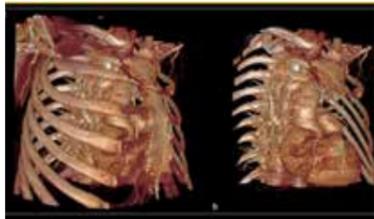


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Promising substitutes for human hearts



Marcello Conviti, CEO of Carmat, the company that developed and now manufactures the total artificial heart

Fully implantable mechanical hearts bring hope to 121,000 heart failure patients who will never receive a heart transplant

Report: John Brosky

It is a world-first. In December 2013, a fully artificial heart was implanted in a 75-year-old French man, who is continues to be doing 'very, very well,' according to surgeons.

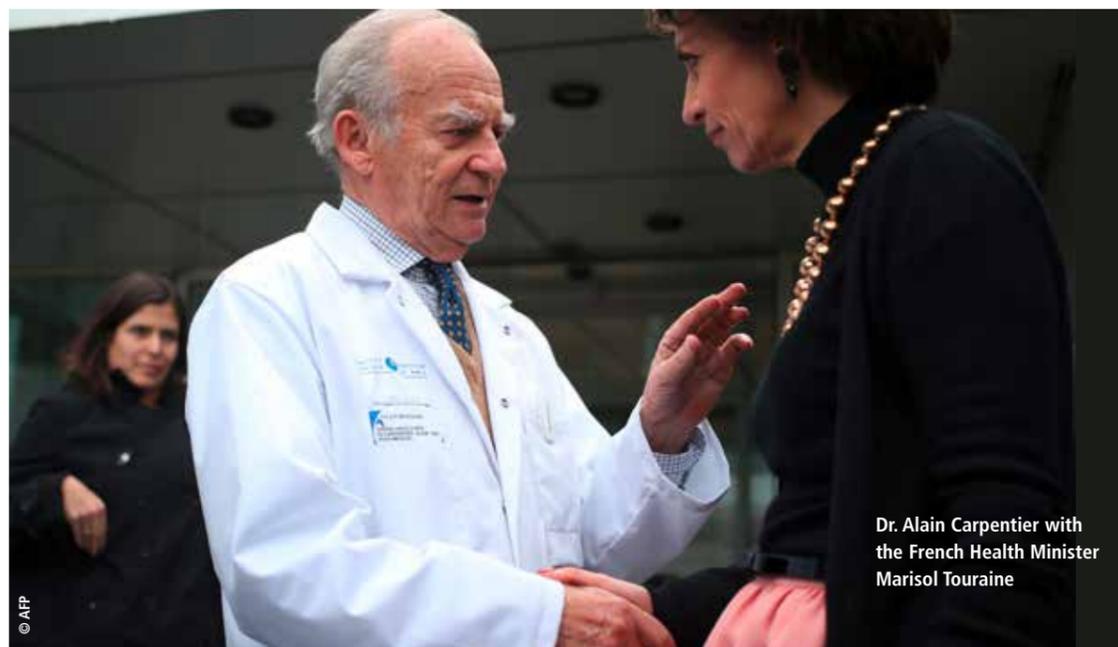
This year three more French patients with end-stage heart failure are expected to receive mechanical heart replacements as part of this first-in-man trial for safety and feasibility. If all goes well, a second group of 20 patients from Germany, Belgium, Poland, Slovenia, and Saudi Arabia will receive hearts in an expanded clinical trial that could lead to CE approval in 2015.

It is estimated that each year 125,000 end-stage patients in the United States and Europe are awaiting a heart transplant, where only 4,000 transplants will be performed.

We have heard about heart failure patients receiving heart-assist devices that serve as a bridge-to-transplantation, keeping them in life while waiting for a human heart to become available. Yet this was the first patient to have his heart completely replaced by a mechanical device that is a destination therapy. If all goes well, that is first French patient will leave the hospital wearing only a lithium-ion battery in a shoulder harness.

'This is completely new, a fully implantable artificial heart and not a ventricle assist device,' explained Marcello Conviti, CEO of Carmat, the company that developed and manufactures the device.

'Ventricle assist devices are used as a bridge-to-transplant, and they work



Dr. Alain Carpentier with the French Health Minister Marisol Touraine

well. However, these devices need an external air compressor that drives the membrane to push the blood. There are also tubes exiting the patient. With the Carmat heart only a wire exits the body to supply electricity and give information about device performance. All the other parts are inside the patient,' he explained in an interview with European Hospital.

A heart from outer space

Developed by a team of engineers from EADS, the Carmat heart weighs 900 grams, nearly three times more than an average healthy human heart. 'What is significant is the level of innovation in our approach.

All the parts that are in contact with the blood are made of biocompatible materials, the same as have been used in artificial heart valves. This should reduce dramatically the level of anti-

thrombotic drugs required because the risk of thrombosis is extremely low, compared to ventricle assist devices.

'Our device is also auto-regulating with embedded electronics, so it's going to deliver output in line with a patient's needs, from two to nine litres per minute. There are sensors to optimise the machine's performance for cardiac output according to the patient position and activities.

'The other devices in the market have pumps that deliver a fixed level of output. This makes a very big difference because it affects not only the quality of life of the patient but the level of precision will maintain a level of health for the patient. 'The Carmat heart is also silent so the patient does not have noise around him,' Marcello Conviti added. 'With heart-assist devices, the patient has a big compressor

pumping air in and out with mechanical valves that you can hear clicking.'

The service life of the device is estimated to be five years. 'We have done bench testing that shows device performance goes well beyond five years,' he explained. 'But time will tell. In bench testing it was very difficult to simulate beyond 10 years.'

Exceeding all expectations: valves run beyond 10 years

Carpentier heart valves, invented by Alain Carpentier MD, a founder of Carmat and the driving force behind the artificial heart, were expected to fail after two years, 'because all the previous generations of artificial heart valves had failed due to calcification; but, after five years, the Carpentier valve was still going, performing very well,' Marcello Conviti pointed out. 'Then these valves performed beyond

10 years. Currently there is a large series of Carpentier biological valves, and they are still performing after 30 years. 'The cost for the heart device cost and implantation procedure is between €140,000 to €180,000, roughly equivalent to reimbursement levels for a heart transplant, a key to the design requirements set down by Dr Carpentier. 'What good is there in developing a device if it is too costly to be used for everybody,' he told the French Sunday newspaper, Le Journal du Dimanche.

Carmat's CEO said he is prudent in his estimations of the value of the business potential for providing hearts off an assembly line. 'We do not provide any guidance at this point, except to say that we hope to start commercial activities in 2015, to be in the USA in 2018, and to reach full capacity with revenues of \$1.5 billion in 2020 - something like that. We are talking about a company that has only one product for the moment, and which has not yet sold anything, yet.'



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In which department do you work?

Are you head of the department?

Are you in charge of your department's budget?

Yes No

Yes No

How much influence do you have on purchasing decisions?

I can only present an opinion

I tell the purchasing department what we need

I can purchase from manufacturers directly

Yes No

Yes No

Yes No

Do you consider that your equipment is

out-dated

relatively modern

state-of-the-art

Yes No

Yes No

Yes No

Do you use/buy second-hand equipment?

If so, what do you use of this kind?

Yes No

Is your department linked to an internal computer network?

Is your department linked to an external computer network?

Is your department involved with telemedicine in the community?

Do you consider your department is under-staffed?

Are you given ample opportunities to up-date knowledge?

Do you attend congresses or similar meetings for your speciality?

Yes No

Yes No

Yes No

Yes No

Yes No

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EH 1/14

National Health Service management under s

UK retail 'star' to examine the
healthcare sector

UK update: Brenda Marsh

London. 14 February – Sweet Valentine's Day, when the government's Health Secretary Jeremy Hunt described Sir Stuart Rose, former Executive Chairman (2004-2011) of the British fashion, food and furnishings chain stores Marks & Spencer (M&S) as '...one of the country's most inspirational leaders'.

The accolade came with the announcement that Sir Stuart is to advise the Health Secretary on how to improve organisational culture and attract and retain exceptional managers as well as to make better use of those who already excel within the NHS by ensuring they spread their expertise to less healthy organisations within the service, or to establish national networks of NHS hospitals and services.

Back in 1972, Sir Stuart began his retail career at M&S as a management trainee and rose through the ranks until his departure in 1989 to join the Burton Group, primarily known for its men's tailoring. From 1997 there followed roles as CEOs of various top retail companies until, in May 2004, he was named Chief Executive of Marks & Spencer



Sir David Dalton, CEO of Salford Royal Hospital, will lead a national programme to examine how high performing NHS organisations can support less successfully managed healthcare organisations

plc and then, in 2008, its Chairman. In that year he was also knighted for his services to the retail industry and corporate social responsibility.

In recent years, M&S had struggled to hold its position, with share value dropping by 30%. Sir Stuart is credited for his management towards to that end and he is now expected to find out how NHS managers can improve and become more visible in hospitals to ensure they are 'in touch with frontline patients, services and staff'.

Apart from a voiced scepticism

about the transition from retail to public service, there is also concern regarding a potential 'conflict of interest', since Sir Stuart is on the advisory board of the international private equity group Bridgenorth, a major shareholder of the private health provider Care UK; additionally, the firm is reported to be lined up to take over the running of NHS Trusts. (As one observer put it, 'the stench of hypocrisy and opportunism is suffocating'.)

However, Sir Stuart's appointment came when ministers were providing an update on the 'significant progress' made by 14 hospital trusts in which, previously, 'special measures' had to be taken. This resulted in an overhaul in which 650 additional nurses or nurse assistants and 130 more doctors were recruited and 49 senior management changes were made. According to the report, the first 11 trusts targeted by those special measures last July are 'turning around' and, Jeremy Hunt pointed out, 'critical problems at those hospitals have been resolved'.

'The difference between good and bad care can often lie in leadership,' the Health Minister said, in reference to the appointment of the former M&S chief – who, it is reported, will not receive any remuneration for his work, but is officially to

Diabetes: The value of fermentation

Yoghurt consumption reduces type 2 risk

Raise your intake of low-fat fermented dairy products, including all yoghurt varieties and some low-fat cheeses, and you could lower your risk of new-onset type 2 diabetes by 28%, according to new research published in *Diabetologia* (the journal of the European Association for the Study of Diabetes)

The authors, scientists at the University of Cambridge, not only found that higher consumption of yoghurt, compared with no consumption, can do that, but also that higher consumption also reduced the relative risk of diabetes by 24% overall.

Lead scientist Dr Nita Forouhi, from the Medical Research Council (MRC) Epidemiology Unit at the University of Cambridge, said: 'This research highlights that specific foods may have an important role in the prevention of type 2 diabetes and are relevant for public health messages'.

Dairy products are an important source of high quality protein, vitamins and minerals. However, they are also a source of saturated fat, which dietary guidelines currently advise people not to consume in high quantities, instead recommending they replace these with lower fat options.

Because previous studies on links between dairy product consumption (high or low fat) and diabetes had inconclusive findings, the authors decided to make a far more detailed assessment of dairy product consumption.

Based on the large EPIC-Norfolk study, which includes more than 25,000 men and women living in Norfolk, UK, the Cambridge study compared a detailed daily record of all food and drink consumed over a week at the time of study entry among 753 people who developed new-onset type 2 diabetes over 11 years of follow-up with 3,502 randomly selected study participants. Thus the researchers could examine diabetes risk in relation to total dairy products consumption, as well as types of individual dairy products.

The consumption of total dairy, total high-fat dairy or total low-fat dairy were not associated with new-onset diabetes once important factors like healthier lifestyles, education, obesity levels, other eating habits and total calorie intake were taken into account.

Total milk and cheese intakes were also not associated with diabetes risk. In contrast, the researchers found, those with the highest consumption of low-fat fermented dairy products (such as yoghurt, fromage frais and low-fat cottage cheese) were 24% less likely to develop type 2 diabetes over the 11 years, compared with non-consumers.

When examined separately from the other low-fat fermented dairy products, yoghurt, which makes up more than 85% of these products, was associated with a 28% reduced risk of developing diabetes. This risk reduction was observed among individuals who consumed an average of four and a half standard 125g

pots of yoghurt per week. The same applies to other low-fat fermented dairy products, such as low-fat non-ripened cheeses e.g. fromage frais and low-fat cottage cheese. A further finding was that consuming yoghurt instead of a portion of other snacks, e.g. potato crisps, also reduced the risk of developing type 2 diabetes.

The authors emphasise that, while this type of study cannot prove that eating dairy products causes the reduced diabetes risk, dairy products do contain beneficial constituents such as vitamin D, calcium and magnesium. In addition, fermented dairy products may exert beneficial effects against diabetes through probiotic bacteria and a special form of vitamin K (part of the menaquinone family) associated with fermentation.

Although the limitations of dietary research that involves asking people what they eat and not accounting for dietary changes, the authors point out that their study was large, with long follow-up, and had detailed assessment of people's diets that was collected in real-time as people consumed the foods, rather than relying on past memory. The researchers therefore conclude that their study helps to provide robust evidence that consumption of low-fat fermented dairy products, largely driven by yoghurt intake, is associated with a decreased risk of developing future type 2 diabetes.

Dr Forouhi stated that, whilst there's much evidence against eating sugar reinforced foods and drinks, 'it is very reassuring to have messages about other foods like yoghurt and low-fat fermented dairy products, that could be good for our health'.

vice scrutiny

report (briefly) on his findings at the end of 2014.

So, what will Sir Stuart do – and not do?

He will not review ownership structures, out-sourcing or the use of the private sector in providing NHS care.

Since NHS problems and failings have been blamed on poor management, during several hospital visits this lean, silvery-haired, immaculate management guru will act as a mentor to senior managers and explore the leadership challenges the NHS faces.

The NHS fast-track leadership programme

A 10-month programme organised by the NHS Leadership Academy is to include executive education by Harvard Kennedy School, an industry placement, and six months delivery of a transformational change programme in a top NHS Trust under a chief executive mentor. More than 1,300 non-NHS employees have applied for the 50 places on this fast-track leadership programme, which will begin in June 2014.

Critics have been quick to query the ability of anyone whose basic knowledge lies in retail. As Columnist Yvonne Roberts queried in *The Observer*: 'What could Rose possibly import from M&S to Britain's best-loved, albeit permanently re-organised, semi-privatised, constantly criticised and battered institution?'

Well, as Sir Stuart is aware: 'Clearly the NHS is a very different institution from M&S, but leadership, motivating staff and creating a culture where people are empowered to do things differently are crucial to the success of any organisation and I'm looking forward to helping in any way I can.'

Among the leading NHS hospital CEOs is Sir David Dalton, at Salford Royal Hospital, and he has also been appointed to look at how best practice can be shared and how the successful managers can get involved with the poorest hospital performers, as has been shown in the case of appointing those proved to be 'super heads' to focus on poorly performing schools and turn them towards success.

Sir Stuart and Sir David could make a 'very powerful' combination, declared Rob Webster, CEO of the NHS Confederation, which represents hospital trusts. Many people in this country believe that appointing top entrepreneurs from the business world (e.g. popularly Sir Richard Branson) to run the country could prove far more successful than having it run by career politicians.

After all, it is not unusual for the government to turn to such 'immortals' for specific guidance. We have yet to see whether the management of very sick people, knowledgeable professional medics and highly complex institutions where emergency situations can occur extremely rapidly, can indeed equate to the organisation of retail outlets, no matter how large.

Inevitably, Sir Stuart's report will be much discussed at the end of this year.



The major German statutory health insurer AOK and its scientific institute (Wido) presented the Hospital Report at a Berlin press conference. Panellists, from left to right: Dr Kai Behrens, AOK press officer; Professor Max Geraedts, Director of the Institute for Healthcare Systems Research at Witten/Herdecke University; Jürgen Klauber, Managing Director of Wido, and Uwe Deh, Managing Director of AOK-Bundesverband

Statistics: Where is there safety in numbers?

Doctors slam claims of 18,800 preventable hospital deaths in just one EU country, Bettina Döbereiner reports

The *Hospital Report on Patient Safety*, recently published by major German statutory health insurer AOK-Bundesverband, has provoked indignation in physicians and hospitals alike. Above all, they question the report's estimate from 2011 alleging that 18,800 patients died in German hospitals following preventable adverse events.

Since 1993 the insurance group's scientific institute (Wido) has published an annual Hospital Report to focus on a specific topic. In the current issue, Wido took an in-depth look at patient safety, with experts from research and clinical practice discussing the problem from different angles. The 500-page report was barely off the press when the reaction set in.

Max Geraedts found himself in the line of fire: it was he, as professor for healthcare systems research at Witten/Herdecke University, who had made the calculations, based on the data of a systematic review of the international research literature from 2006, updated in 2007, which indicated that five to ten percent of all cases in a hospital are accompanied by adverse events, two to

four percent by preventable adverse events and one percent of all medical interventions are burdened with a medical error.

The data further allow the conclusion that one per million patients treated in a hospital suffers a fatal error. In its 2007 report the German government's Expert Panel on Health calculated that, based on these data, 17,000 patients died due to preventable adverse events. Applying these data to 2011 figures, 18.8 million cases, Professor Geraedts arrived at some 18,800 deaths caused by errors in the country's hospitals – an alarming figure, indeed. The literature review of the 2006/2007 was headed by Professor Matthias Schrappe, then chairman of the patient safety group Aktionsbündnis zur Patientensicherheit, who states that the updated literature review encompassed 241 studies from 1995 to 2007. While the majority of these studies were published in the USA, with only five percent conducted in Germany, Prof. Schrappe emphasises that it was legitimate to apply the figures to this country because results from German studies were identical with those from interna-



Professor Max Geraedts explains his estimate of the number of preventable deaths during a press conference held by insurer AOK

tional research. Supporting this, Professor Geraedts underlined at the report's presentation press conference: 'Smaller, more recent studies on patient safety do not indicate that the figures have changed significantly since 2007. Quite the contrary: new results from different event areas make the older estimates appear rather conservative.'

The physicians' and the hospitals' association (German Medical Association / Bundesärztekammer and German Hospital Federation / Deutsche Krankenhausgesellschaft – DKG) begged to differ: they claim the results of the literature review neither reflect the German healthcare landscape nor the current, i.e. 2011, situation.

In a statement, Professor Frank Ulrich Montgomery, President of the German Medical Association, criticised the calculation in that all healthcare systems are lumped together with no regard for individual differences: 'The AOK Hospital Report ignores the fact that the majority of healthcare systems internationally is weakened by waiting lists, limited access to in-patient care and rationing of medical services and pharmaceuticals.'

Georg Baum, Managing Director of DKG, objected to old data being applied to 2011. Particularly during the last decade, he emphasised, the significance of clinical risk management has increased immensely and a host of risk-reducing measures, such as quality circles, operating theatre checklists and morbidity and mortality conferences, as well as the Critical Incident Reporting System were introduced. Therefore the older data used for the report, he believes, are invalid.

Both the physicians' and hospitals' association lambasted the health insurer and its research institute Wido as publishers of the Hospital Report for creating the impression that they have reliable data – which, they claim, do not exist. Indeed Germany maintains neither a medical error registry nor any other data pool on medical errors. Alfred Dänzer, President of DKG, went beyond criticism by demanding AOK apologise for its misleading assertion that 18,800 patients per year die from preventable adverse events.

It is unfortunate that the fight about the figures – which only offer supporting evidence on patient safety – dominates discussion. The important and complex issue of patient safety is thus reduced to numbers, veiling the fact that there is an urgent need for action. Beyond the commotion, all actors agree that a lot can and needs to be done to improve patient safety in the country's hospitals and that every single death caused by a preventable adverse event is a death too many.

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Company profile

Among the NASDAQ 100 'Henry Schein Cares'

Among the big players in retailing specialist medical products in the German healthcare market, Henry Schein Medical GmbH is one of around 40 subsidiaries of Henry Schein Inc. based in Melville, New York. The firm's medical, dental and veterinary sectors are represented in 14 European countries.

This full service provider offers customers a comprehensive range of consumables, furnishings and medical devices as well as technical and various other services, which include a comprehensive training programme at the Henry Schein Academy. European Hospital talked to Juergen Hahn President of the European Medical Group, about the comprehensive company offering and the growth markets in Europe.

'We see ourselves as a 360° full service provider aiming to support all non-clinical processes in general practices and hospitals in the best possible way,' he said, describing the core of the business. 'With more than 200,000 products for the different medical sectors offered worldwide, we offer an all-round service ranging from disposables to devices and IT-solutions, financing and training packages.

'Our philosophy is based on our key competencies, which also includes strong logistics. This allows us to deliver to hospitals and surgeries overnight. Besides, our range includes almost everything that doctors in general practice and hospitals need, including our own brands, which usefully complement and enhance products offered by original manufacturers.



'For doctors, the principal task is a focus on the clinical processes, and we assist them with all the non-clinical processes. Our cooperation over the last few decades has taught us *what* is required *when* and *how*, and we can optimally support patient care.'

What are the advantages for customers in the firm having own-brand products?

'We see a need to more strongly anchor Henry Schein in the market as a brand. Our own-brand products offer a good opportunity to achieve this. They complement the original manufacturers' products well. This concerns mainly disposables, but also some medical devices. The Henry Schein own-brand offers the highest quality with outstanding cost effectiveness.

'As one of the largest suppliers in this field, worldwide, we can produce in large quantities. We have very strong partners in all areas, whose products we complement with our own-brand portfolio. Strong partnerships, which we have established and nurtured with many companies for decades, are an important pillar of our business. 'We also have a separate, annual catalogue for care products. Our customers in the care sector are large group providers of care services whom we've supplied with our products and services for many years. This will continue to be a growth market.'

Could the firm help hospitals and surgeries that have insufficient capital resources for investments?
'In cooperation with external finan-

cial institutions, Henry Schein Financial Services offers financial solutions for hospitals, medical centres, surgeries and rehabilitation facilities. This includes standard financing solutions for higher-end devices and practice equipment and furnishings, usually in the price range up to €100,000. On the other hand, we also see the need for alternative financing models such as "pay by use", in which the customer does not pay directly for the product but for its use, as seen in various medical sectors.'

Where in Europe is Henry Schein represented?

'In the medical sector, our seven key countries are: Germany, Austria, Switzerland, Great Britain, Spain, Portugal and The Netherlands, with our own subsidiaries. We are also present in other European regions via our export group. Overall, we have seen a large investment backlog regarding the refitting of hospitals and surgeries. We'd like to make a contribution here and become a strong partner in those countries where we do not have our own representation.'

In your portfolio, what is the continuing education element?

'The Henry Schein Academy is our own brand, which promotes internal training and further education of employees across the divisions and, on the other hand, also acts as a strong training partner for its customers. A large range of training is offered that goes far beyond actual product training and helps



Jürgen Hahn is President of European Medical Group and Managing Director Germany of Henry Schein Medical Europe. With a degree in Business Management/Marketing, he has worked with manufacturers of medical devices, including Hitachi Medical Systems, Fresenius Medical Care in Japan and Germany, Novartis/CIBA Vision and the Zeiss Group as well as the F. W. Duerker iron foundry. He is a frequent guest speaker at business schools and healthcare events across Europe and Asia.

our customers strengthen their own position. This includes courses in infection prevention and control for medical staff, practice management and marketing, communication training, telephone training and much more.

'We are very open to our customers' needs and provide individually adapted training with internal and external partners. The company also provides individual assistance with financing these services.'

Henry Schein background:

Slotted among the 100 NASDAQ companies, in 2013 more than 16,000 employees in the company's subsidiaries, in 25 countries in all five continents, generated an annual turnover of \$ 9.6 billion. Under the motto 'Henry Schein Cares', the firm reports that it demonstrates exemplary social responsibility and provides worldwide support for projects in medicine, education and culture.

Stop that talk about price

Value contributions matter most as hospital supply chains undergo a major transformation, Michael Reiter reports

With the rising demand for medical services and expenses, cost control is paramount in the USA's healthcare sector – as in most countries. This trend produces significant challenges; the current reform aims at cutting expenses by 20 percent over the next 5-7 years – a fifth of the overall revenue of hospitals.

Obviously, care providers expect help from their supply chain managers to close that gap. However, speaking at the Procurement Congress, held in Berlin late last year, Joseph M Dudas outlined value contributions that go way beyond price and quantity issues.

With a staff of around 60,000, the Mayo Clinic is active in three regions – Arizona, Florida and Minnesota. 'The supply chain function is part of the entire value chain in our organisation, which particularly includes the physicians,' explained Joseph Dudas, who heads a staff of around 500 people in Mayo's supply chain unit, which structures activities from sourcing of contracts, and buying to delivering a product for use in a care setting.

At most US hospitals, costs generated by supplies make up roughly 20 percent of a hospital's expendi-

tures. Optimising price and quantity parameters may reduce those costs; engaging suppliers in the best utilisation of those supplies provides additional, indirect benefits helping to reduce the 60 percent of costs – labour. 'We need to look at the strategic nature of the supply chain and put it to good use for patients and the hospital,' he said. 'In addition to cutting cost, leveraging the supply chain can support outcomes, quality of care, and efficiency in hospitals.'

Sourcing beyond price aspects

The healthcare market in the US and elsewhere has been changing, and hospital strategies are responding. As a result, supply chain and category management has been going through a transformation, according to the manager: today, the department's focus is no longer merely on pricing and quantity – it is about taking on all the opportuni-

Overall cost structure:

- Supplies: 20 percent
- Facilities: 20 percent
- Labour: 60 percent

Value contributions that matter New tasks characterise supply chain departments:

- Traditional: pricing and quantity
- Emerging challenges: sourcing for innovation, outcomes, utilisation, ecology and sustainability
- Further contributions: align activities with the corporate image to enhance positioning in the market.

ties offered by a diverse supplier market, helping the hospital to realise the value attributes that are of strategic importance. This includes sourcing for innovation, outcomes, utilisation, ecology and sustainability based, for example, on the elimination of waste, as well as further factors that have begun to play a key role.

In addition to integrating these criteria, hospitals now look for partnerships with suppliers that tie in with the hospital brand. At Mayo, cultural diversity characterises the staff, as well as patient population; the pool of suppliers maintained by

supply chain managers also reflects this diversity, which helps support competition fostering innovation and cost control ... contributing to an overall positive image of the organisation in its various markets.

Implementing technological innovation

Information and knowledge management, integrating scientific findings into healthcare delivery, and regenerative as well as individualised medicine are the current major trends in the sector. In that context, 'we will look at the evidence of benefits offered by a new device before we consider purchasing it', he explained. The impact on length of stay and on re-hospitalisation count among the hospital quality measures reimbursement is based on, and are therefore relevant criteria. 'We follow a patient's care path from pre- to post-procedure, for example including telemedicine, and we scrutinise the total cost. Our investments include capabilities to do counsels based on electronic communication with affiliated care providers.' In-house pilots and testing programmes are part of the Mayo's purchasing scheme.



'In addition to cutting cost, leveraging the supply chain can support outcomes, quality of care and efficiency in hospitals,' declared Joseph M Dudas, head of the Mayo Clinic's Category Management unit, which covers sourcing and contracting.

