

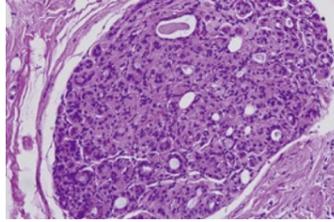
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ECR 2016
special issue

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Could cancer be contagious?



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The Zika mystery

Scapegoat or villain?

Report: Brenda Marsh

From the beginning the accusation somehow beggared belief. A 'mild' virus was blamed for causing hideous malformations in babies' heads. Brazil, a country suffering its worst recession since the 1930s, as well as political upheaval, became the focus of a worldwide healthcare scare.

Among mosquitoes enjoying a nice environment there one fairly innocuous 'new kid on the block' – *Aedes aegypti* – which, okay, is a vector for diseases – went hardly noticed when it first migrated to this country. Good heat, poor human dwellings surrounded by lots of stagnant water, all offered a comfy place to live and breed in a new country, with plenty of blood around for the ladies.

History and origins

Aedes aegypti, part of a mosquito family, hosts Zika, a flavivirus related to the viruses that transmit yellow fever, dengue, West Nile, and Japanese encephalitis to humans. It was discovered just under 70 years ago, and that's important to remember.

In Uganda in 1947, researchers on a Rockefeller Foundation investigation into jungle yellow fever, put a rhesus monkey – numbered 766 – into a cage on a tree platform in the Zika Forest. 766 was there to be bitten. Two days later, the feverish monkey was taken to the Foundation's laboratory and its serum inoculated intracerebrally into mice. 10 days later those mice were ill. The researchers isolated from their brains the transmissible agent, later naming it Zika virus (ZIKV).

In early 1948, in the same locale, ZIKV was also isolated from *Aedes africanus* mosquitoes. Serologic studies showed humans could also

become infected. In 1956, ZIKV was transmitted to artificially fed *Ae. aegypti* mosquitoes and was transmitted to laboratory mice and a monkey.

Nigeria, 1968: ZIKV was isolated from humans during studies and then also in 1971–'75; 40% of people in one study had neutralising antibody to ZIKV. Human isolates were also obtained from febrile toddlers and a sick 10-year-old.

1951-'81: Evidence of human ZIKV infection was reported from Uganda, Tanzania, Central African

Republic Egypt, Sierra Leone, and Gabon, as well as parts of Asia – India, Malaysia, Thailand, Vietnam, Indonesia and the Philippines.

2007: An outbreak of ZIKV infecting about 75 percent of the population of Yap Island, Micronesia, revealed *Aedes* had travelled beyond Africa and Asia.

2011: *Aedes* alighted in French Polynesia, bringing outbreaks of dengue and chikungunya.

2014: Brazil was alerted to the arrival of a new virus in that country, after the FIFA World Cup. However, genetic analysis of the virus revealed that the strain was most like the one found in the Pacific – from which no football teams had come.

Suspicion also fell on an international canoe event in Rio de Janeiro in August 2014, which drew competitors from Pacific islands.

On the other hand, some thought it had come overland from Chile, where a traveller returning from Easter Island had a Zika infection.

2015: With 22 years' experience, obstetrician and gynaecologist

Adriana Melo, working in the state of Paraíba, in the poor semi-arid north-east Brazil, identified microcephaly in a 20-week-old foetus.

Two weeks later, she found the same diagnosis for a 24-week-old foetus. News also came from Recife, in the neighbouring state Pernambuco, that Dr Ana van der and daughter paediatric neurologist Dr Vanessa van der Linden Mota had observed a peak in microcephaly foetuses and alerted the health ministry. Suspecting Zika to be the culprit in her two microcephaly cases, Melo contacted other specialists in her field and had sent amniotic fluid from the two mothers for analysis at a national science research institution in Rio de Janeiro. Three different tests detected the Zika virus in the fluid surrounding the microcephaly foetuses. Melo called for public-health officials to test amniotic fluid.

By mid-November the country's Ministry of Health requested all doctors to report pregnancy cases where red spots appeared on the mother's skin. Within a short time, the Ministry reported that suspected cases of microcephaly numbered 2,401 in 19 states and the Federal District, with 29 resulting in death.

The World Health Organisation (WHO), said to be still 'stinging' from criticism that it did not declare an international emergency over ebola, issued its international

warning regarding ZikaV. *Aedes* became top international public enemy overnight.

Could ZikaV cause such huge harm?

Whilst rapid and expensive research is being undertaken globally to find the true cause of microcephaly, as well as a Zika vaccine, there is no big evidence that it could cause such developmental damage in the unborn. Yes, the virus has been found in amniotic fluid and brain tissue in a handful of cases. Also 1970s study showed the virus could replicate in neurons of young mice, causing neuronal destruction and more recent genetic analyses have suggested that strains of Zika virus might be undergoing mutations.

However, controversy erupted in Brazil first regarding the very definition of microcephaly – the yardstick by which to measure head circumference. After the identification of an excessive number of suspected cases, the Brazilian Ministry of Health declared a reduction in the cephalic perimeter measurement to suspect microcephaly, from 33 cm to 32 cm, instantly lowering cases.

Figures plummet

Microcephaly is an uncommon condition. In the USA, birth defects tracking systems estimated that the condition ranges from two babies per 10,000 live births to 12 microcephaly babies per 10,000 live births – totalling 25,000 microcephalic babies born there per year.

First declaring 2,401 microcephaly births, Brazil had to admit to a far lower number of confirmed cases, now reported to be around 460, but 3,850 are still 'suspected' and being investigated.

Rumours rumours ...

People want tangible answers. Without them trust is lost. One popular theory among Brazilians has been that expired doses of measles, mumps and rubella vaccine have caused the gross head defects.

Just before 2016 dawned, Brazil's federal government's central information services tried to address this concern. It stated: it is 'totally false that an expired batch of rubella vaccines, rather than the Zika virus, has caused the microcephaly outbreak'. In addition, health minister Marcelo Castro said he held '100 percent certainty' that Zika and microcephaly are linked.

Where might he have gained such a positive conviction?

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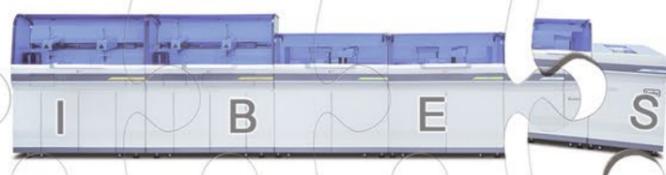


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Immigrants could fill medical professional gaps

Migration brings opportunity

A unique pilot project to promote entry into professional life in Germany for refugees with a medical background might counteract the acute shortage of qualified employees in healthcare. The programme is scheduled to start this spring. Our correspondent Bettina Döbereiner interviewed Marco Büniger, initiator of the 'National Matching' concept

Marco Büniger predicts a shortfall of at least 1,000 to 1,500 medical professionals per year in Brandenburg State's healthcare system in the future, based on an analysis of expected employee needs, an ongoing drop in numbers completing their education and those retiring from medical professions in the State, the second most sparsely populated in Germany (population around 2.46 million). However, the zone contains the State of Berlin at its centre, jointly forming the European Berlin/Brandenburg Metropolitan Region, in which about six million people live.

The calculated requirements pertain to geriatric nurses and other nurses, but occupational therapists and technical medical assistants will also be needed in the future, along with a shortfall in doctors. Some hospitals are already spending up to € 250,000 for headhunters to seek doctors, Büniger notes.

Against this background, the business consultant developed the idea of recruiting the predicted shortfall in medical personnel from incoming refugees. This was based on the Swedish model project 'Nationell Matchning', which attempts to win

back immigrants with an academic background who are working in non-academic professions and place them in academic jobs. Convinced by the idea, the Brandenburg Ministry for Health commissioned a working concept and Büniger developed the programme 'National Matching' in collaboration with the Niederlausitz Hospital in South Brandenburg.

National Matching begins the process early – at the initial registration centres – and aims exclusively at refugees with training or prior experience in healthcare. All refugees selected for participation in National Matching will be mentored from the initial language course through to starting work – a process that can take between one and a half to six years, depending on the participant's prior knowledge. The refugees complete a variety of modules in this process, starting with language support, assessment of qualifications, their soft skills, transfer or additional qualifications and an introduction to the legal, ethical and medical care principles in the German healthcare system, which is compulsory for all participants.

Potential employers are also involved in the programme and

Büniger envisages an event where the employers meet participants. Sitting in on lectures and going on excursions to hospitals and outpatient departments aims to promote mutual familiarity.

However, this will not be easy. Brandenburg's rural areas are not exactly known for their open-mindedness. These have little experience of migrants and, accordingly, are prejudiced and may even exhibit hostility towards foreigners. Büniger plans workshops and seminars with a focus on awareness of different cultural backgrounds to promote greater openness on the part of employers. This is based on strategies used in Great Britain and efforts made by the National Health Service (NHS) to integrate ethnic minorities into the healthcare system.

Other important aspects of National Matching are an in-depth assessment of specialist knowledge and professional experience, as well as participants' social competence. This applies to refugees with and without evidence of their qualifications in the form of degrees or work references. Any participating refugees with false documents are rapidly revealed, Büniger says.

The comprehensive assessment is also important for other purposes because we cannot even begin to imagine the conditions in which refugees have lived. 'Does commitment mean anything to a refugee from Somalia? Is the refugee able to deal with conflict? We want and need to find out all of this if we want to achieve successful integration,' Büniger points out.

Currently he is testing an IT-based system to evaluate social competence that has already been used in Sweden.

He also wants to adopt another of Sweden's ideas: an investigation there revealed that 98% of the immigrants had a smartphone. As a result, a trial app was introduced in all languages spoken by the refugees. The immigrants can use this to create a professional profile for themselves, provide a personal assessment of their competence and upload certificates and documents. The job centre and educational providers can access their data and thus liaise more rapidly. It remains to be seen whether this can also be implemented in Brandenburg. To date, the State uses paper questionnaires for this purpose.

The concept of National Matching is unique in Germany, so there is still no coordinating office to oversee the entire process of professional integration for a specific



Marco Büniger has been the chief executive of the business consultancy Adler Management Berlin since 2013. Before this, he was chief executive of a regional redevelopment company for the metal and electro-industry (EPL). Commissioned by the Brandenburg Ministry of Health, he developed the National Matching concept in partnership with the Niederlausitz Hospital.

professional group, from start to finish. Presented to the general public at the beginning of March the programme will start this spring.

Büniger is still seeking a sponsor. Once found, he hopes to being with 80-100 participants. The first of these could then enter into professional life as 2018 begins, with the majority probably taking four years to do so.

Details: Swedish project info (in Swedish): <http://www.arbetsformedlingen.se/Om-oss/Var-verksamhet/Projekt-och-samarbeten/Projekt/Projektsidor/2012-06-13-Nationell-Matchning---skapar-moten-mellan-utlandska-akademiker-och-arbetsgivare-i-hela-landet.html>. Colour-based methods to assess soft skills, developed in the Czech Republic and already employed in Sweden are planned for use in Brandenburg: www.camethod.com

The Zika mystery

Continued from page 1

Certainly not from the group of Argentinian doctors who blame a larvicide, Pyriproxyfen, for the rise in microcephaly births. This has been added to people's water tanks to combat mosquitoes. Although there is said to be no supporting scientific evidence of this cause, and the Health Ministry rejected the 'non-scientific report, at least one Brazilian state ended distribution.

Theories theories ...

Yoichi Shimatsu a science writer based in Hong Kong has an intriguing belief – that microcephaly cases were caused as a side effect of RIDL gene-transfer. 'The so-called Death Gene blockage, using the GATA binding protein, can affect the same gene in human embryos as in the targeted mosquito pupae,' he states. This protein has been introduced into male mosquitoes,

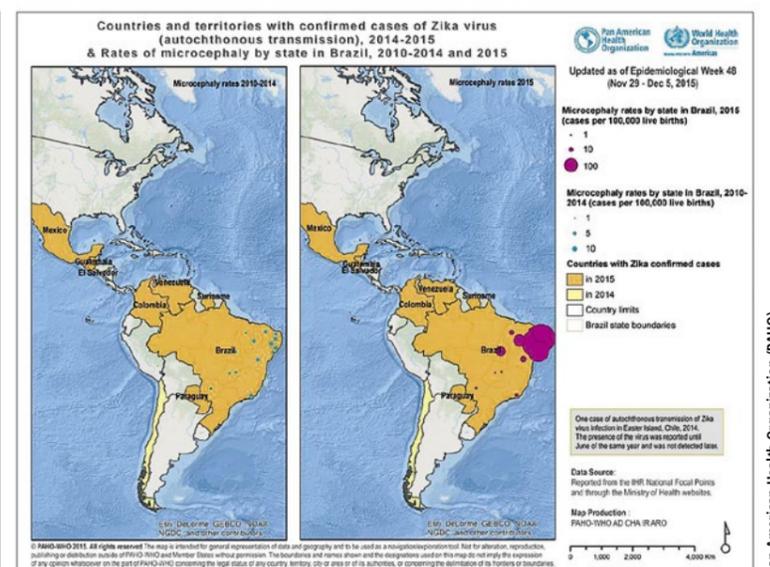
which are then released as part of the OX513-A captive mosquito programme. Out there they successfully mate with wild local female mosquitoes and the protein enters the eggs to disrupt embryonic growth. The larvae self-destruct before adulthood. 'However,' writes Shimatsu, 'these same mother mosquitoes can then transfer the dangerous protein into women, thereby seriously harming human embryonic development of the brain, nerves, heart and testicles. Damage to the GATA-1 protein in human embryos is associated with Down Syndrome, a brain disorder similar to Brazilian microcephaly.'

This population control by gene transfer science is ingenious. The OX513-A is produced by Oxitec Ltd, near Oxford, England. The firm's description of various mosquito control methods found at <http://www.oxitec.com/health/dengue-information-centre/vector-control/> is a worthwhile read.

Environmental issues

Amy Y Vittor MD, Assistant Professor of Medicine at the University of Florida's Emerging Pathogens Institute, studies the interface between vector-borne disease and land use. She is studying another mosquito-borne virus, Madariaga, the cause of many cases of encephalitis in a Panamanian jungle. Her team examine 'the association between deforestation, mosquito vector factors, and susceptibility of migrants compared to indigenous people in the affected area'.

'In our highly interconnected world, which is being subjected to massive ecological change,' she underlines, 'we can expect on-going outbreaks of viruses originating in far-flung regions with names we can barely pronounce – yet.'



So, what about deforestation? Resulting landslides of soil enter rivers and so deposit large amounts of mercury, which in water becomes methylmercury, an organic form of mercury – a neurotoxin, easily bioaccumulated in organisms i.e. entering the food chain through fish.

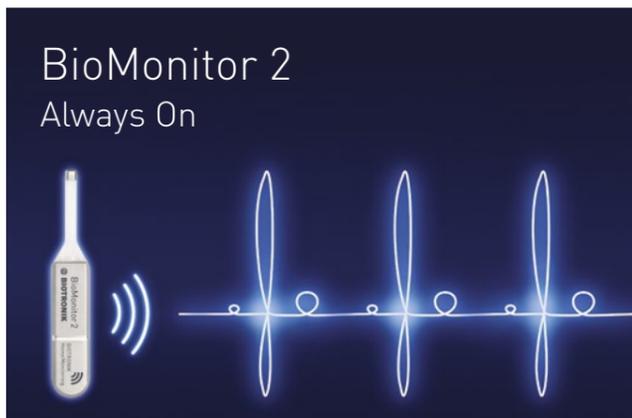
Brazil, a meat-eating nation, in recent years encouraged a fish farming industry. Current per capita consumption of fish is still low there – 6.8 kg per year. However, campaigns in 2003 focused on national and international markets for Brazilian aquaculture products. Much research shows that farmed fish can be high in methylmercury a known cause of microcephaly. Accidental leaching from aluminium processing might affect the food chain.. Checking for its presence in the microcephaly inquiry perhaps should not be ignored.

Life before ZikaV

Sandra da Silva Mattos of the Círculo

do Coração de Pernambuco and colleagues dug into medical records of over 16,000 babies born between 2012 and 2015 at one of 21 medical centres in badly Zika affected Paraíba state. Since 2012, they found a strikingly large number of babies – 4-8% were suspected of microcephaly within its broadest definitions, and the number peaked in 2014 – before Zika was detected in Brazil. 'What we expected was that we'd have around three to four cases a year of microcephaly – which has been documented in the official sites,' Mattos said in an interview. 'Then we noticed we had much, much higher numbers.'

The researchers then narrowed the definition to extreme microcephaly cases and found the rates – 0.04% to 1.9% levelled to global reports of the condition. Still, hundreds of babies had microcephaly: the nationwide incidence of reported microcephaly in years before 2015 was below 200 annually. 'It's possible, she noted,



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Cases are rare but rising due to human migration

Should we screen for sickle cell disease?

Every year around a quarter of a million children worldwide die from sickle cell disease. In Germany around 3,000 people suffer from this rare inherited blood disorder. However, the trend is rising: the influx of refugees is most probably linked to this increase, since the disease exclusively affects those from a migrant background.

Report: Sylvia Schulz

Patients who do not have sickle cell disease diagnosed in time often die in childhood or adolescence. In countries such as the USA, The Netherlands and France tests for this disease are already part of standard newborn screening.

The families of those affected originate from areas where Malaria has been, or still is, endemic. The prevalence is highest in West Africa. In this region, every fifth death amongst children under the age of five is caused by sickle cell disease.

Testing for sickle cell may become routine for babies

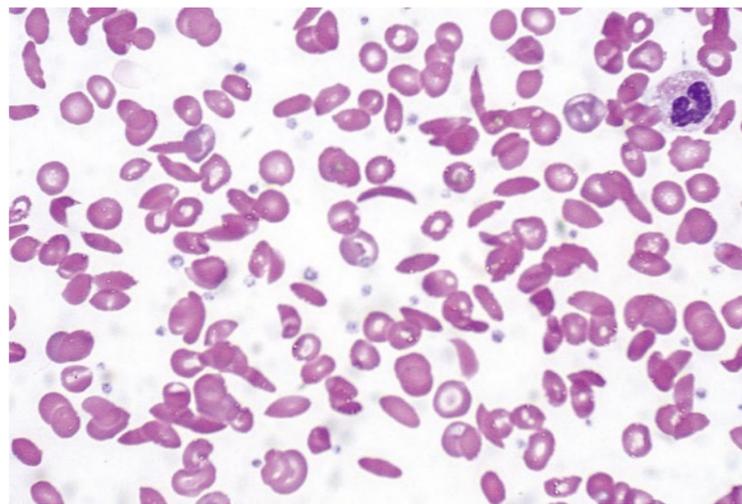
In countries such as Germany early detection is currently not assured. However, three model projects in Berlin, Hamburg and Heidelberg have now been set up to find out whether testing for sickle cell disease can and should become part of regular newborn screening.

Only once the disease has been diagnosed can the appropriate treat-

ment commence. 'Even very simple measures can reduce the impact of the disease and the high early mortality rates drastically,' point out Dr Stephan Lobitz of the Clinic for Paediatrics, Division of Oncology and Haematology at the Charité Hospital in Berlin, one of the three centres participating in the study. 'Educating parents to recognise acute anaemia and to seek medical help quickly if a child develops a fever, along with prophylactic treatment with penicillin and vaccinations, can prevent almost all related deaths in childhood and adolescence.' However, a prerequisite for this is that the blood disorder has been diagnosed and that the parents have been informed about it.

'that a high incidence of milder forms of microcephaly has occurred well before the current outbreak, but that only those extreme cases, with classical phenotypes, were being notified. As the number of extreme cases increased over these past three or four months so did awareness of health professionals who started to notify milder forms.' (Ref: Report published Feb. 4 in the Bulletin of the World Health Organization. Mattos's team did find an increase in the most severe forms of microcephaly in the last months of 2015, and doctors have reported a recent rise in the number of severe microcephaly cases in Brazil. Critical to understanding the degree of microcephaly is the need to standardise diagnostic criteria. Researchers at the Federal University of Pelotas, Brazil reported that '...the number of suspected cases relied on a screening test that had very low specificity and therefore over-estimated the actual number of cases by including mostly normal children with small heads.'

Currently, health coordinator Dr Adriana Scavuzzi and team at IMIP, a maternal and infant care hospital in Recife, is leading a case-controlled study in which 200 women are being interviewed regarding their lives and health history – including vaccinations received. Half the mothers have microcephaly babies. The rest are normal. Whilst she herself is 'almost convinced' of a microcephaly-Zika connection, this could blow away at least some demanding questions. Meanwhile, a cloud of pesticide 'fog' looms over Brazil – prompting questions about the health of people liberally sprayed from moving vehicles, without prior warning, in the battle to kill Aedes – scapegoat or villain.



Red blood cells under the microscope: In the case of sickle cell diseases they may take the form of sickles

Therefore, Lobitz believes, standard newborn screening is essential. Sickle cell anaemia results from inherited changes to the haemoglobin in red blood cells (erythrocytes). The most important function of haemoglobin is to carry oxygen from the lungs to organs and tissues. Erythrocytes are filled with fluid and haemoglobin usually remains dissolved in this fluid.

However, the haemoglobin of patients with sickle cell anaemia clumps together into solid structures inside the erythrocytes once it has released the oxygen and loses its functionality. These solid structures

Erythrocytes can be deformed

impact on the usually very high flexibility of the erythrocytes and damage the cells, shortening their lifespan. As a result, the erythrocytes become deformed, remain in small blood vessels and block them. This leads to small infarctions and very small damage to the organs, which, over time, can add up and in turn lead to a significant impairment to the function of certain organs, and even their total destruction. Simultaneously, the premature death of blood cells causes an increased accumulation of metabolic products, which in turn can damage larger blood vessels.

Along with these slow, but steadily progressive changes there are also acute problems caused by the sudden accumulation of large numbers of sickle cells.

Screening with tandem mass spectrometry

These so-called crises, the triggers of which are not yet entirely clearly defined, often go hand in hand with severe pain, frequently can only be treated in hospital and should be treated with the strongest painkillers, severely impacting on quality of life. There are other acute and serious complications, such as splenic sequestration, where blood only flows into the spleen but not out again. Every ninth patient is destined to suffer a stroke before his or her 18th birthday. Viral infections can lead to acute, life-threatening anaemia.

The project is now examining whether testing for sickle cell disease in Germany is possible with standard laboratory procedures. 'German laboratories are usually not equipped with the devices that are



Dr Stephan Lobitz works in the Clinic for Paediatrics, Division of Oncology/ Haematology at the Charité Hospital Berlin. After completing his medical degree at the Heinrich-Heine University in Dusseldorf he worked as a research associate at the Charité Paediatrics Clinic. He has specialised in Paediatric Medicine since 2012 and is also a Speaker for the management of the GPOH (Society for Paediatric Oncology and Haematology) Sickle Cell Disease Registry Study.

used internationally,' Lobitz reports. However, he believes that tandem mass spectrometry, which is usually part of standard screening in this country, could also be used to diagnose sickle cell disease. 'We would have to ensure that reliable results are available fast and that the affected newborns can be transferred quickly to wards that specialise in the treatment of blood disorders,' he emphasised.

So far, 90,000 children have been examined in the context of screening at the three locations (Hamburg, Heidelberg, Berlin); 24 were confirmed with sickle cell disease. It is not yet clear how the findings will be translated into actions. The relevant political negotiations are currently taking place, Lobitz reports. Researchers are also receiving support from the German Society of Internal Medicine (DGIM). 'The most important concern for DGIM members is also to find solutions for the best possible diagnosis and treatment for diseases that only affect a relatively small number of people,' says Professor Ulrich Fölsch, General Secretary of the DGIM from Kiel. Therefore the DGIM welcomes advances made by this research group.

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Still ranking 1st for organ donations and transplants

Spain: 24 years on top of the world

With 4,360 transplant operations from 1,682 donations in 2014, Spain broke the country's own record and confirmed its place as the world leader in organ donations, a position it has held for the past 24 years. Our correspondent in Spain Mélanie Rouger spoke with Dr Rafael Matesanz, founder and director of the Spanish National Transplant Organisation (ONT), to understand this undisputed achievement.

What is the key to your success?
Dr Matesanz: 'When the ONT was created in 1989, donations were falling and waiting lists were very long. So we broke with tradition: instead of being a non-profit foundation, like every other transplant organisation back then, we became a

part of the Spanish Health Ministry. Another move was to place an intensivist, instead of a nurse or technician, to coordinate donations directly in the hospital and detect potential donors.

'We have trained over 14,000 specialists involved in organ transplant

– from detecting donors to talking to relatives. We also work to keep the public informed. In 1992, three years after we started, we became the world leader in organ donations. People are generous but you can't expect donations to fall from the heavens. A good system must train and motivate professionals; what works in the end is organisation.'

