by interoperability of regional EHR systems.

Connected to the epSOS project (European Patient - Smart Open Services) this project allowed for both direct (region known) and federated (region unknown) search of patient records and for document retrieval.

The Italian e-health pipeline is still buzzing with activity with ongoing and prospective projects co-financed by the Presidency and the National Research Council. One particular project presently underway involves the evolution and interoperability of the EHR project. The project objectives include the definition of services for remote monitoring and telemedicine and the integration of these applications with EHR, the adaptation of software modules rendering them available as open source components to all stakeholders, among others.

The ultimate aim of such information technology projects is to establish a cohesive system that can support healthcare integration at least on a national level. The water is there to drink. Let us hope the horse takes it in once it reaches there.

Mario Ciampi PhD MSc, studied Computer Engineering at the University of Naples Federico II, Italy and, as a post-graduate, gained a first Master's degree on Critical Networked Systems in 2007, followed by his PhD on Information Engineering in 2011, both from the University of Naples Parthenope. Since 2004, Dr Ciampi has worked at the National Research Council of Italy (CNR) and is currently a technologist at the CNR's Naples branch of the Institute of High Performance Computing and Networking (ICAR). He is involved in national projects for the development of interoperability infrastructures for EHR systems.
Dr Ciampi also serves on the editorial boards and programme committees of several international journals, conferences and workshops, and is a member of iHealth lab, AMICO, HL7 Italia and @ITIM.

Epigenetic drugs

Reprogramming to help correct Nature's mistakes and possibly revolutionise cancer staging and therapy

Report: Michael Reiter

'All human body cells contain the same DNA, but every type of cell – for example a muscle cell compared to that of a nerve – has a different gene expression pattern', said Dr Sonja Stadler, speaking at the 2012 congress of DGKL (German Society for Clinical Chemistry). Epigenetics, explained the expert from the Institute for Laboratory Medicine, Clinical Chemistry, and Molecular Diagnostics, University Hospital Leipzig, Germany, is all about regulating specific patterns in cells, which are propagated not by changes in the DNA sequence but by epigenetic mechanisms, such as DNA methylation and histone modifications. 'These mechanisms modulate gene expression by changing the state of the chromatome, not by changing the DNA sequence itself.'

Effects include the expression of genes or the blocking of expression. 'The turning on, or off, of genes is influenced by epigenetic effector molecules, and it can be triggered by signalling pathways, by environmental inducers such as smoking and diet.' New approaches may help detect and influence epigenetic changes, with potential major benefits in diagnostics and therapy.

Breast cancer cells, for example, show a specific pattern of DNA methylation and histone modifications compared to their normal counterparts, and they come with genes that are frequently over-expressed or not expressed. Some of these genes are suitable indicators for staging, or predictors of therapy outcomes. 'Tumours that are no longer receptive for oestrogen will not respond to chemotherapy, which targets hormone-induced genes and tend to be more malignant … the possibility to read the methylation pattern of certain genes could be a huge advantage in assessing and treating tumours', the expert pointed out.

With this background, changing or reversing an epigenetic pattern of a cancer cell appears to be a very promising approach. 'Recently, a lot of attention has been focused on developing epigenetic drugs', Dr Stadler explained. In the USA, a small number of drugs have been approved to treat difficult-to-cure diseases, such as rare T-cell lymphomas and myelodysplastic syndromes. They inhibit DNA methylation or histone deacetylation. 'Further epigenetic drugs are currently at the clinical trial stage … It will take another five to ten years to find out how epigenetic drugs really work in the body: What are the conditions for targeting? What is the dose required? What are potential side effects, and so on.'

At the 2012 DGKL Congress: Expert Dr Sonja C Stadler, from the Institute for Laboratory Medicine, Clinical Chemistry and Molecular Diagnostics, Leipzig University Hospital, describing the potential of epigenetics for cancer diagnosis and therapy (Photograph: MR)

Future drugs, she added, ought to include highly specific formulations for effects on individual enzymes compared to more global patterns.