'In everything we do at Mayo, the needs of patients always come first,' Joseph Dudas underlined. 'We work with patients and focus on quality of care.' The goals of optimised sourcing can be best achieved in collaborative groups, he added. Forming relationships with partners is the right way to move forward. Other providers, group purchasing organisations, and distributors make significant contributions in an end-to-end supply chain setup.

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Russia: Scanners plentiful but radiologists too scant

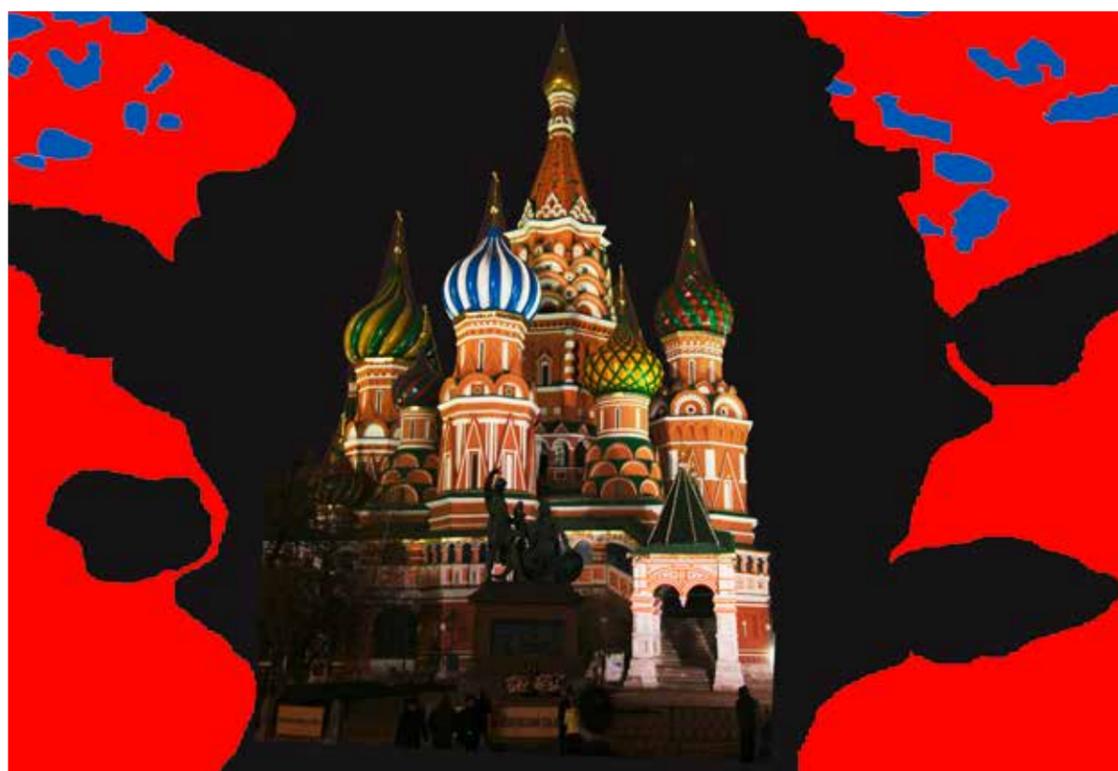
However, investments in equipment and advanced training are attracting medical students, John Brosky reports

'Going back 20 years we had problems with access to high-end technologies for radiology. CT, MRI and PET scanners were quite rare,' sighed Valentin Sinitsyn MD. Then, he laughed. 'Now suddenly we have the opposite problem with more and more new technologies and a shortage of radiologists qualified to operate all this equipment.'

Over the past decade, he explained, the Russian Ministry of Health has invested heavily in the acquisition of high-end radiology platforms, significantly including information systems to process, store and share images. 'In absolute numbers, we can claim to have between 14,000 or 15,000 radiologists, but most have been trained in basic examinations for X-ray or else specialised in just CT or MRI. There simply wasn't a need for more advanced training,' he said.

As a result, the Russian Society of Radiology has endorsed the European Training Curriculum for Radiology developed by the European Society of Radiology (ESR) as a basis for a national training programme.

Chief of Radiology at the Federal Centre of Medicine and Rehabilitation, Dr Sinitsyn is also a member of the ESR Executive Council and, over the past year, served as the Chairman of the Congress Committee responsible for the scientific and educational programme. He has given special attention to organising a special session, 'ESR meets Russia,' that will feature some of his country's most prominent radiologists, two cultural interludes and a panel discussion



Christian Lauer, Belgium-based radiologist and artist (www.art-in-radiology.com), is fascinated by the idea of using radiology images to fuse art and medicine. The work of art on our front cover links Russia – one of this year's guest countries and home of this year's ECR President – with the European Congress of Radiology.

on the theme, *Future developments in Russian radiology: which path to take?*

'I would not want to predict what the panellists will decide, but my own greatest hope is that we will encourage and support this great interest that young people are showing in radiology,' said Dr Sinitsyn, who is also a professor and the Head of the Radiology Course at Moscow State University. 'Radiology

has become very attractive for Russian medical students. They find it exciting with all the high technology, computerised processes, information technologies, 3-D imaging and functional imaging. It is a field that is developing very fast, which also appeals to them.'

'Most of these students speak a high level of English, which is essential as so much data and information is available for them every-

where in English-language journals and, of course, on the internet. To the point where increasingly we can offer radiology courses for Russian students in English,' Prof. Sinitsyn explained.

Among the students and residents he teaches he said he is impressed by their drive and enthusiasm to be successful, well-trained and knowledgeable professionals. Attending international congresses has con-



ECR 2014 Congress President Prof. Valentin Sinitsyn is Chief of Radiology at the Federal Centre of Medicine and Rehabilitation in Moscow

vinced them they also need to demonstrate an expertise by presenting results from their work.

'I am very pleased that we have seen an increase this year of more than 60% in papers and posters submitted to the European congress from Russia. My country is now among the leading contributors of scientific work this year and I believe it is a general trend and that we can expect it will be sustained with future congresses.'

There remain significant challenges for Russia with its uneven expansion of capabilities in radiology, he added. 'While we have seen an acceleration in the development of digital networks and PACS, many hospitals have boldly gone ahead purchasing these expensive systems without building the required infrastructure or assuring they have a sufficient number of workstations. Often they cannot see further than acquiring stand-alone systems. On the other hand, we have quite successful programmes at hospitals that are fully equipped and fully-digital with regional radiology networks and teleradiology. It becomes a question of cultural change, of finding the appropriate approach for creating these services.'

'Service for the new equipment is another, quite complicated issue,' he added. 'Sooner or later something will stop a scanner operation, of course, but repair or replacement takes a lot more time than radiologists may be used to in western countries. One one hand, we have very complex regulations and custom requirements in Russia. The required registration of tenders can be quite long. Even where a hospital has the funding there are very lengthy delays.'

'On the other hand, we continue to have challenges for maintaining operations with the manufacturers themselves. These are very big, international companies, but I regularly find myself telling them they need to improve service and support. They have a shortage of technicians, of spare parts, even for minor parts, and this takes time.'

These obstacles can be disturbing, frustrating the smooth operation of a radiology group by leaving a scanner standing idle for months, 'a waste of resources, especially human resources,' he pointed out.

Nevertheless, Prof. Sinitsyn believes that Russian radiology is now moving in a positive direction and that current challenges will be resolved with continued progress and improvements.

The real risk in radioprotection may be the radiologist who thinks there's not a problem

Are you safe?

EuroSafe Imaging is a wake-up call, an ambitious campaign launched by the European Society of Radiology (ESR) to increase awareness about the risks of radiation in medical imaging, but also to better promote the benefits of exams.

Some radiologists may be tempted to hit the 'snooze' button, believing that radioprotection of patients is a tired topic, not worth their attention at this year's European Congress of Radiology (ECR) in Vienna. This would be a mistake. According to ESR President Guy Frija MD, anyone concerned about daily workflow,

CT exam protocols, and the cost of doing business in radiology, needs to think differently. The landscape in Europe is shifting. He respectfully suggests radiologists plan on joining the discussion during the launch session of EuroSafe Imaging entitled 'Dealing with Challenges of Radiation Protection' at this year's congress. 'This topic is not very sexy for radiologists,' he admits, yet as he wrote in the ESR Statement On Radiation Protection, 'radiation protection has become a worldwide issue and the [society] considers it as its responsibility to act.'

Dr Frija notes that ESR 'is aware about the increasing inappropriate medical exposures to ionising radiation and wide variation in patient doses for the same examination... and realises the compelling need to act against the lack of adoption or adherence to requirements.'

Key words to keep in mind are regulation, guidelines, audits and certification.

'We will be increasingly challenged to demonstrate the appropriateness of our exams, to show they are clinically justified. This becomes very significant,' he said in an interview with *European Hospital*.

Thanks to impressive innovations and advances by industry, radiologists may have been lulled into



ESR President Guy Frija is Head of the Imaging Department at Hôpital Européen Georges Pompidou in Paris

complacency about radioprotection. Some believe that the issue is behind them, thanks to what has been called the magic button for iterative reconstruction that renders a diagnostic quality image from ultra low dose exposure for the

Continued on page 6

The Image Gently campaign enters 7th year

A time to celebrate greater child protection

Report: Cynthia E. Keen

The words 'Image Gently' are synonymous with protecting children from unnecessary or excessive exposure to X-rays. A grass-roots campaign started by a handful of US paediatric radiologists and medical physicists who were deeply concerned about the radiation doses paediatric patients were receiving from CT scans has become a highly effective, on-going worldwide message and movement to make diagnostic imaging safer for children.

The Alliance for Radiation Safety in Paediatric Imaging consists of over 80 member societies representing more than 800,000 medical imaging professionals. On 1st January 2014, 28,298 medical professionals had taken the Image Gently pledge to 'child size' radiation doses, keep radiation dose



in CT, nuclear medicine, diagnostic fluoroscopy, interventional radiology and, most recently, digital radiography. 'Young radiographers don't think about over-exposure, and dose creep has been a concern ever since the introduction of computed radiography in the early 1990's,' Dr Goske pointed out. Like all of the campaigns, the 'Back to Basics' campaign includes quality improvement tools and a 10-step approach to performing digital radiography, which emphasises that the body thickness of a child, not age, height or weight, should determine radiation dose.

The European Society of Paediatric Radiology has been very active in promoting harmonisation of radiation dose guidelines, especially for the fluoroscopy, interventional radiology, and nuclear medicine campaign. Efforts are underway to translate educational materials into each of the world's major languages.

Safer and better imaging for children needing radiology exams is also a factor of training. This gained a big boost with the establishment in May 2011 of the World Federation of Paediatric Imaging (WFPI), created to coordinate the work of paediatric radiology societies throughout the world and create a strong unified voice on the global practice of child imaging. The Federation's founding members included the regional societies of Europe, North America, Central and South America, and Asia/Oceania. Formed shortly thereafter, an African society soon joined WFPI, as did several societies representing individual countries.

WFPI's founding president and chair, Dr Ines Boechat – head of paediatric imaging at UCLA Mattel Children's Hospital and professor of radiology and paediatrics at the University of California-Los Angeles David Geffen School of Medicine – pointed out that the organisation's



Dr Marilyn Goske, paediatric radiologist at Cincinnati Children's Hospital Medical Centre, Ohio

primary objective is to reduce global health inequalities and promote safe and appropriate child imaging. 'The group has been focusing on providing education, training, and partnership across national boundaries,' he said, adding that there is tremendous diversity in the levels of training and expertise even among European countries, not to mention the world. WFPI aims to establish, through member consensus, standards for imaging paediatric patients and to define standards of training in paediatric imaging, which could create more uniform standards of care across national borders.

From the beginning, WFPI has worked on multiple fronts to promote its cause, including efforts to offer education to paediatric radiologists. It has provided on-site training in Ethiopia, Haiti, Malawi, Mozambique, and South Africa, and works closely with the World Health Organisation and Médecins Sans Frontières by providing volunteer teleradiology interpretation services.

Because the world is connected via the internet, WFPI provides online education. The European Society of Radiology contributed financially towards a new website www.wfpweb.org, which now supports streaming training videos. The website also links directly to Image Gently, and the two organisations work very closely together on issues relating to radiation protection and child safety.

Are you safe?

Continued from page 5

patient. 'They are right and at the same time wrong,' said Dr Frija. 'It is true that with iterative reconstruction we have diminished dose exposure considerably, from 50% to 70%. Yet they are wrong because today the scientific view held in esteem around the world, the linear no-threshold model, says that even an infinitesimal dose of radiation has a potential risk.'

'This is no more than a hypothesis that has never been proven. Yet, even if some believe that low dose exposure does not carry a risk, they are wrong to dismiss the patients' concerns. The key goal is to assure the patient who may be worried. Rather than disputing this hypothesis, we are going to frame the radioprotection discussion as a matter of benefit and risk for an exam,' he said.

Radiologists, he pointed out, need to know how to explain to patients that the best protocols possible and best equipment, are being used in the best interest of the patient.

During this year's ECR opening ceremony, Dr Frija will officially introduce the EuroSafe Imaging campaign that he has personally taken up as the Centrepiece of his ESR presidency. The fullness of the campaign will be presented in the special session 'Dealing with Challenges of Radiation Protection'.

Key themes are promoting appropriateness in radiological imaging, maintaining radiation doses with-

in diagnostic reference levels and using the As Low As Reasonably Achievable (ALARA) principle to further reduce doses while maintaining the image quality needed for clinical purposes.

All stakeholders will participate, including the European Commission and the WHO. 'We will hear from American colleagues who organised the successful radioprotection campaigns Image Gently and Image Wisely so that we can profit from their experiences,' Dr Frija added.

An exhibition area is also dedicated to the EuroSafe Imaging Campaign, featuring posters prepared by stakeholders.

ESR has been involved as either a coordinator or partner in a number of EC projects centred on radioprotection concerns, including European Medical ALARA Network (EMAN) focused on optimisation, the Referral Guidelines project addressing the implementation of the Medical Exposure Directive's requirements on justification, or appropriateness, Medical Radiation Protection Education and Training (MEDRAPET) and, very recently, a project to establish diagnostic reference levels for paediatric imaging.

'We've convinced all our partners, including the EC, that beyond developing guidelines we can enhance the adoption of those guidelines through a programme called Clinical Decision Support with IT tools,' said Dr Frija.

Management
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Management in Radiology (MIR) is a subcommittee of the ESR Professional Organisation Committee, set up to address current challenges and provide a forum for education and the exchange of ideas and concepts. For ECR 2014 the MIR group has gathered leading radiologists to present technological advances and new imaging techniques during two sessions: 'Clinical Decision Support and Radiation Protection Training' and 'Patient-centred Radiology and Economics'.

Session 1

Radiologist Denis Remedios (UK), co-author of the Royal College of Radiology guideline for the United Kingdom, will discuss 'Appropriate imaging: Aspiration, inspiration or reality'.

Professor of Radiology at Harvard University, James Brink heads the radiology department at Massachusetts General Hospital. He will report on clinical decision support (CDS) based on lengthy experience at MGH.

Lluís Donoso (Spain), vice-president of the European Society of Radiology (ESR) and Chair of Radiology at the University Hospital

ESR has also influenced the orientation of clinical audits that will become mandatory under the revised Basic Safety Standards (BSS) directive of the European Atomic Energy Community (Euratom) and an ESR committee is preparing support materials that it will propose as the basis for a guide for conducting clinical audits.

With the launch of the EuroSafe Imaging campaign, ESR will also make available on its e-learning platform training modules where radiologists can earn a certificate in radioprotection standards on a voluntary basis.

Dr Frija: 'At this stage we are providing to our members a means for proving that they are up-to-date and capable. At some future point, this may no longer be a voluntary process of certification. If the EC decides to require certification, then it will be mandatory through the Member States.'

Convinced that the different components of radiation protection are often interrelated and cannot be considered in isolation and independently, the ESR is taking a holistic approach it calls GPS, or Globalisation, Personalisation and Safety. The ESR vision involves all stakeholders for safely delivering personalised, patient-centric medicine in clinical settings.

Details: www.eurosafeimaging.org



levels as low as reasonably achievable (ALARA) to obtain a diagnostic quality image, and to substitute non-ionising exams, such as ultrasound and MRI, whenever possible.

The Image Gently campaign promotes radiation protection for children through an all-volunteer social marketing campaign that just keeps gathering momentum, according to the Alliance's chairperson, Dr Marilyn Goske, a paediatric radiologist at the Cincinnati Children's Hospital Medical Centre in Ohio, USA. Dr Goske attributes Image Gently's success to global agreement by medical professionals, allied health groups, regulatory and advisory organisations, government agencies and medical device manufacturers because this is the right thing to do. Its messages are also directed to parents, whom it works hard to educate. Its authoritative website (www.imagegently.org) is a steadily expanding resource for medical professionals and parents alike.

Since its inception, the Alliance has sponsored awareness campaigns



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in Barcelona, will explain the ESR initiative on CDS.

Peter Vock, chairman of the ESR working group on radiation protection, will present the new ESR initiative to promote radiation protection and two physicists from the, Dr Donald Peck (USA), co-founder of ACR initiatives on radiation protec-

tion, and Dr Annalisa Trianni (Italy), Board Member of EFOMP, will seek to clarify any truth in talking about radiation risk? It is often difficult for radiologists to discuss the benefits vs. risks on specific imaging procedures with referring physicians and patients; thus expert knowledge is mandatory.

Session 2

The two sides of the radiology coin are individualising treatment, i.e. a patient centred approach and, the flip side, economic considerations.

Elisabeth Schouman (France), Professor of Radiology and a Member of the MIR-Board, will



Professor Peter Mildenerger from Mainz is the current Head of Management Subcommittee of the POC

explain the results of a European survey on the economic situation, while Dr Mansoor Fatehi (Iran) will

report on challenges experienced in 'special situations', providing a real example of economic impact on radiology practice at national level. Better understanding and appropriate acting by radiologists can only be achieved with better knowledge of basic economic rules, to be explained by economics expert Professor Giuseppe Turchetti (Italy).

Improvements in patient-centred radiology involve a better culture of safety and communication. Dr Catherine Mandel will reveal experience with a 'Radiology Event Register' in Australia and New Zealand, while radiologist Charles Kahn (USA), chair of the RSNA

reporting templates committee will discuss communication and the need for a 'visible radiologist'.

Winding up the session, Dr Eric Briers will present the patient's perspective.

Both sessions include discussion time and audience participation.

ECR DIARY DATE

Saturday, 8th March 2014,
Satellite Symposium session
13:00-17:30, Room M-B.



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The future of radiology: A

Two things that radiologists resist – structured reporting and (computer-assisted) quantification – are the very things that Gabriel Krestin believes are essential to advance diagnosis in the brave new world of omic-medicine that is emerging. Thus, during the Sunday session *Imaging In Precision Medicine*, he will develop the subject in detail during an ECR 2014 presentation 'Radiogenomics and personalised (precision) medicine'. Ahead of the congress, Professor Krestin spoke with *European Hospital* about the potential of linking genomic mutations with imaging phenotypes, the quantification of reporting it will require, and his views on changes necessary in both radiology and society.

Report: John Brosky

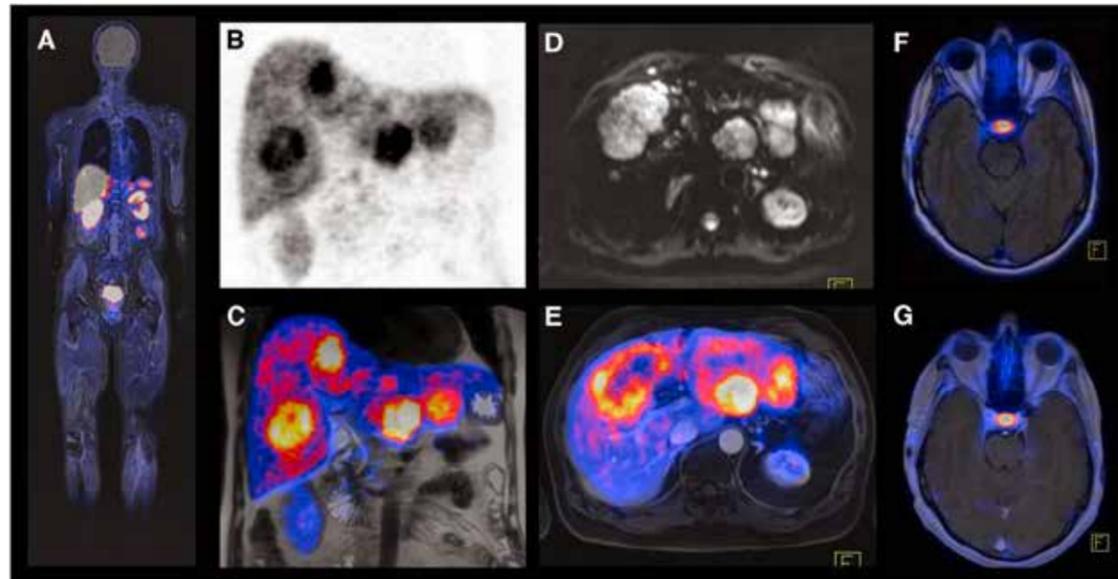
EH: What is this new world of radiogenomics?

Gabriel Krestin: Radiogenomics has been used as a term in finding associations between the genetic signature, or genome, and certain imaging phenotypes, whether there are any imaging markers that are associated with genetic mutations. This is the term we, in radiology, usually use for this correlation between genomics and specific imaging signs. Imaging genomics is, more or less, the same definition and I think imaging genomics is the better term.

This is no longer a dream but a reality?

This is absolutely a reality. These types of studies have been exponentially increasing in recent years since the start of the Human Genome project. Now that we can increasingly sequence the whole genome in large numbers of cases and controls, people try to determine whether there is anything changed within a gene that is associated with a certain disease or a certain phenotype. Multiple cases have been found where such genes correlate or are associated with people who develop Alzheimer's disease, or diabetes, Crohn's disease or specific types of cancer or other chronic diseases.

The same techniques have been applied in large population studies. One of the first that we published, from Rotterdam, was whether there is a genetic mutation associated with white matter lesions in the



brain. These lesions are a predictor for the development of cerebral vascular disease or Alzheimer's disease. The question was whether there is a gene that predicts or is associated with white matter lesions. There is a potential for a lot more.

Where does radiology play a determining role in the universe of -omics?

A very exciting area that is not based on the overall genetic profile of the patient is leading to the genetic signature of a malignant lesion. This can become significant.

First, we can identify a certain number of patients with a certain type of cancer, biopsy that cancer, sequence the active genes that are expressed within that cancer type,

and then correlate the genetic signature, the gene expression sequence, with hundreds of different imaging signs, like size, contours, the enhancement pattern, signal intensity on MR images and many other features that can be identified and characterised in a binomial way. Are the margins sharp or not sharp? You give it a 1 or a 0. Applying statistics, people have found very strong correlations between imaging features and the genetic signature of those tumours

It seems these imaging features may very well be a product of a certain genetic expression in that specific tumour – aggressiveness, for example. It seems there are certain genes that contribute to hypoxia in some tumours. We can find a corre-

lation between that expressed gene and the enhancement pattern of that tumour. This will tell us if the tumour is hypoxic, or not. These are very relevant findings that have an implication on the possibilities to treat that tumour, because we know that tumours that are hypoxic will not respond to certain chemotherapies or radiotherapies.

Radiology has a 100-year tradition of interpreting images and reporting findings. Will this change that?

Absolutely. We are moving towards applying precision medicine in imaging. I'm absolutely convinced this is the way forward, and if we don't want to be completely sidelined and made obsolete as radi-

ologists, we have to move toward precision. Precision is measuring, structuring and standardising. I can understand that sometimes measuring and using these tools can seem quite boring. It's much more rewarding to apply knowledge as an art instead of applying it as a science. I know how much resistance there is because it limits the freedom of professionals who are very much used to use their own words, to give descriptive findings.

Yet there is no way we can survive as a scientific specialty if we are only providing qualitative reports. We need to structure our reports. There are many activities in this area within the RSNA (Radiological Society of North America), within the ACR (American College of

“ If we don't want to be made obsolete as radiologists, we have to move toward precision. Precision is measuring, structuring and standardising. I can understand that sometimes measuring and using these tools can seem quite boring. It's much more rewarding to apply knowledge as an art instead of applying it as a science. I know how much resistance there is because it limits the freedom of professionals who are very much used to use their own words, to give descriptive findings. Yet there is no way we can survive as a scientific specialty if we are only providing qualitative reports. We need to structure our reports. There are many activities in this area within the RSNA (Radiological Society of North America), within the ACR (American College of

Radiology), and within the ESR (European Society of Radiology) – all pushing to adopt this concept of structured reporting.

In Europe it becomes more difficult because of the many languages, and it is difficult for diverse European societies to play a key role in adopting structured reporting. Yet, I believe there is no other way forward for the future.

Some radiologists also resist computer assistance for readings. . .

There is no way we can do this manually or even only based on visual interaction. Instead we develop imaging algorithms that do this work fully automatically. Processing image data with tools give us the numbers without any interaction between the reader and the images. We get brain volumes, the thickness

Protecting hospital information systems (HIS)

Healthcare IT must adopt top se

With eavesdropping into secure systems brought sharply into focus as a result of revelations of monitoring by the US National Security Agency (NSA), a leading communication expert has warned that many hospitals across Europe need to take further steps to better protect the sensitive data stored on their healthcare IT systems.

While acknowledging that some healthcare establishments have implemented measures to ensure eavesdroppers cannot access their systems, Torbjörn Kronander is concerned that others are still exposed to intrusion from outsiders. As head of the Swedish firm Sectra, which develops and sells products and services for medical imaging IT and secure communication, he believes hospitals often do not realise how easy it is to eavesdrop into secure conversations or archives and how common it is.

However, he is sensing a change of attitude among healthcare organisations and an increased demand for his company's knowledge and expertise in data security in a medical IT setting, coupled with greater awareness of the risks of data breach and the importance of a security component for hospital archives.

Challenges still remain, he notes, in implementing the need for secu-

rity into daily practice and ensuring the medical community understands the need for effective data security. Another issue for Europe's health sector is the lack of uniformity in secure systems adoption in hospitals. The risk of data breach and eavesdropping, he explained, was vividly highlighted by the case of American computer specialist Edward Snowden, where the former NSA contractor revealed details of global surveillance by the NSA.

Torbjörn Kronander maintains that it is not difficult to keep internal and opportunist hackers out of hospital systems but stressed that many need to take practical steps if they want to remain IT secure. 'They need an awareness and knowledge of data security at IT level and also understand how to make the system secure so that no one can go into the system and change data. Changing data is the worst thing you can do in a hospital; it's worse



Torbjörn Kronander, Chief Executive Officer at Sectra

than losing data or eavesdropping on the data.'

He cited an example of a case a decade ago in a European country: a doctor who had made a clinical error went into an image archive and changed the picture he had used for the procedure. 'Security comes at different levels and you

can do a lot with software but in the initial phase it is a systems approach; how you look at security in hospital, support it, and then how you enforce it. No chain is stronger than its weakest link, so all systems must be secured,' he added. 'For a hospital, the first need is to understand that there is a problem and then adopt a symptomatic specification on a hospital level on how this should be tackled, so that you don't solve security in different ways in different places.'