Why should the coordinator be a doctor?

'A nurse is crucial at the time to talk with relatives; but an intensivist is on the same level as a surgeon and will understand all the clinical questions. Our coordinators work directly within the intensive care unit (ICU), so that they can influence donation very early. '87% of our coordinators are intensivists but they can come from any other medical specialty.

'Presumed consent is very characteristic of southern European countries and informed consent is more common across northern Europe. But even with presumed consent, relatives are consulted and have the final say. Only in Singapore do they enforce presumed consent.

'According to Eurostat, those most in favour of donations are northern countries.

'But, once faced with a relative's death, how you conduct the interview matters much more than previous beliefs.

'Presumed consent doesn't necessarily lead to more donations. For instance, attempts to switch to presumed consent in Brazil led to a backlash against organ donations.

Who are Spain's donors?

More than half of them are over 60 and die following brain death. Traffic accident victims, who used to represent over 40% of donors, now only account for 4%.'

What are the most transplanted organs?

'Kidney transplants represent three quarters of the 120,000 transplants performed in the world annually, followed by liver, heart, lungs, pancreas and intestine.

In 2014 there were 2,678 kidney transplants, 1,068 liver transplants, 265 heart transplants, 262 lung transplants, 81 pancreas transplants and six intestine transplants in Spain.'

Has the economic crisis affected donations?

'The number of airplanes used for transplants has reduced by 20% since the crisis began. As a result, paradoxically, we've become more efficient and transplant more than in 2009. That's because our system is very solid.'

'It could have serious consequences for both Catalonia and Spain. Our current system is well balanced. There's a fluid exchange of organs and a fifth of transplanted organs come from a different region.

'Catalonia has a lot of cutting edge and specialised teams; but it has fewer donors than regions, such as La Rioja or Cantabria.'

How do you tackle transplant tourism?

'There isn't any black market within the EU because it's very controlled. Outside, that's another story. It's a North-South problem; people from high-income countries buying from low-income countries.

'According to the WHO, five to 10% of all transplant operations originate from trade. Some people also buy their way up into waiting lists. Internet enables those exchanges.'

Spain attracts many EU citizens who want to benefit from its efficient public healthcare system...

'As long as they can validate a second residency in Spain, all EU citizens can enjoy our health benefits, including organ transplant.'



Nephrologist Rafael Matesanz is founder and director of the Spanish National Transplant Organisation (ONT), part of Ministry of Health, Social Services and Equity. ONT plans and coordinates cells, organ, tissue and bone marrow transplants. He is responsible for the 'Spanish Model', which led Spain from mid-to low- donation levels in the '80s to world leader from 1992, with rates more than double EU rates. He presides over the Spanish National Transplant Committee, and the IberoAmerican Council of Organ Donation and Transplantation, and advises the USA's Institute of Medicine (IOM) and the WHO on global transplantation strategy.

'This works both ways: eight to 10% of our donors are not Spanish, which matches the proportion of foreigners living in the country.'

'Interestingly, when asked if they'd agree to donate a deceased relative's organs, 40% of the British who live in the UK said no; but when they live in Spain, only 8% refuse to donate. The British donate far more in Spain, and this is also true for other communities living here. This proves that consent is not based on cultural beliefs but on the system.'

What are your plans for the future?

'We expected more donations than ever in 2015, and we plan to increase the number of donors by 10% and transplanted patients by 20% within the next five years.'

'We're implementing the EU's ACCORD programme, which we developed with the UK to involve emergency physicians in donor detection.'

'Globally, we expect donation after cardiac death to continue to augment the number of donations and to become the main expansion strategy in deceased donors.'

The gruelling fight for trust

Organ donation in Germany

Whilst Spain has announced a new record for organ donations the number in Germany is stabilising at a 'low level'. The good news? The number did not fall any further following scandals surrounding the manipulation in the allocation of donor organs.

Report: Sylvia Schulz

The German Organ Transplantation Foundation (DSO), the coordination centre for post-mortem organ donations in this country, reports the number of organ donors nationally increased slightly from 1.5% in 2014 to 877 in 2015 – 10.8 donors per one million inhabitants (2014: 10.7) compared to Spain with 39.7 organ donors per one million inhabitants.

Thus the dramatic decline in willingness to donate halted, for now. Although 1,296 donor organs were available in 2010, the number decreased continuously over following years. There are currently around 12,000 patients await donor organs. According to the DSO, the reason for the drastic decline is transplant scandals uncovered in four hospitals – in Göttingen, Regensburg, Munich and Leipzig. They are accused of manipulating patient data and misrepresenting

the severity of patients' conditions to improve their allocation ranking.

'In the third year following the transplant scandal no end to the problems is in sight. The legal follow-up to the scandal continues at the forefront,' said Professor Björn Nashan, President of the German Transplant Society (DTG), during the society's congress a few months ago. Both politicians and the media reacted: A number of fundamental changes to improve transparency and quality assurance have now occurred in transplantation work.

The Transplant Law, which came into effect in August 2012, has been modified several times in the light of the above events of 2013. Along with extended governmental control over transplants, the law also introduced a statutory offense to address potential future manipulations. A nationwide transplant register is also envisaged. This law also created the legal necessity to employ-

ment of transplant coordinators, to be employed by all donor hospitals.

Additionally, the law has introduced a formalisation of processes and continuous monitoring, as well as the implementation and expansion of quality assurance procedures for organ removal, donor hospitals and transplant centres.

Living kidney donors have a slightly increased risk of developing kidney disease or even needing dialysis compared to healthy non-donors. Younger women donating a living kidney are at higher risk of complications during pregnancy. Further effects can be raised blood pressure and protein secretion in urine. As German Transplant Law stipulates regular medical follow-ups for all living kidney donors, transplant centres offer annual examinations. However, Banas emphasises, 'If there were sufficient post mortem organs available we'd only advise living donations in certain people.'

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Focusing on personalised radiology

Report: Mark Nicholls

With precision imaging playing a greater role in daily radiology practice as patients receive ever more personalised care, the detail and extent of that shift is outlined in the ECR session 'Personalised radiology: myth or reality?', which includes a presentation from renowned radiologist Professor Gabriel Krestin, chairman of the radiology and nuclear medicine department at Erasmus MC, University Medical Centre, Rotterdam, entitled 'From

personalised to precision imaging: the impact on clinical practise'.

Speaking ahead of ECR, Professor Krestin told European Hospital: 'Personalised medicine and personalised imaging means the customisation of the whole healthcare continuum tailored to the individual patients - it's the right treatment to the right patient at the right time. In this context many radiologists would say radiology has always been personalised because what is more personalised than an image?' To demonstrate this, he will offer

six images showing very different diseases all manifesting with the same leading symptom - right lower quadrant abdominal pain. 'The image gives a very personalised diagnosis, but also allows us to personally stage the disease and see how extended it is and which organs are involved and also to show whether the disease is homogenous or heterogeneous, where exactly disease is located and what structures are involved,' Krestin explained. In this context imaging facilitates personalised treatment, with monitoring and adjustment, and optimal treatment choice and

route of access for surgery. But that is taken a stage further with precision imaging.

Defined as stratification medicine, Krestin - awarded the Gold Medal of the European Society of Radiology at this year's ECR - said it revolves around the idea that individual characteristics, molecular or otherwise, can improve medical research and daily practice.

'For that, molecular methods and also imaging should be standardised, structured and quantitative

Continued on page 6



Gabriel P Krestin is full professor of radiology and chairman of the radiology and nuclear medicine department at Erasmus MC, University Medical Centre Rotterdam, NL. Graduated at the University of Cologne, Germany, he completed his residency in radiology in 1988 and was later appointed radiologist and head of the MRI centre at Zürich University Hospital, Switzerland, where he became associate professor of radiology and head of the clinical radiology service, before moving to his present position.

Your ECR 2016

Placing a foot in two disciplines

Congress president Professor **Katrine Åhlström Riklund**, Deputy Head of the Department of Radiation Sciences and Director of the Medical School at Umeå University, Sweden, as a representative of two professions - radiologist and nuclear physician - has shaped the face of the congress

After last year's success, with about 25,000 visitors, 2,000 more than in 2014, the extensive programme matches the demands of the international radiological community. There are three state-of-the-art symposia, nine Professional Challenges sessions, 15 Special Focus sessions, over 70 refresher courses and three multidisciplinary sessions, which feature radiologists, oncologists, gynaecologists and surgeons.



Katrine Åhlström Riklund from the Medical School at Umeå University, Sweden, is this year's congress president.

The Education programme covers educational issues, from undergraduate medical education to specialised continuing professional development. A major addition this year is 'The voice of EPOS', a new poster presentation format. Also, for the first time, posters will be available in digital form as well as presented by the authors themselves.

Hybrid imaging - In quite a few European countries the distinction is clear. Generally nuclear medicine specialists read PET images and radiologists read CT or MRI images; however, at Riklund's university all physicians working with hybrid imaging are dual licensed in radiology and nuclear medicine. Reason: particularly in cancer cases, hybrid imaging gives more information than only structural or only molecular/functional imaging. The hope is that treatment will become more effective and prognoses more accurate. Hybrid imaging is defined

as the fusion of two or more imaging technologies into a single, new form of imaging. Typically, this new form is synergistic - i.e. more powerful than the sum of its parts.

The importance of this discipline is underlined by the official launch of Europe's latest subspecialty society, the European Society for Hybrid Medical Imaging (ESHMI). 'We hope that this new society will help to stimulate a much closer collaborative relationship between radiology and nuclear medicine, and will provide a framework for the future development of training, education and standards in hybrid imaging,' explained ESR President, Professor Luis Donoso Bach (Barcelona, Spain). 'It's very important that this unique field is represented by its own European body.'



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Biomarkers increase impact

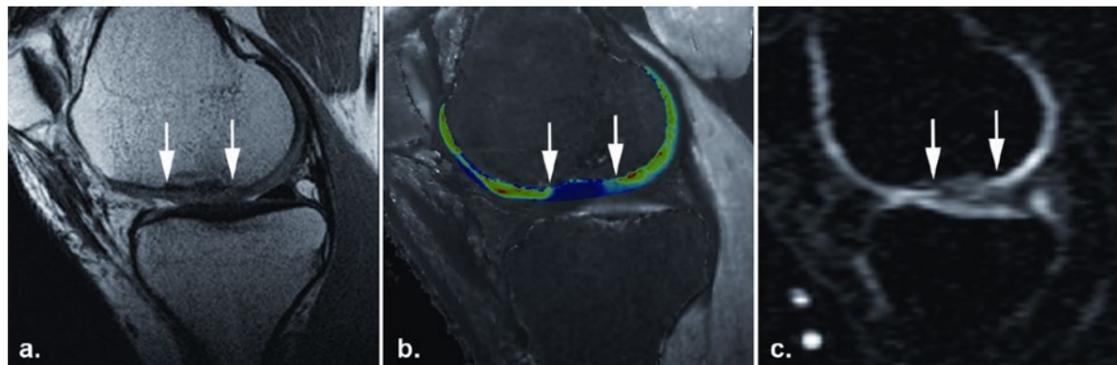
Report: Michael Krassnitzer

'In imaging there is a trend towards quantification,' said Professor Siegfried Trattnig, Medical Director of the High-Field MR Centre (HFMR) at the Medical University Vienna, Austria. Whilst before, radiologists' findings were subjective, qualitative results, based on signal intensity and grey scale, he pointed out. 'Today imaging can draw on quantifiable and comparable parameters with diagnostic value.'



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Dr Siegfried Trattnig is a Professor of Radiology with a focus on high-field MRI at the Medical University in Vienna, Austria. He has been Medical Director of the high-field MRI research scanner since 2000 and, from its founding in 2003, of the High-Field MR Centre (HFMR) at MedU Vienna. He is also a member of more than 50 scientific committees in all major international radiology, orthopaedics and MRI societies, and has chaired the European Imaging Biomarker Alliance (EIBALL) since its establishment in 2015.



Sodium cartilage transplant: a morphological MR image of a cartilage transplant (arrows indicate the boundaries) on the left, a proteoglycan-specific contrast enhancement (centre) and a sodium MR image that is also proteoglycan-specific (right). Sodium imaging can quantify the proteoglycan concentration, which is relevant since proteoglycan plays an important role for the biomechanical functioning of the cartilage transplant

Biomarkers are playing an increasingly important role in imaging,' the professor emphasised.

All imaging modalities use biomarkers, which can be defined as anatomic, physiologic, biochemical or molecular parameters detectable with imaging methods used to establish the presence or severity of disease.

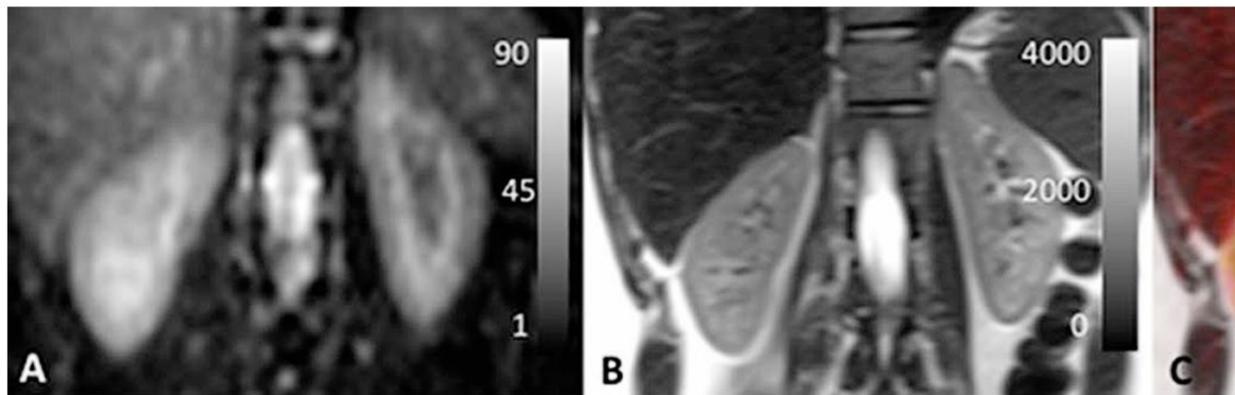
Applying quantifiable parameters

A very straightforward example of an imaging biomarker is the size and volume of a tumour determined in computed tomography. But spectroscopy and nuclear medicine also apply quantifiable parameters. In tumours, for example, changes can occur in the cell membrane involving the metabo-

lite choline: an increased choline concentration in tissue detected by spectroscopy indicates a malignant

tumour. In nuclear medicine tracers that dock onto particular metabolites are injected into the body.

Sodium imaging allows the measurement of concentration characteristics of the kidney, differentiating between renal cortex and renal medulla. Sodium image of kidneys (left); conventional morphological MR image (centre) and a coloured overlay of the sodium image over the anatomical image



Personalised radiology: myth or reality?

Continued from page 5

and different types of information should be integrated,' he said. 'In this way quantitative imaging biomarkers have been developed, and validated, that can predict disease with high accuracy; you can measure the volume of certain brain areas and predict with a high probability the development of Alzheimer's disease. These biomarkers are now translated from research into daily practice.'

Algorithms automatically measure brain structures volume

His team at Rotterdam has developed automated image processing algorithms that allow radiologists to measure accurately, using full automation, the volume of different brain structures, using dedicated work stations that calculate automatically these volumes and allow

a clinician to see whether they are within the age-related norm or below, meaning that the patient has a relevant atrophy predicting the development of Alzheimer's disease.

Another example is measuring coronary artery calcification as a strong prognostic factor for predicting those at risk of fatal coronary heart disease.

Research has also shown great potential in the evaluation of therapy response of cancer patients by combining molecular information and imaging. Krestin believes this has already had an impact on daily practice.

While RECIST is a recognised method for evaluating a certain lesion under cancer therapy, he believes more sophisticated ways of assessing response to treatment are already entering daily practice, either with nuclear medicine

methods such as the metabolism of lesions with PET-CT, or looking to the perfusion of lesions with dynamic contrast-enhanced MRI.

He foresees more of these imaging biomarkers being validated and entering clinical practice with the combination of different diagnostic tools - not only for imaging but also molecular, biologic and biochemical tests - leading to integrated diagnostics.

Treatments will become more customised

The evolution of a personalised approach combined with precision imaging will see fewer unnecessary treatments and side effects for patients. 'The whole treatment will be a lot of more customised and, because we are using personalised prediction, it will help to identify, much earlier, those individuals who may be at risk of developing diseases.'

Krestin also believes the shift to personalised and precision medicine and imaging will be cost-effective. 'An unselected use of very expensive drugs will be a lot more costly than the precise selection of those individuals who could benefit from a certain expensive treatment.'

Acknowledging that radiologists need more expertise in molecular biology, he suggests that they should also apply more measurements in their daily practice, because it is more accurate than descriptive reports. 'Structuring reports, including quantitative data, is helpful in order to really compare results and deliver the relevant information to

the clinicians,' he suggested.

'I also think integration of other relevant findings from pathology or laboratory medicine into the final report in the sense of an integrated report is the way forward.'

A range of imaging methods will still play a role because each has benefits and drawbacks and many are complimentary, depending on whether radiologists want to 'predict, screen, make a diagnosis or monitor therapy'.

Machine learning and Big Data will help manage the enormous amount of data and support the clinician in measurements, he said, as 'perception with only the eyes will not reveal all the subtle findings. Some of these measurements are time-consuming, therefore algorithms based on machine learning and big data will help us to perform these relevant measurements in an automated or semi-automated fashion.'

'Big data will allow us to establish correlations between our imaging biomarkers and other "omics" information, putting imaging into a crucial role of elucidating pathophysiology and assessing on an individual basis the relevance and extent of disease.'

ECR 2016
Thursday 3 March
8:30-10:00 a.m. Studio
2016 PC 5
Personalised radiology:
myth or reality?

Establishing a European bi

Integrating and 'omics

An official collaboration between the European Society of Radiology (ESR) and the Biobanking and Biomolecular Resources Research Infrastructures - European Research Infrastructure Consortium (BBMRI-ERIC) began last November when the organisations signed a Memorandum of Understanding on to seal their partnership.

Through its European Action Plan for Medical Imaging, launched in November 2014, the ESR has drawn the attention of EU institutions and other stakeholders to the importance of integrating imaging and 'omics' data and the need for a structured repository for imaging data to facilitate personalised medicine, clinical trials, and new drugs evaluation.

The society has since worked on a strategy to support the development of European biobanks in medical imaging to simplify access to knowledge, improve interoperability, standardisation, and data management, and to ensure a harmonised approach to data quality assurance. The immediate purpose of imaging biobanks will be to allow the generation of imaging biomarkers for use in research studies and to support biological validation of existing and novel imaging biomarkers.

The ESR reports that the society is particularly pleased with the BBMRI-ERIC collaboration, which will facilitate development in the

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marker Alliance (EIBALL),

on imaging

the fact that the sodium-potassium pump in healthy cells ensures that the sodium concentration within cells is higher than without. When a cell diseases, the ion pump is one of the first elements of the cell to be impaired. Consequently, tumour cells show a much higher sodium concentration than healthy cells.

The European Imaging Biomarker Alliance

This new MRI approach measures intracellular and extracellular sodium levels and 'allows us to detect and quantify the earliest stages of cancer on the cellular level, the professor said. This might be relevant, for example, in breast cancer therapy: current imaging technologies can visualise tumour response to chemotherapy after four to six weeks; sodium MRI might be able to do that within days.

To support these new developments, last year the European

Society of Radiology (ESR) re-organised its imaging biomarker activities: several subcommittees and working groups on imaging biomarkers were combined to form a single unit, the European Imaging Biomarker Alliance (EIBALL).

'We aim to move imaging biomarkers to clinical application,' explained

Trattnig, the EIBALL chairman.

EIBALL cooperates with other organisations, such as the Quantitative Imaging Biomarker Alliance (QIBA), which has been coordinating the biomarker imaging activities in the USA for several years. 'QIBA drove technological development and designed a number of standardised parameters,' Trattnig said. 'However, large multicentre studies to compare several parameters cannot be conducted in the USA for bureaucratic reasons. In Europe it's much easier to apply

biomarkers in large clinical studies.'

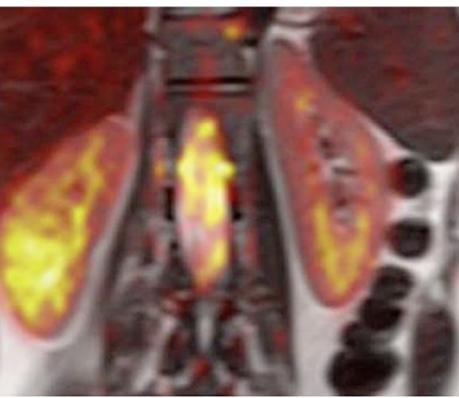
EIBALL also works closely with the European Organisation for Research and Treatment of Cancer (EORTC), the coordinator of all large European multicentre cancer studies. 'Until recently, oncological societies disregarded imaging due to the lack of standardisation; but now radiologists are members of the disease-oriented groups of EORTC,' Trattnig is happy to report.

Thus, for the first time, radiologists are involved in the design of such studies and can ensure that

imaging biomarkers are included.

At the ECR, the European Imaging Biomarker Alliance will be presenting itself for the first time in an afternoon session.

ECR 2016
Thursday 3 March
16:00–17:30. Room F1
An introduction to the
European Imaging Biomarkers
Alliance (EIBALL)



obank for medical imaging

g imaging

integration of imaging data with biobank databases.

In a joint workshop in October 2015, the partners discussed collaboration in detail and identified their common objectives under the guidance of ESR President, Professor Luis Donoso, the ESR Research Committee Chairperson, Prof. Hans-Ulrich Kauczor and the BBMRI-ERIC Director General Professor Jan-Eric Litton.

The main goals of this collaboration are to promote the importance and visibility of imaging biobanks, to coordinate efforts to establish a European imaging biobank infrastructure and to ensure its linking to existing biobanks.

The two organisations will work together on the linking of MIABIS 2.0 (Minimum Information About Biobank data Sharing) with DICOM (Digital Imaging and Communications in Medicine) and with regard to the BBMRI-ERIC Directory 2.0, a tool for sharing aggregate information about the biobanks that are willing to start external collaboration.

ECR 2016
Friday 4 March
8:30–10:00 a.m. Studio
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The best place for radiologists

A German or Swiss paradise?

The current political framework changes healthcare structures and competitive dynamics for medical services providers. These issues were raised at the 11th Management and Strategy Congress MARA (Management in Radiology) in Bonn, in autumn 2015. Dr. Martin Maurer, one of the congress organisers, explained: 'The objective of the MARA Congress is not to hold pretty lectures but primarily to address the current weak points in the field of radiology.'

Are challenges to radiology management comparable in these countries?

Maurer: 'Generally, the challenges and management objectives in radiology are not country-specific and are similar in Germany and Switzerland. Demands are increasing everywhere, due to the growing subspecialisation, with very specific requirements and requests from referring doctors and the expectation of fast, high quality diagnoses – and this in the light of massively rising amounts of images. Radiologists also need additional time for activities such as participation in interdisciplinary tumour boards – and all this against a background of decreasing reimbursements.'

Do financial aspects affect outpatient care?

'Unfortunately, these are increasingly coming to the fore in both countries. However, the conditions for radiologists are still a lot better in Switzerland. Although medical services there are also calculated on a point scale and evaluated and reimbursed according to time spent

on a service and the average time to establish a diagnosis, Swiss radiologists in private practice still receive realistic compensation for services. This obviously leads to considerably higher reimbursements for all radiologists. In contrast, cost structures – for staff, cost of living and property are much higher.

'Swiss patients receive invoices for all services provided. This creates transparency and an awareness of the value of individual medical services. German patients covered by statutory medical insurance do not have this awareness, which promotes an overuse of services.

'Looking at conditions for radiologists in Germany you have to ask how the system is supposed to work in the long term. From the service provider's perspective, reimbursement for treatment of a statutory health insured patient in many cases only just covers the costs. It may sound painful, but providing standard services for statutory health insured patients generates hardly any money for radiologists. From a health-political perspective the intention appears to be for the private medical insured to subsidise treatment for those with statutory insurance, significantly to keep the infrastructure of out-patient care going.

'Two-class' medicine is often quoted in this context. However, all German patients, regardless of their insurance cover, receive almost identical medical treatment, apart from some better comfort in hospital and quicker appointments. Therefore, it's a rather a "two-class" system from the service providers' perspective because identical services are

reimbursed in different ways and radiologists in private practices are expected to simply accept this.