The outlook

The combination of epigenomic data with information coming from genomics and transcriptomics will greatly increase our understanding of tumourigenesis and lead to better epigenetic biomarkers for detection, prognosis and therapy prediction for leukaemias, as well as for solid tumours.

There is also some future potential for increased accurate and personalised medicine by developing epigenetic drugs against specific isoforms or mutated variants of enzymes involved in specific tumour types. However, such an approach would be extremely costly, Dr Stadler said: Compared to establishing a patient's genome, analysing the individual epigenomic mutations and the totality of pertinent factors cannot be standardised to date and is significantly more demanding.

The human cancer epigenome platform is a huge research initiative designed to provide cornerstones for future activities in the field. In the USA, the recent NIH epigenetic road map has also supported major advances.

Cancer geneticists, epigeneticists, and oncology therapists might integrate their respective expertise and work together to create new drugs – Dr Stadler's postulation for collaboration across disciplines aims at enabling improved outcomes for cancer patients.

Pathology

UK labs face changes and ch from new healthcare legislati

Report: Mark Nicholls

Aspects of new healthcare legislation are causing concern among medical laboratory experts in the United Kingdom – including the lack of future funding for innovation and development under a new reimbursement model, little appetite to quantify the cost effectiveness of laboratory testing, reduced staffing and a shift in emphasis that will see the need to make profit over-ride initiative and innovation – all issues highlighted during the Frontiers in Laboratory Medicine conference held in Birmingham in January.

Speaking to European Hospital in his capacity of President of the Association for Clinical Biochemistry, Dr Michael Thomas said a key factor was the new Health and Social Care Bill 2012. When it comes into effect in April this is set to impact on the landscape of service commissioning in England.

Laboratory services are increasingly subjected to tendering for the work they have traditionally provided through direct access arrangements with their local General Practitioners (GPs) and under the new process, a range of reconfigurations are occurring. These include the development of networks that range from those based on simple collaboration amongst NHS service providers, to joint venture partnerships between NHS and private pathology providers, while some acute Trusts are also totally outsourcing their pathology services.

Dr Thomas believes one impact will be fewer laboratories with a greater centralisation of specialist services, though that may also provide better use of complex and expensive equipment.

The other challenge is in how UK pathology labs are being funded. Traditionally, pathology budgets have been provided through secondary care host organisations. However, the costs of pathology tests are increasingly attributed to the source of requesting through recharge arrangements.

The suspicion remains that commissioning groups will aim to reduce the cost of pathology spend-

Digital path

Although evolving as a tool in medical pathology for years, several factors have hampered its widespread use in this field. Now, a Scientific American article asserts that the time has come for a digital imaging revolution

Report: Jacquie Michels

Digital images can now be used in a few 'niche' applications, such as making primary diagnoses, offering second opinions through telepathology and allowing archiving and image sharing. However, cost, technical factors, and pathologists who fear the advances of technology have hindered widespread use of digital pathology. According to Dr Liron Pantanowitz, those drawbacks can be overcome: 'These are exciting times in pathology. New technologies are available; they are exciting and can be used now.'

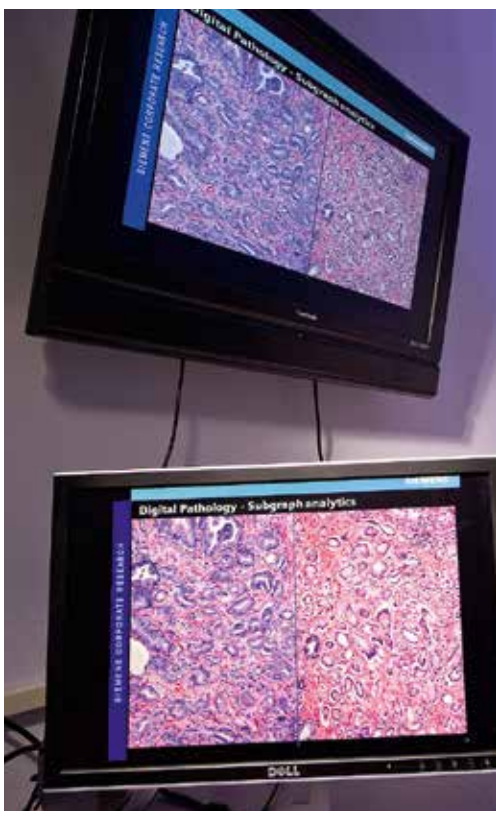
Digital images of medical samples are composed of pixels that are converted to binary code so that they can be stored at high resolution online. Although the four steps (image capture, saving, editing, and viewing) are clearly defined, none of them have been standardised, which makes them more time-consuming and the results less reliable. While whole slide imaging (WSI) has advantages in being more interactive and easy to share, it still has drawbacks, unable to completely overcome certain limiting factors, such as thick smears and 3-D cell groups in cytopathy.