Security that pays off

While secure systems cost money and take up some staff and time commitment, the cost is not always as high as hospitals fear. 'Security costs money but a breach of security costs even more money. It is like insurance; insurance costs money but if you do not have insurance and something happens it will be even more expensive.'

Sectra, which has evolved over the past 35 years into an international company with more than 500 employees across 12 countries, is now seeing interest in securing the



medical imaging infrastructure and PACS the Company sells in its other division.

The company underpins its success with long-term and close collaboration with customers, understanding their daily life and routines and combining this with leading-edge expertise in technology.

Security awareness, he pointed out, remains generally low in standardisation bodies such as DICOM, and there is no consistent way of solving security issues within them. He also advises hospitals to demand

Art or science?



Professor of radiology and chairman of the radiology department at Erasmus University Medical Centre in Rotterdam, **Gabriel Krestin** is also the past-President of the European Society of Radiology and serves on the editorial and advisory boards of several journals, including European Radiology. He founded the working group Management in Radiology (MIR) and the European Institute of Biomedical Imaging Research (EIBIR).

what people would like in medicine, that you know what is going on, you know what to expect, you know what it will cost, and that, wherever you go, you will get the same type of care and cure without huge qualitative differences.

This is an ideal for the future. Yes, for many years there will continue to be differences, with better doctors than others, because so

much is still not explained, and so much is still based on intuition and not purely on science.

Yet, the more we move toward finding the molecular basis of disease and the causes of disease, I hope we will move closer to the garage situation where you know exactly what you get, and whether it can be fixed or it can't.

Who is going to pay for all this?

For the time being it's interplay between the scientists and the organisations that are willing to fund these types of studies, such as national governments and European grants. Probably the pharmaceutical industry should be increasingly interested in this area because, through imaging genomics, they will get additional markers that can help in drug development.

Still, I have a different question. I never understood why the increasing cost of healthcare, in an industry that is growing much faster than other industries, is a problem. What's bad about increas-

ing the economy around healthcare? If 20% of a country's population is employed in some way related to healthcare, why are we not willing to pay, or to allow that a significant part of the GDP goes into this industry? What is bad about that?

People want and need health. They are probably willing to pay for health, or the system should be willing to pay for health. I don't see a huge problem. I have spoken with important economists about this and never received a good explanation as to why we want to limit the healthcare industry. We need a change in the mind-set.

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of the cortex of the brain, or the volume of the white matter lesions, or the volume of the hippocampus.

Is there room still for art in radiology?

Good question. Hopefully there always will be and computers will never take over the integrative power of the brain. On the other hand, I'm very much in favour of standardisation. In a presentation on this topic I advocated that a patient, like someone taking a car to the garage, would like to know exactly what he would get for what he pays. Today in a garage they work with lots of electronics tests to say what's wrong with the car, and you immediately get an estimate to fix the problem. That is approximately

Security



certain levels of security specification from a vendor when they buy a PACS, RIS, or HIS system and also adopt the information security management systems standard ISO27001 for security of data, which is used by vendors and security companies such as Sectra.

Kronander warned that these days, obviously no information can be perfectly safe, but added that with Sectra, hospitals can "make their IT systems immensely more difficult to eavesdrop and listen in to."

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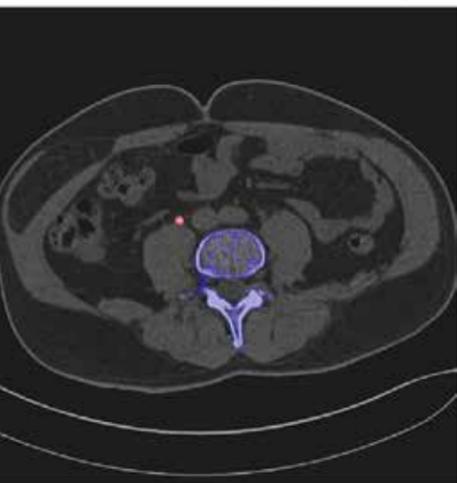
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Answers for life.

Spectral imaging offers morphological plus functional and molecular data

Dual energy brings more to meet the eye



How does spectral – or dual energy – imaging work? Very similar to red and green light used in black-and-white photography. A black-and-white camera provides information on the colours of the photographed objects: an object that is black under red light is actually green. Different photon energies generate differently coloured light. 'Spectral imaging applies the same knowledge to X-rays in order to increase the informational content in the images,' says Professor Thorsten Johnson who until recently headed the CT department of the University Hospital Munich at Grosshadern. With his team he shaped the development and the clinical application of dual energy imaging.

While in spectral imaging the X-ray image is created in conventional greyscale, but using different photon energies, the system manufacturers follow different approaches to achieve their results.

Dual energy: More information but same radiation dose

Siemens places two CTs with two X-ray tubes in one device. These radiation sources can be operated at different kV levels; they fire from different angles but from the same position on the axis simultaneously on two detectors. 'We reconstruct images from both projections,' Prof. Johnson explains, 'and in a second step we analyse the images as to their spectral characteristics. In the data set we can identify different substances, particularly heavy elements such as iodine, xenon or calcium.' Most – the most successful – applications use contrast agents

Top: Xenon ventilation shows a defect in the right upper lobe

Centre: Spectral imaging confirms the kidney stone (in right ureter) is a uric acid stone, which does not require surgery

Bottom: Iodine image of the lung shows a triangular defect indicating a small embolism

that provide information on metabolic activities that indicate tumour presence.

With electricity shared by two tubes, valuable additional information is generated using normal dose. Thus high image quality can be achieved with a neutral 'radiation footprint'.

Different technological approaches

Another approach – used, for example, by GE – is the so-called rapid KV switching technology (RAKV) however, which, as Professor Johnson points out, is not entirely dose-neutral. Philips, another major player in diagnostic imaging, offers a system with a detector equipped with two scintillator layers of different sensitivity. The crystals on these layers convert the incoming X-rays into visible light that in turn is detected by optical sensors.

Applications

Spectral imaging is suited for a wide range of applications. 'In angiography the specific and quantitative detection of iodine contrast agent allows the complete removal of the background, including bone structures. This provides a much better overview of the region of interest and significantly facilitates diagnosis. In peripheral artery occlusive disease the vascular structure is much easier to see and evaluate,' Prof. Johnson explains. In terms of 3-D reconstruction, projection without bones accelerates the assessment of intracranial aneurysms or arteriovenous malformations. In addition, with strokes speed is of the essence. During his term as Head of the CT Department at the Grosshadern University Hospital, he adds, '30-50 percent of all protocols were geared towards dual energy'.

The competition: MRI

For Prof. Johnson, MRI is clearly a competitor of spectral imaging. However, patient cohorts and the

resource situation are completely different for the two modalities. While MRI scanners are rarely quickly available, and imaging takes quite some time, dual energy CT scanners are not yet widely used – also because in Germany, for example, the statutory health insurers do not reimburse the additional costs of spectral imaging.

Looking ahead

Where is spectral imaging development heading? According to Prof. Johnson, one trend is increased performance of the X-ray tubes: voltage changes in 10 kV steps, higher maximum, higher density filters. 'This new generation of dual energy systems provides even better contrast – and thus more precise information.' Whilst, so far, the focus has been on image quality, dose reduction is gaining importance. Today, the performance of the X-ray tubes can be optimised and the low-energy part of the spectrum, which significantly contributes to the radiation exposure, can be removed. Only radiation that travels through the patient is being used, not the radiation that 'gets stuck' in the patient's fatty tissue. 'Low-dose studies, for example of the lung, are possible with such a filtered spectrum,' the radiologist emphasises.

To date, even applications once considered impossible due to the contrast-to-noise ratio seem promising. Bone marrow oedema, for example, might be visualised with enhanced spectral imaging. The same holds true for tendons, ligaments and cartilage – which are all difficult to image because of the weak signal. How can such potential be explored? Clinically indicated exams, the professor suggests, could simply be performed using conventional dose and spectral imaging. 'This would be a dose-neutral way to see how precise the information is.'

Will Professor Johnson himself – having helped shape the devel-



Graduating in medicine (summa cum laude) and undertaking research at Siemens AG's CT department in Forchheim, **Thorsten Johnson** continued his physician training and his habilitation in radiology at Ludwig Maximilian University (LMU) in Munich. He was a senior resident and head of the CT division at the Institute of Clinical Radiology at LMU Hospital and held a senior position at the institute's MRI division. In 2013 he was appointed professor. With his medical expertise on CT and MR imaging his awards are numerous, and he is a peer reviewer on several editorial boards and for other publications.

opment of dual energy as a long-term researcher and consultant for Siemens – continue to play an active part in spectral imaging? Within his institution Dr Johnson recently transferred to MRI – not without mixed feelings – but, 'as a radiologist I aim to master all modalities. Today, it's simply not enough for a clinical radiologist to only be familiar with CT.' Nevertheless he will continue to lead several research projects in dual energy CT and he is curious to see whether, and which, applications are technically feasible and which one will make it from the research lab to clinical usage.

Summing up

'Conventional CT can only visualise morphology. It is the physician who must draw conclusions regarding functional aspects,' Prof. Johnson points out. 'Dual energy introduces functional imaging to CT. It shows perfusion defects, or whether a kidney stone is composed of uric acid and can therefore be dissolved with drugs, or whether a haemorrhagic renal cyst does not take up contrast agent, which means it's not a tumour. The additional information that functional and molecular CT imaging provides allows a much more specific diagnosis without higher radiation dose. I'm proud that today this method, which I was fortunate to co-develop, delivers on its promise in clinical practice and in research worldwide.'

Aiding maxillofacial, small joints, cervicals and ENT diagnoses

'A precursor in Cone-Beam Computed Tomography (CBCT) imaging, NewTom is the unrivalled benchmark in radiology thanks to highly effective research standards, flawless reliability and sheer quality,' the manufacturer reports. 'These ingredients make 5G the best way to explore new fields of application. NewTom 5G is recommended for medical radiology specialties with a focus on maxillofacial, small joints, cervicals and ENT diagnosis. Users can explore several clinical applications, thanks to the open pass-through style gantry and the motorised patient table.'

'NewTom 5G couples a revolutionary flat panel X-ray detector

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technology with a very small focal spot (0.3mm), so to produce the clearest, sharpest images possible. The size of the FOV available on the device can vary from the smallest 6x6 cm to the biggest 18x16 cm.

New protocol saves dose and time

'The EcoScan is the novelty among the various scan protocols available on 5G. This protocol reduces scan

time and X-ray emission time, as well as dosage, without affecting the high quality of the image.

'The device features the proprietary NNT software, that creates different kinds of 3-D images, compatible with all major software on the market.'

Finally, the firm points out, NewTom optimises the use of radiation via its SafeBeam technology so 'the actually absorbed dose is less than with a comparable exam using a conventional MSCT'.

Details: www.newtom.it



Virtual anatomy

Software sustains a link between anatomy and imaging procedures

In 2007, Sara Doll (Institute for Anatomy and Cell Biology, Heidelberg University) and Dr Frederik Giesel (Clinical Director, Radiology Clinic, Department of Nuclear Medicine at Heidelberg University Hospital) initiated the development of virtual anatomy for a seminar aimed at students in the pre-clinical phase of their medical degree course. For the seminar, Roland Unterhinninghofen Dr.-Ing, at the Karlsruhe Institute of Technology, developed an interactive educational software package.

The objective was, and continues to be, the creation of a link between radiological image data collated in clinical routine and anatomical content for educational purposes. These image data are then shown in 2-D and 3-D so that students can, for instance, carry out virtual dissections.

Due to high demand for the clinical study phase, Dr Giesel also introduced a seminar entitled 'Virtual Radiology, Nuclear Medicine and Radiotherapy', to cover pathological and hybrid imaging and the use of image-guided radiotherapy.

These links between pre-clinical and clinical subjects (anatomy and radiology) happened against a background of rapid technological change in computer-aided teaching concepts. The introduction of particularly the touch screen made it possible to offer students more post-processing software for images data. Therefore, the software environment in Heidelberg was also adapted for tablet computers. The teaching and learning environment already facilitates an interactive surf-by 3-D anatomy teaching and learning function. The software facilitates 3-D viewing and virtual dissection as well as 2-D viewing with axial, coronary and sagittal

visualisation in real time.

This new technological concept facilitates individual and intuitive work with radiological-anatomical image data and can help to improve spatial imagination. At this year's ECR, the software developer Dr Unterhinninghofen will introduce, for the first time, this technological implementation and new potential.

Most recently, the teaching and learning concept at Heidelberg has also been supported by a CT-scanner in the anatomy department. This makes it possible to digitise preparations prior to macroscopic anatomy with high-resolution procedures and to explore and analyse them alongside the dissection, almost as in 'real' medical routine.

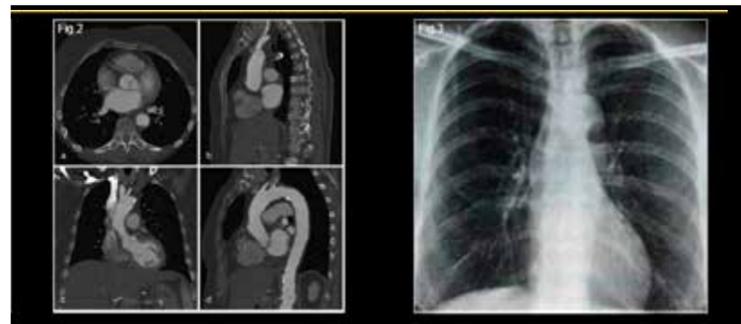


Figure 2a-d: The data can be viewed in axial (a), sagittal (b), coronal (c) and arbitrarily adjusted oblique images planes (d). Identification of the same anatomic structures in different orientations facilitates three-dimensional appreciation

Figure 3: Radiographic chest plain film to visualise only the summation of lung, chest and bone, which is better understandable by prior 3-D and 2-D-image viewing

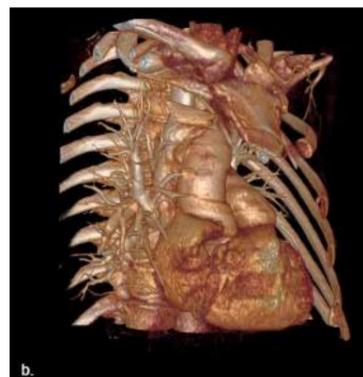
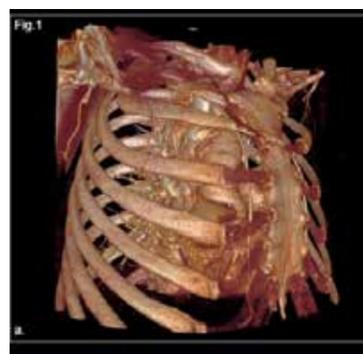


Figure 1a-b: Virtual anatomy and virtual dissection of the heart and the thoracic vessels. At the beginning (Figure 1a), the heart and vessels are hidden by the chest. In order to make the topographical relations and anatomical structures more graspable, the chest is removed using the sculpting tool (Fig. 1b).

The thoracic aorta and its major branches, the pulmonary trunk, pulmonary veins, superior vena cava and ventricles can be clearly depicted

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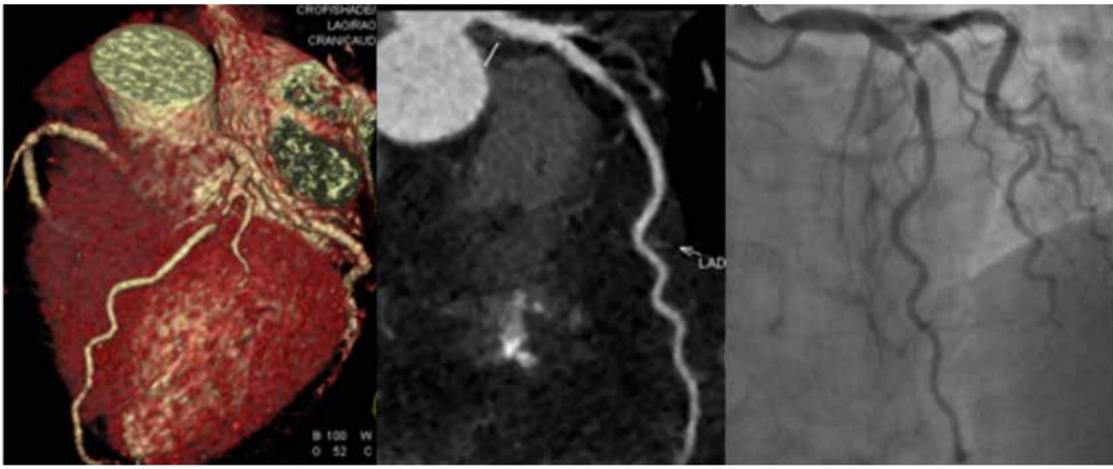


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Prospectively ECG-triggered high-speed coronary CTA of the heart. Performed at 70 kV with 30 ml of contrast agent and iterative reconstruction, the scan had an effective dose of 0.17 mSv. The image clearly shows a stenosis in the proximal ramus interventricularis anterior

Should CTA become a screening procedure?

With low tube voltage, reduced radiation and contrast agent dose, the system delivers sufficient and meaningful data

CT angiography (CTA), an objective method to visually assess cardiovascular risk, provides reliable data that can help save treatment costs. As CTA is becoming less invasive due to reduced radiation and contrast agent dose, low tube voltage and new technologies the technique's popularity among physicians is increasing. In view of these facts, could CTA become a screening tool for disease prevention? Radiologist Professor Uwe Joseph Schöpf, specialist in cardiology and paediatrics and Director of the Division of Cardiovascular Imaging at the Medical University of South Carolina in Charleston, is carefully optimistic: 'At least we are now in a position to collect sufficient and meaningful data on this issue.'

Selective procedure

A CTA frequently shows that an alleged high-risk patient is not at such a high risk after all – a fact that has obvious implications for treatment costs. For example, a patient with a high lipid level undergoes a CTA but the scan shows no arteriosclerosis whatsoever. Imaging thus indicates that a long-term therapy to rigorously decrease lipid levels might not be necessary. In short: Imaging shows which patients really



Austrian-born Professor Uwe Joseph Schöpf studied medicine at Ludwig Maximilian University in Munich, Germany, where he then became a resident at the diagnostic radiology unit at Klinikum Grosshadern. His cardiothoracic imaging interests led him across the Atlantic to Brigham & Women's Hospital, Harvard Medical School in Boston. Today he is professor of radiology, cardiology and paediatrics and Director of the Cardiovascular Imaging Division at South Carolina Medical University in Charleston, SC, and a renowned expert in CT and MRI diagnostics. His national and international medical societies' awards and honours are numerous, and Medical Imaging Magazine has twice ranked him among the 'Top Ten Cardiovascular Imagers in the Nation'.

Alpha and omega: low tube voltage

Radiation dose depends on tube voltage and obviously patient physique. 'With normally built patients we perform a prospectively triggered exam at 100 kV, which means a radiation exposure of 1 mSv and less,' the expert explains. The adjustment of tube voltage to the individual patient is an important and very simple tool to reduce exposure effectively. Tube voltage also affects the signal transfer of the contrast agent: the lower the voltage the stronger the signal and lower the necessary contrast dose. Professor Schöpf: 'Today, a complete CTA at 80 kV can be performed with 30 ml of contrast agent.'

Increasing new technologies

In recent years the discussion – initiated primarily by US physicians – focused on dose reduction. Today, many technological innovations aim to reduce voltages, independent of patient physique. 'Now there are even programmes that determine the optimal tube voltage automatically for each patient. This makes the standard protocol of 120 kV, which is very popular in the US, obsolete,' Prof. Schöpf adds. Another factor that previously limited voltage reduction was the actual capacity of X-ray tubes. The systems could develop sufficient current to scan a patient at low voltage only if the patient was very lean. 'This is another technological problem that has been solved: Now we can use low tube voltage across the board.'

Imaging for preventive screening?

He believes that more patients can benefit from this technology due to three major factors – low tube voltage as the precondition for reduced radiation dose and reduced contrast dose – which continuously reduce CTA invasiveness. 'In view of these innovations we should seriously consider CTA as preventive screening procedure,' the expert suggests. Whether in the end cardiac CT will really be a suitable procedure to risk stratify patients and to determine medication remains to be seen – currently the available data do not allow a final conclusion. Since there are low invasive techniques and procedures, Prof. Schöpf sums up: 'It's our task to do further research on cardio CT and to provide meaningful data to assess the suitability of the procedure.'

vides reliable and precise diagnostic information. A major advantage: Heart rate does not affect this procedure; 80 to 110 bpm are no problem and do not result in artefacts as long as the heart rate is not too irregular. 'It is important to trigger during systole, not diastole – a fact not every CT operator is aware of,' Prof. Schöpf points out. Contrast agents are applied when stenoses need to be detected or when arteriosclerotic changes, including unspecified coronary plaque, need to be visualised comprehensively. High-speed CT allows further dose reduction – currently, however, this new technology is limited to patients with a suitable heart rate.

“With technological developments significantly reducing invasiveness of cardiac CT, it is very likely that the procedure will be used for early detection of coronary heart disease.”

do need therapy and prevention. 'This is an important contribution to cost efficiency – made by an imaging procedure. Quite a surprise in view of the fact that imaging is often considered expensive and a prime candidate for cost reduction initiatives,' the cardiologist points out.

Prospective triggering supports dose reduction

High risk or not, and is there a stenosis in the coronary arteries and if so, how severe is it? These are important questions for cardiac patients – 80 to 90 percent of whom can be examined using a prospectively triggered CTA protocol (approx. 1 to 3 mSv), which pro-

CT developments excel those for



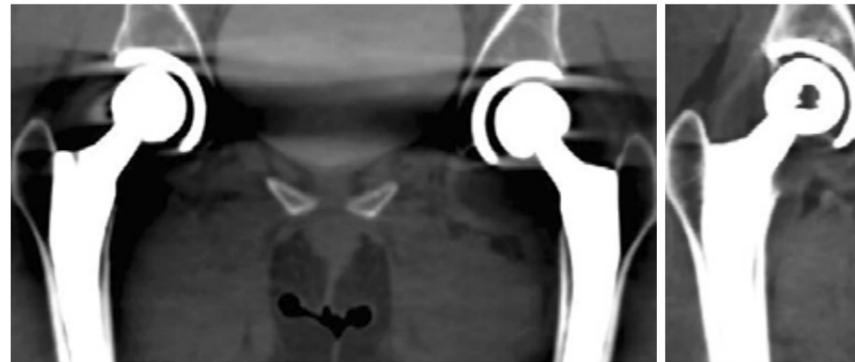
Alain Blum, organiser of the French CT Symposium, which recently took place in Nancy

For the sixth time, Alain Blum MD has invited the French CT community to Nancy to attend a symposium on multi-detector CT. The last invitations, two years back, drew several hundred radiologists and every CT manufacturer to Nancy for two days of debate, discussion and demonstrations. 'There have been leaps in technology and developments that are shaking up clinical practice,' explained Dr Blum, head of the radiology department at the University Hospital Centre in Nancy. 'Every year we hear that CT is finished when, in fact, manufacturers continue to make enormous investments in research and each year has

seen new developments far more significant than we have seen for MRI. Besides, this is also a personal thing – inviting people I like a lot.'

A third reason for organising the symposium, he told *European Hospital*, is that 'Everyone in France is a bit depressed about the financial crisis that has impacted on the possibility for hospitals to acquire scanners. I think it becomes important to have a more optimistic discussion, telling colleagues we need to move forward, that we must not fall into a psychological morass, that technical developments are beneficial to everyone – the patient, radiologists, healthcare institutions,' he explained. 'We see, in some recent purchases, that people are ordering low-cost scanners to spend the least amount possible without taking into account that this will affect diagnostic quality and, after all, we need to maintain a sufficient level of quality.'

Images of a 27-year-old female with double hip implants. At left (1), an image acquired at 1.2 millisievert and processed using iterative reconstruction. At right (2) an acquisition at 1.2 mSv using advanced adaptive iterative dose reduction with metal artefact reduction sequence



Foreseeing the of CT systems

Lower radiation dose and improved workflow in advanced systems will increase uptake up to 2019

Reporting on the CT market up to 2019, GBI Research predicts that lower radiation dose, greater patient comfort and improved workflow in advanced systems will raise implementation rates for computed tomography.

The report presents key trends affecting three systems segments: high-, mid- and low-slice computed tomography systems, and analyses the 'market dynamics', all based

on data sourced from proprietary databases, primary and secondary research and in-house analysis by the firm's industry experts.

With a focus on key geographies – the USA, Canada, United Kingdom, Germany, France, Italy, Spain, Japan, China, India, Australia and Brazil – the company share data for 2012 is quoted as \$3.8 billion and annual market revenue data is forecast to become \$5.9 billion by 2019, at



Although some clinicians say computed tomography is dead...

ents far or MRI

Endorsed by the French Society of Radiology, this year's symposium was jointly organised by Dr Blum and Marc Zins MD, who leads the radiology group at Saint Joseph Hospital in Paris.

Innovations affecting diagnostic strategies and practice will be a focus for discussions with presentations on dual-energy image acquisition, spectral imaging, perfusion, iterative reconstruction and metal artefact reduction (MAR). Additionally, back end operation for image processing, structured reporting, or archiving and storage will be highlighted.

Managing radiation and dose will fill a whole session, as 2014 sees hospitals across France deploying new software for tracking and monitoring patient and staff exposure.

In Manufacturer's Corner every CT-scan vendor will present products and the symposium will close with its signature final session featuring a face-off of consoles in a real-time demonstration.

In charge of departments for musculoskeletal, emergency and neck radiology, it is not surprising that Dr Blum singles out advances in MAR as among symposium high-

lights. 'Today all manufacturers offer with different levels of effectiveness a reduction in metal artefacts,' he said. 'This completely changes orthopaedic imaging. Up to this point we have been troubled with all the metal hardware, and now it is no longer a real obstacle. For example, with hip implants standard radiology shows the prosthesis and bones while the scanner can now show the implant, and show the bones, cement and affected soft tissue better. This becomes important taking into account that

patients with pain associated with a prosthesis sometimes present with articular and peri-articular pseudotumours linked to a reaction that can be inflammatory or allergic.'

In other practice areas, the increasingly rapid speed of scanners has created new opportunities, notably for cardiac investigations, he added. This has come alongside reductions in radiation dose, and today effectively all CT exams are performed at lower dose. 'Thanks to algorithms for iterative reconstruction, there have been great advanc-

es, and we will see this go even further with coming improvements,' he said. 'We've seen improvements in post-processing of image that's much faster and efficient, which improves workflow.'

'We can also do thoracic scans at very low dose, which is why I invited two specialist to debate this around the question 'Can We Leave Behind Thoracic Radiography?' In other words, with a dose equivalent to traditional chest X-rays, can we do better with a scanner?'