'Germany's problems result from too many statutory health insured patients making too small contributions in relation to their costs. This isn't necessarily their fault: The overall level of income among the general public is too low for patients to make an appropriate contribution. In Switzerland the mean income is considerably higher and even an insured patient with a low income can still make a contribution that adequately covers costs. In Germany, I miss health politicians who make the general public honestly aware of these problems and finally will tackle structural problems that have been discussed for years.

What is the hospital situation?

'Swiss hospitals have also introduced DRGs, but are still unaccustomed to them and they worry about their high own costs. As a German I'm more relaxed about it, especially as the Swiss DRG base rates are about three times those of Germany. However, there is still a tendency to increasingly consider radiology as a cost factor that should ideally be kept low, meaning that the significant benefit of radiology departments for hospitals is being ignored. German hospitals don't appear to value this, especially looking at the reimbursement proportion for radiological services compared to overall DRG reimbursements: "basic" radiological services, such as a chest or abdominal CT scan, now receive extremely low reimbursements – a worrying situation where large parts of stand-

ard radiological examinations merely contribute towards breaking even. 'Swiss hospitals primarily must deal with high costs, which has resulted in a "clear-out" process for smaller hospitals that cannot be run profitably. On the other hand, the Swiss public is emphatic about the provision of hospitals in remote locations, making it very difficult to close unprofitable facilities, from a political perspective.

'Although many smaller hospitals also have high-quality radiological equipment e.g. CT and MRI scanners, they often don't have radiologists on site overnight and at weekends for cost reasons, preferring to use the teleradiology services provided by Bern University Hospital.'

Which country offers the brightest future for radiologists?

'It's becoming increasingly risky and unattractive for German radiologists to invest their own capital in infrastructure of their own practice because the costs are particularly high. Incalculable political decisions, such as the often discussed abolition of private health insurance, would soon have existential implications for many private radiologists. Therefore, having their own practice is no longer attractive to younger radiologists. Existing practices are also investing less and less and a many older colleagues appear intent on just reaching retirement age. This promotes the development of larger networked practices to minimise risks and cut costs through economies of scale.

'I worry about the emergence of large practice networks with exclusively profit-oriented investors who



Dr. Martin Maurer is well placed to assess healthcare changes from the perspectives of two countries. The German radiologist, who worked at the Charité University Hospital in Berlin for several years, is now a Consultant at the Institute for Diagnostic, Interventional and Paediatric Radiology, at Bern University Hospital (Switzerland). He also has a degree in business administration and holds a Master in Health Business Administration. Along with clinical-radiological research Maurer has carried out numerous health-economic studies in radiology.

buy up practices on a large scale – with no obvious criticism from the National Association of Statutory Health Insurance Physicians.

'The lack of qualified young staff is a problem in both countries, because a large number of radiologists will retire in coming years. One positive situation is that many younger women – and men – see this profession as easy to combine with family.

'It's no use moaning about radiology's prospects which I consider nonetheless being excellent. The need for radiological services will grow, as will a need for subspecialisation which will need comprehensive education and further training, whilst the cohesion as a profession must be maintained. We should focus on making patients and referring doctors aware of the importance of radiological services and continue to fight for adequate reimbursement.

A key to CDS implementation for better imaging utilisation

The ESR iGuide

ESRF iGUIDE
EUROPEAN SOCIETY OF RADIOLOGY

Report: Cynthia E Keen

Electronic radiology clinical decision support (CDS) systems, designed to help doctors order the most appropriate imaging examinations for patients, offer a way to practice better medicine, to reduce the costs of radiology and help increase patient safety by preventing radiation exposure from inappropriate or unnecessary exams.

CDS technology has existed for years. Evidence-based guidelines from the American College of Radiology (ACR) and the ESR have been recommended for decades.

Electronic medical record (EMR) systems, with the capability for ordering diagnostic tests that CDS systems interface with, are in use in many hospitals. The challenges that exist are adoption, trust, utilisation and proof of improved results.

Physicians and hospital administrators recognise the importance and value of radiology CDS systems as imaging becomes more complex and increasingly relied upon for its diagnostic capabilities.

Early adopters, such as Massachusetts General Hospital in Boston, which first started to use the technology in 2001, have docu-

mented impressive, tangible benefits. But medical practice is a highly individual profession. The symptoms and conditions of patients are often unique and not uniform. Even though USA federal legislation mandates the use of CDS when ordering advanced imaging exams for Medicare patients before the end of this decade, adoption by American hospitals has been slow. Longstanding methods of patient management that do not include the use of appropriateness criteria, the need for customisation for a specific hospital's needs, and the overall complexities of medicine have created barriers. Some are real, some imagined. All need to be overcome.

For several years, the ESR has worked to establish a foundation for Europe-wide CDS implementation. After announcing a partnership with the ACR and its commercial CDS partner, the National Decision Support Company (NDSC) at ECR 2014, the ESR began to work on developing appropriateness guidelines for European harmonisation.

First, the ESR conducted a full review of the ACR appropriateness criteria following a scientific method. It adapted these criteria to European practice standards and the latest evidence available. Content was divided into nine categories, largely corresponding to body areas. The ESR's

CDS Committee conducted rounds of content reviews with specialist members. ESR discussed the changes members recommended with the ACR Rapid Response Committee to determine where and how the European imaging referral guidelines should differ from, or be the same as, the North American guidelines.

The prototype ESR iGuide was launched at ECR 2015, and includes more than 1,500 unique clinical scenarios, linked to more than 10,000 clinical end points. These cover approximately 80% of imaging requests for breast, cardiac, gastrointestinal, musculoskeletal, neurologic, thoracic, urologic, vascular and women's imaging. Under the direction of Professor Luis Donoso, the Hospital Clinic de Barcelona has been the pilot site. Its 24+ months' CDS use, in a limited capacity, is currently being analysed. News for 2016 is that the ESR hopes to launch six additional ESR iGuide pilot programmes in hospitals in various European countries.

Marcel Wassink, director of NDSC Europe, explained that the ESR iGuide is designed specifically to meet the highly diverse requirements of the numerous European healthcare systems.

The iGuide will be available in multiple languages. Its content is configurable to support individual country, region and hospital-specific

practice guidelines and protocols. Users can add or modify criteria, which will be traceable to enable NDSC Europe to make local changes efficiently and provide automatic feedback to the ESR. These features will enable sites to adapt the guidelines to their own environments, while capturing data from users to improve these guidelines.

'At the most basic level, the objective of the pilots is to start establishing ESR iGuide and the use of imaging referral guidelines in Europe,' Wassink explained. 'Since healthcare systems and practices in Europe are very heterogeneous, it's important to have sites running in different countries to learn from a variety of experiences. The feedback from the pilots' users will help to optimise the system and enable the ESR/ACR review process to continually improve the guidelines.'

After six to nine months, he added, results will start to be analysed, with a focus primarily on changes and hopefully improvements in referring behaviour, measured against the referrals before the CDS system was deployed. 'Other instruments for analysis may be qualitative interviews with users, speed of throughput, reduced waiting times for exams, better scheduling, cost savings, and reduction in overall dose exposure through the avoidance of inappropriate

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of the spine (stitching) to create a 3-D model of the vertebral column, showing a complete spinal view to evaluate spine deformities in cases such as scoliosis, kyphosis, vertebral compression, dorsopathy, posture and balance anomalies.

**DMS Group at ECR 2016
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'BioMod 3S gives information about spinal rotations and twists that are impossible to evaluate in 2-D only. Until now, if 3-D information was needed, patients were sent to a scanner or MRI for additional exams. The system also enables access to 3-D data without added dosage. The device is easily integrated into any existing R/F or RAD suite equipped with digital full spine and long leg imaging.



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Marcel Wassink, National Decision Support Company Director

ate or unnecessary exams, such as CT. Hopefully, in the future, it will also be possible to show improved patient outcomes through better diagnosis because of the use of more appropriate imaging.'

Europe needs evidence-based appropriateness criteria guidelines. Lack of availability especially of CT, MRI, nuclear medicine and PET, lengthy exam waiting lists, and imaging costs are problems that healthcare systems face throughout Europe. A portion of imaging exams performed in European hospitals is inappropriate or unnecessary, a true waste of resources. Clinical decision support systems tackle all these problems, while providing easy and efficient access to the most updated best-practice guidelines from experts.

The ESR-sponsored pilot programmes are intended to identify how best to implement CDS systems. Their experiences, both good and bad, will benefit the next wave of early-adopter hospitals.

CDS is not a 'maybe' technology. Like digital radiography and PACS, this will happen. The question is when and how rapidly.



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PACS and imaging biobank assets combined



Aad van der Lugt, Professor in Neuro-radiology and Head-Neck-Radiology at Erasmus MC, Rotterdam, Netherlands is director of the neuroradiological research programme. In 2007, he expanded his research into imaging biomarkers in large population-based studies. Within these epidemiology studies, the professor is responsible for the imaging infrastructure. He is one of the cofounders of EPI2 (European Population Imaging Infrastructure), co-applicant of NL-BBMRI 2.0 (Biobanking and Biomolecular Resources Research Infrastructure in the Netherlands) and responsible for Population Imaging in the Euro-BioImaging (ESFRI) project. He is also a member of the research committee of the European Society of Radiology.

Report: Marcel Rasch

Personalised medicine relies strongly on biobanking in which medical data are collected on a large scale. Large scale refers both to the amount of data collected per patient as well as to the large number of patients included in the data collection. Although most attention in biobanking has been given to genetic data, proteomics, metabolomics and other -omics technologies, imaging is also being included as part of biobanking. The image features are the final result of gene-environment interaction and will provide information at the structural, functional and molecular level. Biomarkers have thus become increasingly important over recent decades and imaging biomarkers currently are gaining significant attention.

Two problems have arisen. The first is the storage of research image data; the second is the extraction of imaging biomarkers. Radiologists may wonder whether the hospital PACS can solve these problems. Working with a PACS to provide better patient

care by analysing their images and obtaining reports to improve diagnoses is nothing new to most clinicians. PACS provides storage and access to all images acquired during the diagnostic and therapeutic phase of the disease. Nowadays it can be integrated in the digital electronic patient record (EPR). For radiologists, a PACS provides a workspace for planning and reporting image exams. More importantly, the integration of image analysis tools allows the creation of 2-D or 3-D reconstructions and the extraction of imaging biomarkers. It is foreseen that structured reporting will also rely on the digital environment of the PACS and integrated thin client analysis tools.

However, storage of image data for biobanking has specific requirements and there are major differences between a PACS and an image biobank. A biobank contains anonymised data and is accessible by researchers that have permission from the principal investigators of the biobank. PACS data contains the name of the patient and are accessible by all physicians involved in

the treatment of this patient. Image storage in most research projects is not stable and robust, future data access is not secured and a secure data access is not always maintained. In contrast, a PACS is very stable and robust, data can be stored for more than 20 years, a secure access is guaranteed and loss of data is minimized.

An image biobank needs a DICOM viewer and additional analysis tools to review the image data and to perform analysis and interpretation of these data by humans. One of the main advantages of PACS is the presence of these tools. 'In the clinical environment we have a very nice PACS in which to analyse these data, but what we do not have is the possibility of using these analytical tools from the PACS in a research environment. Making full use of the options provided by a PACS system in a research infrastructure could take science to a completely new level,' he adds.

An image biobank with a well-defined structure allows query and retrieve of image data based on available metadata. In addition, multiple



imaging biomarkers can be extracted by fully automated image analysis tools with integrated pipelines that make use of GRID computing. Images of hundreds of patients can be registered, relevant structures can be segmented and quantitative biomarkers can be extracted and automatically stored in the database. A PACS does not allow query and retrieve on a large scale, nor the fully automated analysis of hundreds of image data sets. 'What we need from a research perspective is just not available in a PACS, although some PACS features would be very useful for research.' In the clinical environment, the assessment of image information relies on a description that is provided by an imaging expert: the radiologist. In a research setting intelligent machine

A big update in X-ray and fluoroscopy equipment

Leading hospital installs new generation

The radiology department at the German hospital Asklepios-Klinik Lindau recently received the high-performance R/F table Sonialvision G4, a new generation of X-ray and fluoroscopy systems, which complements examination and therapy options, particularly in internal medicine, as well as general surgery and for spinal disorders, the manufacturer Shimadzu reports

Shortening exposure and exam time – Equipped with the largest available flat panel detector measuring 43 x 43 cm, and a digital imaging platform, the universal Sonialvision G4 offers the hospital a large variety of

applications across all departments. The R/F system provides high-resolution full leg and full spine images, which can be obtained from standing or lying patients. This makes it a valuable tool for clinicians, for

example for digital endo-prosthesis planning.

The high operating speed of the R/F system reduces the exposure dose for patients and medical staff. Images can be viewed immediately after completion of the imaging procedure, thus shortening the examination time overall and reducing stress for the patients. The system's examination table is also designed for the increasing number of bariatric patients and takes a patient weight of up to 318 kg.

Multidisciplinary applications abound

'With this ultra-modern system we can examine patients with diseases of the biliary tract or impaired pancreatic drainage gently and efficiently', explains PD Dr Heinz Linhart, Head of the Internal Medicine Department at Asklepios-Klinik Lindau. 'Typical applications are for patients with pain in the upper abdomen or colics, where there is a suspected blockage of the

bile duct by gallstones. Combined with an endoscope, the biliary tract can be examined and gallstones in the bile duct can be detected and removed if necessary,' Linhart explains. The new system can also diagnose blockages of the bile duct caused by tumours.

'Examining the gastrointestinal tract using R/F technology allows not only a detailed clarification of questions ahead of a possible visceral surgery intervention, but also a review of the surgical result', adds Professor Ulrich Schöffel Medical Director and Chief Physician at the Department for General and Visceral Surgery. 'The dynamic functions of the oesophagus, the stomach and the entire intestinal tract, as well as the renal function, can be assessed reliably after administration of a contrast medium,' he adds. 'Surgically formed joints can be reviewed as easily as the success of a reflux operation on the stomach. In addition, the representation of fistulas and monitoring of their treatment is substantially simplified.'

Asklepios-Klinik in Lindau

Right: Shimadzu's high-performance R/F table Sonialvision G4



Diagnostic range completed

Johann Bachmeyer, the hospital's chief executive, stated: 'The diagnostic range is now complete and significantly improved by this piece of high-tech engineering.'

The manufacturer adds: 'The large longitudinal coverage of Sonialvision G4 and the flat panel detector, for example, provide a



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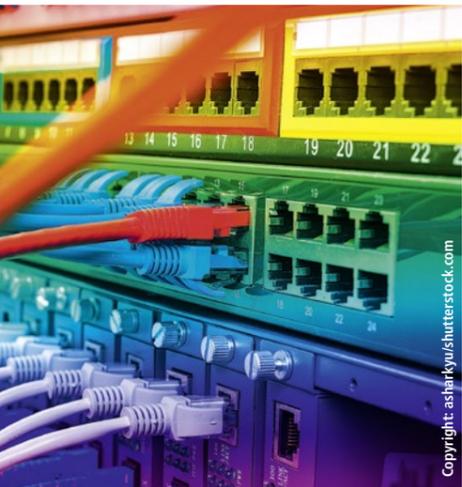
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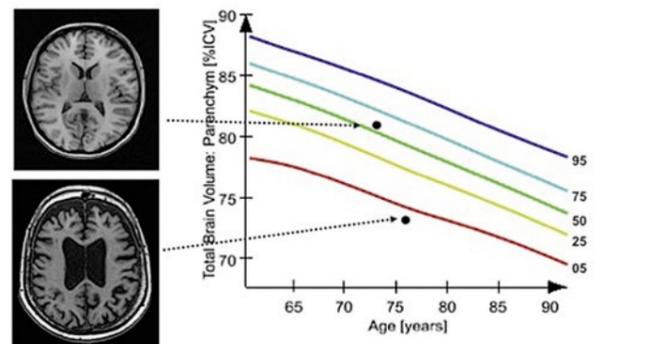
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Closing the gap

'Currently we have a mismatch that must be solved,' he states, specifying his demand: 'We should try to close the gap between the research infrastructure and the PACS system. In other words, using the tools that are available in a PACS in a research environment and using the PACS for more advanced research analysis would be the optimum. Combining the advantages of both approaches would be the best solution.' This includes a strategy of storage of anonymised data in a split PACS system. One for clinical

use and one for research use with a separate access to the two domains, and implementation of automated algorithms that can make use of multiple image datasets that, for example, can detect lesions and automatically measures their size. 'There have to be advanced algorithms that can analyse large scale data and export the quantitative imaging biomarkers to one's research database,' Van der Lugt believes. 'This approach allows the use of the data richness of the images that are available for most of the patients included in biobanks. ■



Total brain volume of an individual patient can be related to a reference based on the analysis of multiple patients. The brain in the lower panel has a volume that is below the 5th percentile of the population at the same age.

learning tools increasingly let the systems learn step by step how to read and interpret the images, but this requires that image data are prepared sufficiently and are made comparable and analysable by computers.

Finally, in biobanking image biomarkers can be related to data in the other -omics domains. However, these tools are not available as yet in the clinical setting.

ECR 2016
Thursday 4 March
8:30-10:00 a.m.
Studio 2016
Biobanks meet imaging

n devices



Peter Wochnik (right) from Shimadzu introduces the new generation of X-ray and fluoroscopy systems Sorialvision G4 to Asklepios-Klinik Chief Executive Johann Bachmeyer (left) and District Administrator Elmar Stegmann (centre).

wide imaging area. In addition, the advanced 'SUREngine' (Shimadzu Ultimate Real-time Enhancement Engine) technology supports excellent image quality. It optimises the entire image for a more detailed rendering of all areas examined, including smaller and otherwise faint target objects.'

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Big data and its role for radiology

The evolution of big data is enabling radiologists to acquire ever-larger amounts of information and exploit that detail to improve understanding and diagnoses, Mark Nicholls reports

Big data has the potential to offer a better understanding of how to aggregate clinically relevant data on a large scale and deliver better computer aided diagnosis algorithms and tools. Yet there are still elements of risk in this evolving field.

The growing importance and potential for radiologists is outlined in a number of presentations at ECR 2016, in Vienna, with a session posing the question 'Big data: why should radiologists care?'

Dr Gianluigi Zanetti, who directs the Data-Intensive computing department at CRS4 (see profile) will focus primarily on aspects of big data scientific research in his presentation 'Big data: Big Science'.

Outlining the role of big data in radiology, Zanetti said: 'The general trend is towards data aggregation and extraction of new information from the aggregated data. The trend now is towards cloud-based PACS. Apart from the obvious economic benefits of sharing computational and storage infrastructures, the integrated data set of radiological images and associated clinical details is expected to be a perfect starting point for the automated training of computer aided diagnosis algorithm based on deep-learning technology.'

'Similarly, it becomes possible to directly use images to query for analogous cases on very large dataset. Another important advantage is

that the image usually contains much more information than is actually directly relevant for the specific clinical question asked.

'Their availability in large-scale collections should make it possible to extract important clinical facts that were not evident or relevant to the originating clinical question.'

The change has been considerable in the last five years with big data technology moving from mostly research to industrial strength solutions. 'Now it's ready to be used in clinical applications as, for instance, analysis engines integrated in cloud based PACS,' he added.

Zanetti believes there are many driving factors behind the evolution towards large scale data aggregation,

the main one being economic, but there are also other factors, such as the move towards cloud based PACS and precision medicine.

He also says that, with wide data collections possibly coming from multiple sources and stored in data lakes, it is important that radiologists are aware of, and care about embracing big data because of the benefits and advantages.

Nonetheless, he does foresee areas of risk – the first related to privacy, similar to what happens when you have access to large amounts of genomic data and more professionals are needed. Zanetti: 'Once the data is available, which I expect it will be, it will not take long before a deep learning algorithm will become sophisticated enough to match human experience and training, most likely on routine exams, and I assume that this will have an

impact on the number of radiologists needed and on the definition of the specialty.

'Judging from what it is happening with Next Generation Sequencing (NGS) it will not take long before modalities will directly talk with sophisticated cloud based systems that will do CAD.'

But patients will see benefits, because he believes precision medicine can be supported only by having 'extremely precise ways to measure a given person's biology' (and thus very data-intensive probes like NGS) and a large enough number of collected datasets to support the patient subgroups stratification needed to identify optimal treatments.

Big data problems are now relevant to 'standard' scientific research, he said, where the latest generation of data acquisition devices have data rates that overpower traditional analysis pipeline. 'This is becoming particularly relevant in biology, which is increasingly a data-intensive science, with the new light sheet microscopes having data rates in the multiple gigabytes per second range, for example.'

As to the future, Zanetti sees big data in radiology offering 'a better understanding on how to combine, at very large scale, clinically relevant data, while staying within reasonable privacy preserving boundaries, and, of course, much better computer aided diagnosis algorithms and tools.'

Also during the session Professor Myriam Hunink, Professor of Clinical



Dr Gianluigi Zanetti is the director of the Data-Intensive computing department at CRS4, an Italian non-profit research organisation dedicated to research and development on IT technologies. His primary research interests focus on problems such as scalable computing pipelines and computable data-provenance, coming from data-intensive biology and now, increasingly, clinical research.

Epidemiology and Radiology at the Erasmus University Medical Centre, Rotterdam, will look at the issue of 'Big data: What's in it for the patient?', while Dr Bruce Hillman from Charlottesville, Virginia, will discuss 'Big data: big business'. Closing panel discussion: 'How to make best use of big data?'

ECR 2016
Wednesday 2 March
16:00–17:30 am.
Room C. NH4
Big data and radiologists



CBCT technology takes a step forward

New CBCT for multidisciplinary dia

A pioneer in cone beam computed tomography (CBCT) imaging, NewTom recently introduced

the only CBCT system with an open gantry and supine positioning, which the firm reports is '...

ideal for a host of diagnostic needs. Exceeding the limits posed by CT systems, the NewTom 5G XL com-

bines high diagnostic resolution with minimum patient exposure.'

Unlike its multi-slice CT (MSCT)

counterpart, CBCT technology can generate ultra-high definition volumetric images of bone tissues, with 'native' isotropic voxel resolution, non-overlapping sections and fewer artefacts, the firm adds. 'A single cone beam scan, instead of a fan beam spiral scan, shortens examination times and considerably reduces X-ray exposure with respect to other CT technologies, while cutting costs significantly.'

'The 5G XL opens the door to radiologists and specialist physicians who need the best possible diagnostic capabilities in ultimate quality 2-D and 3-D. With a wide native 21x19 cm FOV, the 5G XL is perfectly suited to an extensive range of disciplines, such as orthopaedics, otorhinolaryngology, maxillofacial surgery and dentistry. Furthermore, thanks to its motorised patient table and open gantry, the equipment is ideal for post-surgery or traumatised patients, reducing movement to a minimum.'

Reports the 'outstanding diagnostic quality of the 5G XL' the firm points out that this proves useful in multiple medical fields. 'In addition to examination of dental-maxillofacial pathologies, it is also possible to examine the internal ear, fully analyse airways and maxillary sinuses

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Most radiologists want to transfer images for consultations

We need to go into clouds

Cloud computing offers various benefits but also entails some risks. Nevertheless hospitals need to adopt new ways to simplify work processes and enhance care. 'We want to improve patient care and we have the tools but, at the moment, we are using unsafe methods for image transfers,' according to Erik Ranschaert, radiology consultant at the Jeroen Bosch Hospital in Hertogenbosch, and Chief Medical Officer for the Diagnose.me project.

The first and most convincing argument for hospitals to adopt cloud computing is economic. 'At present hospital IT infrastructure costs are high,' says Ranschaert, 'but cloud computing offers the chance to change a hospital's IT strategy. It can turn IT capital expenditure into operating expenditure.'

Currently expenditures include hardware, training, software, necessary upgrades, IT staff, etc. Such costs are increasing, especially due to growing data volumes and storage capacity. Cloud computing allows hospitals to outsource IT, significantly reducing costs. 'Of course hospitals will need to keep some local IT and IT staff to maintain the local hard- and software,' he agrees, 'but the main infrastructure as well as software can be located elsewhere.' Outsourcing will give hospitals more flexibility because different payment models, depending on the hospital's need, are conceivable: per usage, per minute, hour or per software, etc.

Three cloud services formats

Software-as-a-service (SaaS) provides specific software applications in a cloud, Platform-as-a-service (PaaS) offers a suite of virtual applications,



programming languages and tools for the user and Infrastructure-as-a-service (IaaS) relies on remote data storage networks. 'Hospitals won't have to install software on their own devices anymore so won't need upgrades,' Ranschaert adds. A big benefit would be to use and share images faster – even on mobile devices. Image post-processing can be done from a distance, on any workstation or even tablet computer. 'Sharing information between different PACS and HIS, or with other specialists worldwide would become easier. Sharing electronic health records (EHRs) would be ideal.'