The FDA has not yet approved digital pathology for diagnostic purposes. 'Some feel the equipment is too expensive,' Dr Pantanowitz explained. 'Others simply have technophobia and don't want this new advance to become the gold standard. Still others just don't want to change the way they practice, even though it may be vastly for the better.'

Digital pathology has already been shown as valuable in certain clinical settings, such as cytopathology, to help differentiate and classify morphologically similar lesions. Many institutions have come to recognise that it is easier to deliver a biological image for a second opinion across rural areas than to deliver the patients across hundreds of miles. 'This is true in areas like Canada, where vast expanses separate major medical centres,' he pointed out, adding, 'They are finding ways to assure high-quality images by regulating restrictions.' With a glass slide, you can scan in, he explained, 'and look at a digital image, which simulates real tissue, on a virtual microscope'.

'We need broader use of digital pathology to clarify what can be done with the technology. Some see it as a disruptive innovation that may improve a service in a manner that the market does not anticipate. At present, we have yet to see real digital slide-based routine surgical pathology in practice.'

However, Dr Pantanowitz loves the pixel, which he believes show more information than meets the eye because it is binary. 'Is it ready for prime time?' he asks. 'Yes and no; eventually the barriers will be removed and digital pathology will be broadly used to clearly visualise, share, and store images for indefi-



allenges ion

ing, but lab professionals point out that aspects of teaching, training, research, development and innovation also need a funding stream.

Under the new model of reimbursement, Dr Thomas fears the possible disconnection in pathology service provision between primary and secondary care may be an issue where financial stringencies result in poorer quality care and the risk of duplication as patients move across the two divisions. 'It remains unclear,' he said, 'how the new commissioning landscape will impact on the costing and reimbursement of pathology investigations. 'There may also be a possible lack of resources for innovative developments as the business of pathology becomes more focused on financial profit for shareholders and partner organisations.'

Dr Thomas said hospital managers must be persuaded to perceive pathology –which accounts for up to 70% of diagnoses made – as bringing a cost benefit to the overall process of patient care, rather than 'an expensive extra' and with the move to outcome measures it should be possible 'to demonstrate the impact that pathology has on the patient pathway.'

Part of the change will see pathology labs challenged to be more innovative: for some, Dr Thomas pointed out, this will be about reconfiguring services into more effective units where larger bulk provision may provide cost benefits; whilst for others it will be about the introduction of new procedures to diagnose and monitor disease and its response to therapies.

While key areas of innovation remain in genetics and genomics, especially with the cost of whole genome sequencing falling to affordable levels, Dr Thomas said there are other innovation areas in the ways services provision can be delivered, such as outreach opportunities or biomarker developments. He added: 'The impact of phenotypic expression influenced by environment must not be overlooked and hence the use of innovative proteomic biomarkers must remain an important focus of innovation.' He cited the use of BNP and Calprotectin as examples of biomarkers that can impact on both quality and cost in the patient pathway, but it remained largely for pathology to demonstrate the cost benefits of such biomarkers. Much of the traditional assay and technological development is now within the province of commercial diagnostics companies; however, he said there is evidence that innovation is still happening in the NHS.