'In my opinion, we will see a

migration from standard radiology to the CT scanner,' he predicts. Today we do a lot of traditional chest X-rays because there is a good spatial resolution and it's performed at a low dose; but a segmented scan is much more effective and, if today we can perform a scanner exam at the same dose as a chest X-ray, and can improve the workflow, then I believe we will progressively see a shift to thoracic CT and, perhaps in the near future, there will not be as many chest X-rays.'



e future

a Compound Annual Growth Rate (CAGR) of 7%.

The new report states that just four companies – GE Healthcare, Siemens Healthcare, Toshiba Medical Systems Corporation and Philips Healthcare – accounted for more than 75% of the CT market in 2012, with a market share of 22.5%, 22.1%, 17.9% and 13%, respectively.

To further increase revenue, these top firms are also establishing manufacturing facilities in developing countries such as India and China. 'Companies such as Siemens Healthcare and GE Healthcare have set up manufacturing facilities not only to meet domestic demand, but also to export CT equipment to developed countries,' explained Rashmi Nishtala, GBI Research's Analyst covering Medical Devices. 'This move is expected to significantly reduce the operating costs of these firms, which will have a cascading effect on improving profit margins.'

* The industry report 'Computed Tomography Systems Market to 2019' is available at <http://www.gbiresearch.com>



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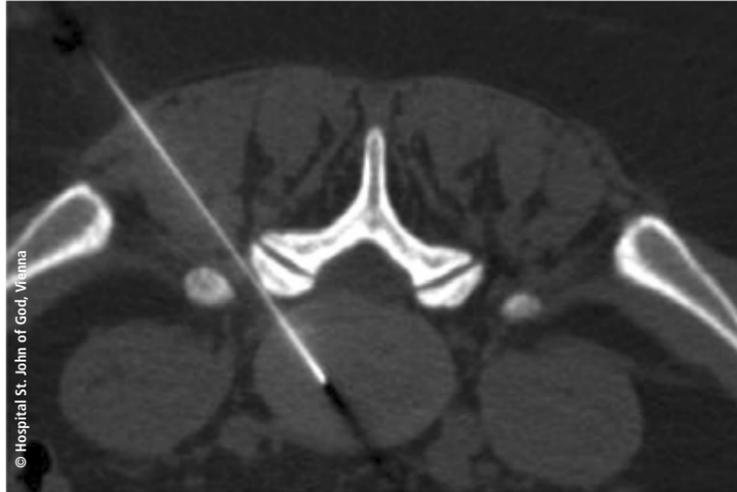
Report: Michael Krassnitzer

'No large incision, no scalpel and no sutures: Radiologically guided, minimally invasive procedures can help many patients with chronic pain when conservative procedures don't work,' said Professor Siegfried Thurnher, head of the Department of Radiology and Nuclear Medicine at Vienna's Hospital of St. John of God. The main focal area is the spine. 'Interventional radiology can precisely access the area where the pain originates and can, for example, administer ozone to the



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A Zurich University Hospital medical graduate, and from 1991-2001 an employee at Vienna's Medical University and the city's General Hospital, and then Deputy Head of Interventional Radiology at the University Clinic for Radiodiagnostics, since 2002 Professor Siegfried Thurnher, EBIR, has led the Radiology and Nuclear Medicine Department at St. John of God Hospital in Vienna. The professor is an internationally sought after lecturer, having delivered around 200 at scientific congresses. He has also been a Live-Case Surgeon as well as moderator of numerous workshops



Angiography: ozone injection in the intervertebral disc

intervertebral discs or inject bone cement into the vertebrae to repair fractures, or fix metal or plastic sleeves in the dorsal area of the spine.'

Interventional Radiological Olbert Symposium (IROS)

At the recent congress of the German, Austrian and Swiss (DeGIR, ÖGIR, SSCVIR) Associations for Interventional Radiology (IROS 2014) held in Salzburg this January, various sessions focused on pain therapy.

Florian Streitparth MD, from the Radiology Institute at the University Clinic Charité in Berlin, Germany, spoke on the treatment of pain caused by herniated discs and disc degeneration with so-called intradiscal procedures. The basic principle: Removal and cauterisation of the discal tissue to reduce pressure and relieve painful nerve compression.

Most important intradiscal procedures:

- Percutaneous laser-disc compression (PLDD): The nucleus of a herniated disc is shrunk using a laser beam
- Intradiscal Electrothermal Therapy (IDET): An electrothermal probe is guided into the disc and heated to 700 Celsius
- Automated percutaneous lumbar discectomy (APLD): The disc nucleus is extracted via aspiration.
- Percutaneous laser discectomy: Water in the disc nucleus is evaporated by laser, which reaches temperatures of up to 6000 Celsius.
- Chemonucleolysis: The disc nucleus is liquefied with the help of an enzyme (chymopain) and then aspirated.

Some of these procedures must still be considered as experimental, the radiologist explains. Initially the entire range of conservative procedures, i.e. medicinal treatment as well as physiotherapy, heat therapy and electrotherapy should be exhausted before one of these new procedures is used, Dr Streitparth emphasised, concluding: 'At the moment, the evidence of success for these intradiscal procedures is not yet that promising. However, with good patient selection the procedures will become a good option.'

The intradiscal procedures must be on a par with well-established and very effective therapies. There is much evidence regarding the effectiveness of medicinal therapy, he points out. There is also periradicular therapy (PRT), i.e. percutaneous infiltration of the nerve roots with pain medication and similar procedures.

'PRT and other, similar procedures are of low impact and strain and effective at reducing pain in around two thirds of patients,' explained Dr Bernhard Oder, Head of the Department of Nuclear Medicine at the Vienna's Hospital St. John of God. In Austria, crystalline corticosteroids are also being used for treatment, he added. However, in Germany crystalline corticosteroids have not been licensed for infiltrations to the spine. German radiologists are therefore hoping for support from their Austrian colleagues to back up their argument. Dr Oder can refer to a study carried out at his hospital involving 700 patients who suffered no retrospective complications after percutaneous infiltration with crystalline corticosteroids. ■



MUSICA highlights in imaging

Revealing all: adult, child or infant, slim to obese

MUSICA software introduced automated, exam-independent digital image processing using contrast enhancement founded on multi-scale mathematics. Now, Agfa HealthCare has added Fractional Multiscale Processing (FMP), to create a new generation of MUSICA that will be available soon for all of the firm's CR and DR systems.

Although the new improved version, developed with input from specialists such as paediatricians and thoracic experts in regional and international university hospitals, is much advanced, Agfa HealthCare's senior researcher Pieter Vuylsteke PhD points out that the software still provides all past benefits but now also meets the evolving imaging needs of the healthcare sector.

'MUSICA is fully automatic, very easy to use and install, and gets maximum information from a clinical image, independent of the patient's body size (adult, child or infant; slim up to obese) or of the exam type,' Jan Leeuws, Business Unit Manager of Digital Radiography added. 'There is no need to configure the image processing parameters for each exam, and the technologist doesn't need to apply specific settings for each exam type and exposure technique. That hasn't changed.'

Fractional Multiscale Processing

Nor has Agfa HealthCare's MultiScale Image Contrast Amplification (MUSICA) mathematical principle. Developed in the 1990s, this has proved to be the most successful image processing technology for digital X-rays, the company confirms. 'One of our key design goals was to let the users obtain consistently high image quality across all exams and all patients at all hospitals, while applying a minimal radiation dose.'

Some fundamental changes have been made to the system's sub-

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Sharper trabecular, carpal and cortical bone. Balanced presentation of soft tissue and all bone structures

being enhanced and represented in a very consistent way. The new software is also reported to be easier to install.

Subtle bone details easily visible

With its larger dynamic range, the new software offers enhanced image detail and visualisation consistency, particularly for images with large variations in signal strength. Image processing is robust and the image is always optimal, independ-

ent of the exposure technique, Agfa HealthCare reports. 'Subtle bone details often tend to fade in the vicinity of implant edges, but these details are now well preserved and easily visible,' added Dr Vuylsteke. 'I compare it to being able to hear a pianissimo passage after an explosion.'

In skeletal imaging, for example, no artificial shadows show up next to long bones or metal implants, making subtle details of the interfaces more visible. Trabecular structure is presented with improved sharpness, and there is appropriate transparency in overlapping structures, e.g. carpal bones. In chest

X-rays, details from the bones, the mediastinum and lower lung area behind the diaphragm are revealed with better clarity, without impairing lung visualisation. All of which, Jan Leeuws notes, provides radiologists with more image details to aid diagnoses in less time.

'When we showed the [contributing] radiologists the new version of MUSICA, many got used to the new image presentation very quickly!' says Piet Vuylsteke.

'Once you appreciate that level of detail,' they said, 'there's no going back.'



Better visualization of subtle details in the abdomen

ts the high imaging

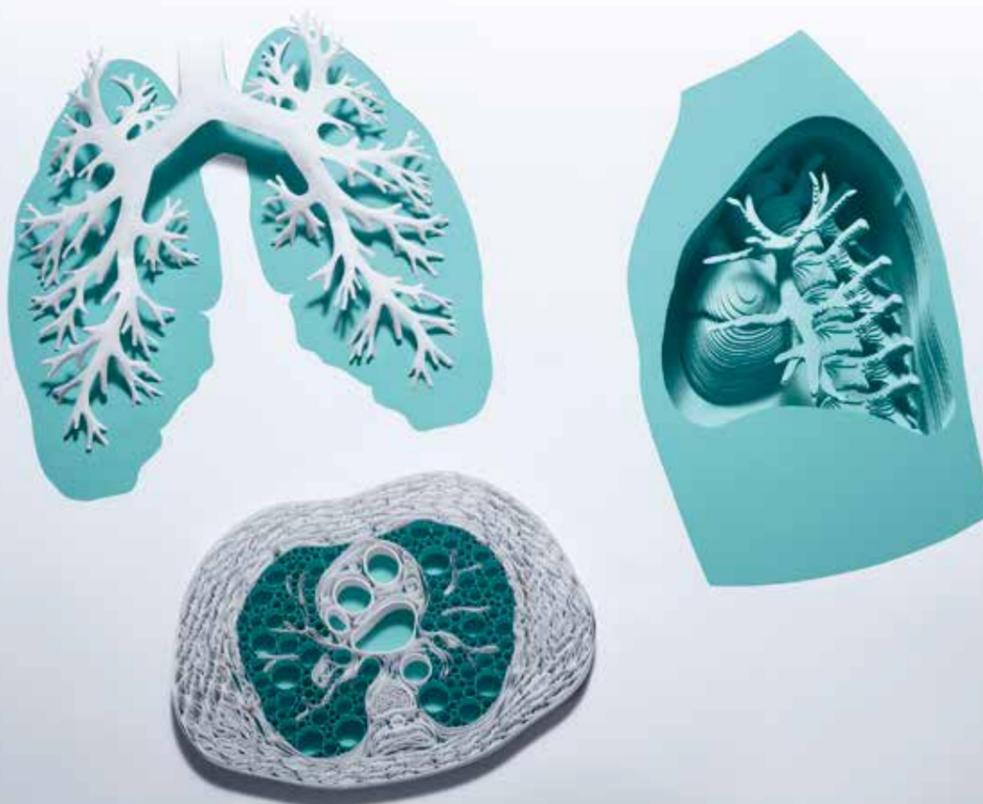
obese

structure. 'To nicely render the most difficult zones of an image, such as the abrupt transitions from low to high density areas, we have applied a new mathematical algorithm - called Fractional Multiscale Processing (FMP),' Dr Vuylsteke continued. 'With this algorithm, the image processing filters are further decomposed to elementary fractions, which are processed separately. As a result, we can represent the greyscale differences in a more natural way, without artefacts.'

FMP also eliminates the need for window level adjustment to enhance visibility of details. Several additional improvements have been made in the mechanisms that adapt the contrast, noise and greyscale of the images. In general, the images are more homogeneous and pleasant to look at for the radiologist, as well as



Pieter Paul Vuylsteke MSc PhD, who graduated in electronics engineering at Leuven's Catholic University, is Agfa Healthcare's senior scientist and expert in medical image processing, currently leading an R&D team of six experts in this field. He is the principal developer of the Musica image contrast enhancement software for digital radiography and inventor of the underlying concept of multi-scale contrast enhancement. Dr Vuylsteke has also filed 40 patents relating to medical image processing. In 1994 he received the Otto Bayer Medal for honouring scientific research achievements.



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PET/CT-specific radiopharmaceuticals for diagnosis and therapy

The multiple benefits of PET/CT are undisputed – one being the fact that radiopharmaceuticals, which are used at pico and nano levels – are not toxic. Newly developed radiopharmaceuticals are highly specific and thus allow precise molecular characterisation of the tumour in question. Today, however, not only pharmaceutical companies but also academic research institutions produce these powerful substances. Ludwig Maximilian University (LMU) in Munich has operated its own radiopharmaceutical production lab since August 2013.

Professor Dr Peter Alexander Bartenstein, Director of the LMU Clinic and Polyclinic for Nuclear Medicine, explains the medical and healthcare policy aspects of this development, first pointing out that the organisation produces about a third of the substance for its own

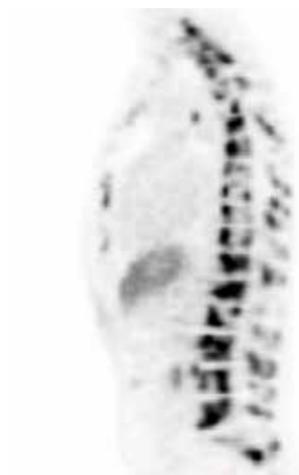
PET/CT study using Ga-68-PSMA in a patient with metastasised prostate carcinoma



clinical purposes. These homemade tracers are extremely important, he adds, because they 'enable us to perform very specific diagnostic procedures that are tailored to the relevant tumour.'

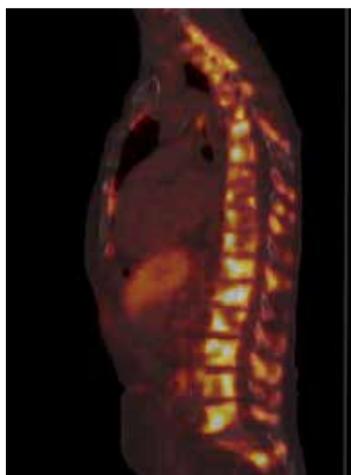
A twofold benefit

Neuroendocrine tumours (NETs) are diagnosed using a substance called DOTATATE, which attaches to somatostatin receptors – expressed by those tumours and thus identifying them. Even more: combined with radionuclides such as Lu-177 or Y-90 the radiopharmaceutical is introduced intravenously and travels through the entire body, allowing precise radiation – i.e. treatment – of the tumour. This is already clinical routine, the professor explains. In 85% of cases considered beyond therapy, this form of radiation may at least stabilise tumour growth. However, with an incidence of about 2.5 per 100,000 people, neuroendocrine tumours are rather rare.



Prostate carcinoma – first successes, but lots to be done

'If we could transfer this principle of combining diagnosis and therapy to treat other, more frequent tumour types, prostate carcinoma, for example, that would be major medical progress that would benefit many, many patients,' Prof. Bartenstein hopes. To diagnose prostate cancer, oncologists today use a substance developed in Heidelberg. This attaches to the prostate-specific membrane antigen (PSMA). If the radiopharmaceutical triggers a signal in the lymph nodes, metastases of a prostate carcinoma are confirmed because PSMA is over-expressed in prostate cancer. 'As far as diagnosis is concerned, this is pretty good news; but we have to work on the corresponding therapy,' he concedes. One of the major challenges is high radiation exposure of the kidneys – which needs further research.



Targeted therapy

The advantage of advanced radiopharmaceuticals is clear: Diagnosis is highly specific, a precondition for a targeted therapy tailored to an individual patient. With prostate cancer, for example, the diagnosis goes far beyond confirming enlarged lymph nodes: The antigen/radiopharmaceutical couple identifies the metastases of the prostate cancer cells. Based on the individual patient's situation surgery is scheduled, or a personal radiation plan can be designed.

No widespread service

Pharmaceutical companies are known to focus their research on frequent – and thus profitable – indications, such as Alzheimer's, to recover enormous costs incurred during the lengthy development and approval procedure for a new drug. However, neuroendocrine tumours are so rare that pharmaceutical firms shy away from any major investments. 'We are closing this gap by developing substances to treat rare congenital diseases,' Prof. Bartenstein explains. 'It goes without saying that we do apply the same high level of safety standards as any pharmaceutical company.'

However, not every clinic though has the resources to operate a production lab for radiopharmaceuticals and, since the substances are cannot be marketed, there is a very real danger of a two-tiered healthcare system. 'Patients who live far away from large research hospitals benefit less from such medical progress,' the professor points out. Despite the much-discussed patient mobility, the reality cannot



Professor Peter A Bartenstein has directed the Clinic and Polyclinic for Nuclear Medicine at Ludwig Maximilian University in Munich since 2006. Following his medical studies and specialist training in nuclear medicine at Münster University, Deutsche Forschungsgemeinschaft (DFG) awarded him a research fellowship with the PET group at Hammersmith Hospital in London. From 1994-99, as senior resident at TU Munich, he led the institution's entire in-vivo diagnostics and the Neurology working group at the PET Centre. He then headed the Nuclear Medicine Department at Johannes Gutenberg University in Mainz before his return to Bavaria. He is Board Member of the German Society of Nuclear Medicine (DGN) and a member of the steering committee of the Biotech Cluster 'm4' of the German Federal Ministry of Education and Research (BMBF).

be denied: The further the geographical distance between a patient and state-of-the-art clinical services, the lower the likelihood that those services will be available for that patient. 'This is a healthcare policy issue,' Prof. Bartenstein says, 'since it was a political decision to tighten pharmaceutical laws that helped to bring about this situation in the first place.'

Offering radiology a growing role in drug development

Validating imaging biomarkers

Report: Mark Nicholls

New imaging biomarkers are helping radiology to play a greater role in new drug developments.

With projects underway to validate imaging biomarkers and make them as trusted as pathology, John Waterton, Professor of Translational Imaging at the University of Manchester in England, believes they are set to be increasingly important tools in the development of new targeted cancer therapies. He will outline their rising role in the session 'Imaging biomarkers in cancer drug development' on 7th March at ECR 2014.

Ahead of the session Prof. Waterton, who is also Chief Scientist (Personalised Healthcare & Biomarkers) for AstraZeneca, outlined how image measurement can be impacted on by factors such as variations between manufacturers' equipment or how each radiologist makes measurements, resulting in reluctance among drug developers to adopt quantitative outputs from radiologists without any form of standardisation. Although many imaging biomarkers have been pub-

lished in cancer research, few are sufficiently robust, routine and well-characterised to be used as routine tools in clinical cancer research. The professor also acknowledged that the qualification and technical validation of imaging biomarkers poses unique challenges not encountered when validating conventional biomarkers measured in vitro with diagnostic devices.

Professor Waterton is a key figure in the Innovative Medicines Initiative (IMI), a €5 billion Joint Undertaking between the EU and European Federation of Pharmaceutical Industries and Associations, which have initiated projects in drug safety, drug efficacy, knowledge management and training, including

developing imaging biomarkers for a role in drug development.

The professor's main project – QuIC-ConCePT, Quantitative Imaging in Cancer: Connecting Cellular Processes with Therapy – is an IMI-funded project designed to qualify imaging biomarkers of tumour cell proliferation, apoptosis and necrosis, and is aimed at trying to standardise and understand imaging biomarkers, particularly FLT-measurement using PET and ADC from diffusion-weighted MRI.

Difficult work on new drugs

'At ECR I will be discussing problems of validating imaging biomarkers in general,' he said. 'There are already two pharmacodynamic

imaging biomarkers that are trusted and highly-interpretable – FDG-PET and DCE-MRI Ktrans. Our aim is to double that number to four.'

Evaluating a new drug in a comprehensive range of cancers at different doses, schedules and combinations, is a difficult challenge. The aim is to use the pharmacodynamic imaging biomarkers to offer a rapid readout to help drug developers decide whether or not to continue work on an investigational drug.

Professor Waterton hopes imaging biomarkers will make drug development more cost-effective, but stresses that will only be so if the outcome of the decision-making biomarker is believed. How, he asked, can you be sure that 'no change in imaging biomarker' really means 'drug is not working'?

He hopes ECR delegates will begin to understand the importance of standardisation of imaging biomarkers across different scanners and different hospitals, as well as the need for biological validation to mitigate the risk of false negatives. 'The ultimate benefit for patients is that we bring targeted anti-cancer drugs to the right segment

of the patient population earlier. Radiologic imaging offers some real opportunities there because unlike pathology we can measure every part of every lesion in almost every anatomic location.

'Obviously we need to do this cost effectively, otherwise the drug price would be so high that nobody could afford it,' he added.

Professor Waterton acknowledged that molecular pathology has been hugely successful in personalised care and cancer drug development over the last decade and, although traditional radiologic structural imaging remains a mainstay to assess objective response or progression-free survival, he noted that the success of pathology has 'eclipsed' pharmacodynamic imaging to a degree during that period. 'One of the reasons for that is that our measurements – the imaging biomarkers – can be difficult to interpret. What this talk will cover is how we can build radiologic imaging biomarkers that are trusted tools for drug developers so radiologists can play an even bigger part in cancer drug development alongside the pathologists.'

ECR DIARY DATE:

4 pm. 7th March. Room I/K.

The session 'Imaging biomarkers in cancer drug development' will include a discussion of functional imaging and quantitative nuclear medicine in drug development, and examine which new imaging biomarkers are on the horizon in drug development

Setting new clinical values in X-ray imaging

Shimadzu, specialist in diagnostic imaging equipment, is presenting its latest technologies and clinical application solutions at ECR 2014. Among these is the Opescope Acteno, a surgical C-arm system that merges high image quality with ease of use, the company reports.

For use in operating theatres and emergency rooms, the C-arm is fully counter-balanced and provides extra-light movements and positioning, Shimadzu explains, adding: 'The exclusive manual vertical C-arm movements enable much quicker height adjustments in routine operations.'

Other devices on display will include: The Trinias angiography series – multipurpose systems for cardiovascular and angiographic procedures equipped with a 30 x 30 cm FPD supporting a wide range of vascular interventions from head-to-toe, or with a 20 x 20 cm FPD supporting specialist cardiovascular interventions, the firm explains. 'Innovative designs applying the *Score, Smart and Smile* philosophy set Shimadzu apart.'

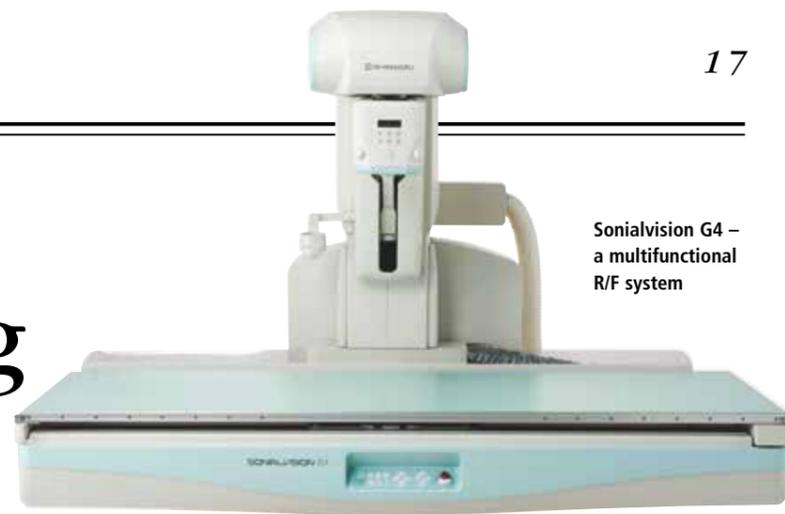
Sonialvision G4 multifunctional R/F system

'The new Sonialvision G4 is a high-performance R/F table providing numerous best-in-class features significantly improving functionality and operability,' the manufacturer reports. 'Sonialvision G4 covers the widest possible range of examinations, including tomosynthesis for general radiographic imaging and

slot scanning. It is equipped with the largest available FPD at 43 x 43 cm and Shimadzu's next generation digital imaging platform. The SUREngine technology contributes to creating excellent image quality and enables the natural enhancement of the entire image for clearer revelation of all examination areas, including small, faint targets.'

Evolving technology with high flexibility

'MobileDaRt Evolution's highly developed functions improve the clinical workflow in mobile DR. Different FPDs with fields of view of 43 x 43 cm, 35 x 43 cm, and 27 x 35 cm are available. The choice of different detectors allows very high



Sonialvision G4 – a multifunctional R/F system

flexibility,' the firm explains, 'like running two different detectors to enhance the range of applications, retrofitting the analogue MobileArt series, or even sharing the detec-

tors with compatible digital X-ray rooms.'

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Professor John Waterton is AstraZeneca's Chief Scientist for Personalised Healthcare & Biomarkers and Professor of Translational Imaging in the Manchester Academic Health Sciences Centre, University of Manchester. He gained his first degree and PhD at the University of Cambridge and, following postdoctoral work in Vancouver and Oxford, in 1980 he joined AstraZeneca (then ICI), where he established the first in vivo magnetic resonance lab outside academia. Over the past 35 years he has deployed MRI and other imaging technologies to support drug discovery. He has a particular interest in the evaluation of imaging biomarkers and their translation into validated tools for decision-making in clinical research and ultimately in patient care.



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Optimised breast cancer diagnosis at any time

Positron emission mammography (PEM) improves breast cancer management

US-American researchers have shown that positron emission tomography (PET), a tried procedure, is a helpful modality to detect breast cancer. Dr Frank Müller and his team of radiologists and nuclear medicine specialists in Ludwigshafen, Germany, are the first office-based physicians in Europe to use positron emission mammography (PEM) successfully.

The medical and psychosocial aspects of breast cancer detection have long been a major focus of Frank Müller's work as he particularly aims to offer a definite diagnosis quickly and transparently in order to spare his patients superfluous examinations and therapies.

The better of two imaging worlds

PEM is a highly innovative specialist application of PET to visualise tiny breast tissue changes. The technique is based on the same principles as its 'big sister' PET: it analyses increased glucose metabolism in the cancer cells via an injected radiotracer – usually FDG, an analogue of glucose incorporating F18, which has a very short half-life.

A special detector head identifies FDG uptake and the data are converted into high-resolution images of the breast tissue. The examination procedure itself is very similar to conventional mammography: the breasts are individually placed between two plates and compressed but, while in a conventional mammography a pressure of about 20 kg is applied, PEM requires only 7 kg.

Benefits in early detection, therapy planning, monitoring and follow-up

'PEM can detect tumours of a mere 1.6 mm – about the width of a rice grain,' Dr Müller explains. 'The most

important advantage: at this early stage breast-conserving surgery is still possible. Moreover, all suspicious lesions in the breast and the axilla can be identified in one session and surgery can be planned precisely, which means that superfluous interventions can be avoided.

'If a biopsy is needed to histologically confirm a preliminary diagnosis, it can be performed right during PEM with a device attached to the imaging system. The tissue sample is immediately tested and the radiologist checks whether the sample is sufficient or whether further biopsies are required.'