The European problem

The Mayo Clinic decided to outsource IT in 2015, selling its entire local IT department to Epic, a major US player in electronic health records and software. 'This is a first move and very significant change,' Ranschaert

says. 'There certainly will be hospitals that follow in the near future.'

Whereas in the USA the implementation of public cloud computing models and virtual private cloud models is becoming popular, most European networks between hospitals or in countries (e.g. NIMIS in Ireland) are based on private networks. These rely on the XDS-I model (private cloud systems), but don't include all functions and flexibility of a full cloud-based model. There are also unanswered questions regarding data security and associated regulations. 'Politics are too slow,' he believes. 'We do have regulations in Europe, but they must be adapted and changed. The directive 95/46/EU is from 1995 and the new version was accepted in 2015, but the regulation still has to be voted on by the European Parliament in plenary during spring 2016.'

Ranschaert is convinced cloud

computing will triumph in Europe: 'It provides so many benefits. Data security is a question of the cloud computing format you use.' Cloud services can be public as well as private or hybrid solutions.' He repeats that with cloud the hardware and software is external to a hospital – no problem if working with a private cloud vendor in the same country. However, a public cloud system, especially with providers such as Amazon, questions where the data are located and stored. Due to the new EU regulation, it's important to define conditions on what security and privacy measures such services should have approved. Ranschaert: 'In the US, the Image Sharing Network from the RSNA provides a key to a patient's EHR, combined with an individual password. The patient can give this key to any specialist or hospital if needed. But legislation in the US differs from legislation in Europe.'

Illegal methods

'The current situation is unsatisfactory. Most hospitals rely on CDs and DVDs they give to patients. Integrating these into other hospitals' systems is sometimes a problem because of different formats. All this takes time and is very costly. In our hospital,' he adds, 'it's a full-time job just to burn CDs and DVDs with patients' data.'

'We are forced to work in a very old-fashioned way; many practitioners go the illegal way and share their images via WhatsApp. They take a picture of the images, or of their screen, and send them to another specialist for a second opinion,' Ranschaert explains. 'WhatsApp is being used because it benefits a patient that images are transferred quickly for discussion; but we're using unsafe methods, not protecting



Erik Ranschaert is a Radiology Consultant at the Jeroen Bosch Ziekenhuis in Hertogenbosch, The Netherlands, and Chief Medical Officer of the Diagnose.me project. He is currently writing his PhD thesis in medical sciences at the University of Antwerp. He is also an active member in the European Society of Radiology (ESR) eHealth and Informatics Subcommittee and a Board member of the European Society for Medical Imaging Informatics (EuSoMII).

a patient's privacy and not following privacy legislation.'

Erik Ranschaert's Netherlands survey* two years ago showed that radiologists need to share images digitally; 93% of respondents wished to transfer digital images to other hospitals. 'This was two years ago. In the meantime technology has developed and doctors still can't do it. We must raise awareness that WhatsApp is very unsafe. Several Dutch studies have shown that WhatsApp is used by 40-44% of hospital physicians. They are unaware of risks and often do not remove the patients' identifiable information on pictures sent. They want to help patients quicker and more efficiently. Meanwhile more solutions, in form of diverse platforms, are launched, but they are not structured and not efficient enough.'

Link to the survey: <http://dx.doi.org/10.1594/ecr2014/C-0684>

ECR 2016
Wednesday 2 March
8:30–10:00 a.m. Room N
Daily use of mobile devices in radiology

gnoses

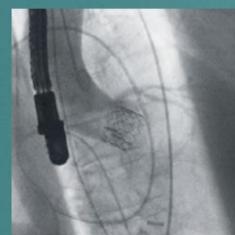
and diagnose chronic or traumatic pathologies involving bones, joints and the spinal column for more in-depth orthopaedic investigation, also in emergency rooms.'

NewTom's NNT software manages and processes the necessary data, from 3-D to 2-D and X-ray video (CineX). Both 3-D and 2-D images, and the CineX function, can be distributed using the NNT Viewer software version, or printed in 1:1 scale to produce personalised reports. Plus, the company adds, 'compatibility with other surgical planning and surgical navigation software and hospital management systems is always guaranteed by the DICOM 3.0 interface (IHE).'



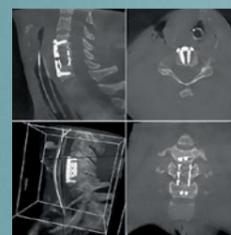
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Robust statistical evaluation depends on the source image

Big data and computer-assisted diagnoses

One thing is certain in big data discussions: Intelligent machines will change our world considerably. What is less certain is exactly how these changes will look. Although networked data processing offers many opportunities, its development is still in the early stages. In medicine, there is great hope that it will be possible to extract and use valuable information hidden in the masses of digital data in a meaningful way. Those currently involved in the research and development of innovative technologies are likely to be among the big winners resulting from this boom. Here, Peter Aulbach, Marketing Manager at Siemens Healthcare, gives us some insights into his company's present and future strategies around big data

There has been some significant success in computer-assisted detection. CAD systems, such as those used for mammography and lung screening, look for typical patterns and recognise irregularities that might indicate pathological changes. 'The software marks the conspicuous parts of the data sets at which the user should take a closer look. The objective is not to replace radiologists but to support them in their work, so that they do not overlook anything. Doctors will continue to make the diagnoses,' Aulbach points out.

Things should become even more exciting once these artificial intelligence learning software programmes can make prognos-

tic statements. Siemens is currently testing software that can differentiate between threatening and non-threatening coronary stenosis.

The analysis programme determines the virtual blood flow reserve (CT-FFR) in the coronary vessels during a cardiac CT scan and decides whether a relevant stenosis is present, or not. In the future this could avoid unnecessary cardiac catheterisations.

What is hardly ever mentioned in the context of the algorithms on which these learning programmes are based, says Aulbach, is image quality: 'Achieving significant results for the analysis and processing of data requires perfect raw data.

Image acquisition therefore calls for the utmost care and precision, as there may be artefacts that later cannot be eliminated. The robustness of statistical evaluation methods therefore depends on the source image.'

The marketing manager does not see a problem in contrast media administration, which concentrates in a different way in each individual patient and consequently produces different image information: 'Dual-energy-CT facilitates mono-energetic CT imaging, which automatically balances the different intensities of contrast media concentration in different image data sets. For the purposes of comparative analysis, it's therefore not relevant whether

some data sets have higher contrast media concentrations than others.'

The big data programmes currently in use are only aimed at assisting doctors. However, at some point, and with the help of learning computer systems, there is a chance that diagnoses will become safer and faster – and all without the human factor. This is a topic in which Siemens is also interested.

Currently, one of the main objectives is the development of a fundamental telecommunication base because comprehensive data processing necessitates feeding the machines with information. As a global manufacturer of medical technology, Siemens has access to masses of usable data. However, utilising this data requires the customers' consent. Currently, the company is developing a cloud-based network entitled 'Teamplay', which not only is used but also 'fed' by doctors, clinicians and other healthcare providers.

Customer data is anonymised, collated and processed, based on certain patterns. 'One of the first applications we will offer with this



Peter Aulbach is a marketing manager at Siemens Healthcare

IT platform is the optimisation of dosing protocols,' Peter Aulbach reports. 'We derive and evaluate patterns from the dose values supplied by the users.

'We then replay the results to the customers. This enables larger hospitals, for instance, to check whether their CT scanners adhere to the threshold values in all locations.

Even more interestingly, it also allows different centres to measure themselves against one another. If a hospital is hoping to be among the world leaders when it comes to curbing radiation doses it can use our system to check what it should do to keep up with the ten best centres in this field.

'Quality assurance, such as found in the manufacturing industry for years, could then finally become reality in the healthcare sector as well,' Aulbach concluded

Give a computer enough image data and the algorithm assesses details

Deep learning software

In a recent skin cancer study, computer software out-performed experienced doctors by such a wide margin that Harz says: 'I wouldn't have to think twice about which diagnosis to trust more'

'In the Automation in Medical Imaging (AMI) project, we will build the necessary tools and infrastructure to ease the development of a special kind of computer software,' computer scientist Markus Harz explains. 'This software is capable of learning, so that it can at some point understand images as well as a human. As the project name implies, we are not trying to teach the computer to understand any image, but medical images in particular. This requires infrastructure: loading clinical image data into the computer software development process is not straightforward, and making standard desktop computers learn is cumbersome. This infrastructure helps to develop the software efficiently.

'AMI is an international research project jointly headed by Horst K Hahn and Markus Harz between Fraunhofer MEVIS in Bremen and the Diagnostic Image Analysis Group (DIAG) in Nijmegen, The Netherlands. The DIAG group has renowned expertise in state-of-the-art self-learning software for medical image analysis. Fraunhofer MEVIS has years of experience in industry-grade software development.' The combination has already proved complementary, he points out: through shared learning and fusing development systems.

Scientific, commercial, technical objectives

'The greatest goal is to create software that solves real clinical problems. We are convinced that automation helps. Automate the

processes clinicians hate most, like searching for the right images, or comparing details from two examinations. Clinicians will want the software, thereby increasing marketability, so we'll have reached our clinical and commercial goals.

Self-learning software

'This software is similar to a person who learns. When a radiologist decides whether a suspicious area in a medical image is harmless, or reason for concern, she will use all her experience and knowledge,

Deep learning algorithms autonomously find interesting spots in new digital images of tissue samples based on an automated analysis. Starting with the highest resolution, these neuronal networks compress the data until information and image interpretations emerge

to compare form and structure, perhaps making judgments based on location and assessing other features. This is very similar to various approaches taken by machine learning. More traditional methods use criteria such as those used by radiologists. The magic lies in teaching the software to "see" with a radiologist's eyes and judge by her criteria.'

Deep learning algorithms

'Deep learning comprises a variety of neural network architectures. Neural networks emulate the brain's neural connectivity with neurons and synapses. Deep-learning neural networks are special among these approaches. They contain many more neurons and synapses than previous neural networks. Perhaps most significantly for machine learning, deep neural networks can learn directly from data. Previously,

experts had to translate between image and learning algorithms: They designed the image features for the computer to use. In a way, an expert taught the computer to see. Deep learning is different, giving the computer huge amounts of data and hints about the meaning, so that the deep learning algorithm can discover the most relevant image features – often much more useful than those constructed by a human.'

Areas of use

'We have three clinical applications in mind, but the deep learning approach imposes a clear restriction: it requires large amounts of data, and this data has to be prepared. The project tackles this problem: We want to ease the development of deep-learning computer software by simplifying data preparation by doctors, to collect large amounts of data quickly. Thereafter, trained computer software helps to collect more data. A virtual circle! We begin by focusing on three applications for which substantial data already exists – digital pathology, ophthalmology and oncology.'

'The objectives vary for each of these fields.

Oncologists monitor the health of cancer patients in screening or after treatment.

They search for minute, suspicious changes, but the images are most often completely unsuspecting. We want to present these tiny changes to the oncologist even before he's viewed a single image.

The software must learn about the body and organs, how they normally appear, where they are. Finding and capturing them automatically greatly helps later processing.

'For digital pathology, the challenge is to manage extraordinarily large images. The search for tiny cancer cell clusters resembles seeking a needle in a haystack. This is exactly what a computer can do very well and very accurately.

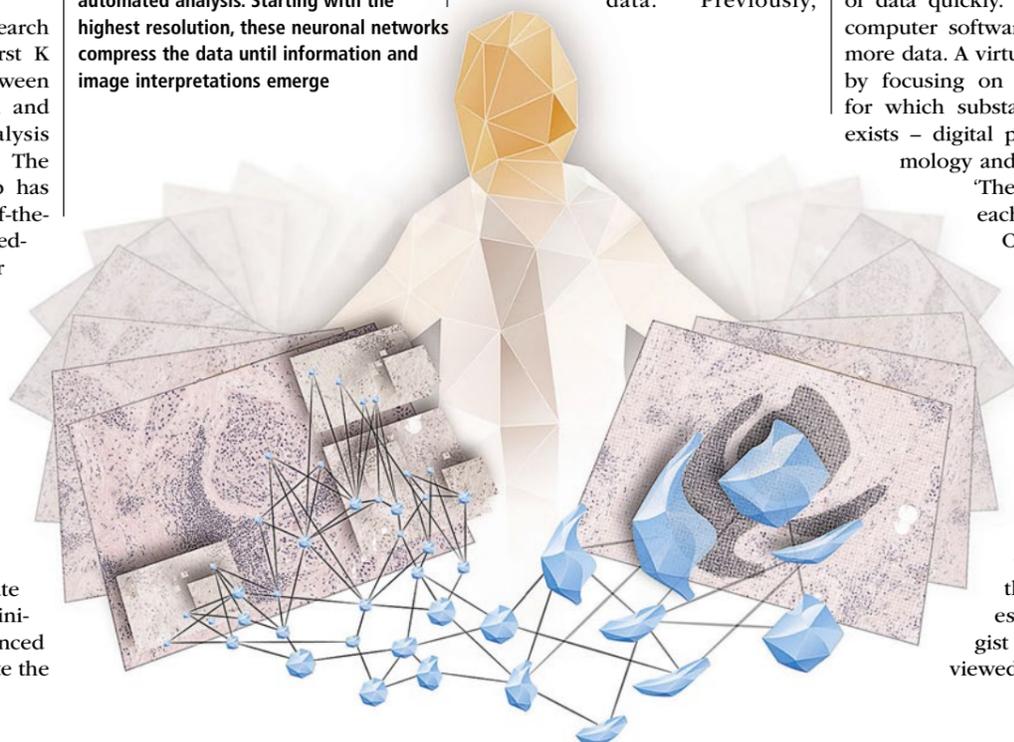
'For ophthalmology, we want to improve treatment decision-making, for example, by teaching software to detect and measure fluid compartments behind the retina. The change of this exact value from exam to exam determines the treatment.'

Software diagnostic advantages/disadvantages

'Computers can now match clinicians' performances, at least for isolated tasks. The most prominent examples include tumour detection in breast and lung cancer screening and diagnosis of skin cancer images. However, the algorithms can only perform well when provided with sufficient data and information. Doctors often have an information advantage: they may know the patient from a prior visit, or read a relevant journal article, or discussed the topic with a colleague. Computers cannot easily access such implicit knowledge. Therefore, I think humans will certainly be part of the picture for quite some time.'

Endangering medical jobs

'The help of 'intelligent' computer software in medicine is a means to extend and improve healthcare. I see radiologists struggle with the sheer amount of medical images they must review. How long can this continue? Employing more radiologists seems unfeasible, given already exploding costs in high-tech medicine. Simultaneously, public awareness of the benefit of modern, image-based diagnostics increases the demand to offer this to a broader public. This is possible, but hardly imaginable



New portal gives all medical caseworkers access to images and data

'It is happening now!'

Report: John Brosky

Two years ago European Hospital spoke with Hans Vandewyngaerde, President for Europe, the Middle East and Africa (EMEA) for Agfa HealthCare, about a sweeping vision the company called 'Images without Boundaries'. The idea was to build a capability to share images from anywhere to anyone involved in a patient's care.

'Imaging without boundaries is a success story,' Vandewyngaerde told us ahead of the 2014 European Congress for Radiology (ECR). 'The boundaries are gone. Agfa has launched with its customers large-scale programmes that fundamentally transform how they exchange images.'

'The next step,' he added, 'is to integrate care. This is the logical step in the journey that has taken us from analogue to digital in radiology, then to sharing the digital images. Now there is a need to converge those images with relevant data that can really help advance a patient-centered view of healthcare.'

ECR 2016 will see the introduction of the Agfa Healthcare Portal, a suite of capabilities that pulls data from any standards-based source, integrates it with imaging and makes it available to everyone involved in a patient's care in every format, from desk-top to laptop to hand-held mobile device.

EH: Have you found Holy Grail of Health Care? For 15 years people have said this is the future. Why should we believe it this time?

Hans Vandewyngaerde: 'Because we have done it! At ECR 2016 we'll show very specific use in cases where we have done this in the USA. We are now installing the Health Care Portal in Europe and have specific cases to show. We have

this is going to help reduce costs and improve patient treatment. Cost is a big pressure point and while countries are moving at different speeds, and with different blueprints, it is something that's really happening – already in England, France, and Belgium.

'It's very important to see how powerfully patients are becoming part of the process and a driver for this change. Today, it's not very organised, varying greatly from diabetic patients to wound care management, or ophthalmology care. But clearly there is an expectation, it is going to grow stronger, and patients are already beginning to steer workflows according to what they expect.'

history, a history of medications or radiation dose. A patient can log in to view the results of the exam. Immediately the patient may want to share images with the physician, may wish to schedule follow up appointments. All of this should be possible and right away, which brings us to a very basic use case calling for a portal. Which is what we will show at ECR 2016.

What did Agfa build with the Healthcare Portal suite?

'The portal was introduced less than a year ago and it has advanced rapidly since then. It is built on an open architecture that is compatible with existing operating systems. It is browser based, cloud-ready, easy to install and seamlessly integrates with any data or image source be it PACS, EMR or EHR, and much more beyond this, including social services.'

'We recently announced Agfa has taken a significant stake in the company My Personal Health Record Express. We are continually building cases of use with them, advancing further every month in terms of viewing images, lab results, and clinical notes. There is secure messaging between a patient and a physician. The patient can upload images and documents. Physicians can have peer-to-peer communication with other providers. There is a great focus on integrating into mobile devices with iOS and Android.'

'The Agfa Healthcare Portal goes beyond grabbing data and images by gives meaning to the data. This is very new and very unique. It is a very cool thing that distinguishes our portal, an architecture that builds in a semantic layer so that data from different sources can talk



Hans Vandewyngaerde is President EMEA at Agfa HealthCare

to other data in different semantic formats, from Chinese to English. We have some highly innovative intellectual property built around this, so that we can input data and images from different sources, add a meaning to this data, and configure the display through the portal.'

What will all this mean for radiologists?

'The radiology community has a crucial role to play because they have done this before and they know how to do it. They have worked through the digital transformation. They know what it takes to move from a departmental workflow to an integrated network. They are the best placed if they believe and accept that this is happening.'

'The radiology community, if they play it right, can become – and should become – a centre of competence on image management, which is a crucial component of the digital convergence that underpins integrated care. The radiology community has the deepest and best experience with the management of images, to view or to share, with standardisation, archiving and, crucially, with the workflow around images.'

'Radiologists at ECR should come to the Agfa stand where we can show relevant cases of use on what has already happened and where we think integrated care is going to go.'

**ECR 2016
AGFA is here.**

“Data from different sources can talk to other data in different semantic formats, from Chinese to English”

a platform technology that is ready to be used, is already being used and is unique.

'Healthcare systems are increasingly ready. Countries are changing their governance to support the integrated care ecosystem, there's a movement to shift from volume-based reimbursement to outcome-based reimbursement, to adapt security, patient consent and authorisation.'

'This is not happening because payers want to enable our technology. It's happening because there are persistent, powerful drivers. There is a strong belief on the part of payers, especially governmental payers, that

Let's take a step back. What is integrated care?

'Integrated Care is multi-agency, multi-disciplinary collaboration focused on meeting the medical, and also social needs of patients. It is highly patient-centric in a coordinated way. The vertical management of healthcare is now going transversal, across boundaries, across agencies, across disciplines. To do this you really need to look beyond the hospital, beyond acute care. Integrating care also mean involving social care data.'

'Patients need a portal where there is a lot more than images, to also view data such as a medical



For computer scientist **Markus Harz PhD** six-months' work in a USA breast care centre has added much to his seven years in project management and ten years in medical image analysis. He has also contributed to several international research projects, scientifically and through project management. His PhD proposed methods for computer assistance in complex image-based clinical tasks. Machine learning and computer vision are always important tools in his approach.

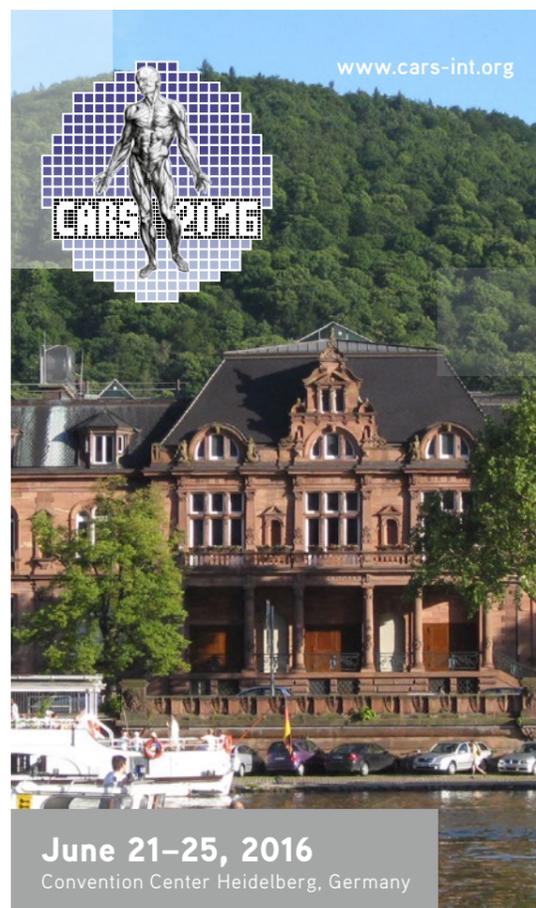
without computer assistance.'

Algorithm development

A massive amount of data is needed for the algorithm to learn good image features. Deep learning algorithms also must be tuned. 'Imagine recreating the visual system from eye to brain with only very small building blocks. How are these connected to each other? How many layers of abstraction do you need? You have to strike a balance between abstraction and differentiation. You don't want to be too fine and only detect meaningless dots and lines and circles. You also don't want to be too coarse and fail to distinguish e.g. between cancer types.'

Shaping future diagnoses

Harz believes computer-prepared and computer-aided diagnoses are the future (but 5-10 years before market approval). Indeed, in some scenarios, man-made decisions might no longer be accepted. In a recent skin cancer study, computer software 'outperformed even experienced doctors by such a wide margin,' he said, 'I wouldn't have to think twice about which diagnosis to trust'



CARS 2016

COMPUTER ASSISTED RADIOLOGY AND SURGERY

30th International Congress and Exhibition

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- Medical Imaging
- Computed Maxillofacial Imaging
- Image Processing and Visualization
- PACS and IHE
- Telemedicine and E-Health
- Computer Aided Diagnosis
- Computer Assisted Radiation Therapy
- Image and Model Guided Therapy
- Personalized Medicine
- Surgical Navigation
- Surgical Robotics and Instrumentation
- Surgical Simulation and Education
- Computer Assisted Orthopaedic and Spinal Surgery
- Computer Assisted Head and Neck, and ENT Surgery
- Image Guided Neurosurgery
- Minimally Invasive Cardiovascular and Thoracoabdominal Surgery
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PET imaging enhances dementia understanding

Visualising amyloid deposition

Report: Mark Nicholls

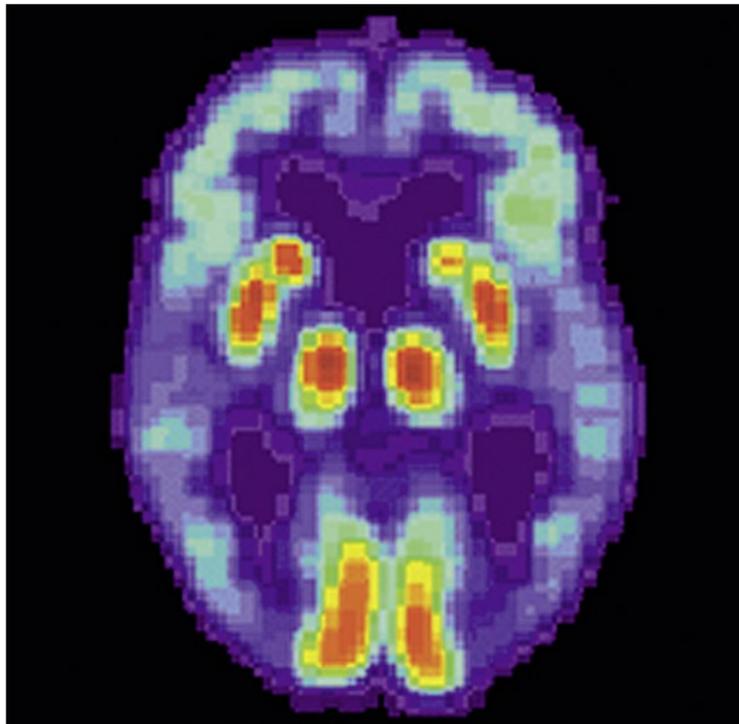
Neurologists are gaining new insights into dementia imaging by harnessing the latest opportunities offered by Positron Emission Tomography (PET).