Dr Mike Thomas is Clinical Director of Inflammation and Infection Services and Head of Clinical Biochemistry for the Royal Free London NHS Foundation Trust and President of the Association for Clinical Biochemistry

ology

South African born **Dr Liron Pantanowitz**, a pathologist at the University of Pittsburgh Medical Center in McKeesport, Pennsylvania, has written more than 200 publications on all aspects of pathology. He presented his ideas on digital pathology and how it can shape medical diagnosis and treatment as keynote speaker at the Cambridge Healthtech Institute conference held in San Francisco in February this year.

nite amounts of time. The pixel shows more information than the eye, and the computer can pull the whole picture together.

POC testing technology

Julian Baines, Group CEO of EKF Diagnostics Holdings plc, considers the present role of point-of-care tests and their potential value to health services

By its very nature, Point of Care Testing (POCT) technology does not strictly sit within the hospital sector. Rather, the rationale behind POCT is to keep the patient out of the hospital system and within the primary care setting. This is because lying at the heart of the concept of POCT is the principle that medical tests are convenient and immediate to the patient. Consequently, in countries that have fully embraced POCT, patients can visit a general practitioner (GP) or a nurse to provide a tiny blood sample and undertake a test for haemoglobin levels, lipids, glycated haemoglobin (HbA1c), CRP, to name but a few, and receive a lab-accurate result before leaving the surgery.

By putting resources into POCT, governments can free up funds and resources that can then be invested in other critical hospital services. Therefore, rather than resist the inevitable drift towards POCT, hospitals should embrace technology that is focused on providing a better patient experience and reduces the total cost of basic patient care by enabling clinical decisions to be made at the earliest opportunity.

Currently, the barriers to the wider use of POCT are not so much technological, providing products are designed and manufactured with quality and ease of use at the forefront to rapidly deliver accurate results, but those of politics and acceptance.

Using the United Kingdom as an example, the National Health Service (NHS) is a political hot potato and any change is deemed to be negative or, in the case of the current government, an attempt to privatise. This is an extreme point of view because POCT has the potential to save the NHS vast sums of money through earlier diagnosis and treatment, or even the reduction of unnecessary treatment. However, when the former Minister of Health, Andrew Lansley, tried to tweak the system to allow more POCT he was criticised. The UK has a highly structured and complex central laboratory system and making changes will not be easy due to the highly politicised nature of the NHS. It is a similar story in France, although there is a move there to radically reduce the number of central laboratories that might, in turn, make the French health authorities more open to the POCT concept.

Julian Baines has extensive experience and understanding of the global diagnostics and POCT market stems from his decade as Group CEO of British Biocell International (BBI), where he was responsible for selling the business to Alere Inc in 2008. He is still a BBI Board Member, as a non-executive director. In December 2009 he was appointed CEO of EKF Diagnostics Holdings plc and completed the acquisitions of Quotient Diagnostics, Argutus Medical and Stanbio Laboratory. EKF Diagnostics, he points out, is now one of the world's fastest growing diagnostic businesses.

Diabetes detection and management: Then Quo-Lab POCT analyser measures glycated haemoglobin (HbA1c)

Not surprisingly, there are varying degrees of POCT acceptance between countries and continents. In countries such as the USA and Germany, where health insurance pays for treatment, POCT is embraced because of the cost efficiencies it offers. In emerging markets the opportunity is even greater, as they do not have a pre-established dependence on central laboratory testing and therefore are often early adopters of diagnostic innovation that improves patient care. Without doubt, emerging markets are catching up with the western world regarding patient care, and the effective use of POCT is a key contributor to this.

Another key driver stimulating the growth in POCT uptake in emerging markets, such as Asia, is an increasing per capita GDP with subsequent escalation in incidence of western diseases, for instance diabetes. This has been evidenced by growing demand in these regions for our Quo-Test and Quo-Lab analysers for easy and reliable measurement of glycated haemoglobin (HbA1c), which is used to detect and manage diabetes.

The on-going world economic downturn should further influence the greater adoption of POCT within countries not currently widely using such technology. This is because POCT offers excellent patient care and monitoring at a significantly lower cost to traditional laboratory and hospital based care. In times of austerity POCT offers an avenue for reducing the financial burden on health services.