The more tissue samples are analysed, the more precise the histological results. PEM offers a further major advantage: therapy response



Dr Frank H H Müller studied medicine at Free University Berlin. As research associate at the Institute of Human Anatomy, his dissertation focused on glucose metabolism. During specialist training in imaging diagnostics and nuclear medicine at Charité, Berlin, in 1996 he became involved in establishing its first PET service. From 2001 he led the organisation of a nuclear medicine and PET centre at Auguste-Viktoria-Krankenhaus in Berlin-Schöneberg. Dr Müller has been an office-based radiology specialist in Ludwigshafen, Germany, since 2003 and, from 2011, chairman of chairman of PET e.V.

Observed PEM advantages:

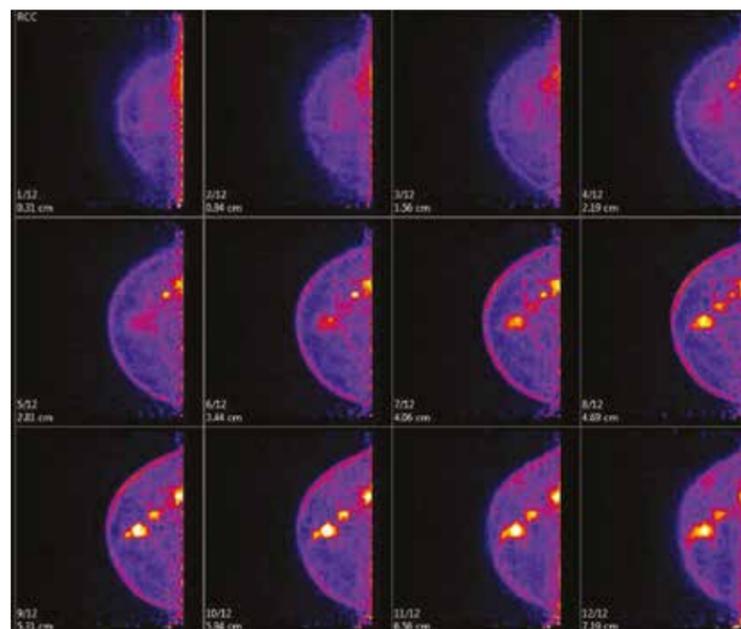
- Unambiguous and fast diagnosis. Suspicious lesions can be biopsied and evaluated quickly and reliably
- Dense breast tissue and menstruation cycles do not affect the quality of the procedure
- Patient-friendly examination in a sitting position, no tube, no claustrophobia
- Higher specificity than MRI, which means fewer unnecessary biopsies particularly in smaller lesions
- Increases options for breast-conserving surgery
- Chemotherapy response can be evaluated after two weeks.

can be evaluated reliably after only two weeks. While other modalities allow assessment of therapy response only after about three months, PEM can indicate a necessary change of therapy much earlier. 'Thus patients are spared ineffective therapies with their negative side effects and they are informed early about therapy successes. This strengthens motivation and confidence in the physician's work,' Dr Müller points out.

In addition, because its performance is not affected by scar tissue, PEM is well suited for follow-up and relapse detection.

High specificity and sensitivity

Müller's own research supports study results by US-American researchers: PEM detects breast tumours with a sensitivity and specificity of more than 90 percent. In a comparative study of PEM and breast MRI in 68 women with suspicious lesions Dr Müller found PEM to show a sensi-



PEM produces a 12-slice tomographic image display

Dr Frank Müller is convinced that PEM promises to fill a diagnostic gap



tivity of 100 percent and a specificity of 94 percent with tumours of 9 mm. He is convinced: 'PEM offers superior precision at high resolution compared to other modalities, such as mammography, breast ultrasound or breast MRI. It thus offers many advantages for the patient with suspected and confirmed breast cancers.'

ECR DIARY DATE

10 March 2014. Room F2
14:00-15:30 and 16:00-17:30
1. PEM, PET and novel MRI techniques
2. Emerging breast imaging technologies

Digital breast tomosynthesis

Overcoming the technical challenges

Report: Mark Nicholls

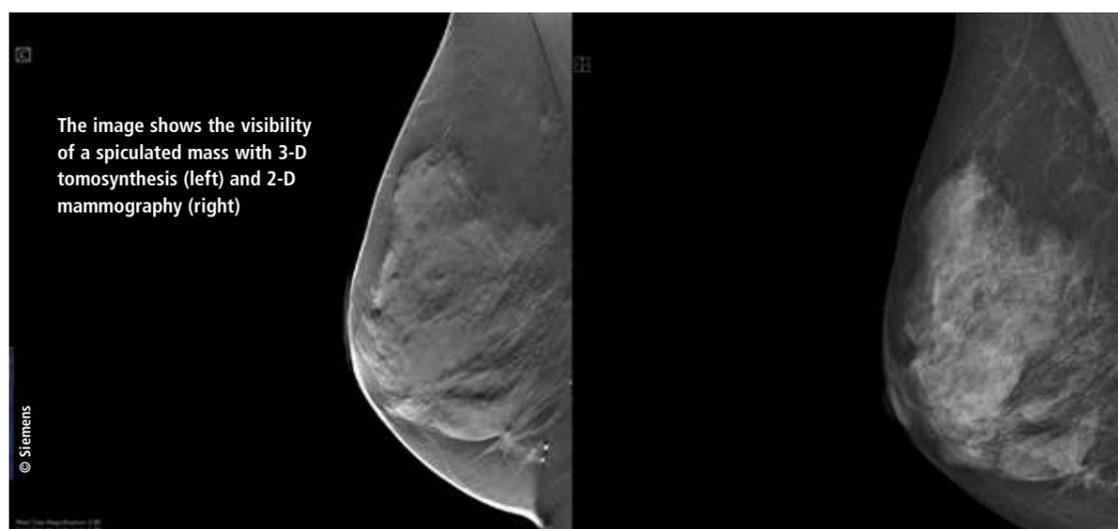
Digital breast tomosynthesis offers a number of benefits over other modalities but challenges remain in its optimum clinical application.

A major obstacle is reading time at digital breast tomosynthesis generates extensive image data sets.

That is the view of Dr Pontus Timberg, from Lund University in Sweden, who will outline a number of the technical challenges in using digital breast tomosynthesis (DBT) at a Satellite Symposium scheduled for ECR 2014 in Vienna on 6 March.

Dr Timberg, who has conducted extensive research in the area of digital breast tomosynthesis in recent years, will highlight some of the issues faced by radiologists involved in the implementation of DBT in a screening situation.

Speaking to *European Hospital* ahead of his ECR session – 'Technical optimisation of digital breast tomosynthesis for future breast screening' – Dr Timberg said: 'Technical optimisation generally aims to improve cancer diagnostics with DBT, but a



The image shows the visibility of a spiculated mass with 3-D tomosynthesis (left) and 2-D mammography (right)

major challenge is the reading time, which is one of the major obstacles when interpreting 3-D image volumes.' During the session he will present different approaches to reduce reading time and also cover limitations with current breast compressions. However, he points out that DBT does have advantages over other modalities. 'It has the ability to

reduce the effect of superimposed tissue, which limits 2-D mammography; digital breast tomosynthesis is also a relatively cheap technology that utilises similar technology as used in 2-D mammography,' he added.

Dr Timberg is hopeful that ECR delegates will take away a number of learning points from the session.

'There seem to be optimal conditions that are dependent on the type of lesion and diagnostic task,' he said. 'Delegates will hopefully consider methods to reduce reading time and viewing conditions in their own optimisation.'

However, there are clear advantages from DBT for patients in respect of improved lesion visibil-

ity, which ultimately leads to better cancer diagnosis. He is also optimistic that clinicians will see benefits in terms of reduced interpretation times and improved image quality.

The Satellite Symposium has been organised by Siemens Healthcare Digital and focuses on breast tomosynthesis and low dose mammography, looking at how innovations compliment clinical routine.

Along with Dr Timberg's contribution, the session will also look at digital breast tomosynthesis from an initial concept to clinical routine and high image quality with lower dose mammography, and will pose questions on whether DBT is the new standard in the diagnostic breast imaging and how to implement DBT as a method in specialist training.

ECR DIARY DATE

Thursday, 6 March,
Satellite Symposium session
14:00-15:30, Studio 2014, SY 5.

Company profile

Medicor Germany celebrates 21 successful years

Report: Daniela Zimmermann

Created by the Dutch industrialist family Hilekes, in 1993 Medicor expanded beyond the Benelux countries to enter the German-speaking world as Medicor Germany GmbH, selling contrast media injectors for CT, MRI and angiography. Winfried Backes and Heinz Gerhards, now the company's Managing Director, were there at the beginning, 21 years ago. 'We basically started with the purchase of a fax machine, a telephone and two company cars,' Heinz Gerhards recalls.

Initially, the new business was the exclusive representative of Liebel-Flarsheim (LF). However, a few

Hologic Selenia Mammography – main driver for Medicor's success



Hologic-Cup award ceremony on February 1, 2014: Alphonse Yombi, chairman of the German Cameroon-Help Organisation, handed over the trophy to the winning team of the Weimar FFC

years on, it lost the distribution and service rights due to the LF sale to Mallinckrodt and Covidien Medicor respectively. 'This was a sign for my colleague and I to take over the reins ourselves. With the main product from Lorad, now called Hologic, we began a new era at Medicor, which to this date continues to be characterised by a focus on diagnostic and interventional breast imaging.'

Perhaps it was a fortunate coincidence that mammo-

graphy screening was introduced in Germany at around the same time that Medicor realigned itself. This resulted in an increase in business of 25-35% per year, and the service and maintenance range also had to be significantly expanded. Medicor fully utilised this opportunity and now has the biggest service network in Europe's German-speaking areas, with more than 40 technicians based between the Baltic Sea to south of the Alps.

Thanks to this large network the medium-size company, based in Kerpen, North Rhine-Westphalia, is now an attractive business partner for firms wanting to enter the German market with service-intensive products.

Even Samsung, the giant Far-East player, trusts the competence of Medicor, by entering into a sales partnership with the firm two years ago. The range of services is round-

ed off with the bone densitometry programme from Hologic, goods from the microwave ablation devices manufacturer AMICA and products from a large, Chinese HIFU manufacturer, Chongqing Haifu Medical Technology Co., Ltd.

Medicor offers hardware as well as software: partnering Visus, Medicor was the first supplier and service provider to offer and sufficiently service the two information systems used for screening in Germany.

Heinz Gerhards attributes the company's current market leadership in breast diagnostics not least to this unique selling point. 'More than 55% of newly installed systems in Germany are from Medicor, followed, with a slight gap, by Siemens and then a large gap by all other providers. We have more than 350 digital mammography and tomosynthesis scanning systems on the market, along with just under



Heinz Gerhards, CEO of MMS Medicor Medical Supplies GmbH, Kerpen/Germany

100 analogue devices and the first positron emission mammography in Europe,' he explains.

This managing director is out to win. A passionate football trainer, in his spare time he trains the female A-Juniors of the VSP Grenzwacht Pannesheide e.V. team, aiming for their promotion to the German Football League. Heinz Gerhards' dedication to Medicor is just as whole-hearted and his enthusiasm does not stop at national borders. With the founding of Medicor Austria and Medicor Switzerland he launched two further, prospering companies hoping to repeat the success achieved by the German company by becoming the respective market leaders in breast diagnostics and X-ray and MRI-guided biopsies.

In his private life, apart from soccer coaching, he is on the board of the German Cameroon-Help Organisation, which aims to improve living conditions for people in Africa and the provision of cultural exchange. He repeatedly succeeds in combining his passions, such as with the first Hologic-Cup held at the beginning of February in Herzogenrath, or the sale of soft toy giraffes at the ECR in aid of Cameroon-Help.

Heinz Gerhards and Medicor, like many medium-size German companies, stand for a unique success story and laudable commitment.



anges



Dr Pontus Timberg works in Medical Radiation Physics at the Department of Clinical Sciences, Malmö and the Faculty of Medicine in Lund University, Sweden. He is a member of the Malmö Breast Tomosynthesis Group and has conducted several studies of digital breast tomosynthesis, including on the feasibility of using slabbing to reduce tomosynthesis review time and the visibility of single spiculations in digital breast tomosynthesis. Dr Timberg's work has also covered pressure distribution in mammography and compression of breasts with malignant tumour masses; visibility of micro-calcification clusters and masses in breast tomosynthesis image volumes and digital mammography.

Find out how radiology can improve communication with referring physicians. Scan the code or go to the report at sectra.com/report



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First results of the global Quantitative Imaging Biomarkers Alliance (QIBA) initiative

Liver fibrosis emerges as a breakthrough for elastography

Clinicians agree elastography is an essential functionality in ultrasound, though they are divided on how to use it

Report: John Brosky

'Elastography is in a position much like Doppler 20 years ago,' according to David Cosgrove, BMBCh, MA, FRCR, FRCP, Professor of Clinical Ultrasound at Imperial College School of Medicine in London. 'Back then Doppler was new and people were excited about it. They wouldn't buy a high-end machine without the capability. Yet they didn't quite know what they would do with it. That's now the situation with elastography.'

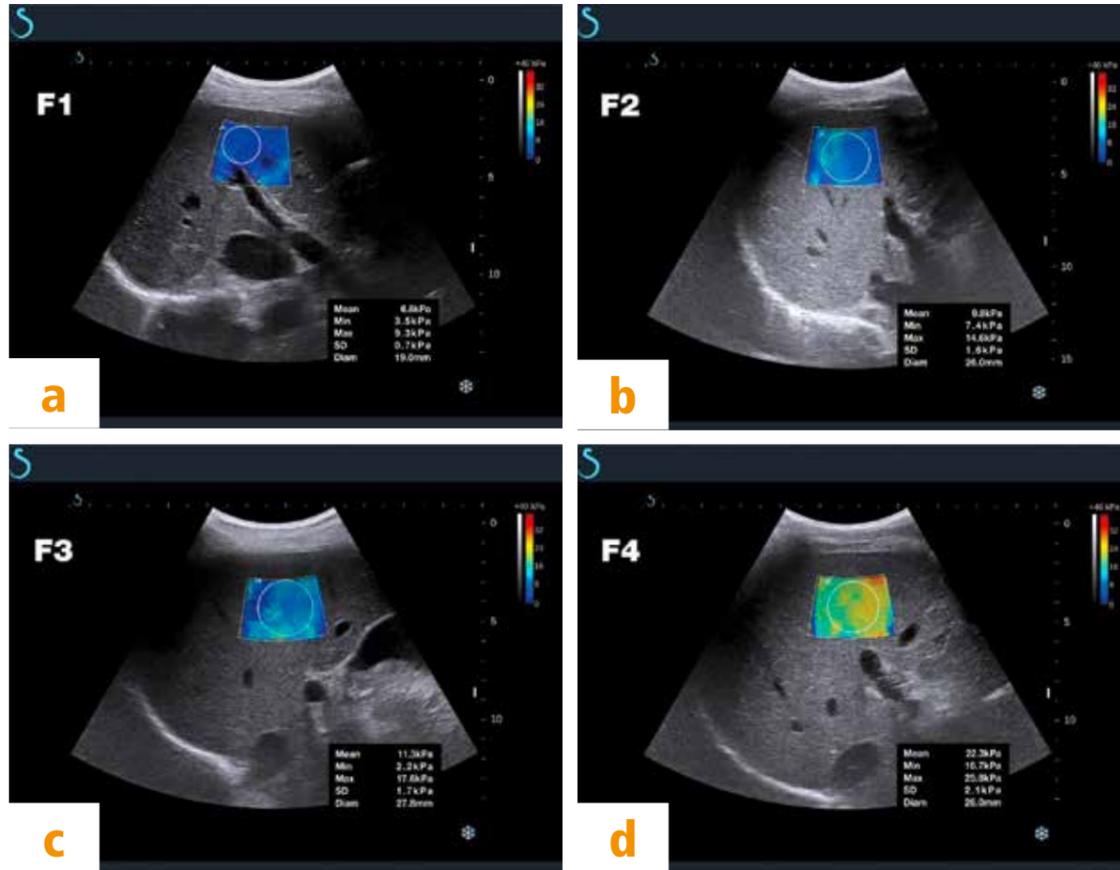
A renowned expert in ultrasound, Prof. Cosgrove has authored numerous publications and is a key contributor to the 'Guidelines and Recommendations on the Clinical Use of Ultrasound Elastography' from the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) that spells out the basic principles and technology as well as the clinical applications of ultrasound elastography. In a similar effort, he helped compile guidelines for the World Federation for Ultrasound in Medicine and Biology (WFUMB), with publication expected later this year.

'The guidelines have been effective in getting people launched in the right direction, suggesting where to put their efforts, as well as helping to know what has been found wanting,' he explained, adding that they also provide a good meta-analysis, with the writers of each section summarising the available literature and adding their own experience.

According to the professor, the reason for the uneven adoption of elastography is that the quality is extremely variable: 'There are so many technologies, some good, some very good, whilst in others the results seem random, in some cases regrettably rather poor.'

The turning point in the wide adoption of colour Doppler came with deep vein thrombosis (DVT) when it became clear that it was a much easier diagnostic technique and gave greater confidence. Once clinicians found it indispensable for this application, they were more assured in applying it elsewhere, Prof. Cosgrove pointed out.

He believes the breakthrough for greater adoption of elastography will come with investigations of liver fibrosis. 'Classifying this dis-



Four patients with hepatitis C and liver fibrosis in four different stages.

Metavir scores (F1 to F4) were obtained from liver biopsy.

Elasticity charts of each case were acquired with a single pulse.

a) Patient with F1 liver fibrosis and SWE values of approx. 6.8 kPa, standard deviation 0.7 kPa

b) Patient with F2 liver fibrosis and SWE values of 9.8 kPa, standard deviation 1.6 kPa

c) Patient with F3 liver fibrosis and SWE values of 11.3 kPa, standard deviation 1.7 kPa

d) Patient with F4 liver fibrosis and SWE values of approx. 22.3 kPa, standard deviation 2.1 kPa

ease is difficult,' he said. 'Biopsies are not nearly as easy as in the breast, and take just a tiny sample of a rather large organ, whereas elastography can sample much, much more. There are a lot of reasons why liver elastography is probably going to be the most important and widely used application.'

The United Kingdom's National Health Service Technology Adoption Centre (NTAC) found ultrasound elastography, using the shear-wave speed technique, 'enables a non-invasive, and therefore safer, diagnosis and subsequent monitoring of liver fibrosis when compared to the traditional gold standard procedure of liver biopsy.'

NTAC concluded: 'the findings suggest that for a cohort of 27,620 patients, the estimated number of patients diagnosed with liver disease in England and Wales, imple-

menting ultrasound elastography is predicted to save a total of £14 million, or £520 per patient'.

Benefits to patients included a low risk of complications for the non-invasive procedure, no pain, and an outpatient exam of 15 minutes against a hospital stay of up to three days for biopsy procedures.

'It is a small study with three centres, not as thorough as NICE (National Institute for Health and

Clinical Excellence) would have done, but it is quite a strong recommendation,' Prof. Cosgrove notes.

For the ultrasound component of the Quantitative Imaging Biomarkers Alliance (QIBA) project sponsored by the Radiological Society of North America (RSNA), the work group also narrowed its focus to liver fibrosis, and also selected the shear wave speed elastography technology.



David Cosgrove, Professor of Clinical Ultrasound, Imperial College School of Medicine, London

Ultrasound based platforms in this class include the Fibroscan from Echosens, the Siemens S2000, S3000, Philips iU22, and the Aixplorer from SuperSonic Imagine. All systems are capable of quantifying tissue stiffness, but only two produce an ultrasound image.

'Siemens' Acuson S3000 produces a still image on which you can take measurements, whereas SuperSonic's Imagine's shear wave elastography technology produces a real-time, moving image, which is a significant improvement and is probably the pre-eminent of the technologies,' the professor pointed out. The first results of the global QIBA initiative, presented at the RSNA congress in December 2013, showed very low inter-observer variation on phantoms, 'a reassuring result,' according to Prof. Cosgrove. Currently a study of so-called confounders, like inflammation and liver congestion, is underway with the Harvard Medical School at the Massachusetts General Hospital. A second generation of phantoms featuring a viscous component that simulates fat content, or steatosis, will now make the rounds of QIBA participating centres worldwide.

Prof. Cosgrove: 'The overall point is to establish an undisputable clinical application for elastography. Adoption will ripple out from that.'

Noted at Medica and th

The flexible 6-megapixel 30-inch LED backlit colour display

Recently launched, Totoku's new six megapixel colour display CCL650i2 has a 30-inch screen and brightness of 800cd/m², making it highly suitable for all diagnostic conventional X-ray applications, the manufacturer reports, adding that the model is equipped with a new LED backlight.

The successor of the CCFL technology is based on semiconductors and is known from a variety of consumer products. 'The benefits are both ecological as well as financial and qualitative nature,' said Marcel Herrmann, Totoku Medical's Marketing Manager for displays. 'Compared to CCFL monitors, LED displays save up to 20 percent of electricity and have a longer life span of about 30 percent - a positive effect on the user's budget. Furthermore, the CO₂ emission decreases due to reduced energy production. Specifically, those dis-

plays will use 15 percent less power than their predecessor.' He also mentioned environmental benefits because LEDs 'do not contain critical elements such as mercury'.

Additionally, the standby power consumption has been reduced by 80% due to a newly developed power supply.

The CCL650i2 also offers a newly developed flexible input concept, with a dual DVI and Dual DisplayPort Input. 'In this way users can decide to connect two signals from one workstation or to connect two workstations,' Totoku adds. 'With Display Port, all recent AMD or NVIDIA cards can be connected. For older Matrox MED or RAD cards the CCL650i2 support a 3MP simulation mode, this ensures full compatibility here [in Europe].'



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Innovation shows up and sharpens breast images

Three tiny grills deliver high contrast X-rays

Mammography scans with lower dose and higher contrast – that's the declared goal of Dr Nik Hauser, Medical Director of the Women's Clinic and Director of the Interdisciplinary Breast Centre at Kantonsspital Baden, Switzerland, and Professor Marco Stampanoni of Paul Scherrer Institute in Villigen, Switzerland.

By building upon a procedure used in materials research to cull more information from X-rays the added significant value to mammography for breast cancer diagnosis. When passing through tissue, X-rays are not only absorbed but also refracted and scattered. The researchers used this additional information to generate breast scans with more detail and higher contrast that show even minute tissue changes.

'While this principle is theoretically suited for any anatomy, it presented itself for breast scans, because of the high proportion of soft tissue in the breast, which means the effects are particularly well visible,' Dr Hauser explained.

Core components of this innovative procedure are three tiny grills, one being placed directly behind the X-ray source, the two others behind the tissue sample. 'By slightly moving these grills we

can see which X-rays pass through the tissue and which are attenuated. Since these effects happen at the molecular level, the grills have to be of nano dimensions to be able to register the minute angle scattering

used to generate the usual image quality at lower dose.

The fusion image allows a better evaluation of breast tissue. Minute structures are visualised in enhanced sharpness, which enables more precise evaluation of microcalcifications and tissue changes. Even

study stuck to familiarity – black and white.

Whilst Dr Hauser is sure this technique can also be used in 3-D, in vivo studies come next. He hopes to present data next year. So far, the researchers have performed their tests on mastectomy samples. To be able to use the technique for human patients the mammography systems will have to be equipped with the grills. 'Currently,' he explained, 'we are working with a prototype that is not suitable for clinical routine use. Right now, we are fitting the grills and make sure that the system remains stable and precise and that the results are reproducible. The foundation has been laid.'

The research project aims to achieve enhanced quality, resolution and diagnosis using the same radiation dose as conventional digi-



Chemistry graduate **Nik Hauser MD** worked at domestic and foreign university hospitals before studying medicine at the University of Basle. Specialising in gynaecology and obstetrics, he gained five years' clinical experience at the renowned Women's Clinic in Ulm University Hospital, Germany. Working at Kantonsspital Baden since 2007, he established the Interdisciplinary Baden Breast Centre, which was certified in 2008. In January 2014 he was appointed Medical Director of the Women's Clinic.

“Thanks to increased sharpness cancer could be detected at a very early pre-stage.”

of the X-rays,' the Director of the breast centre explained. The detector records this information, which is transferred onto separate images.

In a next step the conventional absorption image of the mammography and the new scatter images are fused. Alternatively, the grills can be

the fine extensions of the growth are distinctly recognisable.

The fusion images themselves can be presented in different ways, e.g. with colour codes. However, the radiologists who evaluated the images in the Hauser/Stampanoni

tal mammography to be able to detect and treat tumours earlier. 'If this method turns out to improve tumour detection and delineation and thus pre-surgery evaluation,' Dr Hauser confirms, 'I'm sure it will prevail.'

X-ray images of breast tissue generated with conventional mammography and with the new mammography procedure. The latter show a significant improvement in image sharpness and visibility of the tumour extensions (right). Image: Paul Scherrer Institute/Kantonsspital Baden

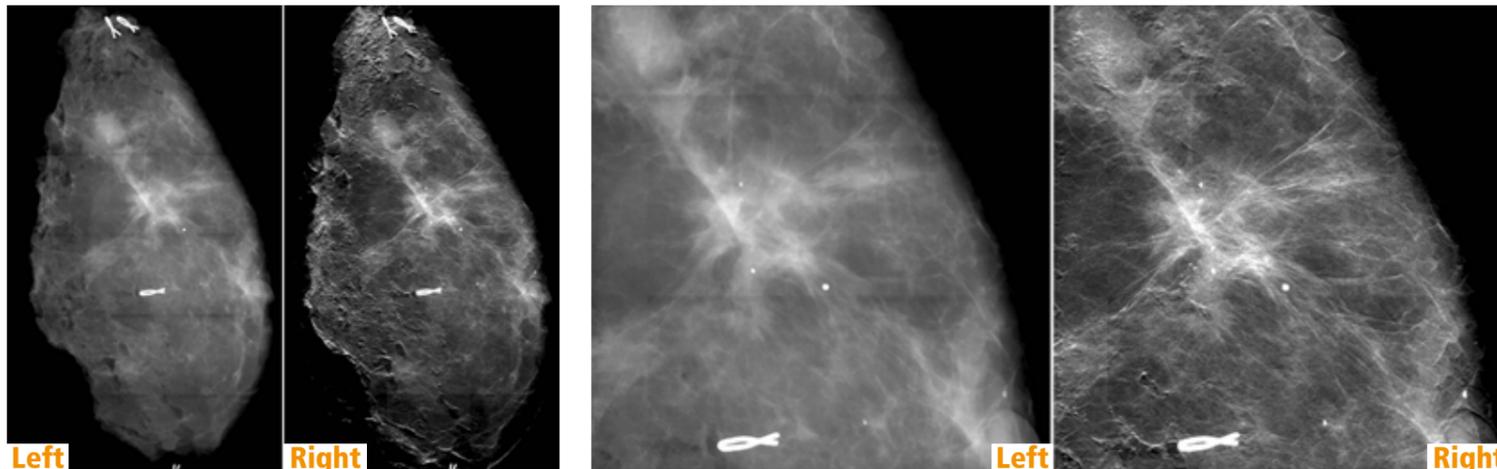


Image of the spectacles case from the new technology (bottom) reveals the cleaning cloth



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Mega information technology

In the era of Big Data radiology is left behind

Reports are little more than a Tweet, while hundreds of data points from an exam are irretrievably lost, John Brosky reports

There is a wealth of information in every radiology exam, but even a phalanx of super-computers at the National Security Agency (NSA) could not extract it.