In a session at ECR 2016, Professor Karl Herholz will highlight how the modality is not only making an important contribution to enhancing diagnostic accuracy but also adding a new dimension to imaging dementia by helping to select patients for therapies at an earlier stage.

As Professor of Clinical Neuroscience at the Wolfson Molecular Imaging Centre at the University of Manchester, UK, he will discuss latest developments in PET imaging in dementia in a session on that will also examine advances in other modalities in the imaging of the condition.

Having conducted extensive research in this area, Professor Herholz will focus on recent developments, outlining how advances in brain imaging have transformed the way clinicians think about, understand, and characterise Alzheimer's and other dementias.

'Among these, amyloid imaging has moved rapidly from a highly select carbon-based research tool,



With positron emission tomography (PET), radiologists can now detect human brain -amyloid plaques, one of the pathological features of Alzheimer disease

available only in centres with cyclotrons, to full commercialisation, with three fluorinated amyloid PET tracers (florbetapir, florbetaben, and

flutemetamol),' he explained. Amyloid deposition a common feature of Alzheimer's and effective amyloid imaging - via PET scanning

- is being recognised and will permit earlier detection and intervention.

Professor Herholz believes the ability to more directly visualise, in vivo, aspects of pathology in the brain - in this case amyloid deposition, which was previously only possible at autopsy - represents a significant step forward.

All three amyloid imaging ligands have been tested in well-conducted, blind studies and all demonstrate a robust correlation with brain amyloid deposition, he added. 'The development of amyloid imaging represents an important step change in our ability to characterise and assess patients with cognitive impairment and dementia.'

While suggesting there are clinical situations where it promises to make an important contribution to enhancing diagnostic accuracy, he believes the real advance of amyloid imaging is not just about improving diagnoses, but 'about appropriately selecting subjects at an early stage for disease-modifying therapies.'

'In addition, as part of a wider biological profiling of a complex disease, it promises to drive forwards new ways of understanding and classifying the dementia,' he said.

In addition to the role of PET in dementia imaging, other modalities and developments in imaging dementia will be highlighted.

Professor Frederik Barkhof, Consultant Neuro-Radiologist, Professor of Neuroradiology and Scientific Director of the Image Analysis Centre at the VU University Medical Centre in Amsterdam, will



Karl Herholz is Professor of Clinical Neuroscience and head of Neuroscience Research at the Wolfson Molecular Imaging Centre, University of Manchester. Also an honorary neurological consultant at Salford Royal Hospital and honorary consultant at the Nuclear Medicine Department, Central Manchester Foundation Trust, he is a fellow of the Royal College of Physicians and the Royal Society of Medicine. He graduated in medicine at the University of Erlangen in Germany in 1980, and later became professor of neurology at the University of Cologne before moving to Manchester in 2005. His research interests include neuro-imaging studies (PET and MRI) of dementia and brain tumours.

discuss 'MR contribution to diagnosis and differential diagnosis' and Sebastiaan Engelborghs, Professor of Neurosciences-neurochemistry at the University of Antwerp, will focus on 'The neurochemistry of the Alzheimer's continuum.'

ECR 2016
Sunday 6 March
8:30-10:00 am. Room G
Imaging in dementia

Making data management intelligent and stress-free

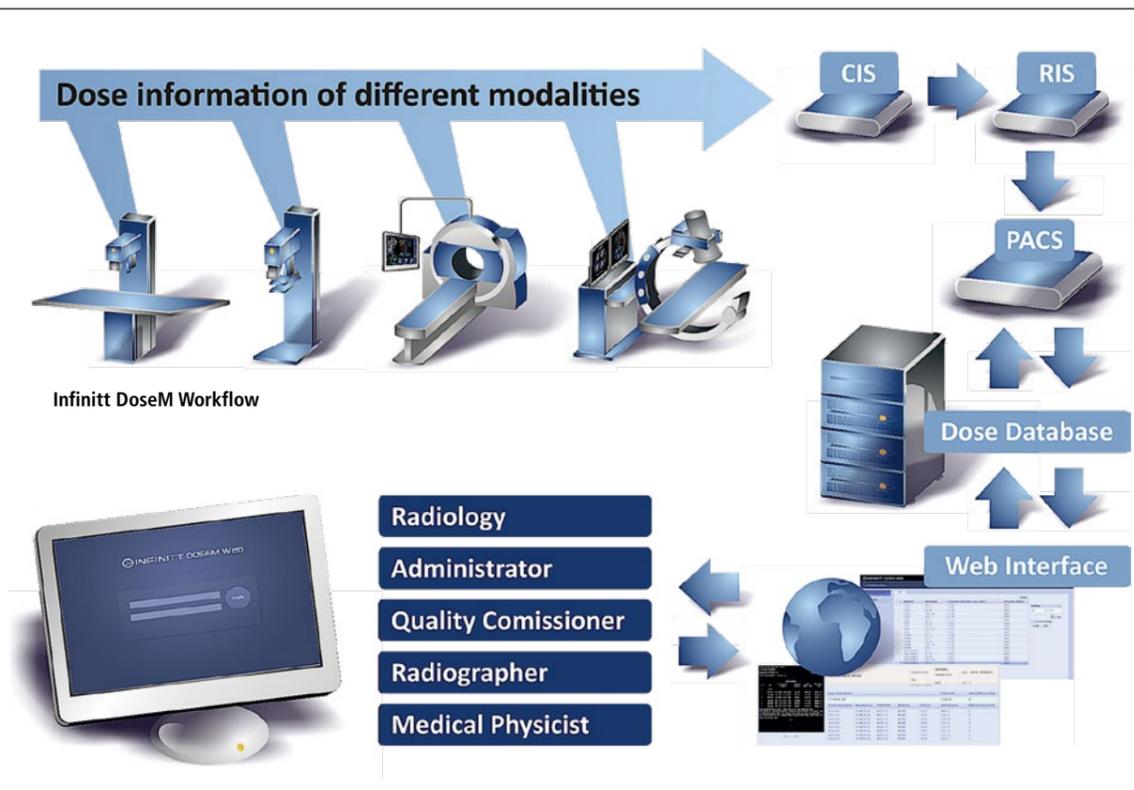
Coming your way: Vendor neutral archives

Vendor Neutral Archives (VNA) will become an integral part of every hospital in the near future. So what's a VNA? In short, a medical imaging technology in which images, documents and potentially any file are stored in a standard format with standard interfaces that enable other systems - independent of their vendor - to access it.

At the 2015 Healthcare Information and Management Systems Society (HIMSS) convention, that acronym could be heard in educational sessions and around the exhibition - as it will no doubt be again at the end of this February and early March in Las Vegas. Infinitt's VNA, the Infinitt Healthcare Platform (IHP), is not just an average vendor neutral enterprise storage solution, the manufacturer point out. 'It not only archives, manages and distributes, but also allows users to share all DICOM and non-DICOM data, including audio, video, and document files. Also, as the IHP complies with major industry and security standards, such as HIPPA, HL7, IHE, its integration into other systems becomes easy.

'Furthermore, it supports RESTful APIs and open APIs, making data integration from other systems possible.'

Does that mean the IHP takes over all existing systems, such as departmental PACS, costing the hospital previous financial and technology investments? 'No,' the firm reports. 'Instead, the IHP integrates with any major hospital systems including EMR, making cross-departmental and cross-enterprise referrals much easier.



'Moreover, the IHP maximises data management efficiency and reduces overall cost, by supporting intelligent Information Lifecycle Management (ILM). ILM refers to a wide-ranging set of strategies, from removing unnecessary studies automatically, based on configurable rules for moving and deleting data, over exceptions (exception conditions setting) to real-time system monitoring.' Another advantage of the IHP is an accompanying zero-footprint viewer (Universal Viewer,

ULite) where both DICOM and non-DICOM data can be viewed. 'This patient-centric viewer allows you to see a comprehensive view of each patient, helping you to have better clinical insights,' the company points out. 'All together, the IHP will make medical data sharing and collaboration easier, removing PACS and storage migrations needs in the future, eventually cutting IT management costs and profiting you with a smoother workflow and full data ownership.'

Optimising radiological procedures

X-rays used in medical diagnosis and treatment became daily routine. 'Although the methods have become more precise and medical devices achieve better results with even smaller amount of radiation dose, a certain exposure to the patient is inevitable. Taken this into account, the most basic guideline of medical radiation protection, the ALARA-principle (As Low As Reasonable Achievable) is always followed,'

Infinitt reports. 'To achieve continuous improvements of image quality while reducing radiation dose, specific management systems are required that provide the relevant information and assistance. According to the implementation plans of the EURATOM Directive into national laws (e.g. X-ray Radiation Protection Regulation), a dose management system will be an integral part of the legal requirements.'

Infinitt DoseM is a modality and vendor independent, web-based portal solution for management support and quality assurance optimisation. The system provides



Data Management using the Infinitt Healthcare Platform (IHP)

Interventional radiology brings new hope for the obese

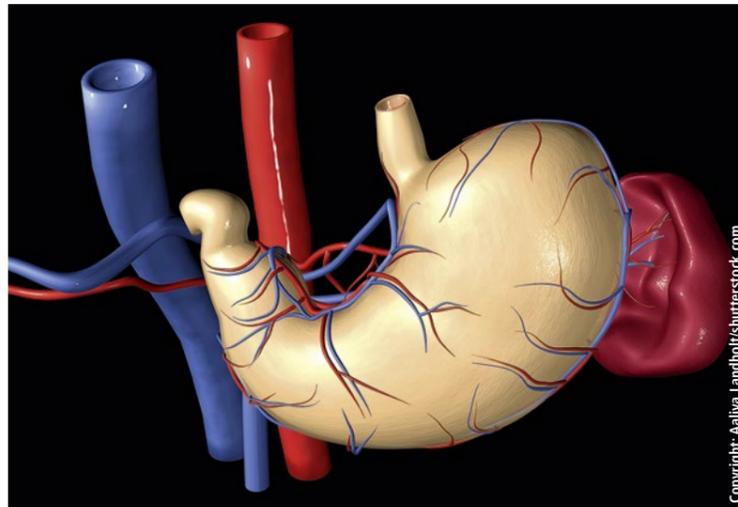
Bariatric arterial embolisation

Radiology is going beyond assessing body fat, bringing a notable contribution in weight loss therapy. Clifford Weiss from Johns Hopkins University is one of the pioneers of a new procedure, bariatric arterial embolisation, details of which he will unveil at the ECR in Vienna this March

Report: Mélisande Rouger

Overweight and obesity affects people's health worldwide. In Europe alone, experts estimate that about 20-25% of the population is obese. Obesity is also developing at an ever-earlier age, increasing lifetime exposure to the risks. The percentage of morbidly obese patients – who have a body mass index (BMI) above 40 or 35 with co-morbidity such as diabetes or stroke – is increasing the fastest. Obesity also places an enormous burden on healthcare. According to McKinsey Global Institute, its global cost on society is 2 trillion USD, the same as smoking and death in a war zone. (Ref: *How the world could better fight obesity*, Richard Dobbs, Corinne Sawers, Fraser Thompson, James Manyika, Jonathan Woetzel, Peter Child, Sorcha McKenna, and Angela Spatarou, McKinsey Global Institute. http://www.mckinsey.com/insights/economic_studies)

Traditionally, the best obesity treatment has been bariatric surgery, which provides major and long lasting weight loss. Now, interventional radiology is quickly becoming an area for the development of obesity



treatment, and one USA team is currently leading promising clinical trials for a ground-breaking method called bariatric arterial embolisation (BAE).

'This is exciting because it's the first time that we, as interventional radiologists, have been able to intervene in this important area,' said Dr Clifford Weiss, Associate Professor of Radiology, Surgery and Biomedical Engineering, and Director of Interventional Radiology Research at Johns Hopkins University, Baltimore, MD.

Along with his mentor, Dr Aravind Arepally, Weiss began to develop the procedure on swine ten years ago. A small plastic catheter is inserted into the arterial system from the wrist or leg, and then directed into the celiac artery. From there, specific arteries that feed the top of the stomach (fundus) are blocked with tiny embolic

microspheres in the micron range. Those spheres are commonly used in interventional radiology procedures to treat bleeding.

The metabolic principle of BAE is theoretically the same as bariatric surgery, Weiss explained. 'The stomach is not just a food receptacle. It produces a number of hormones, including ghrelin, which is responsible for stimulating the appetite. It's a well-known fact that most diets eventually fail. When a person restricts their calorie intake, it leads to a rise in ghrelin, which in turn leads to intense hunger. This makes it extremely difficult for a person to maintain this lower calorie level.'

Bariatric surgery either removes or bypasses the fundus of the stomach where most ghrelin is produced. Afterwards, ghrelin drops, hormones that signal fullness rise, and patients

are less hungry. Weiss' team decided to emulate the metabolic and hormonal effects of open surgery using a minimally invasive technique. By taking advantage of the anatomic location of ghrelin-producing cells in the fundus and the specific vascular supply of the stomach, they determined that they could block certain blood vessels and decrease the production of ghrelin, even in a fasting state.

Weiss and his team received a government grant to study this procedure further in animal models. They also received industry sponsorship for an FDA approved clinical trial, which they named Bariatric Arterial Embolisation for the Treatment of Obesity (BEAT Obesity). He is presenting the results of his first seven human patients at ECR 2016.

'Despite this being a trial designed to study the safety of BAE, we have seen clinically significant weight loss in our patients, all of whom were treated with 300-500 micron Merit Embospheres,' he said.

To date, they have safely embolised seven patients, and have recently obtained FDA approval for a total of 20. This expansion has allowed them to open a second study site at Mt Sinai Medical Centre in New York City. Eligible candidates must weigh less than 400 pounds, have a BMI of 40 or above and no other co-morbidities. Once enrolled, patients undergo a rigorous screening process, which includes lab tests, anatomic and functional tests of the stomach, and assessment by an interventional radiologist, bariatric surgeon, and weight management specialist. In the month prior to the study, they are seen in the Johns Hopkins Weight Management Center, in which they work with a registered dietician, psychologist and gastrointestinal doctor, and learn how to follow a healthy diet.

Weiss has published papers on the topic* and has candidly shared his clinical protocols in order to encourage scientifically valid study of this new procedure. (*Bariatric Embolisation of the Gastric Arteries*



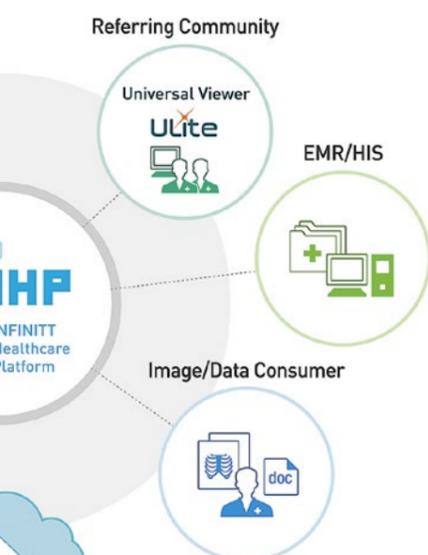
Clifford R Weiss is associate professor at the department of radiology and radiological science, surgery and biomedical engineering at Johns Hopkins University, where he also serves as director of interventional radiology research, and medical director of the centre for bioengineering innovation and design. In 2001 he gained his medical degree from Johns Hopkins University, where he subsequently completed his residency in radiology and a fellowship in interventional radiology. Between 2008 and 2009 he worked as an MR applications developer for Siemens AG in Erlangen, Germany. He also has extensive laboratory experience. He has authored over 30 peer reviewed original science publications and numerous invited reviews. A prolific researcher, he also holds several patents in his field and his work has attracted many grants.

for the Treatment of Obesity. Clifford R. Weiss, MD, Andrew J. Gunn, MD, Charles Y. Kim, MD, Ben E. Paxton, MD, Dara L. Kraitchman, VMD, PhD, Aravind Arepally, MD <http://dx.doi.org/10.1016/j.jvir.2015.01.017>). 'My hope is that, by publishing our protocol and techniques, we will encourage others to perform similarly designed research. If we all apply consistent methods, we have a better chance of maintaining patient safety and collecting valid and powerful data,' he said.

Next, Weiss is planning to compare his results to diet and exercise alone in a larger randomised clinical trial. 'We're many trials away from making BAE ready for clinical use, but the data are promising. Between the questions we're asking and the trials we're performing, this is going to be an important way to treat obesity in the future. ■

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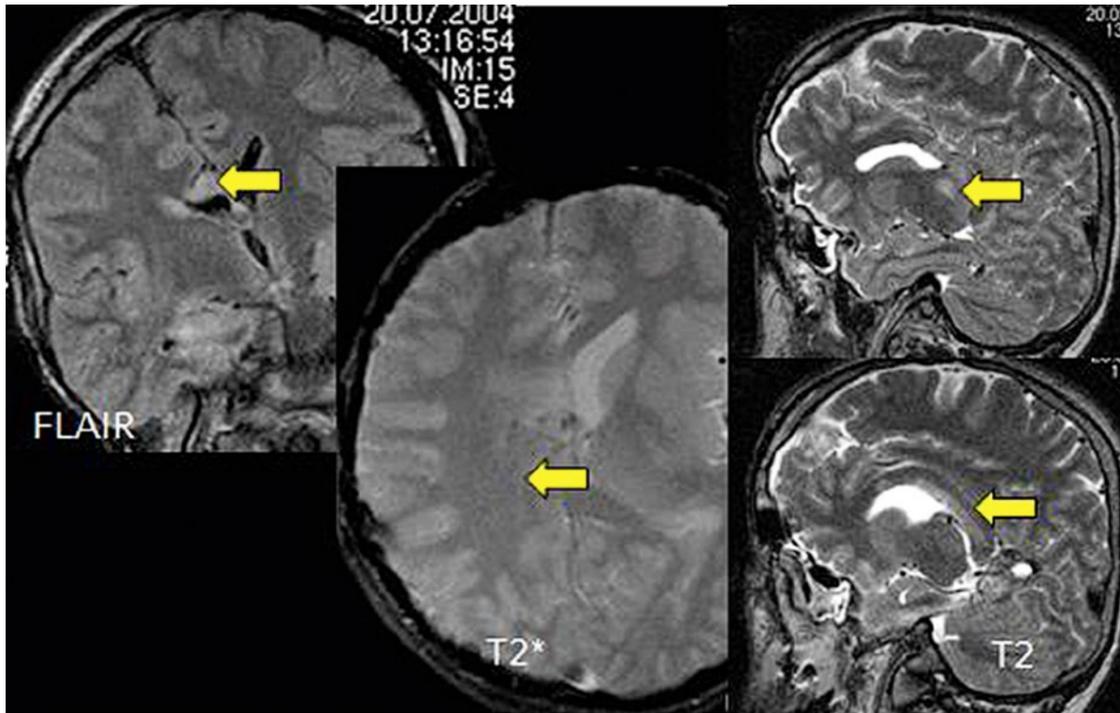
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Emergency care depends on standards and experience

Keep it simple and straightforward

Emergency medicine requires smooth, patient-oriented and perfectly timed cooperation of several clinical disciplines. 'Today, radiology is much more than a service provider. In emergency medicine we are an integrated and active component of the diagnostic process – and beyond', says Professor Stefan Wirth, Managing Consultant at the Institute of Clinical Radiology, Ludwig Maximilian University Hospital, Munich



Report: Sascha Keutel

What would constitute a typical emergency case? The first thing most people think of is trauma, particularly polytrauma, explains Professor

Polytrauma CT: root of the lung completely severed, right, massive haemorrhaging, lethal outcome



Stefan Wirth. 'Depending on the situation, however, pulmonary embolism, acute abdomen, stroke, myocardial infarction and acute, meaning large internal or external haemorrhages, are typical cases. We have

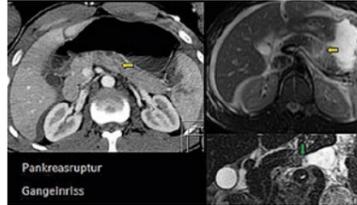
Aortic rupture with haemothorax. CT: thorax with traumatic aortic rupture in typical location (isthmus) and haemothorax, density approx. 60 HU



Diffuse Axonal Injury (DAI). Top: unenhanced CCT, axial; bottom: MRI 1T

about 500 "real" polytrauma patients each year. Including the other serious and urgent emergency cases, we see more than 5,000 patients per year. If we add the less urgent emergency

Traumatic pancreatic rupture. Left: CT. Right: MRI confirmation



cases and those that need exclusion, such as cerebral haemorrhage, the number of patients increases to 25,000.'

A typical diagnostic check-up for trauma

'Generally speaking, trauma patients are patients who suffered accidents of any kind, but not every trauma patient is an emergency case. Therefore, there are different routines. Ultrasound is very well suited to evaluate many musculoskeletal issues. While fractures are usually visualised in radiography, for some of them, such as spinal, elbow, pelvis or knee fractures, CT is not infrequently the better modality. Obviously each individual case requires a patient-oriented decision, taking into account issues such as radiation exposure.

'Actually, the diagnostic workup for polytrauma patients is pretty straightforward: The first step is the decision as to whether indeed we are dealing with a polytrauma patient, meaning a patient with acute and most likely life-threatening injuries. Simply sending the patient to the shock room won't suffice. In a facility with the appropriate infrastructure – building and organisation – the severely injured patient immediately – meaning during patient handover undressing and initial stabilisation – undergoes a so-called eFAST. The aim of this extended focused assessment with ultrasound for trauma is to identify within 30 to 60 seconds intra-abdominal free fluid, haemoperitoneum or pleural effusion. An experienced physician will also be able to recognise pneumothorax during the eFAST. In all other cases

Traumatic disc prolapse 5/6 with secondary neurology



Professor Stefan Wirth MBA EDIR, studied medicine and informatics at the Technical University Munich and Ludwig Maximilian University (LMU) Munich (1988-98). He also holds an MBA from Munich Business School, a European Diploma in Radiology (EDIR) and is Managing Consultant at the Institute of Clinical Radiology at the LMU Hospital. He has also served as President Elect of the European Society of Emergency Radiology since 2015 to become President in 2017.

immediate standardised whole-body CT is recommended.

'In our hospital we use the shock room simply as transit room, so to speak, and take the patient straight to the CT table. Thus we save time and in an emergency, every minute counts.

'I recommend positioning the patient feet forward into the CT gantry and folding the arms across the abdomen. This is easy to standardise, avoids cable clutter in the gantry, provides easy access to the head for any type of anaesthesia and spreads the artefact the upper extremities present across thorax and abdomen. Then we do a quick CT scout scan that shows all relevant pathologies as clearly as an X-ray scan, but is performed much faster. Moreover, the scout scan shows whether the standard protocol can be followed or whether a different route is preferable, for example in arterial and/or urography phase with pelvic injuries, or expanding the scan to the proximal femur if a serious femur fracture is involved.

'Surprisingly, there is no guideline regarding the CT workup. Whilst only head, neck, thorax and abdomen scans are mandatory, there is evidence that whole-body CT increases patient survival rate. Therefore, I recommend unenhanced CCT, followed by neck/thorax/upper abdomen in arterial and the entire abdomen in portal venous phase.'

Zone acquisition and channel data processing deliver new-wave ultrasound

Rewarding China-USA research

Report: John Brosky

If you are taking note of any breakthrough in ultrasound, here are two names you will want to put at the top of your ECR 2016 notebook: Resona 7 and ZONE Sonography Technology.

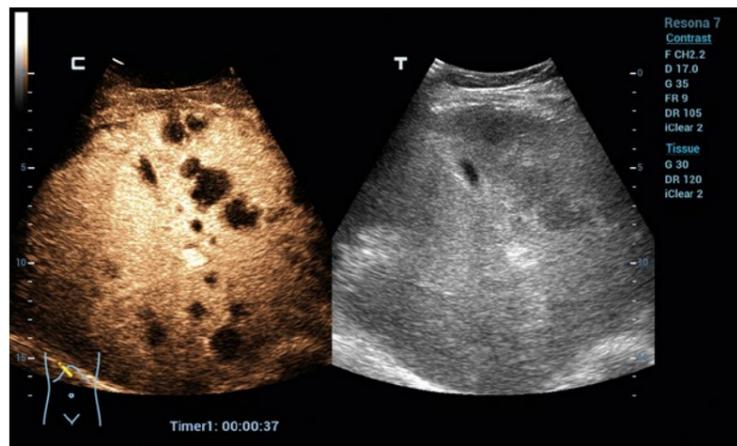
For short, you can jot down ZST and then add 'plus', or simply ZST+ because, with the new Resona 7 system, Mindray has combined revolutionary zone acquisition and channel data processing with a bundle of advanced imaging functions to create a premium ultrasound platform.