That said, POCT is not without limitations. No GP would use POCT exclusively where a second opinion from hospital consultants and experienced biomedical scientists are critical, for example in oncology or HIV. However, POCT can play a key role in identifying early onset of conditions, such as diabetes and anaemia, which can then be investigated by further testing at a central laboratory.

DNA s tackles

'This is a dramatic demonstration that medi the future – it is a technology of the here a

Researchers have used genome sequencing to control an MRSA outbreak in a British hospital, and scientists from the University of Cambridge, the Wellcome Trust Sanger Institute and Cambridge University Hospitals believe the breakthrough could impact significantly on the way hospitals tackle the commonly termed 'superbug' threat in the future.

The team used advanced DNA sequencing technologies to confirm the presence of an on-going outbreak of methicillin-resistant Staphylococcus aureus (MRSA) in real time in a Special Care Baby Unit. By cracking the bacterium's genetic code, they were able to end the outbreak at the Rosie Hospital in Cambridge – and devise a new weapon in the continuing MRSA problem.

Identifying the carrier

Hospital staff became concerned after MRSA was detected in 12 babies during routine screening, but current tests could not tell if this represented a single on-going outbreak within the unit or whether these were unrelated cases.

The research team stepped in and, by comparing MRSA isolates from those 12 patients using DNA sequencing technology, they showed the pathogens were all closely related and part of the same outbreak.

The ward was deep cleaned, but when another MRSA positive infant was detected after an MRSA-free gap of two months, the team used advanced DNA sequencing to show in real time that this strain was

Digita

The scandal shocked the German healthcare sector in 2012 – and investigations continue. Physicians had apparently tampered with patient data and manipulated candidate shortlists for organ transplants. Criminal manipulation of laboratory results appears to have played a key role in the cases – it was alleged that results were wilfully re-attributed, pushing less needy patients up the list for a new organ.

For Professor Joachim Thiery, President of the DGKL (German Society for Clinical Chemistry) and head of the Institute of Laboratory Medicine, Clinical Chemistry and Molecular Diagnostics (ILM) at the Leipzig University Hospital, the route to be taken is obvious: At the 2012 annual DGKL congress he called for high-tech protection of digital lab results.

Background

There used to be strict separation between electronic medical records

equencing s MRSA outbreak

ical genomics is no longer a technology of nd now' Report: Mark Nicholls

also part of the outbreak, despite the lack of apparent links between this case and previous patients. The finding presented the possibility that a member of staff was carrying the MRSA strain.

Tests on 154 members of staff showed that one person was also carrying MRSA, which may have been the source for at least some babies in the unit. The healthcare worker was treated to eradicate the MRSA presence and thus remove the risk of further spread.

Essential distinguishing between the strains

This is believed to be the first time rapid genetic testing has been used to track and stop an outbreak, but the technique could soon become a regular way of stopping MRSA.

Professor Sharon Peacock from the University of Cambridge, said that current bacterial typing techniques lacked sufficient discrimination to distinguish between strains of MRSA that are most often isolated in hospitals. 'In the event that two patients are either carrying or infected with a strain such as EMRSA-15 – the most common clone in the UK – it isn't possible to distinguish with any confidence whether there has been a transmission event from one patient to another, or whether both patients acquired their MRSA through independent acquisition events. So, a driver for evaluating whole genome sequencing of MRSA was to see whether this provided enough discrimination to tell apart strains of the same lineage.'

This was achieved by undertaking whole genome sequencing using a rapid high throughput bench-top sequencer, but the investigations took a decisive turn and became a real-time prospective study as the outbreak unfolded at the Rosie Hospital.

'What we also wanted to achieve was to start the process of translating the technology from being a research tool where timing does not matter, to a real-time clinical tool – so we were using machines that could be used in the future in clinical practice,' she explained, adding that the next step is to devise simple-to-use automated interpretation tools that will enable hospitals to analyse complicated sequence data.

'Our study indicates the considerable potential of sequencing for the rapid identification of MRSA outbreaks. If we have a robust system of this type available for routine use in the future,' Prof. Peacock pointed out, 'we could use it to investigate putative outbreaks at their outset and, if confirmed, put in place infection control measures that bring them to a rapid close.'