Referring physicians, and even other radiologists, have a hard time figuring out if a given report is positive or negative. 'If all a radiologist did at the end of the report was to say if it was positive or negative for the reason it was done in the first place, that would be a major advance in radiology archives,' said Eliot Siegel MD, Chief of Imaging at Veterans Affairs Maryland Healthcare and Director of the Maryland Imaging Research and Technologies Lab.

'Every time we do an examination, for example for CT pulmonary angiography, when we issue a report saying we do not see any pulmonary emboli, we are not including hundreds of different types of data that we could include for computer algorithms to be able to discover in the future,' he told French radiologists at the Sixth Computed Tomography Symposium (Nancy, France).

During a single-shot thoracic scan that takes a few seconds, the CT captures images that can be converted to quantifiable data for lung nodules, breast masses and calcifications, cardiac chamber size, aortic size, coronary artery calcifications, rib fractures, liver texture, lung texture, bone mineral density, loss of height of vertebral bodies, renal function and renal volume.



Eliot Siegel, seen with IBM's cognitive computer *Watson* at the University of Maryland, believes the supercomputer may soon become a routine tool for diagnostic radiologists in addition to PACS, advanced visualisation and speech recognition

In an ideal world, the raw data set from this scan would be stored with meta tags and automated mark-up language, making it discoverable for current health policy information or future research. This data could also be shared locally among other support systems in a hospital for treating patients. Instead, once the radiology report is issued, the data is irretrievably lost, ironically the very moment it is sent to cloud storage.

'We radiologists need to reinvent ourselves,' Dr Siegel emphasised. 'If radiology is going to be important, then just as with lab and genomic data, we need to make our data discoverable, indexed and tagged.'

Much is at stake, starting with incomes earned by radiologists or approvals of capital equipment expenditures for new equipment.

In the United States, he suggested, as the concept of Meaningful Use

becomes more sophisticated, healthcare administrators are going to impose reimbursement for a radiology exam based on providing to the healthcare system basic, discoverable types of information.

'In the era of Big Data, people are looking for benefits and outcomes they can prove with data,' he pointed out. 'If we can't give answers to basic questions, we cannot demonstrate the value of the data in radi-

ology. It's going to become increasingly difficult for radiologists to get reimbursement and funding if people cannot find the data that's hidden inside our scans, and even inside our reports.

'What we issue are reports that are analogue in a digital age. It is essentially a tweet that responds to a specific question; but, unlike a tweet, it is not in a form that can be recognised by a computer.'

If loss of income from hospital administrators is not a sufficient driver to move radiologists to structured reporting, then perhaps armies of liability lawyers can help.

Currently, radiologists often make recommendations, such as a follow-up exam. Yet there is no way of knowing if the referring physician read the report or acted on the findings. 'Radiologists make recommendations all the time but practically no one in radiology follows up to see if the recommendations have been carried out,' Dr Siegel explained. 'Legally, the radiologist is held accountable for the recommendations where there are untoward consequences or adverse events, such as a tumour that grows. Courts have an expectation that recommendations have been carried out.'

Closing the communications loop with digital information input to automated systems would improve the ability to track liability associated with error and could accelerate the movement to structured reporting. Eliot Siegel has been out on the leading edge of radiology for 30 years, advocating change for a profession firmly entrenched for 100 years in a tradition of providing consultative free text interpretations of images. In the 1980s he created the world's first filmless, digital radiology archive for the VA system in Maryland. 'The entire storage capacity we had was one terabyte and it cost us \$800,000, the same terabyte capacity I can buy today at any Best Buy store for \$45,' he said.

He was responsible for the National Cancer Institute's (NCI) Cancer Image Archive and served as Workspace Lead for the caBIG In Vivo Imaging Workspace.

At radiology events, such as the one in Nancy, he pushes for adoption of the Annotation and Image Markup (AIM) developed by NCI that creates a single standard format to store computer-discoverable image annotations.

He also preaches a vision that speaks to the potential of radiology information joining the full power of Big Data. A first advance would be receiving responses to queries in seconds, not days, he said.

Increasingly, pixel interpretation of structures could be compared and matched with other biomedical information, leading to a definition of imaging biomarkers for disease and its progression.

Yet, he sees the true potential in fulfilling the greater promise of personalised medicine, where a patient's imaging can be assigned, cross-referenced and correlated with genomic or histological data, and compared to similar cases to make predictions on treatment and outcomes.

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Consolidating radiology in cloud-based services

Carestream connects UK hospitals

When it comes to storing images PACS remains king across the industry, but increasingly vendor-neutral archives (VNAs), particularly cloud-based examples, are gaining market share fast due to their ability to bring significant financial, productivity and clinical quality benefits.

When Spire Healthcare, the UK's second largest provider of private healthcare, looked for a solution to provide their clinicians with access to patient images from any location and PACS environment, it was to Carestream's cloud-based services that they turned. The seven-year agreement was a natural progression as an upgrade to their existing Carestream PACS. As a result, their Healthcare IT Services will transition from a managed service-based model to a Software-as-a-Service (SaaS) model, an innovative approach to managing imaging information on a predictable, pay-as-you-go basis. Carestream will host the new services in their first independent UK Data Centre.

Spire Healthcare was created in 2007 with the privatisation of British United Provident Association (BUPA) Hospitals and expanded rapidly the next year with the acquisition of Classic Hospitals and Thames Valley Hospital. With steady annual growth, Spire now operates 37 hospitals and 10 clinics nationwide. Quality of care and services is the key factor in Spire's continuing success with nine of 10 patients rating their experience either 'very good' or 'excellent'. Three in four employees consider Spire to be a great place to work.

'Spire was looking for a better way to share diagnostic images, but also saw the potential for financial benefits,' said Ignace Wautier, Business Development Manager for Northern Europe. 'They did not want to continue maintaining and supporting the hardware needed for image storage, workflow management, or network security in the knowledge that the whole system would need replacing four years from now. The aim was to get rid of the complexity and establish a predictable cost month after month.'

The Carestream's solution consists of a cloud archive to consolidate clinical viewing from disparate systems across the enterprise. By doing this in the cloud, Spire can rely on guaranteed performance and a scalable pay-as-you-go structure together with business continuance and disaster recovery, the company points out. 'The cloud archive is combined with Vue Motion, a zero footprint viewer that unifies clinical viewing across the entire Spire network so that clinicians can securely view PACS images no matter which system they are using. This ability to access images across multiple platforms is bringing increased flexibility and productivity to Spire consultants and timely results to patients.'

Vue Motion is not a product but a service for Spire Healthcare, Ignace Wautier pointed out. 'Spire is guaranteed to receive the latest software versions, developments, updates and upgrades. Image availability in seconds is guaranteed plus redundancy of the system, back up and recovery solutions.'

Stephen Hayward, IT Director of

Spire Healthcare, said that having access to care records and reports on a mobile device at the clinician's finger tips will be a great boon going forward: 'In private healthcare the consultant largely decides where he takes his patients. 'To grow Spire's business we need to differentiate our services from those of our competitors so that our consultants want to bring their patients to us and consequently grow our revenues.'

Qaiser Malik MD, a consultant radiologist with Spire Healthcare, took part in the pilot implementation and discovered the benefits of being able to work remotely. 'I no longer have to physically go to the hospital to log in at one of the workstations to view images and previous reports. Although not diagnostic quality, Vue Motion allows me to perform a preliminary report, which can make a massive difference to patient management. I can log in at weekends wherever I am, which is of great advantage. It is an absolutely fabulous tool and advances patient care by providing clinicians with timely reports and a head-start on treatment options.'

According to Andrew Milne, Imaging Manager at Spire Hartswood Hospital, 'From the patients' perspective the fact that we can provide these images and reports very quickly is important as people come to the private sector because they want a prompt service and, using

this new technology, we can provide that.

'The fact that it works across different platforms is a great advantage,' he said. 'Some of our consultants work at multi sites and the Vue Motion system allows them to access images from any Spire hospital. That means greater flexibility for them and greater flexibility for the patients if they are seen at, for example, another Spire hospital in the region.'



Carestream Vue for cloud-based services

Saskia Groeneveld, Worldwide Marketing Manager for Healthcare Information Solutions believes that the cloud solution is a liberating technology for Spire giving users and administrators peace of mind so they can concentrate on healthcare. 'It also gives them scalability,' she added. 'They are a fast-growing organisation and using cloud services allows them flexibility to adapt the service to their changing needs.'

'Cloud services are already a proven platform for many hospitals in countries such as France, Germany, The Netherlands, Belgium, Japan and the US,' she concluded. 'In fact today we operate remote archiving for 320 sites worldwide at 10 cloud platforms. As of today, and it keeps increasing, we have 80 million radiology studies filed, representing two petabytes.'

French radiologists endorse a new management system

Pay-as-you-use

Carestream's Managed Print Solutions (MPS), which combines the image quality of its Dryview laser imagers and medical films with a comprehensive, all-inclusive programme, has been used since February last year by Drs Pascal Hauet and Christian Lunel in their busy radiology practice in Paris, France, prior to its commercial release. They report that the solution corresponded exactly with what they wanted - to digitise everything; images, results, reports, management of remote equipment and to make the information accessible via the internet. Dr Hauet: 'The Carestream solution also means we don't need to invest capital in equipment, a great advantage. Being billed only on our consumption also

fits well with our business model.'

Under the programme, Carestream maintains its laser imagers at the healthcare provider's location and remotely monitors operations. Now, there is very little printer down-

Dr Hauet is very satisfied with Carestream's Managed Print Solution



time, according to Dr Hauet. Regular quality control checks are mandatory for mammography exams, so monitoring the machines via the internet before those checks is a definite advantage. 'I receive alerts before a printer fails, which is essential, particularly when a patient is waiting for their results. When there is a potential lapse in quality, Carestream technicians can detect a failure before it happens.'

He firmly believes the biggest benefits of the MPS solution include streamlining inventory management, consumption monitoring, orders, regulations, and supervising equipment operation. Everything is now simple and accessible for the staff, and having data on the website helps customer relations. Conclusion: 'It's better for them and for us.'



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Latest MR imaging research at the Erwin L. Hahn Institute in Essen

High-field and Hybrid

Report: Cornelia Wels-Maug

European Hospital met up with Professor Harald H. Quick, PhD, who was appointed Director of the Erwin L. Hahn Institute (ELH) for Magnetic Resonance (MR) Imaging this February. Being in charge of highfield and hybrid magnetic resonance (MR) imaging, Quick shared his views on the status of and the imminent research into MRI systems operating at 7.0 Tesla (7T) as well as the combined positron emission tomography (PET)/MR hybrid imaging technology.

7 Tesla MRI is a platform for clinically-oriented research, but not yet a medical product

MR imaging systems at 7T magnetic field strength or above are by now an established platform for clinically-oriented research. According to Quick, there are currently about 50 such systems installed worldwide. They were built to enable highfield MR imaging of the entire human body. 7T MRI technology is "the carrot stick", explains Quick, "which can be used to obtain more details than at 1.5T or 3.0T due to its inherent high signal-to-noise-ratio". However, Quick reckons that "7T is still about two or three years away from becoming a medical product, as issues such as safety and standardisation of the technology have not yet been sufficiently addressed".

The inherent advantage of this technology lies in its excellent soft-tissue contrast, and high spatial resolution which permits to better determine "the anatomical structure down to the finest details", summarizes Quick, who also points out that 7T "enables to further characterize the structure of lesions in multiple sclerosis rather than just counting them. Ultimately, Quick hopes that, for example, depicting tumour vascularisation in a superior way will empower clinicians to pick up structural changes at a much earlier point in time and therefore raise the likelihood of improving patient outcome.

Quick points out that beyond displaying fine structures, depicting tissue and organ function plays an increasing role in highfield MRI. Due to the increased sensitivity of highfield MRI the blood-oxygenation-level-dependent (BOLD) effect detectable during a functional MRI, "7T allows to register increased oxygen consumption in the brain, which means that we can indirectly watch the brain think". But for this

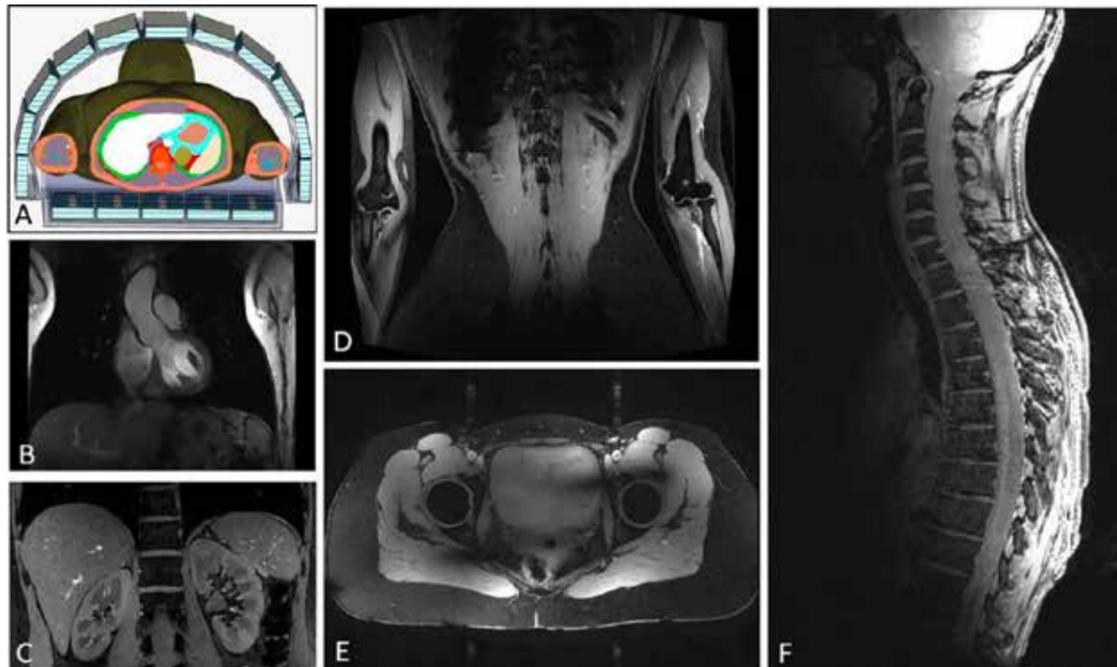


Figure 1: (A) Custom-built 16-channel radiofrequency (RF) transmit/receive body coil for body-MRI at 7 Tesla. Images (B-F) show current examples for 7 Tesla highfield body-MRI, employing different body regions: (B) cine-TrueFISP of the heart, (C-F) gradient-echo images of the kidneys (C), the upper body stem (D), the pelvis (E), and of the spine (F) featuring a two-step examination. All images courtesy of Erwin L. Hahn Institute for MRI, University of Duisburg-Essen, Essen, Germany

to happen, just using strong magnetic fields is not enough. So called radiofrequency (RF) coils, or antennas, are imperative to excite and readout the MR signal from the particular body area to be investigated. As RF coils for the head are already commercially available, the clinical research into the use of 7T technology focuses mainly on imaging the brain. However, imaging the rest of the body is currently a piecemeal attempt with different institutes concentrating on designing RF coils for specific body parts, such as heart, spine or extremities. Institutes do this in collaboration with MR system producers and clinicians.

ELH in Essen, Quick reveals, "has been devoted to a holistic approach, aiming at depicting each part of the body with specifically designed RF coils: Our group is internationally positioned to develop high-frequency RF transmitter and receiver coils plus multi-channel systems". In the field of 7T highfield MRI Quick's team's research focuses on:

- imaging the heart, prostate and mammography
- designing RF coils and RF technology for whole-body imaging
- ensuring the safety of those RF coils
- adapting sequences for clinical highfield MR imaging.

PET/MR is closer to the clinical side than MRI at 7 Tesla

Having worked closely with Siemens Healthcare on the introduction and advancement of PET/MR hybrid imaging during his tenure as professor at the Institute of Medical Physics at the Friedrich-Alexander-University in Erlangen-Nuremberg, Quick brings to his new job a wealth of experience in the PET/MR realm along with excellent contacts to the industrial partners as well as the PET/MR imaging community.

Status of PET/MR

Quick estimates that globally there are currently about 50 installed PET/MR systems. Unlike 7T highfield MRI, PET/MR systems are already labeled as medical products and possess more extensive clinical experience. However, reimbursement and refinancing are still unresolved, as is their use case, which still needs to be defined.

Will PET/MR cannibalise PET/CT?

Quick does not believe that PET/MR will cannibalise or even replace PET/computed tomography (CT): "Both modalities will coexist. Factors such as availability and costs will play a major role, especially with PET/MR being time and cost intensive". It will require a careful assessment of both modalities' strengths and weaknesses to determine their best use cases. Current research suggests that PET/MR is particularly promising as a diagnostic imaging modality in whole-body oncology (for depicting soft tissue tumours), pediatric oncology (due to the reduced amount of ionizing radiation when compared to PET/CT) and neurology (combining excellent soft tissue contrast with high sensitivity).

Future areas of PET/MR research at ELH

Quick is passionate about fostering interdisciplinary PET/MR research,

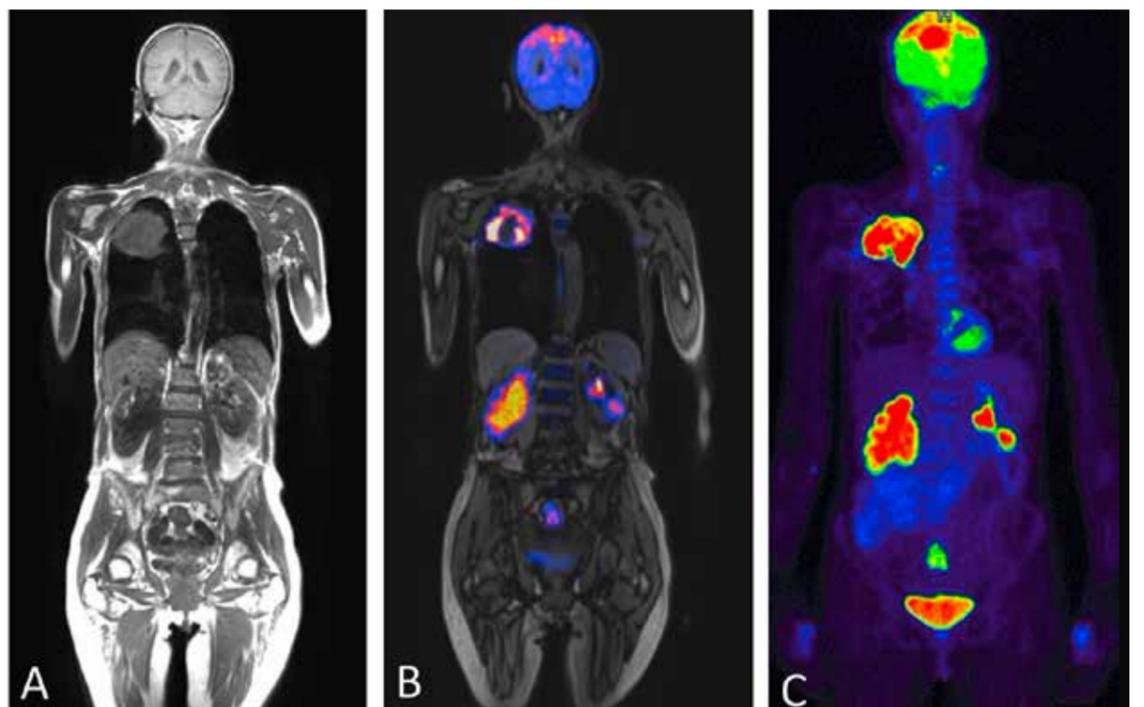


Professor Dr Harald H. Quick studied biomedical and physical engineering at the University of Applied Sciences, Aachen, Germany. Following his first professional appointment as Research Associate at the MRI Centre of the University Hospital Zurich, Switzerland, in 1999-2000 he spent a research year at Johns Hopkins University in Baltimore/USA. Back in Germany, he joined the University Hospital Essen, where he founded MR-Innovation GmbH. From 2006 to 2009 he was Managing Physicist at Erwin L. Hahn Institute for MRI. In 2009 he was appointed Professor for MRI at Friedrich Alexander University (FAU), Erlangen, but on 1 February 2014 he returned to Essen to head the Erwin L. Hahn Institute for MRI where he also is in charge of high-field and hybrid MRI.

joining the efforts of clinicians, manufacturers, physicists and other scientists. Asked about his immediate research priorities, Quick comes up with a long laundry list of projects. He is particularly keen to investigate the potential for reducing radiotracer due to the high sensitivity of the PET detectors in the context of PET/MR, explore "motion correction technologies to correct for breathing and cardiac motion in view of the relatively long PET data acquisition times", work on attenuation correction (AC) and to develop MR sequences, which will help to provide bone information for MR-based AC. Furthermore, Quick wants to optimise the hybrid imaging workflow in such a way that it "maximizes diagnostic information while minimizing acquisition time".

It is certainly an ambitious list, but Quick is optimistic: "There is a lot of research waiting for us, but the team is enthusiastic and with 7T highfield MR and hybrid PET/MR we have two of the latest and greatest tools for MR imaging research available here in Essen".

Figure 2: PET/MR hybrid whole-body imaging of a female patient with known squamous cell carcinoma of the lung. While MR imaging (A) provides high spatial resolution and excellent soft tissue contrast for anatomical reference, simultaneously acquired PET imaging (C) reveals radiotracer accumulation in tumors and metastasis with high sensitivity. The image in the middle (B) shows the fusion of MR and PET data. In this patient further metastasis have been located in the brain, the pancreas, and in the rectum



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Feet first into low-noise head to toe imaging

Toshiba's new 1.5-T MRI Vantage ELAN system is not only cost-effective, the firm reports, but truly compact; it needs only 23 square metres of space. Yet, the system uses the same type of magnet as other Toshiba products to achieve excellent image quality.

'With its widely recognised complete M-Power clinical application software suite and HHS (High Speed Switching) technology to facilitate the use of 16 channel coils, the Vantage ELAN manages to maintain ease of use for the operator while offering a quiet and comfortable patient experience due to Toshiba's renowned Pianissimo noise reduction technology.'

That low-noise level, which significantly improves patient experience, was among the system's features that particularly attracted radiologist Dr Peter Thorsten since it's innovation. When expanding his radiology practice in Güstrow, Germany, he selected this system – the first outside Japan – as a 'natural choice' due to his successful relationship with Toshiba since 2010, when the firm installed a Vantage Titan MRI scanner.

All types of examinations

Dr Thorsten is particularly enthusiastic about the user interface of the Vantage ELAN and because his staff is already familiar with the Toshiba protocols he feels the shift to the new system will be smooth. 'I had the opportunity to look at the system at RSNA in Chicago and was so impressed by its performance and the coil concept that we decided to acquire it,' he explained. It will be used for all types of examinations from the head to the spinal column and joints. 'Abdominal MRI is also an important area in our office and the Toshiba sequence strategy has enabled us to specialise in MR phlebography,' he added.

Aiming to grow its market share, particularly in Europe, Toshiba is confident that the addition of this new system to its MRI portfolio boosts market opportunities.

Alain Bertinatti, Toshiba Medical Systems MR Business Unit Manager in Europe, underlined that the current cost pressure on hospitals and healthcare systems was a major consideration in the development of the new product. Faced with the decision to either compromise on its renowned image quality, design, technical innovation or unique set of features, or to endeavour to deliver a high quality product at a competitive price, the company clearly opted for the latter. The resulting is reported to combine outstanding homogeneity and a 1.5-T ultra-short zero boil-off magnet to provide excellent image quality. In addition, the Vantage ELAN is equipped with Eco Mode technology to ensure highest energy efficiency.

All the latest innovations of Toshiba systems are available on the system, Alain Bertinatti pointed out, 'including Toshiba's advanced non-contrast MRA technology, which



Toshiba's Vantage ELAN combines clinical performance with affordability and patient comfort.

allows exceptional vascular imaging without the use of contrast.'

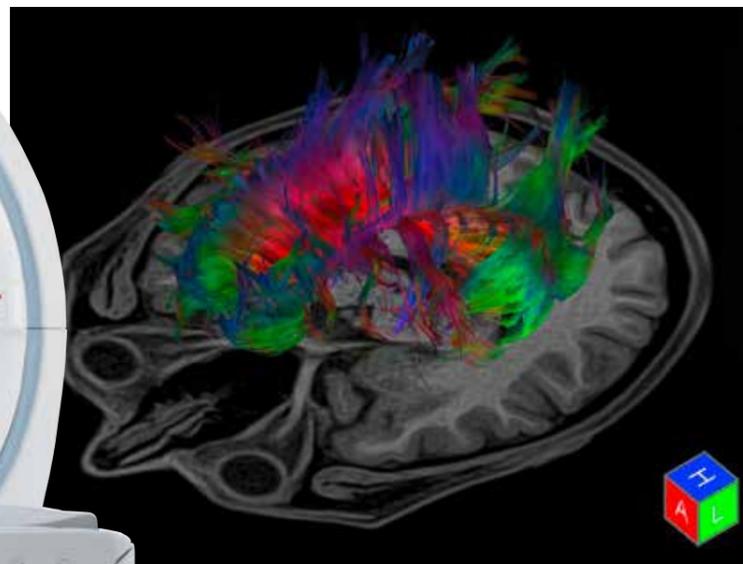
In practice - less contrast agents in MR angiography

Dr Isabelle Parienty-Boyer from the Radiodiagnostic and Medical Imaging Centre, Hauts-de-Seine, France, is a specialist in non-contrast renal MR angiography. She has performed about 700 examinations of renal arteries in renal insufficiency patients. Since referring

nephrologists often ask her to refrain from using gadolinium she works with Toshiba's Vantage MR system without contrast agents because the results are as good as the contrast-enhanced scans, sometimes even better. In her opinion Toshiba offers the best equipment for this type of examination because of the ability to use two planes, axial and coronal.

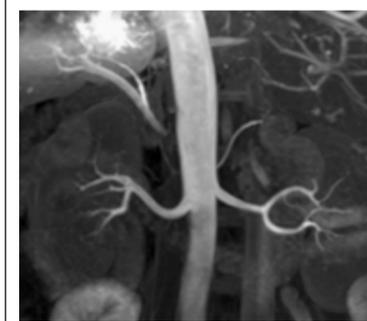
Quick and easy installation

Hans Baartman, Senior Product Manager at Toshiba Medical Systems



Europe, highlighted another major benefit: the ease and speed of installation. Since the new system requires little space it can simply be integrated into the examination room.