Putting it all together, ZST+ powering the Resona 7 means that Mindray delivers more valuable tools for clinical imaging, placing

this new premium system on the leading edge of a new wave of innovation for ultrasound.

Deconstructing the innovation on-board the platform, the fundamental difference in image acquisition is that Resona 7 transforms ultrasound metrics from the conventional signal processing technique of beam-forming to a channel data based processing that is faster.

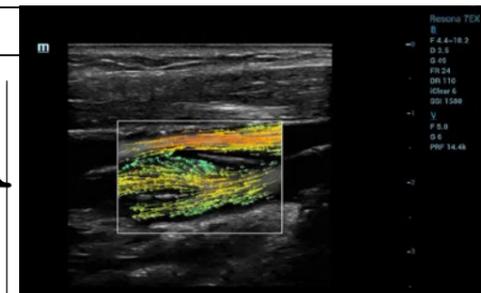
By transmitting and receiving a relatively smaller number of large zones, this unique capability enables Advanced Acoustic Acquisition that extracts more information from each acquisition, 10 times faster than a conventional line-by-line beam-forming method.



Mindray is also able to add Dynamic Pixel Focusing technology that allows the Resona 7 system to achieve an extreme uniformity in pixel level across the entire field of view, eliminating a need to adjust the focal positions in order to achieve uniformity across patient examinations.

CEUS of MLC: CEUS shows MLC with excellent uniformity high penetration more than 16cm in contrast imaging

Enhanced channel data processing means the Resona 7 system greatly improves imaging clarity through multiple and retrospective processing, and it means the plat-



V Flow of Carotid Bulb and JV: V Flow presents simultaneous and instant blood flow of jugular vein and carotid artery bifurcation

form is able to intelligently choose the optimal sound speed to improve image accuracy greatly, even where there are variations in tissue, allowing for adaptive tissue-specific optimisation.

Exclusive functions on the Resona 7 system include Vector Flow with vivid, accurate, and angle-independent visualisation of complex vascular haemodynamics profiles at the speed of up to 600 frames per second, and Smart Planes with fully automatic and accurate detection of the most significant foetal CNS planes and frequently used measurements to enhance diagnostic throughput and reduce dependency

The need for emergency MRI

'Emergency MRI is performed primarily to answer paediatric, neurological and musculoskeletal questions. Blunt trauma of the torso, except certain heart injuries, and acute neurological issues, don't necessarily indicate an emergency MR scan. The following questions help to decide whether MRI is required:

1) Can only MRI answer the question at hand, or are there other important reasons to prefer MRI, such as radiation exposure in children?

2) If yes: is a treatment decision required that will be influenced by the result of the emergency MR scan, such as surgery versus no surgery?

3) If yes: does at least one of the therapy options, based on the MRI results, need immediate action because, otherwise, the patient would suffer irreversible damage, such as re-fixation of joint cartilage?

If the answers to questions one through 3 suggest emergency MRI, limiting the sequences in number and respective time efforts might be discussed to arrive at a quick treatment decision.'

Emergency logistics, technology and staff limitations

'You name them, we've got them; there are building issues, such as short routes, or whether the CT is located in the shock room. Which equipment is available – when and how many devices are available? What types of professional qualifications are available? In Germany, there is a severe shortage of radiology technical assistants because training takes a long time and is expensive and career opportunities are limited – as is the salary.

'Many privately funded institutions offer attractive packages with regard to night shifts and salary, sometimes even a 'poaching bonus'. Thus large public healthcare facilities in metropolitan areas have serious staffing problems. However, without the radiology assistant there is no radiology! That might sound overly dramatic, but indeed currently it is a huge issue.

A colleague said: 'In emergency medicine radiologists are increasingly patient managers.'

'The success of any emergency treatment depends on two things: standards and experience.

**ECR 2016
Saturday 5 March
8:30–10:00 a.m.**

**Room D1
Severe trauma patients: myths, realities and future (SF 13d)**

Emergencies such as polytrauma, or the sudden increase in patient numbers following massive accidents, are practised regularly. It sounds more complicated than it actually is, and can be achieved easily, as long as you keep the standards simple. If you only have one standard protocol

it is quite trivial to spread knowledge and experience over the team. It is just a variant of 'Keep it simple and straightforward' (the KISS principle).

'I'm talking above all about standards such as CT protocols. In general, quality management is also fully integrated in the workflows to ensure parameters, continuous improvement and instruments are part of quality control. We also look at interfaces, for example in the context of morbidity and mortality conferences.'

Polytrauma with blunt cervico-thoracic penetrating injury



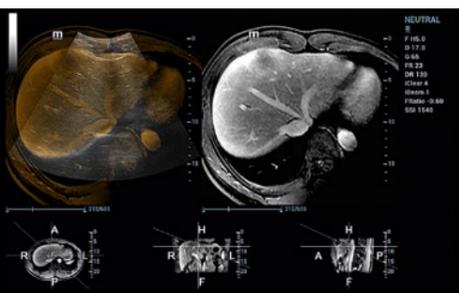
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healthcare within reach

Resona 7

Diagnostic Ultrasound System

New Waves in Ultrasound Innovation

Mindray's Resona 7 is designed to meet the demanding challenges in clinicians' daily diagnosis and researching interests, providing advanced user experience. Powered by the most revolutionary ZONE Sonography® Technology, Resona 7's new ZST+ platform brings the ultrasound image quality to a higher level by zone acquisition and channel data processing. With supreme image quality that redefines the standard of imaging performance, Resona 7 is truly leading new waves in ultrasound innovation.



iFusion: Fusion imaging features precise matching of ultrasound and MRI image thanks to revolutionary respiration compensation technique

on user experience.

Mindray's proprietary and pioneering technology positions the Resona 7 system, elevating clinical intelligence to a new level with a complete solution that enables clinicians to manage both routine and advanced studies more efficiently, consistently, and accurately, from imaging acquisition through to calculation.

Of special note is the fact that the Resona 7 is the first premium ultrasound system solely developed by a Chinese manufacturer, the fruit of collaboration between research teams based in Shenzhen, China and in California, USA.



ECR 2016 No. 203, Expo X3.

Symposium: Time: 12:30-13:30, 2nd Mar 2016
Venue: Room L8, ACV First

Live Scanning: Time: 10:00, 12:00, 15:30,
Date: 3rd to 5th Mar 2016

Ultrasound contrast agents are considered a medical drug

Child imaging has defined rules

Interview: Sascha Keutel

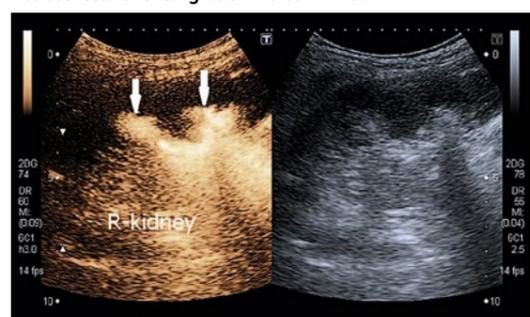
Paediatric imaging is a subspecialty that uses a diverse range of imaging systems, from classical X-ray to ultrasound, CT and MR. In an interview with Dr Damjana Ključevšek, consultant paediatric radiologist at the Children's Hospital of the University Medical Centre of Ljubljana, Slovenia, spoke of the challenges and particularities in paediatric imaging, especially in the use of contrast-enhanced ultrasound in children.

Asked about the distinct aspects of child imaging, Dr Damjana Ključevšek explained: 'Paediatric radiologists deal with different developmental stages from foetal life, through early childhood, to adolescence. As the quote goes, "Children are not small adults". It's very important to be familiar with their embryology, maturation and growth. Many different diseases occur at different ages, and children with the same disease require a different approach at different ages. The International day of Radiology 2015 was dedicated to paediatric radiology, which says a lot about the importance of this imaging subspecialty. In our country, paediatric imaging includes imaging of foetus, individuals younger than 18, and also young adults in the case of rare chronic diseases (e.g. some storage disease, unusual or very uncommon congenital disorders).'

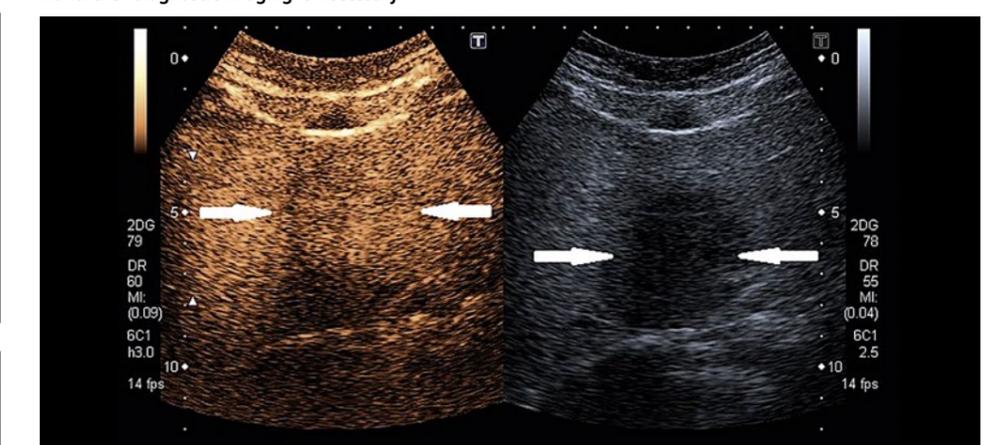
How do procedures differ from adult imaging?

'For a child, diagnostic imaging is stressful. He/she is put into an unknown environment, which is noisy, busy, and full of strange equipment. Therefore, the environ-

ment should be made as friendly as possible for children, and a sense of trust should be developed between the radiologist, radiographer, child and parents. It's necessary to take some time and explain to the parents, why and how the radiographic procedure is going on. Parents are often actively involved in the procedure: they calm, comfort, and undress the baby, if necessary.



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CEUS liver comment: Contrast-enhanced ultrasound (CEUS) of liver as a problem solving method: hypo-echoic lesion in fatty liver (white arrows), seen on ultrasound, was confirmed to be focally spared area of fatty liver infiltration. During the CEUS, uniform enhancement of lesion similar to normal liver parenchyma was observed. No further diagnostic imaging is necessary

CEUS kidney cyst: During CEUS examination the complex kidney cyst was graded as Bosniac III: enhancement of cyst septa and cyst nodule

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'During imaging the child's safety is of highest importance. The first task of the radiologist is to confirm whether the proposed examination is indicated or not, and if the examination answers specific clinical questions. According to the ALARA

(as low as reasonably achievable) principle numerous devices for the child's protection (lead protection, immobilisation ancillary equipment) and paediatric imaging protocols adapted to different ages and clinical questions are used.'

What affects contrast-enhanced ultrasound use in children?

'First, ultrasound contrast agents (UCAs) in general are not registered for individuals younger than 18 years and their current use is off-label, which makes their application in children questionable, because of legal issues. In our hospital we gained approval from our National

Medical Ethics Committee, which allows us to use UCA in children. It's of major importance to obtain written informed consent signed by parents or the legal child's caretaker before CEUS, after a detailed explanation of the examination, procedure, clinical value, and the safety of UCAs.

'UCAs are not officially available in all countries. On the other hand, there is a need for diagnostic innovation and child-friendly imaging in daily clinical routine.'

Are there risks in using Contrast-enhanced ultrasound (CEUS) for children?

'UCAs are considered a medical drug and there is always a potential risk for side effects. Therefore, the safety issue of UCAs' in children is very important. The safety of UCAs, either intravenous or intravesical, has been evaluated in several studies. Intravenous application CEUS

is less widespread, but is slowly gaining popularity among paediatric radiologists as a problem-solving method. Unfortunately, the procedure has not been standardised and there are no official recommendations regarding the dose of UCAs, which should be appropriately adjusted according to the patient's weight or age, the examined organ, and to the probe.

'Recently, a meta-analysis of adverse effects after intravenous application of second-generation UCAs was published by Piskunowicz. Only one severe anaphylactoid reaction in a child following the intravenous administration of UCAs has been described, so far.

'In some children some minor transitional adverse reactions (urtica and rash, a brief alteration of taste sensation, mild tinnitus, light-headedness) were recorded. The European survey and meta-analysis of Darge et al. evaluated the intravesical use

Presenter at ECR calls for more research

Elastography is a promising tool in paediatrics

'Already used in adults for several years, elastography is a promising tool in paediatric imaging,' according to radiologist Dr Mehrak Anooshiravani-Dumont, from Geneva University Hospital. 'It allows detection of changes in the mechanical properties of tissues, such as fibrosis, based on viscoelastic characteristics. The technique is so far validated in paediatric liver

imaging, to evaluate and follow up chronic hepatic pathologies with fibrosis. The current gold standard to stage liver fibrosis is biopsy, which has its limitations – the need for sedation, invasiveness, interobserver and sampling variability.

'Currently, most elastography systems are coupled with ultrasound, which is easy to perform in routine practice in children. The interest in

this technique is that it reduces the number of liver biopsies. There are other anatomical regions (thyroid, renal, muscular pathologies) that are explored by elastography, but preliminary results have yet to be validated by further studies.'

Are there special considerations for using elastography in paediatrics?

'The most common modality of elastography is coupled with ultrasound. In children, we have to consider some specificities: the choice of probes according to a child's size, technical experience to obtain valid results with younger children despite movements, crying, and breathing. Also, we now know that, among the different ultrasound elastography systems available, some

**ECR 2016
Friday 4 March
4:00–5:30 p.m. Room M3
Expanding horizons in paediatric imaging (also see lecture above)**

are more adapted to children than others due to the child's size and difficulty to obtain apnoea.

'We should also consider the necessity to establish normal values for children for different organs.'

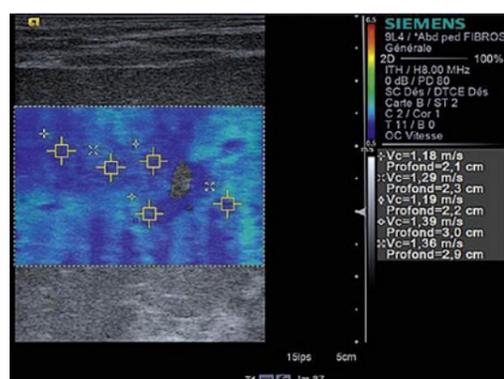
Elastography is used on adults mainly for breast and liver: it is the same for children?

'Although elastography is frequently used in adults for breast and liver imaging, in children it's been only validated so far, by multiple recent studies, in liver imaging.'

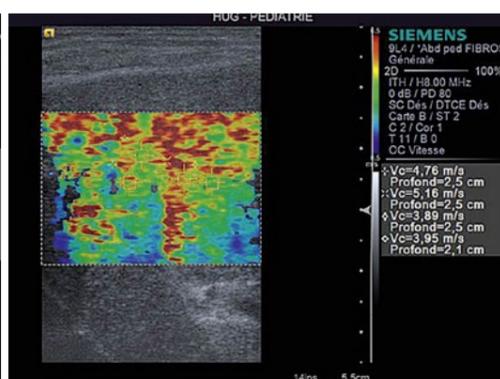
Are there gender differences to consider?

'There is no difference between boys and girls for elastography values.'

In your presentation, what will be your main points?



ARFI VTIQ normal values: blue colour in the liver parenchyma



ARFI VTIQ high values with red colour in severe fibrosis



ARFI VTIQ in the liver: normal value

Ultrasound speeds to the point of care

The precise emergency strength portable



Consultant paediatric radiologist **Damjana Ključevšek MD** graduated from the Ljubljana medical faculty in 1989 and gained her PhD in 2009. Today, she is assistant professor of radiology for medical and postgraduate students at the University Medical Centre of Ljubljana Children's Hospital. Ključevšek is also a member of the European Society of Paediatric Radiology and works as a European coordinator for paediatric radiology in Slovenia.

of UCAs in more than 7,000 children noticed only 0.8% transient adverse events, such as dysuria, haematuria, urinary retention, urinary tract infection, perianal irritation, abdominal or urethral discomfort etc. These are more likely related to bladder catheterisation than the UCAs. All these studies show high safety profile of UCAs administered either intravesically or intravenously.'

Are there established safety measures to protect children?

'As mentioned, the first safety measure is the proper indication for CEUS. We also have to consider the described limitations or contraindications related to UCAs.

'For intravesical application of UCA there is no need for extra safety measures.

'Due to the possibility of a potential anaphylactoid reaction, we are more cautious of UCAs during IV administration, the precautionary measures are the same as for other contrast agents and a possible anaphylactoid reaction and they are an integral part of the equipment in our examination rooms.'

Seattle-based medical ultrasound systems manufacturer SonoSite has aimed to take ultrasound to the point of care (POC) since it was owned by ATL. The parent company had gained a contract from the Defence Advanced Research Projects Agency (DARPA) to develop a lightweight ultrasound device for military use. SonoSite took on the task and, from 1998, successfully strode into the civil sector with its compact, high performance portable systems for hospital use. Today the firm has 26 subsidiaries in its global sales network to serve over 100 countries. In 2011, SonoSite became part of Fuji Film Holding.

At Medica 2015, SonoSite presented the new ultrasound system iViz. Torsten Walther, a seasoned sales manager formerly with GE Healthcare, handles SonoSite's business in Germany. 'SonoSite,' he predicts, 'is well positioned to gain ground. We'll look closely at our users: where and how they use our systems and which additional appli-

cations are possible?' While in many other countries, ultrasound systems are already being used in a broad range of applications, he believes Germany lags behind, particularly in emergency medicine. Ultrasound systems are not standard equipment in every emergency department and therefore not necessarily available.

Walther is also emphatic about training: 'Across the Atlantic training is much more of an investment focus. That's a sensible approach, because many innovations organically evolve from the training ground.' In Germany, SonoSite is supporting emergency care training centres with hardware and personnel. iViz plays a major role in this. 'Participants in the training sessions get to know the system and we are sure they will positively remember the equipment and service quality.'

Walther counts on the junior physicians, because they are usually open for innovative ultrasound systems and their new possibilities, he says. 'We should keep in mind that a resident physician will move up the hospital career ladder, or into pri-

The SonoSite iViz ultrasound system



Volker Keller, Fujifilm SonoSite GmbH's Senior Marketing Manager for Germany & Austria, launched the device last November at MEDICA 2015

vate practice – positions where he/she will make investment decisions.' SonoSite can already draw on customers who are very willing to share their positive experience.

Brian Leck, Vice President & General Manager of Global Direct Sales, explains about the international market 'Every sale, every process, every product is different.' Nevertheless, it is crucial to take into account cultural and regulatory features. 'As long as you understand which part is universal, you will be successful in every market,' he emphasises. However, the 'basics' need adaptation for each country: 'I like challenges. We have to develop a structure that works – for our customers and the company. Flexibility is our strength. We do things in weeks instead of month or years.' As SonoSite's flagship product, the iViz expands the portable US portfolio. Volker Keller, Senior Marketing Manager in Germany, is positive that his product is a top performer. He underscores the particularly high degree of data security iViz offers.

Unlike a regular tablet, which is equipped with an app, the iViz is a proprietary medical-grade system that is fully integrated and fully pro-



Torsten Walther is Country Manager for Germany

tected against external access and internal system crashes. The large transducer port enables high quality images to be transmitted quickly.

The iViz is also well suited to orthopaedic and sports medicine, in which physicians look for ultrasound machines that offer good quality images combined with speed and ease of use, more than having a wide range of functions, they explain.

The system is 'plug and play' due to pre-defined settings, and it boots up within 20 seconds, so an image can be taken within a minute. Keller adds: in line with SonoSite's roots, the system also complies with military requirements regarding application safety and data security.



Mehrak Anooshiravani-Dumont gained her medical degree in 1989 at the Free University of Brussels and completed her radiology training in Belgium in 1994. She has since focused on paediatric radiology and currently works in the paediatric radiology department at Geneva University Hospital, Switzerland. She is an active member of the Swiss Society of Radiology and the Swiss Society of Paediatric Radiology.

'I'll begin my elastography presentation by explaining the basics of the technique and the different types of sonoelastography. I'll also explain how we perform elastography in my department. Then, I'll discuss the main indications in paediatric practice with an overview of some published literature for hepatic imaging. I will also talk about the non-hepatic fields of elastography in children, for example in kidneys and muscles. I will end the talk with the very recent use in children of elastography by MRI, and its recent developments. I will also emphasise the need for further research in the field of elastography.'

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MRI/ultrasound-fusion biopsy improves prostate cancer detection rate

Munich medical duo refine biopsy teamwork

Ultrasound biopsy is rather unreliable to detect or exclude prostate cancer: many tumours are difficult – or impossible – to visualise sonographically and tissue sampling is haphazard rather than targeted. Now, a new technology offers relief. The fusion of MR images and real-time ultrasound allows the targeted biopsy of a prostate tumour and for the first time the examiner can precisely view the region of interest.

Interview: Daniela Zimmermann

Due to technological progress during the past few years MRI today offers a high success rate in the early detection of prostate cancer. Several protocols that look at different parameters, such as perfusion, diffusion or contrast enhancement, provide a wealth of diagnostically relevant information. A so-called in-bore MR biopsy, however, is very time-consuming and resource-intensive: the patient is difficult to access and the magnetic field requires the use of special needles. In contrast, ultrasound is rapidly and easily available, yet the different echo patterns prevent reliable detection of

we can offer better diagnostics and treatment – in terms of patient-focus and science.'

His colleague Dr Boris Schlenker, at the Urological Clinic and Polyclinic, who coordinates the Interdisciplinary Prostate Centre in Munich, adds: 'There was no apprehension whatsoever. With both of us working at a large university hospital we are used to cooperating across disciplines.' Today the two specialists are an experienced team, which smoothly performs the combined MRI/ultrasound procedures in the operating room (OR). While radiologist Clevert focuses on getting the most out of the images and finding the best possible biopsy



Dr Boris Schlenker is Ass. Professor of Urology. He is senior physician and faculty member at the Department of Urology, University Hospital Grosshadern, Ludwig-Maximilians University Munich, since 2013 and coordinator of the Interdisciplinary Prostate Centre, Munich. He is also a Fellow of the European Committee of Sexual Medicine (FECSM), Member of the German Board of Urology and Fellow of the European Board of Urology (FEBU).

path, urologist Schlenker can concentrate on moving the biopsy needle.

Initially, physical and technological issues prevented the fusion technology from being applied to the prostate but the development of a specialised transducer and accompanying software cleared the path for use with transrectal ultrasound (TRUS).

Clevert explains the procedure: 'In a first step, we have loaded the MRI images onto the ultrasound system and then we mark the regions of interest on these images. During the actual ultrasound exam, the MR images are superimposed on the TRUS images. As soon as the images are synchronised and regis-



Prof. Dirk-André Clevert began his medical career at the MRT-Diagnostik-Institut Westend in Berlin and the Department for Internal Medicine at Waldkrankenhaus Gransee. After a three-year residency in the Radiology Department at Passau Hospital, in 2003 the Berliner moved to Munich, heading the Interdisciplinary Ultrasound Centre – the focal point of all ultrasound activities in Munich University Hospital in Grosshadern – since the centre's opening in 2004.

tered, you can move the transducer through the MR images in the same way you'd move a computer mouse through an animated sequence. The MRI markers are virtually displayed on the TRUS images.'

The two physicians use a Philips Affiniti system with its major advantage, speed, as Schlenker reports: 'Most other systems require extensive acquisition of volume data sets. That means you need to acquire MR images of ten to twelve prostate slices and then do the same with your ultrasound system. Thus, the preparation of the data volumes takes quite a bit of time. In the new system fusion is done by plane. Instead of having to circle the prostate many times, fusion is now done by a single click.'

Clevert agrees: 'The number of buttons to be hit to get to your results was reduced to the absolute minimum. Today, we do a fused prostate biopsy in somewhere between five and ten minutes.'

The current German S3 guideline on prostate cancer requires MRI only for patients who previously underwent one or more negative biopsies, but where a malignant prostate tumour continues to be suspected.

The standard for primary diagnosis is randomised punch biopsy – a controversial procedure. In a punch biopsy tissue samples are collected according to a certain pattern in order to cover as many prostate regions as possible. However, the punches themselves are done at random and thus offer limited diagnostic value. Particularly smaller early-stage tumours are frequently missed.

Many of today's well-informed

patients are not prepared to accept this uncertainty as Schlenker and Clevert can tell from their experience in the consultation room. More and more patients bring their own MR images to the clinic to have them used during prostate biopsy.