The team is also building a database of MRSA genomes with 2,000 already collected from across the UK, which will provide an essential genetic framework with which to compare and interpret MRSA genomes in the future.

Cleaning remains essential

The researchers are currently studying all MRSA carriers and infected patients over the next year from a number of East of England hospitals and the community to understand transmission events with the aim of improving infection control management.

'In the future, sequencing will be used for infection control surveillance and outbreak investigation because it adds considerable value to the existing methods of infection control, and could act as an early warning system,' Prof. Peacock predicted. She also stressed that conventional methods of combating MRSA, such as hand-washing, hospital cleaning and care of intravenous lines, remain essential for the on-going prevention of MRSA bloodstream infections, but the introduction of technology to crack the MRSA genetic code will add an extra weapon in the fight against the pathogen.

Sir Mark Walport, Director of the Wellcome Trust, said: 'This is a dramatic demonstration that medical genomics is no longer a technology of the future – it is a technology of the here and now. By collaborating with NHS doctors, geneticists have shown that sequencing can have extremely important applications in healthcare today, halting an outbreak of a potentially deadly disease.'

Professor Sharon Peacock is Professor of Clinical Microbiology in the Department of Medicine at the University of Cambridge and an honorary consultant with Cambridge University Hospitals NHS Trust and for the Health Protection Agency. Her research focuses on the role of sequencing technologies in diagnostic microbiology and public health.

The Genspeed MRSA Test System by Greiner Bio-One is a comparatively inexpensive solution that is already available on the market.

MRSA outbreaks cost a fortune

A new test gives reliable results in just 75 minutes, speeding up combat actions

Since Methicillin-resistant *Staphylococcus aureus* (MRSA) has developed resistance to antibiotic treatments, infections have become a dreaded occurrence in hospitals worldwide. According to one report*, an MRSA infection results in additional costs of €1,600 euros a day and hospital stays can be extended by seven days, pushing total costs to between €5,000-10,000.

Developed by Greiner Bio-One with Amplex Diagnostics (Germany), the *Genspeed* MRSA Test is a DNA-based in-vitro diagnostic tool for qualitative detection of MRSA from human nasal and throat swabs. The system's main advantage is speed combined with reliable results, the manufacturer reports. 'The result is available only 75 minutes after sampling. In addition to low-throughput applications, Genspeed MRSA can also be used in facilities that analyse large numbers of tests. In this case, Genspeed MRSA serves as a fast and reliable tool for night and weekend shifts, when only part of the staff is present.'

The system consists of the Test Kit, a PCR cycler, the Genspeed Reader and the software, which is pre-installed on a laptop.

'In addition to speed, the test system also scores points for its high sensitivity, allowing the complete detection of the main mechanisms of resistance as well as the new resistance gene *mec*C (previously called $mecA_{LGA251}$),' the maker reports. 'Analyses of individual samples are possible at any time. Three controls (for DNA amplification, hybridisation, as well as a negative control) on the Test Chip offer greater reliability.

'Due to its compactness and relatively ease of use, there are no costs for maintenance and support. Particular emphasis was placed on simple and functional design of the software. The individual analytical steps are well structured and intuitive. Pre-filled and ready-to-use supply of the reagents reduces the number of process steps to a minimum,' and, the firm adds: 'The system can be quickly adapted to different diagnostic applications without much effort.'

* HTA Report 100, DIMDI, medical efficacy and cost-effectiveness of preventive and control measures against MRSA infections in hospital

Electronic signatures are a necessity against fraud

al Lab results

(EMRs) or hospital information systems (HIS) used in wards and information management practiced in labs, Professor Thiery pointed out. Significant advances have evolved regarding the technology, and '…we are now close to achieving widespread penetration with EMRs in the hospital sector,' he said, adding, 'This progress comes with major challenges to – and potentials for – laboratory medicine.'

Among those challenges is integrating data from physicians and nurses as well as lab results at a very early stage, and in making that data pool readily available to anybody involved in a case.

If patient data is available at the time when lab tests are ordered, lab physicians can base their analysis on the patient's history and therefore provide a more precise and targeted evaluation. 'Lab information systems (LIS) and HIS solutions now communicate with one another very well' he said.