With all elements integrated, such as ECG and recording equipment, the system is ergonomically designed to be comfortable for operators. Feet first imaging significantly enhances the patient experience, Hans Baartman added, and the Pianissimo capability, integrated coils and sound suppression technology reduce the noise of the MRI. 'There is also the option to tilt the patient's head 10 or 20 degrees to make the patient feel a little more



Time-SLIP of renal vessels, a non-contrast-enhanced MR angio technique

Tractography of the brain acquired with a DTI scan in 49 directions

comfortable. In addition, the new light design of the board helps reduce the claustrophobic feeling many patients experience,' he pointed out. The Vantage ELAN has a 63 cm aperture with feet first imaging available for all types of examinations, except for scanning of the head and upper torso. Full angio and cardio suites are available, and the body package can be extended to include the SpineLine application offering fully automated planning of spine examinations. Together, these options enable head to toe imaging.



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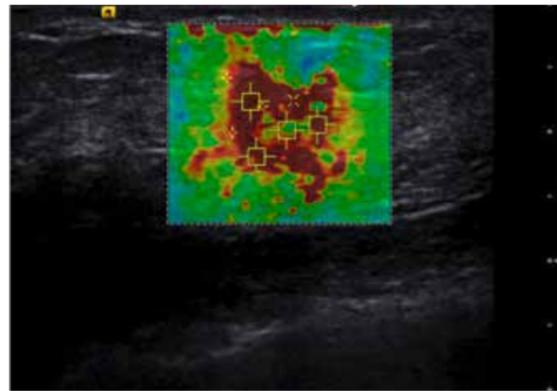
The ability to monitor therapy effects personalises care

Ultrasound technology is continuously developing and competing with the sectional imaging procedures – therapy progress can be monitored, facilitating personalised medicine.

At Heidelberg University Hospital there is excitement about the first use, worldwide, of the latest ultrasound innovation from Siemens. The brand new HELX Evolution not only offers much-improved image quality and far more precise and detailed examination facilities for clinical routine but also, thanks to the special measuring procedure for tissue elasticity, new opportunities to monitor the treatment of cancerous diseases.

The objective in Heidelberg is to use the new scanner to research whether the use of higher-impact procedures, such as CT and MRI scanning, as well as the visualisation of the vessels and ducts with contrast media, can be replaced by much lower-impact ultrasound examinations.

Measuring tissue elasticity with the help of elastography is, in itself not a new procedure, but the HELX Evolution from Siemens also makes it possible selectively to determine tissue elasticity within the ROI (region of interest) after the examination. 'It is possible to not only



Left: Elastography measurement in the mammary gland: The qualitative analysis shows a distinctly higher propagation velocity of the shear waves within a carcinoma (coded red)

Right: Elastography measurement of a nodule in the thyroid. The nodule in the middle of the images is coded green in the qualitative analysis. The determination of the qualitative value shows the propagation velocity of the shear waves to be 2.48 m/s, which is higher than the propagation velocity of the shear waves in the normal thyroid tissue, pointing towards a firm nodule

measure a certain point while scanning, but also to examine the entire ROI of a size of 6cm x 5cm quantitatively at any time.

'With current standards, the scanners only deliver a colour-coded map without absolute values, but now it's possible to extract the absolute value in metres per second at any individual point within the colour-coded map after the examination,' explains Dr Erick Amarteifio, a senior physician in the Diagnostic and Interventional

Radiology Department at Heidelberg University Hospital.

The importance of the actual diagnostic benefit of this absolute value will now be researched. It is known that the speed at which the shear waves spread within the tissue allows conclusions regarding tissue elasticity. The faster the waves spread, the harder the tissue. As many tumours have harder tissue due to high cell density, this can be a first pointer towards a tumorous disease.

One possible application area could be to assess therapy response for hepatocellular carcinoma (HCC) after transarterial chemo-embolisation (TACE). 'At the moment, the determination of perfusion during an MRI allows conclusions as to the vitality of the tumour. With larger subcapsular foci in particular, we believe it is beneficial to evaluate whether the change of tissue elasticity may allow conclusions as to therapy response with the help of elastography,' he explains.



Dr Erick Amarteifio gained his doctorate at the Georg-August University in Göttingen and has worked in the Radiology Department at Heidelberg University Hospital since 2008.

At the German Cancer Research Centre, in 2010, he carried out a one-year research project on functional musculoskeletal imaging.

This would considerably simplify the progress examination for this group of patients. Instead of a complex and expensive MRI examination, in future it may be possible to monitor and assess a focus with the help of a simple, fast and much better tolerated ultrasound examination. 'In any case,' Dr Amarteifio confirms, 'the HELX Evolution improves the opportunities to further utilise elastography.'

Future portable devices will be the norm

Mobile IT has a place within radiology

Workstations and desktops may still be around in future hospitals – will be of clear benefit to medics in a large variety of medical applications. During our interview, Osman Ratib MD, PhD, FAAC, Professor and Division Chair Department of Medical Imaging and Information Sciences, University Hospital of Geneva, and chair of the ECR subcommittee of eHealth and Informatics, discussed the use of mobile IT today and in the future.

'Radiologists will use mobile applications mostly for on-call situations where they require rapid access to studies for a quick review or wet read,' Dr Ratib explains. 'These applications are not used for final interpretation.

'It's important to mention that portable devices are also commonly used by non-radiologists – i.e. referring physicians, surgeons and other care staff – for the convenience of accessing image data in situations

where they don't have access to a workstation close by. It's becoming very popular for surgeons to take images with them into the operating room.'

With what kind of access?

'Various types of applications allow access to images: Web apps enable access to images through a web portal, but all the image manipulation and handling is done on the web server. No data is transferred or stored on the tablet. 'Another type of application will query images from a server and store them temporarily on the device itself. The first solution is easier to implement; the second needs appropriate security features, but has the advantage to allow continuation of the review of images "off line" even without network access.

'The second solution will need special access management to query images from a server. 'In some settings the portable tablet can also be a simple extension of a desktop computer where you transfer or "synchronise" your data by data transfer. Our portable viewer OsiriX HD for iPad and iPhone supports those two last solutions and is fully compatible with DICOM query from most PACS systems.'

'What kind of apps is available? 'Commercial ones provided by imaging vendors as extensions of their PACS – including Siemens, Philips, Fuji, TeraRecon, MimVista, and more – and there are some stand-alone applications, with OsiriX considered the most popular.'

'How do they differ from desktop/workstation applications? 'The tablets don't have the same performance as desktops do. So



Osman Ratib MD PhD FAAC, Professor and Division Chair at the Department of Medical Imaging and Information Sciences, Geneva University Hospital, is dual board certified in internal medicine in the subspecialty of Cardiology, as well as radiology in the subspecialty of Nuclear Medicine. He also gained a doctorate in Biomedical Physics, in digital imaging. After gaining a Master's in biophysics and PhD in medical imaging from UCLA in 1989, Prof. Ratib became one of Europe's most active figures in medical imaging research.

computers will soon disappear from the consumer market and that we will all use "devices". I believe part of that is true and we will use desktop computers only for professional and repetitive tasks. There is no reason to put workstations in the clinical ward if you can do the same thing with a tablet.'

Is acceptance and penetration general?

'There is no reason for differences in different countries. I've seen wide adoption of tablets in medical applications in India and China. On the other hand, all our staff and physicians walk around the hospital with a tablet in hand. Whether or not they use it to assess medical data is just a matter of time – for IT departments to adapt to the demand.'

What are the risks, limitations and barriers to widespread implementation?

'There is always a risk when you handle patient data. Strict rules of confidentiality and data protection must be respected and enforced. This is true for every information technology in medicine. It might require some special settings for securing the tablets, but technical solutions already exist.'

What's the prognosis for mobile IT in radiology?

'In a few years everybody will ask how we did it before. Portable devices will just be part of normal life. While we will have "large" devices or workstations to work on, we'll certainly benefit from portable devices in a large variety of medical applications in radiology, but mostly outside radiology.'

(Michael Reiter)

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Teleradiology and education

Although night diagnoses have high quality, teleradiology services could negatively affect junior radiologists training



Case study: 80-year-old patient with acute liver failure. Imaging was requested to clarify the presence of a hepatic artery thrombosis, indications of acute infarctions in the abdominal region and/or other causes of the acute kidney failure. A four-phase liver CT was performed. While the pre-exam had shown an open coeliac trunk, the present CT showed an initially overlooked closed coeliac trunk (3 cm). (a) Pre-exam (b, c) present exam: (b) axial and (c) sagittal view of the coeliac trunk with thrombosis (circles and arrows). CT= coeliac trunk; SMA, superior mesenteric artery

Given the ever more complex radiological examinations, the need to provide care in sparsely populated regions, or new labour law provisions such as the EU working time directive, radiologists are under increased pressure to find solutions to provide imaging services during off-hours.

This holds particularly true for Great Britain where the severe shortage of radiologists is exacerbated by the fact that implementation of the EU working time directive highly impacts the training structures in radiology. Therefore, several hospitals decided to out-source imaging reporting services to a teleradiology provider. Among those hospitals is University College Hospital, London, where Dr Joachim Hohmann headed the acute services radiology team in 2010.

To gain a better idea of the teleradiology reporting quality, Dr Hohmann and team began to evaluate the images the following day, then recorded their own findings and compared them to the night readings. 'The review of CT scans of 1,028 patients showed only minor discrepancies that could not be considered medical errors but at most led to a delay in therapy,' he recalled. 'A very positive result!'

To structure the comparison of the findings, Dr Hohmann used a disagreement scale from 'no discrep-

ancies' (category 5) to 'significant discrepancies with potentially life-threatening consequences for the patient' (category 1). No imaging report was classified as 1 and in 79% of cases the team matched the assessment of their teleradiology colleagues (category 5). 16 percent of the cases were classified in category 2: discrepancies regarding style or presentation of the findings. Differences in opinion as defined in category 3 and 2 were found in percent, resp. 1.3% of cases – with the latter percentage translating into exactly 13 patients. Since the patients were followed up for six months, Dr Hohmann could assess the accuracy of the readings. 'In eight out of thirteen cases my team was correct, in two cases the teleradiology provider was correct and for three patients we did not come to an unambiguous result. In short,' he concluded, 'the error rate of the teleradiology provider was 0.8 percent, which is not higher than in regular readings'.

Indeed, these results are better than results in comparable studies where the error rate is above 1.6 percent – perhaps because Dr Hohmann demands high quality standards from the teleradiology company: reports between 7 and 9 pm are to be prepared exclusively by specialist physicians in the UK, between 9 pm and 8 am by Australian colleagues on day shifts. 'In Great Britain and other anglophone countries teleradiology is much more common and is organised in a very structured way, since regulation is not as restrictive as for example in Germany. Moreover,' he points out, 'there is basically no language barrier.'

However, teleradiology also has 'adverse effects'. In Dr Hohmann's London-based hospital teleradiology was introduced to avoid night shifts for junior physicians. Whilst with the implementation of the EU working time directive junior physicians are entitled to longer compensatory rest for night and weekend shifts, due to this law they can no longer complete their training in the prescribed period. 'In the short run, professional teleradiology services are a good solution, in the long run they may compromise the level of training junior radiologists receive. 'As a junior physician it is very important to learn to make your

own decisions and take responsibility – that's exactly what night shifts require,' he stressed.

There are also other issues to solve. Dr Hohmann is concerned about price wars for reporting services and job security for hospi-

tal radiologists and he fears that commercialisation of radiology will increase. 'Nevertheless, I'm convinced that we will be able to find a sustainable solution. In view of the fact that demand will increase by ten to fifteen percent, but per year,

we will only have two percent more incoming radiologists, teleradiology is unavoidable.'

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



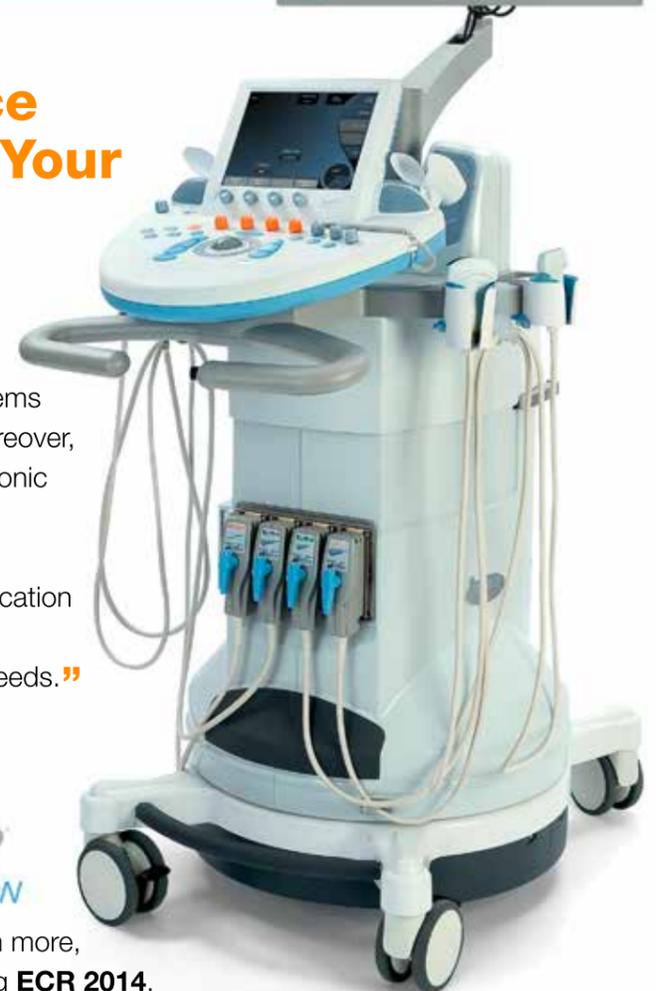
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A medicine and physics graduate from Berlin's Free University, **Joachim Hohmann** then specialised in radiology in the Department of Radiology and Nuclear Medicine at the Benjamin Franklin Campus, Humboldt University. In 2006 he became a senior resident in Basle University Hospital, where, following a year working at University College Hospital, London, in 2011, he was appointed Deputy Director of Abdominal and Oncological Diagnostics.



Small bowel imaging

Cynthia E Keen reports on prototype software with potential to automate motility measurements

For gastrointestinal exams, MRI fluoroscopy offers an alternative to conventional methods of swallowing and gastric emptying that are so repugnant to patients. MRI exams eliminate radiation dose exposure, provide full views of soft-tissue structures, and produce multiplanar imaging. For radiologists, the value of MRI of the small bowel is its ability to display both morphology and

motility. Small bowel motility (the bowel wall motions and contractions of muscles within the intestinal walls) dysfunction can be a symptom of inflammatory bowel disease, e.g. Crohn's, obstructive bowel disease, diabetes mellitus and scleroderma (a disease of connective tissue that causes fibrosis to form). The standard protocol for MRI motility assessment begins with the acquisition of

several coronal 2-D sequences over the entire small bowel using fast imaging pulse sequences, such as echo planar imaging, fast spin echo, or steady-state free precession.

Evaluating small bowel motility is tedious and time consuming. The quantification of small bowel motility patterns, such as contraction frequencies and amplitudes, can be made by measuring the cross-sectional diameter change of selected single small-bowel segments over time. That calculating and plotting measurements is so time consuming and susceptible to errors has formed one of the primary barriers against using MRI-assisted motility assessment in hospital radiology departments. The challenge is that all measurement points must be corrected due to the inherent modality movement or shifting of the small bowel segment.

Radiology researchers at the Institute of Diagnostic, Interventional, and Paediatric Radiology at University Hospital in Bern, with software engineers at Sohard AG in Bern, developed a software prototype (Motasso) to quantify small bowel peristalsis. The software permits semi-automatic measurements of small bowel diameter over long time periods, thus displaying motility.

With colleagues at Zütovh University Hospital, ECR session* presenters Doctors Michael A Patak, Sebastian Bickelhaupt and Johannes M Froehlich, conducted a study to validate Motasso software for small bowel motility tracking by comparing it with the traditional manual measurement method. In January, they reported their analysis of 45 MRI enterography exams online in *Clinical Radiology*.

The research team analysed 91 small-bowel segments. Small bowel motility parameters including contractions per minute, luminal diameter and amplitude were measured three times each in identical segments, using both manual techniques and the semi-automatic software assisted method. They compared the methods for agreement, repeatability, and time needed for each measurement.

The Motasso software worked very well. It produced standardised, accurate identification of the small bowel wall and subsequent quantification of small-bowel motility. It expedited measurement, and performed each assessment in half a minute compared to a minute and a half when done manually. It also provided higher reproducibility and standardisation of data acquisition made by different individuals.

'Measurements with Motasso are faster, more accurate, and significantly more reproducible than measurements by hand. The user-friendly point and click interface facilitates widespread clinical adoption of the software,' the authors wrote. They also believe that the Motasso software can provide new insight into the pathophysiology of small-bowel motility-related gastrointestinal complaints. Research is on-going.

* ECR SS201b: GI Tract: Advances in small bowel imaging

For your diary
2 pm. 6th March, Room E2

Quips and Pain Out provide worldwide pain data

Around 50% of surgical patients experience moderate to severe postoperative pain, and 'minor' surgery patients receive little pain care

Report: Ralf Mateblowski

Among 40 million surgeries performed in Europe annually, and more than 50 percent of the patients experience moderate to severe postoperative pain. The price of poor pain management is high: Pain impedes recovery, causes suffering and consumes inordinate amounts of healthcare resources. However, there is hope. Optimised pain therapy can significantly reduce intensity and duration of pain. This is where QUIPS (Quality improvement of postsurgical pain therapy) and PAIN OUT (Improvement of postoperative PAIN OUTcome) come into play.

Widespread interest in the German Quips project, which has measured the quality of post-operative pain treatment in over 200 hospitals for over a decade, and its international counterpart Pain Out, which began in 2009, clearly indicates that most clinicians want to ensure patients recover with the least possible pain.

Professor Winfried Meissner, project coordinator and Head of the Department of Palliative Care at Jena University Hospital discussed pain management with *European Hospital* correspondent Ralf Mateblowski, who asked why pain management needs benchmark projects such as Quips and Pain Out and what they aim to achieve.

Prof. Meissner: 'Generally speaking, effective pain therapy methods do exist, but they are not implemented consistently clinically; one reason being lack of knowledge – for example with regard to the current pain therapy recommendations. Many physicians are convinced they can do pain therapy "on the fly". It's a popular misconception that the patient's pain will disappear 'sooner or later'. However, acute pain can prolong hospital stay, result in complications, and turn quickly into



A project team member enters anonymised patient data from the questionnaire on postoperative pain therapy in the QUIPS database, in order to run an international comparison of the pain therapy outcomes

chronic pain. 'The other reason is lack of data on outcomes: Because pain assessments are rarely done in standardised way, it's impossible for most hospitals to assess and compare the quality of their services. Quips and Pain Out provide clinicians and administrators with reliable, real-time information on the quality of care in pain management.'

Since pain perception is subjective, what do methodological standards for pain assessment look like?

'Obviously, each individual patient perceives pain differently and we will probably not be able to measure pain objectively, like blood pressure or any other lab parameter. However, despite this subjective factor, there are indeed methods that allow us to gather data on pain, and these data can be compared across hospitals – or across patients – and conclusions can be drawn. As far as

Quips and Pain Out are concerned, we are convinced that getting a feedback directly from the patient ("patient-reported outcomes") is a crucial aspect of quality improvement in pain therapy. You have to really go the extra mile and listen to patients instead of ticking quality assurance checklists.

'We developed a questionnaire, currently available in 18 languages, and this is an effective and valid tool to evaluate pain therapy. On the day after surgery, a random sample of patients answer questions on functional impacts of pain, side effects of pain therapy and patient satisfaction. 'The data, with information on the patient's age, gender and medical history, as well as on the type of surgery and medication added, are anonymised and transmitted to an external data base. There they are immediately analysed and fed back to the participating hospitals. Thus hospitals can easily identify

improvement potential, learn best practices from other hospitals and observe the effects of new treatment methods.'

What kind of results have these comparisons yielded so far?

'As expected, endoscopic interventions are less painful than open surgery, but not always. What surprised us was the fact that laparoscopic appendectomy is experienced as rather painful. Even certain standard interventions in ear, nose and throat (ENT), such as tonsillectomy, can lead to more pain than major thoracic surgery. This might be because a patient undergoing major surgery receives intensive pain management and is cared for by Acute Pain Services, whereas, a patient undergoing a procedure that is regarded as 'minor' receives very little – if any – treatment.

'Providing intensive treatment for major surgery is no doubt a positive result from 20 years of experience with acute pain concepts. Quips and Pain Out are the first projects to allow cross-surgery comparisons in a large sample. This will yield important information on minor interventions whose pain burden is poorly researched.'

What are the advantages of the impending integration of the Quips and Pain Out databases?

'Apart from their benefit as a quality assurance tool for local use, Quips and Pain Out offer staff at the participating hospitals the opportunity to use the worldwide data from the largest acute pain data base – it has more than 300,000 data sets – for research purposes.

'In both projects the same questionnaires as before will be used and the results will be evaluated in the same way but, with a single mouse click, you can expand your benchmark sample to compare results internationally. The time needed to



Professor Winfried Meissner graduated in medicine at the Free University of Berlin and joined the Department of Anaesthesiology and Intensive Care Medicine at the Benjamin Franklin University Hospital in Berlin. In 1994 he became Consultant and Head of the Pain Unit at Jena University Hospital where, since 2009, he has led the Department of Palliative Care. In 2003 he received his first grant for 'Benchmarking in Postoperative Pain Management', funded by the German Federal Ministry of Health. Prof. Meissner is co-ordinator of QUIPS and PAIN OUT, which was co-funded (2009-2012) by the European Commission's 7th Framework Programme.

participate in the project remains manageable, because only a fraction of the patients will be sampled.'

Why is it so difficult for pain therapy to gain clinical ground?

'Today, medical interventions are discussed primarily with regard to their economic benefit. Pain therapy is sometimes very economic – e.g. if it reduces length of hospital stay – but sometimes its economic benefit is not immediately obvious, for example when persistent pain is prevented months or years after surgery; but clearly pain relief has ethical value and should be a goal of every therapy. Healthcare providers are obliged to do no harm to their patients and the experience of pain can be harmful. In palliative care this is not a point of contention.

'I strongly suggest looking at pain therapy in very much the same way as we look at palliative care. Pain relief is a value by and in itself. Finally, and importantly, high quality pain management is one of the most efficient means to increase patients' satisfaction.'

Technology and new techniques cut ICU infections

Improved catheters and biopatch

Report: Brigitte Dinkloh

Patients in intensive care units in hospitals across the UK are benefiting from a combination of new techniques and technology with changes in clinical practice that help to dramatically cut incidences of infection.

The improvement in care and outcomes will be highlighted at the ISICEM event in Brussels by Professor Robert Masterton from the Institute of Healthcare Associated Infection, at the University of West of Scotland, University Hospital Crosshouse in Scotland.

In his presentation 'Recent infection control developments in the ICU', Prof. Masterton will point out that improvements have arisen because of changes made in practice and technology.

'On the practice side the biggest change has been the introduction of standardised pathways of care, where we do the same thing every time to the patient,' Prof. Masterton told *European Hospital*. This has been conducted in a number of



Today based at the Institute of Healthcare Associated Infection University of the West of Scotland University Hospital Crosshouse in Kilmarnock, from April 2011 to May 2013 Professor Robert Masterton was Medical Director and Consultant Microbiologist at Ayrshire & Arran NHS Board, working part time on secondment in his professorial role. His healthcare background is broad, having worked as a general practitioner, hospital specialist and, more recently, in senior general and medical NHS management roles. The professor has also worked on a several UK guideline groups and chaired the UK Working Party that published Hospital Acquired Pneumonia guidelines in 2008. His research interests span Healthcare Associated Infection, infection control, antibiotic management and policy and antibiotic use in variety of clinical conditions.

ways, by the introduction of an integrated care pathway and care bundles – a group of three to five evidence-based interventions which, when performed together, have a better outcome than if performed individually. 'What each of these do is ensure a consistent high quality of care,' he explained. 'However, that has required quite a lot of change because it is not how we have been used to working, so there have been professional cultural changes.' The second significant change has

been through the introduction of technology with new techniques, which have enabled clinicians to reduce infection risks faced by ICU patients. He suggested these centre around devices such as intravascular catheters, with upgrades to existing impregnated catheter devices and tracheotomy tubes that can contain a variety of compounds, such as anti-bacterial agents, to stabilise the condition and aid recovery for the most poorly patients. Some of the compounds are antiseptic, he

explained, but they combine with techniques such as the biopatch, which has seen a reduction of intravascular line testing for catheter-related blood infections.

Professor Masterton pointed out that, whilst these changes have been implemented in recent years, the benefits are now beginning to become apparent, but the combination of practice and technical changes has been crucial. 'It's not possible to separate the practice changes from the technology; both have happened together, and what we see in the intensive care unit is the combined effect of each of these things – and that has been phenomenally successful.

'We now have some units that report no ventilator-associated pneumonia for hundreds of days at a time. If you go back 10 years, over half the patients in the ICU could have ventilator-associated pneumonia. Now, with changes in technique and technology, that has been reduced to zero.' There also has been a ten-fold reduction in catheter-related blood stream infections.

However, not all ICUs within the NHS are implementing these techniques at this stage, and Professor Masterton said further research is still needed to clarify the level of benefit. 'Part of the difficulty is that we do not know what the best combination of technology and technique is; we do not know how these individual elements come together in the best way.'

One line of research that he is pursuing is how the environment contributes to infections – and improved cleaning has emerged as a key factor in seeing a reduction in healthcare-related infection. 'What we would encourage ICUs to do is combine changes in technique with changes in technology to reduce infection control risks and occurrences. There is good evidence out there about that.

'What ICUs need to do is adopt bundles of care that will enable them to reduce infection control and use good techniques every time.'

'Huge progress' in the ICU

International cooperation for rigorous study brings greater precision to defining and treating disease

Report: John Brosky

You'll find **Élie Azoulay** everywhere during this year's International Symposium on Intensive Care and Emergency Medicine (ISICEM). The Editor-in-Chief of the official journal of the European Society of Intensive Care Medicine, he will lead state-of-the-art review sessions for non-invasive ventilation and therapies in sepsis, as well as present talks on infections in the intensive care unit (ICU), the intubation of patients and new admission policies for cancer patients.

On the first morning of the congress, which attracts 7,000 specialists from 96 countries, Dr Azoulay will chair a session aimed at confronting a simple question: 'Have we made progress?' Presentations will cover three of the perennial ICU challenges: acute respiratory distress syndrome (ARDS), sepsis and renal failure.

Ahead of the ISICEM meeting, *European Hospital* spoke with Azoulay in Paris, where he is a professor of medicine at the Sorbonne University and the Assistant Director of the ICU at the Saint-Louis Hospital. Simply asking whether we really have seen progress in the ICU was enough to inspire a highly organised and insightful response.