Fusion technology will become reality

While fusion technology is not yet considered in the guidelines, both interest in the new procedure and positive evidence are increasing. Several studies published in the past two years confirm the benefit of fusion technology in prostate cancer detection, such as a study comparing targeted fusion biopsy and 12-core biopsy [Siddiqui MM, Rais-Bahrami S, Truong H et al (2013); Eur Urol 64:713–719]. Among subjects, 320 out of 582 underwent standard biopsy with negative results, despite an elevated PSA level of 9.9 ng/ml. Additional fusion biopsy led to Gleason score upgrading in 81 of these subjects, which had major implications for the treatment strategy.

The two Munich experts in their different fields are confident that fusion technology will prevail. For them it is already a reality. ■



The urologist and radiologist are collecting tissue samples in a punch biopsy using fused MRI and ultrasound images

prostate tumours, particularly when lesions are small. Fusion biopsy now combines the strengths of both imaging modalities by merging – fusing – pre-acquired MR images with ultrasound images in real-time.

Image fusion, as such, is not a new technology but has already proved its mettle in various other applications: for about ten years this has been used in abdominal imaging to reliably visualise liver, kidneys and vasculature and to differentiate pathologies.

Urologists have the patients, we have the imaging systems

Ever since image fusion was introduced at the University Hospital Munich, the radiology and urology departments have been cooperating closely. 'We realised, pretty much right away, that both parties would benefit from a cooperation,' says Professor Dirk-André Clevert of the Institute of Clinical Radiology, who heads the Interdisciplinary Ultrasound Centre at his institution. 'Urologists have the patients; we have the imaging systems. Together



The two specialists, Boris Schlenker and Dirk-André Clevert, are an experienced team in localising the region of interest



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Elastography: using the entire arsenal

Although breast elastography entered clinical practice many years ago, a large number of breast radiologists are still unaware of its benefits and have not become familiar with its principles. A session during the last Spanish Breast Congress aimed to improve knowledge of this technique.

Report: Mélanie Rouger

'When we talk about elastography, we realise there's still a confusion surrounding its key concepts,' said Dr Sergi Ganau Macias, a senior breast radiologist at UDIAT-Parc Tauli Corporation in Sabadell, Barcelona.

Simply put, it aims at imaging tissue stiffness, which provides additional and clinically relevant information in a non-invasive, non-irradiating way. Soft and flexible lesions are considered benign, whereas rigidity or stiffness is often an indicator of malignancy. 'In that sense, elastography is truly a substitute for breast palpation. The elastogram will appear next to the B-mode image and show different degrees of stiffness,' said Ganau, who has used elastography for almost a decade. Mapping stiffness can either be estimated from the analysis of tissue strain under a stress or through shear wave imaging.

With strain elastography the radiologist applies the transducer and compresses the breast; the applied pressure distorts the breast and lesion to be observed. When the tissue returns to its normal place and shape, the user can assess the elastic modulus. Results are qualitative and can only be measured semi-quantitatively with different ratios or with a colour scale.

On the contrary, shear wave or transient elastography enables the user to measure and quantify lesion stiffness without compression, by assessing wave propagation. The technique provides many benefits. It adds value to B-mode ultrasound and is particularly useful in apparently negative ultrasound studies with uncertain clinical or mammographic findings. It can also be used in case of doubt to characterise small size hypo-anechoic lesions (solid or cystic) and iso/hypo-echoic lesions (fat lobules and/or solid lesions). Elastography can bring additional sensitivity and/or specificity to B-mode especially in type 3 or 4a lesions, and may help to monitor neoadjuvant treatment when this is not possible with magnetic resonance, or when MR is not available. Last, but not least, elastography can help to diminish axilar fine needle puncture aspiration (PAAF) false negatives. 'Elastography nicely complements B-mode imaging and enables to precise indications for biopsy,' Ganau added. Some studies have shown that elastography limits recourse to biopsy and significantly reduces the number of benign breast biopsy diagnoses (<http://www.ncbi.nlm.nih.gov/pmc/>

articles/PMC3558110/, Breast elastography: A literature review, A Goddi, M Bonardi and S Alessic).

However, despite its high specificity and slight correlation with tumoural phenotypes, the technique will never be a substitute for biopsy, Ganau emphasised. 'I think a significant

downside with elastography is the wide variability between the different models offered by the industry. This versatility complicates the conduct of multicentre trials, which would bring vital and much needed evidence regarding elastography's indications and uses,' Ganau explained.

In addition, cut-off points remain difficult to establish in the case of shear wave elastography. 'Which one is the ideal cut-off point? When we search for sensitivity and use a low cut-off point, we will find more cancers and trigger more negative biopsies; but when we use a high cut-off point, we end up with the opposite problem, i.e. a low cancer detection rate,' he said. False positives may be due to the presence of calcium, fibromatous component or mucinous

carcinoma.

Ganau recommends using the whole ultrasound arsenal because techniques are complementary. 'It's very important to use Doppler, B-mode imaging, harmonics and elastography – in a word,' he concluded, 'everything we have to detect cancer as early as possible.'



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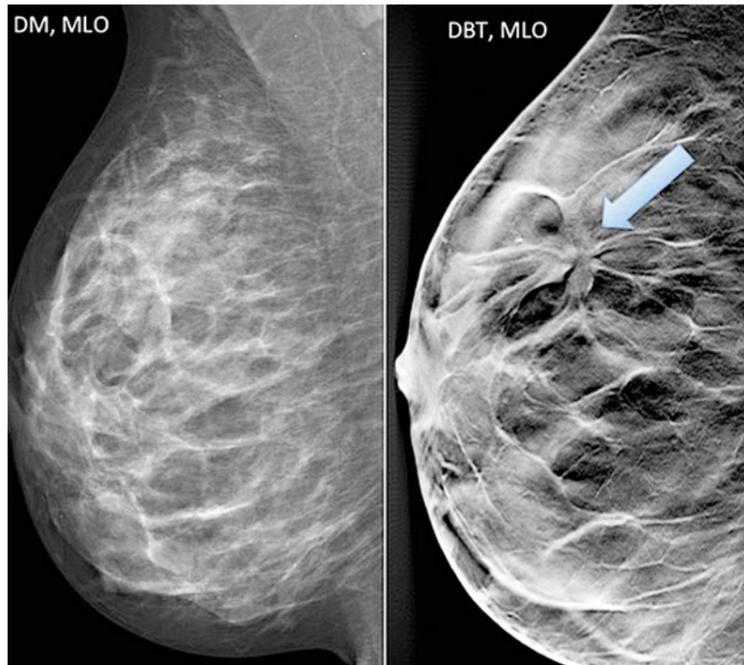


A specialist in breast pathology and gynaecology **Sergi Ganau Macias** is a senior radiologist at UDIAT-Parc Tauli Corporation in Sabadell, Barcelona. With over a decade's experience in the use of elastography he has authored many publications and delivered many talks on this subject.

Digital breast tomosynthesis

Ready to take over?

Results from recent trials are promising: an almost 40% increased breast cancer detection rate from digital breast tomosynthesis (DBT) screening compared to conventional mammography. Therefore, is an introduction of DBT to screening already a realistic scenario? The pros and cons will be discussed at this year's ECR by radiologist and DBT specialist Sophia Zackrisson



Interview: Bettina Döbereiner

The technology in itself is not new. The principle of tomosynthesis was already invented in the early 1930s. The basic idea: several low dose X-ray projections are made in a limited rotation angle around an object. Afterwards, these projections are reconstructed into three-dimensional images. Even though tomosynthesis has a lower radiation exposure than computed tomography (CT) it was put in the shade for a while and often only named 'limited angle computed tomography'.

DBT solves overlapping tissue problem

In the late 1990s, tomosynthesis was reborn and continuously improved – above all in breast imaging, then called digital breast tomosynthesis (DBT). The big advantage of 3-D DBT is that it reduces the effect of overlapping breast tissue that may hide or simulate a tumour in standard mammography projection imaging. 'In the 3-D image where you get 1 mm thin slices, suddenly you can see the tumour very clearly,' explains Sophia Zackrisson, radiologist at Skåne University Hospital in Malmö, Sweden. It is not a real 3-D image, DBT does expose in a 15° to 60° angle and not in a 360° angle around the breast as in a CT scan.

DM v. DBT imaging

The Malmö Trial: One view DBT detects 40% more breast cancers

Two recent large-scale and population based trials compared two view digital mammography (DM) and two view DBT in the so-called combo mode with two view DBT. The STORM-trial (Screening with Tomosynthesis OR standard Mammography) and the first results of the Oslo-Trial showed a significantly increased detection rate of breast cancers in screening by using the combination of DM and DBT.

The Malmö Trial (Malmö Breast Tomosynthesis Screening Trial) from Lund University, Sweden, now proved, for the first time, that even one view DTB as an exclusive method is superior in cancer detection than digital mammography. B background: Typically, a screening mammogram contains two projections from different angles - the mediolateral oblique (mlo) and the craniocaudal (cc) view. However, even with one view DBT (mlo) 40 percent more breast cancers can be detected compared to the two view digital mammography, as the findings of the Malmö-Trial now showed. The characteristics of the additionally found cancers using DBT appear to be the same as with conventional mammography screening.

Up to now, no statistically relevant differences could be proven - we have to wait for the final publications of the Oslo and Malmö trial in the next two years.

Could DBT replace 2-D mammo screening already?

All these promising results from the recent trials could suggest that DBT is ready to become the future gold standard of mammography screening – for this device not only detects more cancers in women, according to Sophia Zackrisson DBT also makes it easier to stage a cancer and its size-estimation is more accurate. Additionally, another positive effect must be mentioned: if DBT is used in the same way as in the Malmö trial it is more women-friendly than mammography because it reduces procedural discomfort. Zackrisson estimates that, in the trial, the compression force on the breasts in DBT-screening was halved. In 2-D mammography compression is needed to reduce the radiation dose and to separate overlapping tissue; but in DBT the separation effect is already solved by the multi-angle-technique that reduces the overlapping tissue effect per se. Also, if only one view DBT is used, as in the Malmö trial, the radiation exposure is lower. Altogether - what stops us subsequently to introduce this new method of screening – bearing in mind that DBT is widely used in the USA already?

DBT screening: possibly in five to seven years

Sophia Zackrisson believes there are several reasons that should stop us going fast forward. First: we must wait for the final publications of the Oslo and the Malmö trial. Next comes the important and not yet answered question: Does DBT-screening also affect breast cancer mortality in the population? For ethical and economical reasons, Zackrisson does not recommend randomised mortality studies to evaluate whether DBT reduces breast cancer deaths in the long run. Instead, she suggests waiting for the follow-up analyses of the trials to see whether DBT screening has an effect on the interval cancer



Sophia Zackrisson is Associate Professor at the Department of Translational Medicine, Lund University, and radiologist at Skåne University Hospital in Malmö.

rates – a term for cancers that are detected within the period up to the following screening. In general the rate of interval cancers is used to assess the efficacy of breast imaging. 'I'd like to see at least some trend of decreasing interval cancer rates in the trials before we translate tomosynthesis into screening,' Zackrisson says. According to her this is important to know, because otherwise it could indicate that DBT is over detecting and its additional findings represent just very small, indolent, non-aggressive tumours that never would have appeared clinically later. However, Zackrisson seems to be confident that DBT will replace 2-D mammography in the long run. Not yet, but approximately in the next five to seven years.

ECR 2016

Digital Breast Tomosynthesis

2-6 March: several sessions focus on DBT

Sophia Zackrisson will speak during the following dates:

- 2 March. 12:15-13:45, Studio 2016. 'Is digital breast tomosynthesis ready for mamm-screening?'
- 5 March. 16:00-17:30 Room F2. 'Should we abandon 2D mammography?'
- The prof. is also moderator for the Satellite Symposium 'Digital breast tomosynthesis out of the daily routine.'
- 2 March. 14:00-15:30, Studio 2016.

Mammo enhance

Contrast enhanced 2-D ar

Using an iodinated contrast agent, I-View software on the Hologic tomosynthesis system enables the user to image the functional 2-D contrast uptake and the morphological mammography images in rapid sequence and combine these

PET/MRI imp breast cancer

A new EU-funded project HYPMED is developing method for more accurate detection of breast cancer and understanding of its response to therapy.

Breast cancer is the most common type of female cancer and continues to be one of the main causes of cancer death in women. Despite the advances made in modern medicine and contemporary targeted therapies, the stage of breast cancer at the time of diagnosis is still the most important driver of patient survival. This means that there is an obvious and persisting need for an improved early diagnosis of this disease.

The project Digital Hybrid Breast PET/MRI for Enhanced Diagnosis of Breast Cancer, HYPMED for short, will develop a hybrid system of two medical imaging modalities (MRI and PET) for improved diagnosis of breast cancer and personalised therapy control. A European consortium made up of nine partners from leading universities, research organisations and industry has recently started their ambitious research initiative. „The HYPMED project combines visionary clinical expertise with excellence in physical and engineering sciences and the developed technology will greatly help us to choose an appropriate treatment that is exactly right for a given cancer in a given woman“, states, Prof. Christiane Kuhl from University Hospital Aachen and Scientific Coordinator of the project.

Tomosynthesis on D2RS redefines the remote controlled table stan

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Tomosynthesis is an advanced application that allows a multi-slice acquisition and provides a reconstruction of a volume.

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Also known as 3-D mammography, tomosynthesis has many clinical applications including chest, orthopaedic exams, extremities, kidneys and sinuses; tomosynthesis is the simplest application to add the third dimension on your digital remote controlled system.

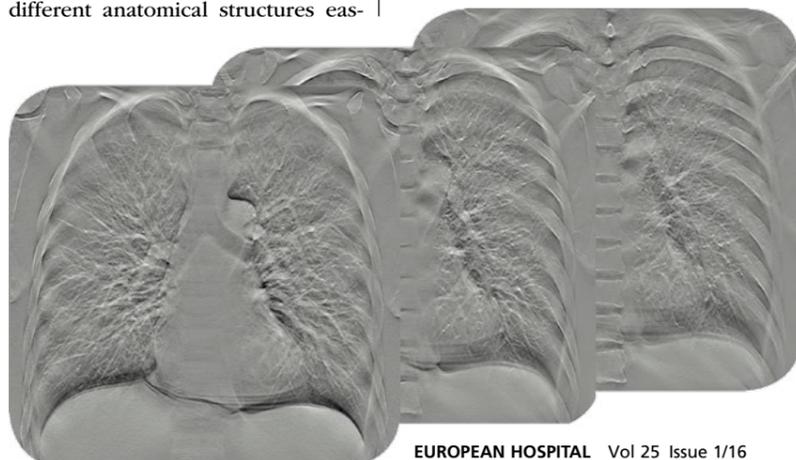
The firm Stephanix has integrated this very exciting feature on the D2RS remote controlled table, which allows a high level of diagno-

sis at very low dose,' the company reports

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graphy fusion ed by contrast and 3-D mammography fusion

three image sets into a single co-registered study.

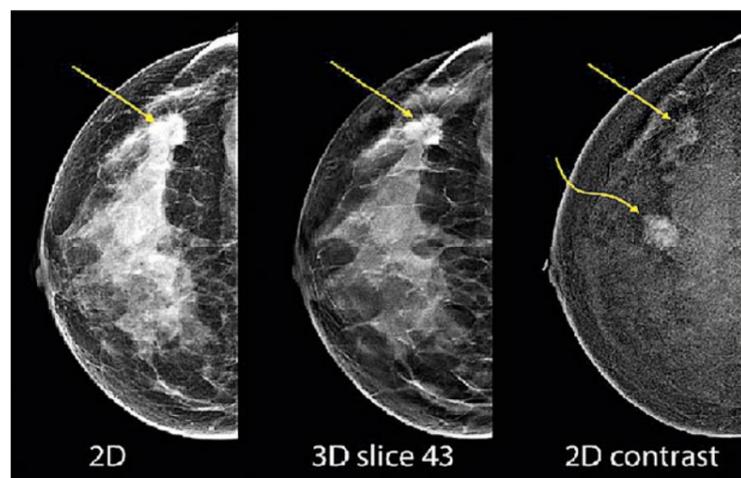
This image set from an iodine contrast mammography study was acquired under a single breast compression. The lesion pointed to with the straight arrow can be identified

with the 2-D image (left), although the tomosynthesis slice (centre) shows the distortion associated with the lesion more clearly, and there is also iodine contrast uptake in the lesion in the contrast image (right).

The lesion pointed to with the curved arrow has strong iodine uptake, but this cannot be identified easily in the dense areas of the non-contrast mammographic image seen here.

In this unique study, the 2-D contrast image can identify potential lesions based on their physiological state, which can cause increased contrast agent uptake. The standard 2-D and 3-D Mammography images can then be reviewed for morphological information.

Landmarks from the mammography images are also helpful for follow-up tomosynthesis guided biopsy procedures.



proves r diagnoses

oping a ground-breaking imaging
st cancer and a better, more personalised,



Prof. Christiane Kuhl, University Hospital Aachen and Scientific Coordinator of the project

The project's ambition is to develop a radiofrequency coil that can be connected to any regular clinical MR scanner and transform the device into a high-resolution PET/MRI hybrid system, which can be used to identify even the smallest breast cancer foci and better characterize the cancer as well as its response to therapy.

Patients will also benefit as the radiation dose of the new technology will, in contrast to other PET-MRI examinations, be comparable to a regular digital mammogram. The HYPMED approach is also likely to be transferrable to other clinical applications, such as prostate cancer detection and hybrid cardiac imaging.

standards

- Distance between 2 slices: 0.1 to 8.7 mm
- Acquisition time: 1 to 4 seconds
- Region of interest height range: 0 to 30 cm
- Reconstruction time < 5 seconds

The acquisition parameters, adjustable for the anatomical body part, offer the best image quality at low dose, Stephanix adds. 'After the reconstruction, you will have the possibility to navigate into the volume, or to decompile the acquisition and extract the most interesting slices. Moreover, to reinforce the 3-D impression, the software of the D2RS makes it possible to browse into the volume in coronal or oblique.

'With these pieces of information, we can conclude that tomosynthesis on D2RS redefines the remote controlled table standards and opens new field of investigation.'

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The € 32 billion diagnostic imaging market at a crossroads

Challenges & disruptions

The annual congress of the ESR is a great showcase for the latest advances in the imaging sciences and an important platform to see where the industry is heading. In an interview with European Hospital, Professor Hans Maier, former President of Bayer Diagnostic Imaging and now Co-Founder and Managing Partner of the healthcare advisory firm BGM Associates, summarises the current industrial and competitive dynamics in imaging and shares his thoughts on how increasing competition, novel technologies and a changing radiology service provider landscape set the industry in motion.



Professor Hans Maier led the Global Diagnostic Imaging Business at both Schering AG and Bayer AG. He serves on the Board of Medical Institutions, such as the German Heart Institute, Berlin, and the Fraunhofer MEVIS Institute for Medical Image Computing. He is also an adviser to pharmaceutical and medical technology companies worldwide through his consulting firm BGM Associates.

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EH: We are witnessing a wave of consolidation and new partnerships in the imaging industry: Guerbet acquired Mallinckrodt's contrast business, Toshiba seeks a partner for its Medical Devices division and IBM has acquired Merge Healthcare. What drives such developments?

Professor Hans Maier: 'To a great extent, our industry has been an oligopolistic market, particularly in devices, contrast media and injection systems. A handful of companies make up the vast majority of the €32 billion diagnostic imaging industry. We currently see a quite unique combination of factors that is likely to change the industry landscape significantly.'

'The market for diagnostic imaging equipment is becoming more competitive with a number of new entrants from emerging markets, such as the South Korean electronics giant Samsung, which has recently presented a 128-slice high-end CT machine with a speed of 0.25 s. per rotation, or China's Neusoft Medical, which has recently received CE-clearance for its 128-slice CT machine in Europe.'

'While innovation still happens, imaging hardware for most indications is fairly mature, therefore it will be ever more difficult for the large engineering companies to differentiate in competition with incremental improvements of hardware specifications only.'

'The leading contrast media companies will see increasing generic competition as the remaining contrast agent patents expire within the next years. The current debate on gadolinium-retention is a critical issue requiring further investigation. I expect this to accelerate the shift towards macro-cyclic MRI contrast agents. The fact that most major players exited molecular imaging shows how difficult it is to develop new promising products and build new areas of growth.'

'At the same time, we see a new group of companies entering the field from the information technology world and IBM's acquisition of Merge has brought more attention and dynamics to this process. These industry trends spur a wave of consolidation in search of scale and access to complementary technologies and end customers.'

In the future, what major innovation drivers could allow companies to gain competitive advantages?

'While the CT technology is very mature, we may see more distinct devices, for instance in intraoperative and interventional applications and specific indications, such as breast imaging. Overall, we see more potential for significant improvement in MRI, with faster devices expanding the range of indications, improving patient comfort and affordability; also, in ultrasound, novel systems may reduce operator dependence and facilitate contrast-enhanced applications. 'The current iodine-based low osmolar X-ray contrast media

and Gadolinium-based macro-cyclic MRI agents are regarded as very safe and gold standards in their respective modalities. Therefore, the development of novel agents faces very high benchmarks and significant investment, while the economic viability remains uncertain in a restrictive reimbursement environment.'

'The fate of Amyloid-imaging greatly depends on the availability of novel Alzheimer's therapies, so we will continue to see novel targeted molecular imaging agents, some of which bear the potential of providing innovation in specific applications, primarily in oncology.'

'However, the major innovation driver will be novel software applications. Large IT companies, such as IBM and SAP, but also start-ups such as Enlitic, Arterys or Zebra Medical, have made great progress in developing cloud-based platforms and learning algorithms to structure medical information and apply abundant computing power to recognise pattern within and across diagnostic data sets. These tools are already selectively available today to support the diagnostic workup and decision-making and we expect them to gain adoption steadily.'

How will those innovations influence radiology service providers?

'The radiological discipline faces a number of critical challenges, such as the variance in quality and a lack of standardisation, vast differences in radiation and contrast dose exposition across hospitals and countries, the high workload of radiologists and a lack of qualified personnel in some parts of the world, as well as the still very fragmented radiology ecosystem.'

'In parallel, we witness a time of cost containment that encourages an 'industrialisation' of radiology workflows and favours the emergence of consolidated and professionalised imaging centres and imaging networks.'

'Some of these problems will certainly benefit from novel software solutions to standardise processes

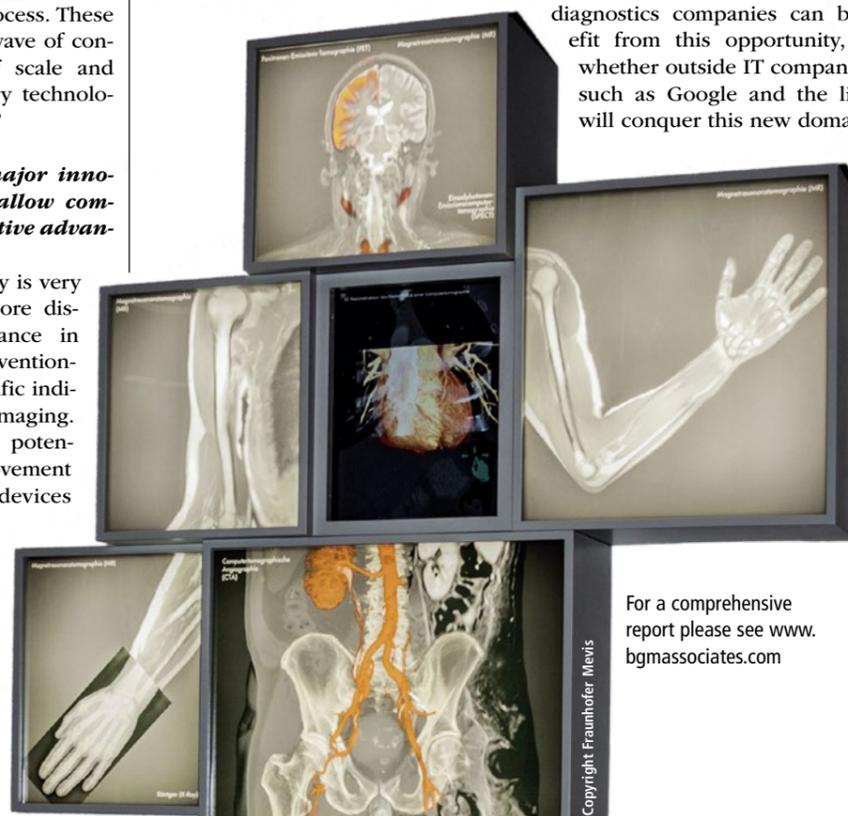
and support image interpretation. Moreover, software will be the basis for radiology to connect with other diagnostic services such as in-vitro diagnostics and pathology, and can help foster the role of the radiologist in a world where ever more medical disciplines make use of imaging technology to prepare and guide diagnostic and therapeutic interventions independent of the radiology practice.'

How can incumbent companies navigate in an environment between generic competition and disruptive innovation?