DGKL President Joachim Thiery insisting that electronic signatures are necessary to combat any tampering with lab results (Photograph: MR)

Protecting results from manipulation

'Now, what we learn from those fraudulent cases is that we can no longer simply and conveniently proceed by feeding values derived from a lab analysis directly into some HIS or EMR. The identity and authenticity of this type of data are at risk of manipulation.' Thus, he adds, lab results – whether abnormal or normal – need to be turned into fixed electronic objects, or documents '… and they require a format, such as PDF, and an electronic signature of top safety level to be attached to them'.

The lab information typically includes reference values and recommendations in an accompanying letter. At the University Hospital Leipzig, lab results are turned into documents and automatically sent into the respective patient's EMR.

Use electronic signatures

When mere values, or figures, are fed into systems, they are beyond the control of the lab physician. The professor's final message: 'We learned the hard way that this definitely must stop. Electronic signatures are readily available, and they've been shown to work properly in everyday routine. Let's start using them – now.'

The Berlin Diagnostica Forum

Scepticism increases among German in vitro diagnostics firms

The 2013 turnover expected by German in vitro diagnostics producers are significantly lower compared to last year, according to a survey of members carried out by the German Diagnostics Industry Association (VDGH) presented in January at the Diagnostica Forum in Berlin. Whilst more than half of those surveyed expected improvements in 2012 only about a third forecast this for 2013.

Report: Bettina Döbereiner

picutres (4): ©Schacht

Top: Karl-Heinz Büscher (right) and Manfred Partsch. Below, from left: Ulrich Orlowski, Joachim Thiery, Martin Walger

Carried out in December 2012, the survey showed only 35.4% of members believe their economic situation will improve. At first glance this may look optimistic, says Dr Martin Walger, Managing Director of the German Diagnostics Industry Association. It is in fact thought provoking, considering that 56% of members expected a positive development for their company when surveyed the previous year. The number of those expecting stagnation accordingly rose to more than half. However, only 10% of those surveyed are predicting deterioration of their situation, and this figure is only marginally higher than the prognosis for 2012.

There are unlikely to be any effects on investment planning and expenditure on research and development, based on the information provided by the 48 in-vitro diagnostics companies surveyed by the association in December 2012 – to the contrary, the previous year's values are even being exceeded – only the dynamics regarding the size of the workforce are expected to slow down. With around 10%, slightly more companies declared their intention to reduce their workforce than did so the previous year. Vice versa, at around 50%, slightly fewer companies announced that they would increase their workforce.

Asked about the greatest obstacles against development, almost half of all companies cited high cost pressure in the German market. In second place was consolidation and concentration on the customer side, followed by the reimbursement levels set out in the German statutory health insurers' fee schedules, which companies consider to be too low.

Member companies also complained about cuts to reimbursements for medical laboratory services and about the drawn-out procedures for innovations before they receive approval and acceptance in terms of the range of services covered by the Germany statutory health insurers.

Test approvals are too slow

This last point in particular was criticised by Dr Karl-Heinz Büscher, Member of the VDGH Board and Head of the Central Lab Marketing Automation Department at Siemens Healthcare Diagnostics, who said, 'The acceptance of new laboratory tests into statutory medical care in Germany takes far too long and has almost come to a standstill in the last few years.' Since 2009, he added, out of thirteen suggested laboratory innovations, only one test has been approved for acceptance into the fee schedules that determine the level of reimbursement for medical costs by the statutory health insurers in Germany – nine other tests are still under discussion.

This situation, he said, is unacceptable in the long run, and he called for the introduction of faster assessment procedures for innovations in the future.

The German diagnostics industry has positive expectations regarding the planned new legislation on the early detection of colon and cervical cancer, which has already been negotiated in the Federal Parliament. This new law envisages an official invitation to screening examinations sent by health insurers to all their members. However, the so-called Law on the Early Diagnosis and Register of Cancer (KFRG) will not come into force for another three years to allow for an implementation period, as Dr Ulrich Orlowski of the Federal Ministry of Health explained at the forum. Therefore, diagnostics industry representatives do not expect a related boom in business much before 2016. More than 50% of companies surveyed also considered personalised medicine to be a very promising area, although currently more than half of those surveyed are convinced that personalised medicine does not have any relevance for their companies.