Greater precision in defining diseases

'The first point is that we have progressed in defining diseases with greater precision. Here we have seen huge progress in focusing on specific diseases rather than syndromes,' he began.

'In ARDS, the Berlin definition launched by the European Society of Intensive Care has very much



improved how we see the disease, going beyond acute lung injury and classifying ARDS for appropriate treatment and therapeutic strategies.

'Similarly, the updated Guidelines on Surviving Sepsis Campaign have also strengthened a common management for patients with septic shock. This was the result of a tremendous multinational effort where the critical care community acted like one person. People from every country provided evidence, giving clinicians an opportunity to establish a minimal standard of basic care.

'This is one of the strengths coming from a new approach to studies and guideline where, before moving to a higher level of management, we are at least providing a common, effective, basic standard for all patients everywhere in the world.

'I was very impressed by the number of times these papers have been accessed online. We've seen up to 30,000 hits for downloads of the papers that are in open access in *Intensive Care Medicine*. This tells me we are reaching the critical care

community everywhere in the world and they find the 2013 updates to Surviving Sepsis Campaign worthy of their interest.

Trials show better patient outcome

'The second point is asking whether interventions translated into improved outcomes. I would say yes, we have progressed here.

'In ARDS, over a certain number of years, we have seen great improvements in survival for these patients by providing ventilation with low tidal volumes. Then, a study on paralytic agents in patients with severe ARDS also reported survival benefits.

Moreover, this year we saw advances in two areas – first there was the PROSEVA study, from a French group, showing there is tremendous improvement in survival in ARDS patients ventilated using a prone position. There was also another paper from the IMPROVE trial, an impressive effort, which shows using the protective ventilation strategy for patients undergoing

operations also decreases the number of post-operative complications.

'In septic shock, we also closed the story on activated protein C with the publication of the multinational PROWESS-SHOCK trial that is impressive for its size and for providing proof that survival was not improved. The Xigris saga is now ended, and while we cannot say we made progress, at least we are avoiding a treatment that may have side effects without demonstrating benefits. Other treatments have been tested in septic shock patients with no significant progress, which brings me to my third point.

Controversial debate about hydroxyethyl starch

'We have made progress in controversy, as well. There is quite a huge debate over patients receiving hydroxyethyl starch (HES) for fluid expansion. Plenty of meta-analyses have shown that these patients could have an increased incidence of acute kidney injury, increased bleeding. Some showed an increased number of patients who were dying.

'This year the CRISTAL study shows there is no harm provided by HES; but the level of suspicion about HES is high. The question is still there; the controversy is still there. I don't think another controlled clinical trial will resolve it. For this, we need to sit together and discuss decisions, because, while official agencies are still reluctant to approve HES based on the level of proof that harm may be real, clinicians still need to be convinced that HES is at least useless.

Studies are warranted in non-ICU patients, such as peri-operative care and emergency medicine patients, as well as collaborative studies with nephrologists that go beyond epi-



In addition to serving as the Editor in Chief of Intensive Care Medicine since early 2013, **Professor Élie Azoulay MD PhD** is a regularly published author of studies on a range of acute conditions for patients in the ICU. He is a world authority on post-traumatic stress symptoms in family members of intensive care unit patients and co-authored the book 'End of Life Care in the ICU: From Advanced Disease to Bereavement'. He founded the French Famirea Study Group to evaluate the ability of critical care clinicians to provide effective information to ICU patients and families.

demology and comparative studies.

'Overall, the critical care community worldwide has very much enriched medical literature this past year with a high level of quality papers and rigorous studies. We've become better at defining standards of care, as well as targets for improvement that will be tested over the next few years.

'In conclusion: 'Many challenges remain,' said Dr Azoulay. 'We need to establish a better standard of care for even more critical care situations; to better define ICU admissions policies; to better work in multinational trials and share data with other countries. This is the only way to move forward, with big patient cohorts for observational studies and big trials, where there is less bias based on a specific type of ICU management.'

Optimising peri-operative procedures

Non-invasive ventilation in the post-operative patient accelerates recovery and decreases mortality

Report: Brigitte Dinkloh

Many physiological and observational studies indicate that non-invasive ventilation (NIV) after both thoracic and abdominal surgery is helpful and non-randomised trials have indeed confirmed the benefits. While there is a global consensus that more research on NIV is required, the European Guidelines recommend but do not mandate NIV in postoperative period. The American and Canadian guidelines at this point do not yet recommend non-invasive ventilation.

Dr Samir Jaber, Professor of Anaesthesiology and Critical Care Medicine and Head of Department at the University Hospital of Montpellier, France, is the coordinator and main investigator of NIVAS (Non-Invasive Ventilation after Abdominal Surgery), a randomised controlled trial, 20-centre (planned to include 300 patients) study designed to evaluate non-invasive ventilation in patients who developed acute respiratory failure after abdominal surgery. Results are expected to be published next year.

Anaesthesia, post-operative pain and surgery can induce respiratory modifications such as hypoxaemia, pulmonary volume decrease and atelectasis associated with a restrictive syndrome and diaphragm dys-

function, which occur early after surgery and may cause acute respiratory failure (ARF). Maintaining adequate oxygenation in the post-operative period is crucial, especially when pulmonary complications such as ARF occur. Non-invasive ventilation refers to respiratory support techniques without endotracheal intubation.

avoid acute respiratory failure in high-risk patients - for example after abdominal or thoracic surgery or in obese patients. Second, post-operative NIV is used curatively for patients with acute respiratory distress in order to avoid intubation. It also seems that NIV patients recover better. Depending on the type of surgery and on the team the

“The Success of NIV depends on the experience and expertise of the medical team.”

Today, the clinical team usually selects the type of post-surgical ventilation. 'The most important factor for the success of non-invasive ventilation is the experience and the expertise of the medical (anaesthetists and surgeons) and paramedical (nurses, physiotherapist...) team,' explains Prof. Jaber, a ventilation expert for over 20 years. 'No experience frequently leads to poor outcomes.' He hopes, with his current study, to confirm the benefits of non-invasive ventilation in patients suffering post-surgical respiratory distress.

Non-invasive ventilation after surgery has two potential objectives: First, as a preventive measure to

hospital stay might be reduced by two to four days and a recent study indicates that mortality decreases, at least after thoracic surgery.

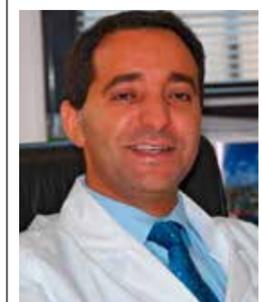
Lung-protective ventilation in the operation room

Professor Jaber focuses not only on post-operative ventilation but emphasises the importance of ventilation during the intervention. 'We try to optimise the ventilation setting in the OR by using protective lung ventilation in the same way we do in ICU patients. For patients suffering acute respiratory distress syndrome we apply so-called lung-protective ventilation: a low tidal volume of 6 ml per kilogram instead

of 10 or 12 ml and a positive end expiratory pressure (PEEP) between 6 and 8 cm H₂O.' In August 2013, the *New England Journal for Medicine* published the results of a study by Professor Jaber and his team showing that, in abdominal surgery patients with healthy lung function, the protocol described above significantly decreased post-operative respiratory complications compared to standard ventilation with a tidal volume with 10 ml per kilogram and without PEEP. 'With lung-protective ventilation we decreased the post-operative complication rate from 27% to 12%.

'While this is good news, it does mean that at least 10-20% of the patients will still develop complications; that's why we use non-invasive ventilation after surgery. My approach is not only to see what happens after or during surgery. We absolutely have to look at the entire procedure. Therefore, I prefer the term peri-operative ventilation, which starts with general anaesthesia and ends after extubation of the patient. Also, it's better to prevent than cure.'

'The most important risk associated with non-invasive ventilation is the patient's negative response to the procedure - and delayed intubation. Intubating a patient in poor condition is extremely risky



Following medical studies at UFR Cochin-Port Royal in Paris, **Professor Samir Jaber** began work as a physician in CHU Creteil, where he gained his degrees (DESC) in re-animation (DESC) and ventilation (DEA). He has been Professor of Anaesthesiology and Critical Medicine and Head of Department of Critical Care Medicine and Anaesthesiology at Montpellier School of Medicine and Saint Eloi University Hospital in Montpellier since 2007. Since January 2013, he has also served as the president of the scientific committee of the Société Française d'Anesthésie et de Réanimation.

and will frequently lead to poor outcomes. Thus, non-invasive ventilation may be indicated for patients who underwent surgery. However, before applying non-invasive ventilation to patients with acute respiratory distress it must be ensured that no post-surgical complications are present and, most importantly, if the patient's status does not improve, discontinue non-invasive ventilation immediately and intubate!

The use of blood tests to diagnose and monitor tumorous diseases

Curse or blessing?

Report: Brigitte Dinkloh

A small prick to sample blood instead of complex pathological or other diagnostic procedures – this is how early cancer diagnosis will be in the near future. Blood tests to diagnose tumorous diseases early are already being researched for clinical use. However, the results of those tests are not always clear and of benefit for patients. One such negative example is the PSA test to detect prostate cancer, which continues to be controversial due to its frequent false positive and false negative results.

For Professor Roland Repp, Head of the Medical Clinic for Haematology and Medical Oncology at Bruderwald Hospital in Bamberg, blood tests to detect cancer early are of much scientific interest, but their current clinical use is not yet advisable. 'With the current state of play, I believe it would be highly problematic to use the procedure for therapy control, screening or prediction of therapy response. Should a one-off detection of changes in the blood really be equated with a clinically relevant tumour?' Prof. Repp asked, during our *European Hospital* interview.

The professor sees over-diagnosis as a major problem. After all, the body's own defences may well be able to deal with individual, abnor-



mal cells in the blood but, based on blood test results a patient might end up being labelled as a tumour patient, with all the diagnostic and personal consequences this entails, yet possibly be completely unnecessary. Therefore, this leading oncologist insists that the most valid parameter, i.e. proof of mortality being lowered, must be met before blood tests can be used for screening. There is no doubt that there are indications that abnormal cells

can be detected early and that even, in the case of isolated tumours, tumour cells can be found in other parts of the body, and can also circulate in the blood. This appears to have an impact on the patient's prognosis as well as being useful as an early parameter for therapy response.

Various laboratories are working with procedures that make it possible to detect and purify circulating tumour cells, and even to sequence

the entire genome for individual tumour cells. 'Admittedly, this is fascinating, but we also know it means there are many questions we still have to answer,' Prof. Repp points out. The most important question is: Does the cell or DNA found in the blood really reflect the driving changes in the tumour cells or is it just a sub-clone or a derivative that is not truly representative of the tumour character?

A positive example

Dr Martin Grimm, an Oral and Maxillofacial Surgeon from Tübingen, is much more optimistic about the use of these new tests. He hopes to be able to use the EDIM blood test, trialled in a study for the early detection of prostate, breast and oral cancers, in clinical routine in just a few months' time. The results of the study, recently published in *BMC Cancer*, point towards the blood test being utilised as a further diagnostic tool. 'At the moment, all we can say is that our blood test really does identify cancer patients. In the study, 90% of the tumour patients were correctly, positively identified as such, and the specificity, i.e. the number of non-tumour patients detected, was also around 90%,' explains the head of the study.

The blood test, which was jointly trialled by Tübingen University Hospital, the German Cancer Research Centre in Heidelberg and the Clemenshospital in Muenster, uses phagocytes that have absorbed enzymes from the tumour and confirms their existence via flow cytometry. According to Dr Grimm, the long-term objective of the procedure is to monitor patients, i.e. more precise therapy control, which manifests as an increase or decrease in recirculating Apo 10 protein and transketolase-like protein 1 (TKTL1). A positive blood test result can also



Professor Roland Repp is Head of the Medical Clinic V at the Bruderwald Hospital in Bamberg and Extraordinary Professor at the Christian-Albrechts University of Kiel. He also heads the Bamberg Oncology Centre and is speaker for the working groups on 'Haematologic Neoplasms' and 'Clinical Studies' at the Oberfranken Tumour Centre. The professor's habilitation focused on the 'Clinical Relevance of Fc Receptors of Myeloid Cells'.

help to facilitate the use of further diagnostic steps. 'Before scheduling a PET/CT examination at a cost of €1,000 it would be much cheaper to check whether there might be an indication of a tumorous disease with the help of the blood test,' he points out.

Ultimately, the entire diagnostic and therapeutic procedure will not be impacted, because it will continue to conform to the S3 guidelines for the respective tumour entity. 'It's an additional diagnostic tool, and we have shown that it works.' The procedure has limitations and must not be used for patients with immune suppression, i.e. patients with HIV, or organ transplant recipients. For all other patients the EDIM test is 95% concordant with PET/CT, as shown in a study published in *Future Oncology* in 2012.

Prof. Repp believes that, in the future, this procedure could compete with PET/CT in terms of sensitivity. However, he points out that, despite many publications, in Germany PET is not yet used to monitor early therapy response of tumours in clinical routine, except for Hodgkin lymphoma. 'It's likely,' he predicts, 'that we will have to expect similar delays for the use of blood tests to detect cancer.'

Mobile POC applications and educational resources

'Physicians and clinicians treating patients at the point of care (POC) can benefit greatly from easy access to materials and resources via their handheld devices,' comments Jamie Gramz, Director of Global Marketing at Siemens Healthcare Diagnostics. 'That's why Siemens is committed to developing mobile applications and educational resources for point-of-care testing. Currently, for example, we offer the e-book, 'Rapid Analysis – Blood gases and More', a 135-page

comprehensive reference manual on blood gas testing, and the 'ABG Guide' blood gas application for iPhone or iPad, which identifies normal and abnormal ranges for pH, arterial blood gas, electrolyte and analyte results. Both resources are complimentary and available from the www.siemens.com/pocresources website.

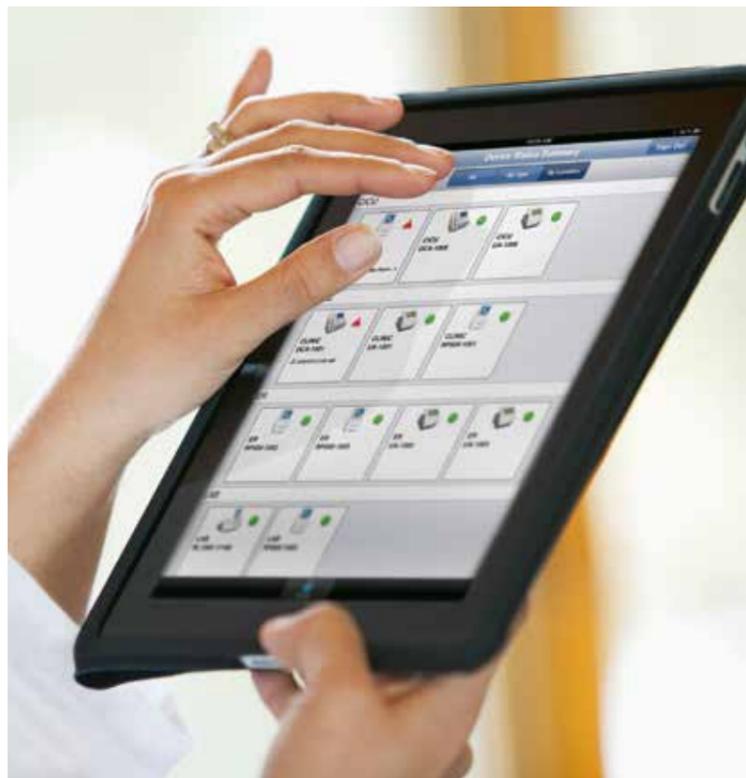
The next educational mobile resource from Siemens is a Urinalysis app that will benefit

healthcare professionals performing urinalysis testing at the point of care. 'We are also incorporating the use of mobile resources into our workflow solutions for POC testing. Our latest version of software for our RAPIDComm Data Management System supports a new web application, as well as an interface to our web-based Personalised Education Plan (PEP), a virtual, single source education and management solution.

'The RAPIDComm web application allows customers to quickly view the status of POC instruments and troubleshoot issues, even from a hand held device.

'For Siemens blood-gas analysers, the updated software makes it possible to remotely view and control instruments directly from an iPad, regardless of location,' adds Jamie Gramz. 'Operator training is also simplified through the new interface to PEP, which includes a comprehensive library of educational and training materials. POC managers can also use PEP Administrator with Qualification Plans, an addition to PEP, to tailor learning plans and create and assign custom e-quizzes to integrate competency management directly with automatic recertification for operators.

'The use of mobile resources and hand-held devices will continue to play a stronger role in POC testing and Siemens is focusing on these types of solutions for our customers.'



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Tiny tools, big effects

imec, the European research centre for nanoelectronics, has linked with Johns Hopkins University in Baltimore, USA, to develop the next generation of highly miniaturised medical tools. We asked Robert Bollinger, professor and director at Johns Hopkins School of Medicine, and Mark Shaver, senior director for strategic alliances at Johns Hopkins Medical, what are these 'tools' and where do they fit in future healthcare

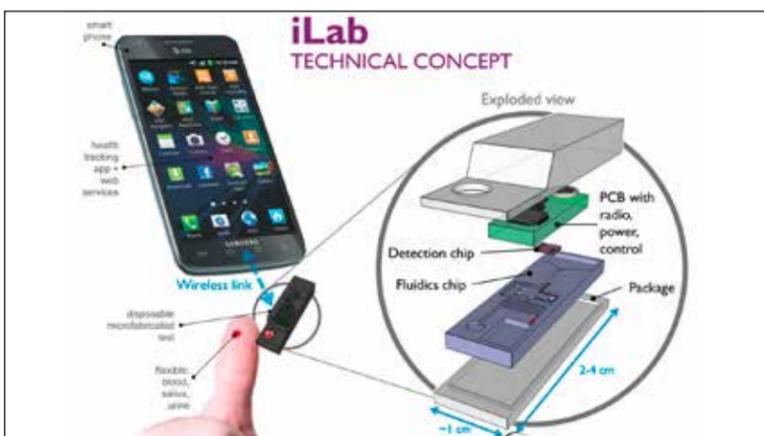
Like so many medical people, Robert Bollinger is concerned about people with limited or no access to medical care. 'For many,' he points out, 'it's simply too expensive to go and see a doctor. In some regions there are no hospitals or healthcare providers, or they are too far away. And, for many, the social threshold to access the system is too high.'

Thus he welcomes all initiatives to improve access to diagnostics, particularly for chronic diseases such as diabetes. New infectious diseases, such as SARS, or bird-flu, or new drug-resistant diseases, also arrive. 'Some cancers,' he adds, 'are becoming resistant to treatment. The challenge here is finding ways to identify when that happens and to select treatments best suited for each patient. Again, we'd need more high-quality diagnostic tests and individualised tests to be available anywhere.' He is not idealistically unaware of that major issue – cost. 'Success,' he says, 'will largely depend on how we can reduce cost. Our iLab-project promises to answer those challenges.'

Available for everyone

'With iLab,' explains Mark Shaver, 'we want to integrate diagnostic tests on a chip – tests for which patients now go to medical facilities. iLab will allow them to do them at home. Our vision is a silicon chip with the ability to diagnose multiple diseases, integrating multiple laboratory tests, for under US\$10, giving a result under 10 minutes, available and easy-to-use for anyone – anywhere in the world. We chose to start our collaboration with iLab because, as a concept, it's most mature, and because we already have a pretty good idea how to make it.'

'Technically, we're not going to push the edge on detection limits, or find new types of biomarkers. We're going to miniaturise and integrate existing technology and tests, on a



platform that can be mass-produced with standard chip-fabrication processes. We have selected a number of infectious diseases for which we want to develop better diagnostics, among them HIV infection. We've chosen these because they will push us to the limit of what's possible with iLab. It will involve, for example, detecting and counting viruses, identifying proteins, quantifying metabolites, and identifying and separating types of cells.'

Changing HIV care

'Just look at the current state of care for HIV and see what could be achieved with iLab,' Robert Bollinger suggests. When someone is diagnosed with HIV, their eligibility to take medication and which suits them is assessed. When taking medication, another set of tests are run to see how the patient is responding to treatment, and whether there are side effects. 'In much of the developed world, HIV patients have access to a wide range of diagnostic tests. Typically, we do a viral load test (counting virus numbers in a blood sample), a count of CD4 cells (specific type of immune cell), and the kidney and liver functions are measured.'

However, these tests, are not available for the majority of HIV patients

worldwide. Without tests, he points out, it is difficult to monitor and optimise HIV treatment.

'We envisage building a test kit with the form factor that may resemble a USB stick, to put into the hands of people who are HIV-infected. With the kit they can prick their finger and draw a tiny drop of blood to be analysed by the lab inside the kit. Ideally, this test kit would diagnose the viral load, CD4, liver function, kidney function all simultaneously. Then they can plug it into a smartphone and uplink the test results to their care provider – and in this way without even coming to the clinic, they can be diagnosed and managed at home, even in resource-limited communities.'

iLab could not only change the way medical research is done, but also be a 'game-changer' e.g. in drug discovery, Robert Bollinger adds. 'It's extremely expensive to develop new drugs, particularly because clinical trials involve hundreds to thousands of people who have to be tested regularly. This technology could greatly speed up and optimise how clinical trials are done.'

'iLab could also be greatly beneficial for disease surveillance,' he suggests. 'A big issue with transmittable diseases, such as influenza, is to identify people who actually

have the disease. Then we can link them with care and isolate them from others at risk. Right now, this is done with expensive and complex systems. Imagine having that ability with a low-cost chip that you can distribute throughout communities very easily.'

The iLab partnership structure

imec and JHU bring complementary expertise to the project. 'Together, we will develop the building blocks of iLab, the platform on which to develop the actual diagnostic products,' explains Mark Shaver. 'We're also having conversations with a number of potential partners who are willing to invest in the initial research in this first three-year phase. These will be leaders in the biotech industry, for example, who will help us identify quick pathways to new diagnostics. They will also define the products based on our platform and make them available to patients. We've worked intensively with imec over the last year, and discovered a really shared culture. Innovation and research is a primary driver of what we both do. So, we're very confident going into this collaboration.'

What really drives JHU are developments that can have a positive impact in healthcare worldwide. Our goal is to have a transformative impact on health. This collaboration, starting with iLab, could ultimately transform healthcare. Not just in our communities, but globally. Epidemiology, public health care, research ... could all be affected by results from this collaboration.'

Healthcare evolution in the next half century

'I'm greatly interested in the notion of the point-of-singularity,' Robert Bollinger says. 'In our medical context, this is the point where we know enough about prevention and



Associate director of the Johns Hopkins Centre for Global Health (Baltimore, USA), Robert Bollinger (right) is also a professor of infectious diseases in the department of medicine of the Johns Hopkins School of Medicine, and has a joint appointment in the department of international health of the Bloomberg School of Public Health. The professor has more than 27 years' experience in international public health, clinical research and education in a broad range of global health priorities, including HIV/AIDS, malaria, tuberculosis, leprosy and emerging infections.

As senior director of business development and strategic alliances, Mark Shaver (left) leads the unit within Johns Hopkins Medicine charged with the exploration, expansion, development, and management of collaboration with corporate and strategic partners. In this role, he works in partnership with a wide range of the Johns Hopkins faculty and senior leadership across the Johns Hopkins medical enterprise.

health to radically improve people's long-term quality of life and health expectations. Imagine that you could reach the biological age of 25 or 30 and maintain that quality of health for another 60-70 years.

'How will we reach that point? We still have to learn a lot about the mechanisms of ageing, but we know it will be crucial to individualise prevention and treatment for everyone. We'll need individual and early prevention, diagnosis, and treatment.'

'It's going to be all about the individual, and that individual will take much better care of him- or herself. We will diagnose our own diseases and receive our treatments at home for a majority of things; going to hospital or a clinic will be a last resort. The point-of-care is going to be where we are. We are already moving in that direction with the development of a tool such as iLab.'

German In Vitro Diagnostics Industry

Cautiously optimistic

Report: Bettina Döbereiner

Despite a slight drop in sales in 2013 compared to the previous year, for 2014 the German medical diagnostics manufacturers anticipate a positive business development, according to the trend indicator presented by the business association Verband der Diagnostika-Industrie (VDGH) in Berlin. A major topic was the proposed revision of the EU Directive on In Vitro Diagnostics and its likely impact on the industry.

Preliminary figures based on the first three quarters of 2013 indicate that total sales of in vitro diagnostics (IVD) in that country decreased for the second year in a row. The good news: the sales volume dropped by only 0.7 percent compared to 1.5 percent in the previous year. As in 2013, the decrease was driven by losses in the rapid diagnostic test segment, above all blood sugar tests. Matthias Borst, VDGH Chairman of the Board, pointed at Germany's statutory health insurers for not reimbursing test costs



Dr. Martin Walger, VDGH CEO (left) and Matthias Borst, VDGH Chairman of the Board (right) presenting the trend indicator

for type 2 diabetes patients who do not need insulin, and price pressure from increasing international competition.

On the European level, with a preliminary total sales volume of €2.1 billion, Germany remains the major market for in vitro diagnostics while, according to Matthias Borst, preliminary EU market figures also indicate a slight drop for the second consecutive year. Only Scandinavian countries, he says, report any growth to speak of, but these countries account for only six

percent of the European IVD market. As in 2012, Southern European countries recorded the most severe losses, with Spain taking top position from Greece – estimated loss 11 percent.

A more optimistic outlook

Unfazed by the slight sales decrease, German IVD firms are 'cautiously optimistic' about the coming business year, according to an internal survey among VDGH members. Matthias Borst: 'Our industry trend indicator slightly rises for 2014 com-

pared to 2013.' About 70 percent of the association members, who manufacture products for labs and patients, participated in the survey. Companies that offer IVD products for basic and applied life sciences research were not included.

For several years, the entire industry had foreseen a bright future, until late 2011 optimism disappeared. Although about 42 percent of respondents anticipate an economic upturn and two thirds expect sales growth, Association members were asked, for the first time, to comment on the anticipated shortage of qualified staff: a third of respondents considered this a relevant problem and worried about potential problems recruiting technical customer services and sales staff.

IVD Directive revision

IVD manufacturers worry about the proposed regulation to replace Directive 98/79/EC on In Vitro Diagnostic Medical Devices, which proposes a new risk-oriented product classification system, toughening requirements for product approval and monitoring. Around 40,000 existing lab tests Europe-wide will

have to undergo a new conformity assessment, Matthias Borst explains.

According to estimates by the European Diagnostic Manufacturers Association (EDMA) the new classification system will cost European IVD manufacturers an additional €580 million, while the EC anticipates additional costs of approx. €425 million. Thus association members, which are mostly small and medium-size, face an enormous financial burden and might also have to increase employees.

Nevertheless both EDMA and VDGH support the proposed regulation. In a first plenary vote in October 2013, the European Parliament adopted a draft version which contained several changes the ENVI Committee of the EU Parliament had proposed to the Commission's draft. However, they do believe the currently discussed transition period of three years is 'absolutely unrealistic' and demand five years to implement a new regulation. It remains to be seen, though, whether and to which extent the changes proposed by the EP will be included in the final legislation.