Having discussed the outlook for 2013, the forum considered the 2012 business year. Based on the first three quarters sales statistics, the German market showed negative growth in in-vitro diagnostics of 1.5%. 'We have a twofold picture here,' explained Dr Martin Walger. Laboratory diagnostics had an upward trend of just under 3%, but there was an almost 8% decrease for the fast tests sector. He believes the reason for this decrease to be the large drop in tests for self-monitoring of blood glucose. 'The health insurers have stopped reimbursing self-tests for blood glucose monitoring for Type 2 diabetics who are not insulin dependent,' he said, and the budget for the test strips generally has been tightened a lot by the health insurers and the Association of Statutory Health Insurers.

Market crash effects

With this negative balance, Germany is in line with the European trend, as a look at growth in Europe is also sobering, Dr Walger said. Only three of the larger European markets (Belgium, Switzerland and Great Britain) still show positive growth based on preliminary sales statistics – in 2011, however, all eight larger European markets still showed positive growth. 'The crash in the Southern European markets, which already loomed in 2011, is dramatic,' he said. Greece is in first place with a minus of 10.7%, followed by Portugal with a minus of 9%. Italy, which in 2011 still had a turnover of €1.7 billion, putting it in third place behind Germany and France within the European market, has a negative growth of 3.6% based on preliminary figures. The EU-wide growth rate of almost 1% seen in 2011 is unlikely to have been achieved in 2012, Dr Walger pointed out.

Professor Joachim Thiery MD, President of the German Joint Association for Clinical Chemistry and LaboratoryMedicine and Director of the Institute for Laboratory Medicine, Clinical Chemistry and Molecular Diagnostics (ILM) at the Leipzig University Hospital, looked at the future of diagnostic procedures. The automation and networking of analytical processes, in the shape of highly standardised methods, has almost been achieved in Germany. Around 80% of diagnostics is now being performed by so-called high-throughput platforms, which have continued to revolutionise laboratory diagnostics worldwide since the 1950s. But, the professor said, 'We are going through a saturation phase regarding automation.' Instead, new approaches, such as metabolism and protein analysis will become much more important in the future.

Re-agent-free instruments, such as mass spectrometry, are increasingly used in the context of multi-parameter analysis, Prof. Thiery said, and sees this sector's future in the development of systems medicine laboratory diagnostics that takes into account the increasing density of information and which further develops laboratory-focused bioinformatics. Even if, he added, medical demand is not quite keeping up with existing technological developments, such as seen in metabolic and protein analysis, sooner or later it will become an important growth area for diagnostics companies. ■

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: Olaf Skrober
Managing Editor: Brigitte Dinkloh
Senior Writers: John Brosky, Michael Reiter
Executive Director: Daniela Zimmermann

Correspondents
Austria: Michael Kraßnitzer, Christian Pruszinsky.
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UK editorial address
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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
Germany, Austria, Switzerland:
Ralf Mateblowski, Hintergasse 1, 55234 Hangen-Weisheim, Germany
Phone: +49 6735 912 993
E-Mail: rm@european-hospital.com
France, Italy, Spain: Eric Jund, 2264 Chemin de Sainte Colombe, 06140 Vence, France Phone: +33 493 58 77 43
E-Mail: ej@european-hospital.com
GB, Scandinavia, BeNeLux: Simon Kramer, Willem Alexander Plantsoen 25, 2991 NA Barendrecht, The Netherlands
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, MCI, Room 103-1011, Brown Stone, 1330, Baekseok-dong, Ilsan-Ku, Goyang-si, Gyunggi-do, Korea 410-360
Phone: +82 2 730 1234
E-Mail: chp@european-hospital.com
USA & Canada:
Hanna Politis, Media International, 8508 Plum Creek Drive, Gaitherburg, MD 20882, USA
Tel: +1 301 869 66 10
E-Mail: hp@european-hospital.com