'I believe It's important for incumbents to think beyond the current company boundaries and to engage in new, maybe unconventional, partnerships. The time is right to integrate the components of the radiology ecosystem, for instance, to expedite a much closer integration of image acquisition and contrast injection protocols, but also beyond radiology with other diagnostic and therapeutic disciplines.'

'Organisational research tells us that it's challenging to overcome the legacy of a company and to implement such significant change. However, I would advise companies to create a philosophy of open innovation that promotes partnering with other companies and a closer collaboration with academia, radiology and diagnostic service providers and payers.'

Many companies have pursued the vision of integrated diagnostics – to date with only modest success. Now that this vision becomes a reality, it remains to be seen whether the diagnostics companies can benefit from this opportunity, or whether outside IT companies, such as Google and the like, will conquer this new domain.'



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A bright outlook for bona fide personalised medicine

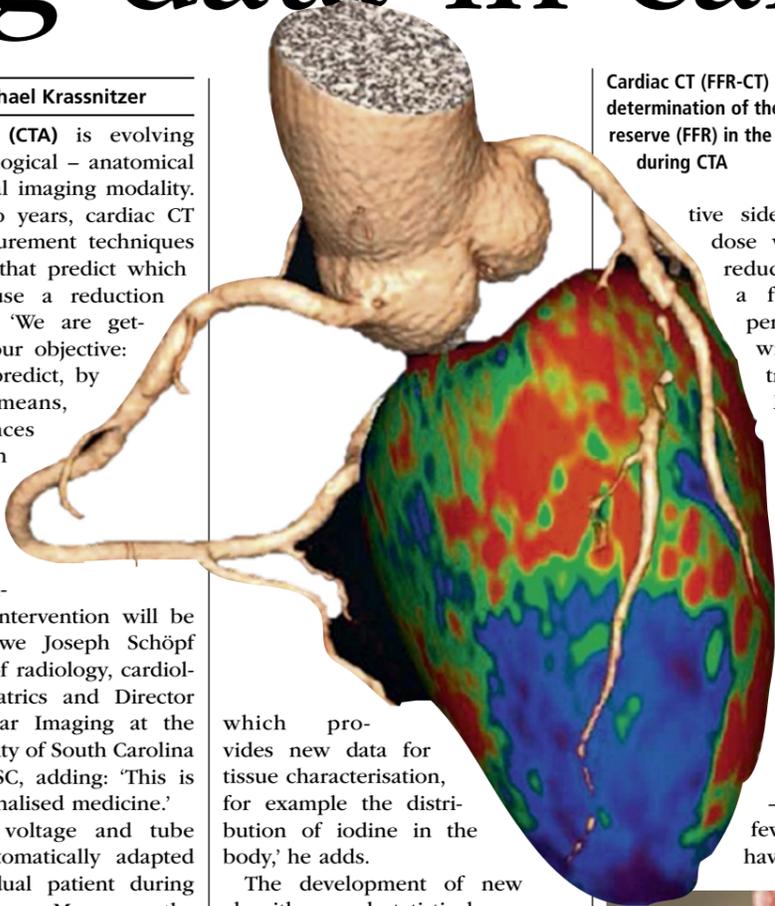
Big data in cardiac CT

Report: Michael Krassnitzer

CT angiography (CTA) is evolving from a morphological – anatomical – to a functional imaging modality. In the past two years, cardiac CT perfusion measurement techniques were launched that predict which lesion will cause a reduction in blood flow. 'We are getting closer to our objective: to be able to predict, by non-invasive means, the consequences of a stenosis in an individual coronary heart disease patient and to evaluate whether and which intervention will be useful,' says Uwe Joseph Schöpf MD, professor of radiology, cardiology and paediatrics and Director of Cardiovascular Imaging at the Medical University of South Carolina in Charleston, SC, adding: 'This is bona fide personalised medicine.'

Today, tube voltage and tube current are automatically adapted to each individual patient during a cardiac CT scan. Moreover, the new generation of multi-detector CT systems offer new insights: dual energy scanners, i.e. scanners that use two tubes in one scan, enable assessment of blood content in the heart muscle. 'We can directly and dynamically measure blood flow within the heart by scanning quickly back and forth across it while the contrast agent bolus moves through the heart muscle,' Professor Schöpf explains.

Another promising technology is the single photon detector, currently under development. 'These detectors allow us to look at each individual photon and its behaviour



which provides new data for tissue characterisation, for example the distribution of iodine in the body,' he adds.

The development of new algorithms and statistical procedures is contributing to the rapid progress in imaging technologies. Thermodynamic models are being used to predict blood flow, or even more impressive, artificial intelligence concepts are applied in radiology. Computers 'learn' by analysing hundreds of cases of coronary stenoses to determine which stenosis will be dangerous for the patient. Schöpf sees enormous potential: 'This is a Big Data application, but by no means science fiction. Initial results are expected to be published later this year.'

The new techniques and procedures have an important posi-

Cardiac CT (FFR-CT) enables the determination of the fractional flow reserve (FFR) in the coronary arteries during CTA

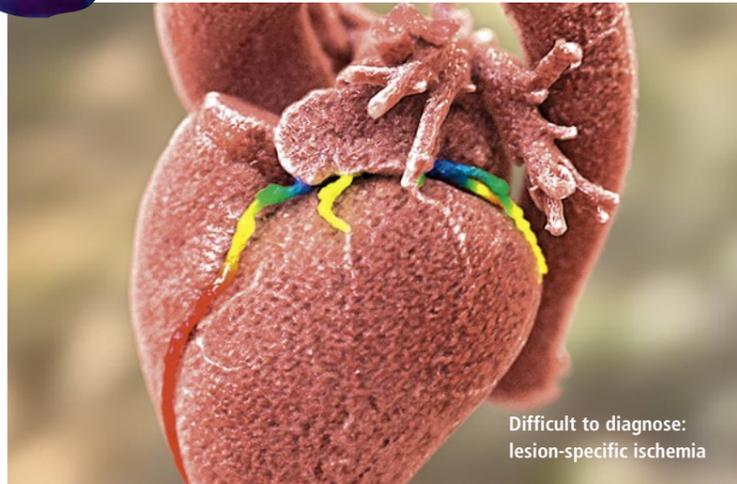
tive side effect: radiation dose will be drastically reduced again. Today, a full CTA can be performed at 80 kV with 30 ml contrast. A study at the Medical University of South Carolina, co-authored by Professor Schöpf (Spearman et al, Radiology, 16 Oct 2015) indicates that the introduction of automated kV selection in 80,000 exams, worldwide, reduced average radiation dose by 14 percent – a result which, a few years ago would have been considered

revolutionary. Albeit, as Professor Schöpf points out, 'Here, in the US, the discussion about radiation dose is petering out.'

Radiation dose as a dominant issue, above all in the USA, appears to have been largely a matter of domestic political interests. Many radiologists assume that radiation dose was used to prepare the ground for 'ObamaCare': an argument to decrease the use of imaging in order to save as much money as possible in the context of the planned US healthcare reform.'

Today, with President Barack Obama's healthcare reform being well established 'the issue of radiation dose has all but disappeared,' Schöpf observed.

However, on the level of technology dose reduction remains important, the professor emphasises. The objective is to further reduce radiation and contrast dose while achieving the same high level of image quality. According to Schöpf, results so far are encouraging and, in some cases, image quality was even enhanced. 'What we need to



Difficult to diagnose: lesion-specific ischemia



Austrian-born Uwe Joseph (Joe) Schöpf is a professor with appointments in Radiology, Cardiovascular Medicine and Paediatrics at the Medical University of South Carolina (MUSC) in Charleston, SC. There he directs the Cardiovascular Imaging Division and is Director of Computed Tomography Research and a Director of the University Designated Centre for Biomedical Imaging. Schöpf grew up in Munich, Germany, where he graduated in medicine at Ludwig Maximilian University (LMU) and received specialist training at its Institute of Clinical Radiology. In 2001, already an accomplished radiologist, he left Munich to pursue his interest in cardiothoracic imaging at Brigham and Women's Hospital, Harvard Medical School, in Boston, MA. The professor joined MUSC in 2004.

do now,' he believes, 'is to enhance our diagnostic expertise.'

Tissue characterisation, dual energy, single photon detectors – these are the current top priorities on the research agenda.

However, for Schöpf there are even more important questions to be answered: 'We know that CTA is a good, precise and patient-friendly procedure. Now we need to ask how we can make best possible use of this procedure. Is it cost-efficient? Which clinical scenarios can we envisage? Which patient cohorts will benefit most from these new procedures? Where should these exams be performed? These are crucial issues we must deal with in the coming years.' While clinical evidence does exist, as Schöpf points out, 'Our focus is on the creation of even more evidence that tells us where CTA should be applied.'

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Rethinking acute aortic syndromes

Next-generation CT aorta angiography challenges 30-year-old definitions, John Brosky reports

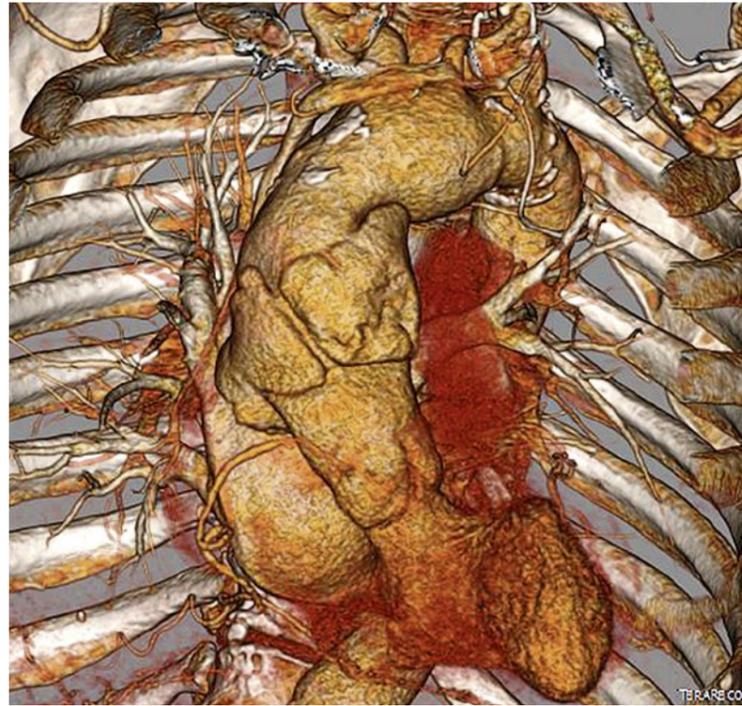
Technological advances in CT imaging have sparked a veritable explosion of imaging data. Pushing against the rush of novel imaging findings there is, what Dr Geoffrey Rubin calls, the slow wave of adoption in medicine, the acceptance and agreement of the clinical community for new diagnostic assessments

More than 10 years ago advances such as dual-energy and multispectral imaging arrived, offering new perspectives yet, Rubin points out, they continue to challenge medical imagers today. 'Here, there is not so much a new method as one that has only very recently become practical to implement,' he explained.

As Co-President of the 9th Internationales Symposium Mehrschicht CT und Aktualisierungskurs, Rubin presented a lecture on 'CT Angiography of the Aorta', which he hopes will 'advance an understanding of how to fully interpret the images we are acquiring in the setting of acute aortic syndromes.'

Interviewed here, he outlines key points covered in his presentation at the International CT Symposium (20-23 January).

'Acute aortic syndromes are an evolving construct,' Rubin states. 'These constructs have been bouncing around the consciousness of imagers for about 30 years yet, with the introduction of CT and, to a certain extent, MR, we are beginning to understand them better than when they were initially described using conventional angiography. We have come to observe that the traditional



Huge advances in computed tomography imaging, such as dual-energy and multispectral imaging still challenge today's radiologists. These images in CT aorta angiography provide great definition of internal organs

descriptors are not really how we should be thinking about acute aortic syndromes.'

Can you provide an example?

'The original description of intramural haematoma (IMH) was stagnant blood in the wall of the aorta, but



this description is identical to an aortic dissection where the false lumen does not communicate with the true lumen. IMH is a phenomenon that can be seen in all types of acute aortic syndromes. Identifying IMH is like saying you see a red car. The car being red may tell you something about the driver, but any car, BMW, Mercedes, Volkswagen can be red.

'The presence of IMH is a sign of the severity of an abnormality. When we take IMH out of the list and are left with two pathological entities, aortic dissection (AD) and penetrating atherosclerotic ulcers (PAU), then we have to add a third one that we have not talked about much, which is ruptured thoracic aortic aneurysm, an entity that causes acute aortic syndrome as well, though it has not been part of the traditional list. In a sense we go from a list that was three, where IMH was viewed as this specialised case of stagnant blood in the wall of the aorta, and we say instead, let's pull that to the side. It's an imaging finding we will see in AD, PAU, and the newly included rupturing aneurysm.'

Do those findings affect the clinical management of these patients?

'That's a good question. The clinical management is determined by more than just the identification of the pathological entity, but other issues about where it is located. In the case of aortic dissection, the patient may go immediately to the operating room, or the patient may be observed, or they may go to the cath lab for an intervention. There remains quite a lot of variation in treatment plans, and not a lot of science around the best therapy.



Geoffrey Rubin MD MBA is the George Geller Professor of Radiology and past Chair of the Duke University Department of Radiology in Durham, North Carolina, USA. A former President of the prestigious Fleischner Society his research interests focus on coupling cardiovascular and pulmonary CT and MRI with novel image processing techniques to detect, characterise, quantify and visualise structures as aids in diagnosis and treatment planning.

'These designations are not sufficient unto themselves to direct management. What these designations do is explain the underlying pathology, the underlying disease that caused this problem in the first place. These entities can be divided in terms of different sets of causes, though ultimately they converge toward a common final pathway, which is an aortic wall that is falling apart while trying to contain all the blood flow from the heart. And if the wall does fully break down, then it will be a catastrophic event for that patient.

'We understand pretty well what we are seeing. What we are trying to do is much like looking at an automobile that has been in an accident and trying to figure out how it got here. Was it caused by lots of little accidents, was it one big crash, was it a crash with another car, or did it fall off a cliff. This is what I will focus on, how it got there, which is a rich and complex subject, and less about what might be done about it.

'Key for us is to make sure that whoever is going to treat the patient has a comprehensive understanding of what is wrong, what the scan shows is going on.'

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EU job portal for refugee scientists

The EU has launched a new website to support EU refugees and asylum seekers holding university degrees in applying for research positions in the 28 Member States of the European Union.

Called Science4Refugees, the new initiative of the European Commission in Brussels is specifically aimed at qualified scientists among the refugees in Europe. This online platform allows them to find out about job opportunities commensurate with their qualifications and professional experience, to submit short CVs and publication lists and to request application forms. The new EU online portal Science4Refugees is part of Euraxess, a pan-European platform for "Researchers in Motion" in which 40 European countries are currently participating with more than 500 Euraxess Service Centres. Here, professionals offer personalised assistance to researchers and their families in matters such as moving house, finding accommodation, obtaining visas and work permits, language courses, schools for their children or social insurance issues. Euraxess offers this service free of charge.

FIRST: A Model-Based Iterative Reconstruction (MBIR) automatically lowers patient exposure up to 80% in clinical routine

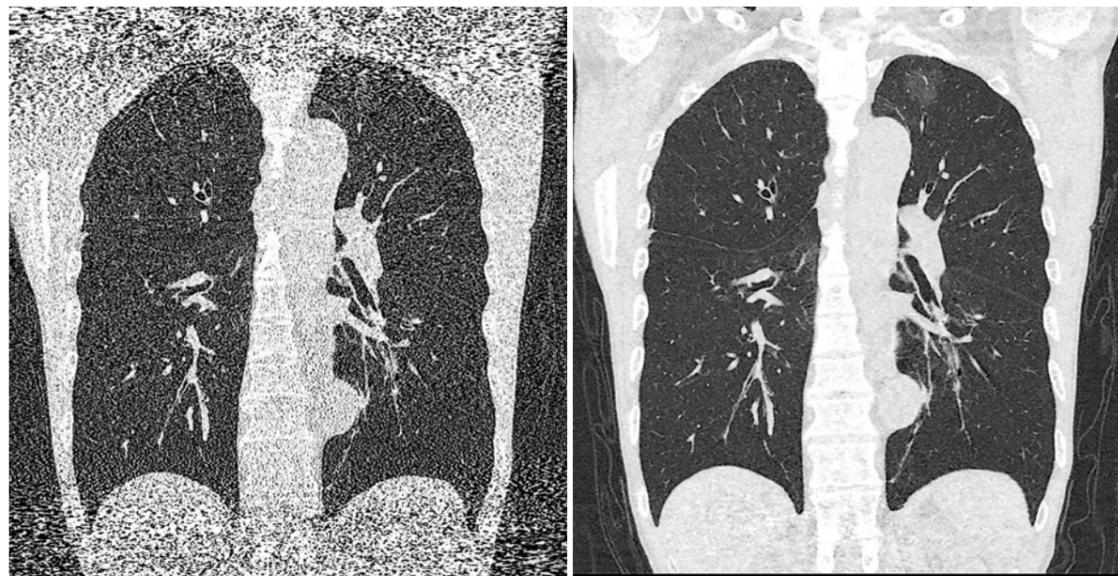
Ultra-low dose delivers diagnostic quality

The first thing to know about FIRST is how easy it is to use. For clinicians the system makes ultra-low-dose iterative reconstruction simple, an automated process that fits seamlessly into daily workflow, Toshiba reports.

'For radiologists who want to look under the hood and study the engine driving this technological breakthrough, fast will be the first word that comes to mind. Toshiba accelerated computational throughput to bring their true iterative reconstruction technique FIRST to the clinic for which extensive reconstruction times are not acceptable.'

Available for the Aquilion ONE Family of CT systems, FIRST – Forward projection model-based Iterative Reconstruction SoluTion – visually improves high-contrast spatial resolution while making exams safer for patients by providing ultra-low dose examinations, Toshiba explains.

Professor Alain Blum MD, from the University Hospital of Nancy, in France, scanned over 250 patients with the system in the first week



FIRST, with forward projection in the raw-data domain and using optical models visually improves spatial and low contrast resolution while making exams safer for patients by automatically providing integrated ultra-low dose settings to enhance clinical routine.

after installation and was impressed by the speed and image quality. According to Blum it contributes to

a significant improvement in image detail and it was possible to reduce dose to levels he never saw before.

'With the new algorithm we can reduce the dose by a factor three compared to currently state of the art

iterative reconstructions, this is very impressive,' he said.

'The new system is integrated in SUREExposure, Toshiba's AEC tool, to ensure automatic dose reduction of up to 80% in volume and helical scanning respecting the user-required clinical image quality. Using dedicated hardware the reconstruction of a complex volumetric data set only takes approximately three minutes,' the manufacturer reports.

Blum: 'We see an improved image quality with fast reconstruction that's easy to use, even at two o'clock in the morning. What we also see with FIRST is an opportunity for new protocols and applications, such as ultra low dose chest CT exams for pulmonary embolism with frail patients who have renal or cardiac insufficiency, for pregnant women or patients in a coma.'

Henk de Vries, Senior Product Manager at Toshiba Medical Systems: 'Quite simply our approach is that advanced iterative reconstruction should not be a technological challenge, but an automated technology that fits seamlessly into daily clinical practice. FIRST works with forward projection in the raw data domain using optic models to improve spatial resolution; it is incredibly robust for data with extremely low photon counts and improves image quality. The automated process translates into an easy and fast application to significantly reduce the radiation and improve image quality.'

The notable progress of Maltese radiology

Small country takes a big leap

Living in a small Mediterranean island has its own advantages; nevertheless there are certain limitations. In healthcare, for example, resources may be somewhat more limited in such a small country and some of the latest technologies may not always be available to patients. Moira Mizzi reports



Specialist radiologist Dr Warren Scicluna, at the Medical Imaging Department, Mater Dei Hospital, shares his experience as a radiologist trained in Malta where he currently practices. Up to just a few years ago, he notes, all the country's radiologists worked as general diagnostic radiologists and relied on conventional imaging, such as plain radiography, ultrasound, mammography, computed tomography (CT) and magnetic resonance imaging (MRI).

He explains that with regards to interventional procedures only a few were provided by the Medical Imaging Department at Mater Dei Hospital. These, to mention a few, included image-guided drainages, image-guided biopsies, percutaneous nephrolithotripsy, peripheral angiography and angioplasty. As a result, patients necessitating more specialised radiological techniques

or investigations, had to be sent abroad, or would be reviewed by a visiting consultant. 'This obviously placed an extra financial load on departmental resources,' he points out.

In 2008, just four years after Malta joined the European Union, a post-graduate Radiology training programme was set up. The training curriculum is largely based on the UK Royal College of Radiologists training curriculum. Trainees spend five years in training, at least one year of which needs to include sub-specialty training in a centre of excellence abroad. A Certificate of Completion (CCT) is awarded to trainees who have completed five years in-training, have successfully passed their annual review of com-

petency progression (ARCP), passed the final FRCR examination and spent a year of subspecialty training abroad. So far, seven residents have successfully finished training and have been awarded CCT. Five trainees are about to embark on subspecialty fellowship abroad. Six other trainees are currently undertaking pre-FRCR general radiology training rotations at the Medical Imaging Department in Mater Dei Hospital. Dr Scicluna recalls how, when he himself was a trainee, he and his fellow trainees were encouraged to choose different specialties so as to widen the local diagnostic and interventional scenario. 'Today, we have a wide range of specialties, including urology, neuroradiology, interventional oncology, gastrointestinal, breast, paediatric and cardiac imaging, and,' he adds: 'this was supplemented by the addition of new equipment, such as a 3-Tesla MRI scanner, new mammography and ultrasound machines, while a new angiography suite and a 256-slice CT scanner are also in the pipeline.'

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'In the meantime, the specialists were also provided with new devices, such as wires, stents, microwave and radiofrequency ablation devices, an insufflator for CT colonoscopy, ultrasound contrast, embolisation spheres with and without drug loading, to mention a few.'

The new services available in every radiology sub-specialty in Malta are various. In the case of urology, Dr Scicluna's own specialty, these include MRI of the prostate for local staging and diagnostic purposes, targeted transrectal ultrasound prostate biopsy, MRI of

the penis for staging or imaging of Peyronies' disease, transrectal ultrasound to assess infertility amongst other conditions and ultrasound Doppler of the penis for erectile dysfunction.

The Neuroradiology section now offers a 24-hour on-call service for mechanical thrombolysis, carotid stenting services and meningioma embolisation, whilst the radiologists working in interventional oncology have introduced microwave ablation of liver, renal, pulmonary and pancreatic lesions and transcatheter arterial chemo-embolisation (TACE). Gastrointestinal imaging services include CT colonography and CT/MR enterography, while breast imaging now provides triple assessment and stereotactic biopsy and vacuum-assisted core biopsy are to be introduced soon. Cardiac CT and MR have also been recently added to the repertoire. Although certain specialised techniques, such as coil-

ing of aneurysms and transjugular intrahepatic porto-systemic shunts do not form part of the currently available local services, possibly due to the small number of patients needing such interventions, Dr Scicluna insists that, despite its limited resources, the local healthcare system can still boast of a state of the art Medical Imaging Department.

'We've come a long way in less than a decade, starting off with the most basic of expertise, to the diversity and wealth of experience we enjoy today, mostly by changing the way we utilise our resources,' he states with pride.

This was indeed a big leap from the 'small island mentality' of the past, where limitations shaped the perspective of both the individual professional and the healthcare system at large. It only took one small shift to change the department for the better and irrevocably.

Between revolution and slow-moving evolution

Digital Health in Germany

Professor David Matusiewicz PhD, from the University of Applied Sciences for Economics and Management, in Essen, reflects on the current attitude to and future outlook for digital health

The spectrum of the Digital Health ranges from online information, to the digitisation of processes (e.g. clinical pathways in hospitals), the evaluation of big data (e.g. routine data/secondary healthcare data),

medical technology, diagnostics and therapy to billing procedures of payers. A practical significance lies in increasing the compliance or adherence of patients regarding their medication (e.g. pill reminder) and

prevention to care. A few years ago, the Digital Health scene was in an establishing phase. Currently the profiling phase has been initiated and market growth can be observed. The importance of Digital Health is also increasingly an important issue in health policy, health reporting, evaluation and control of the healthcare system.

In addition to this euphoria towards Digital Health there is also a more reserved attitude from the established actors, interest groups and health insurers. First venture capital donors lost money by supporting Digital Health start-ups and became more selective. According to the Federal Association of German Start-ups the proportion of start-ups under the heading Digital Health deal at 0.9% (in a market with a €314.9 billion spend on health and 5.1 million workers in 2013).

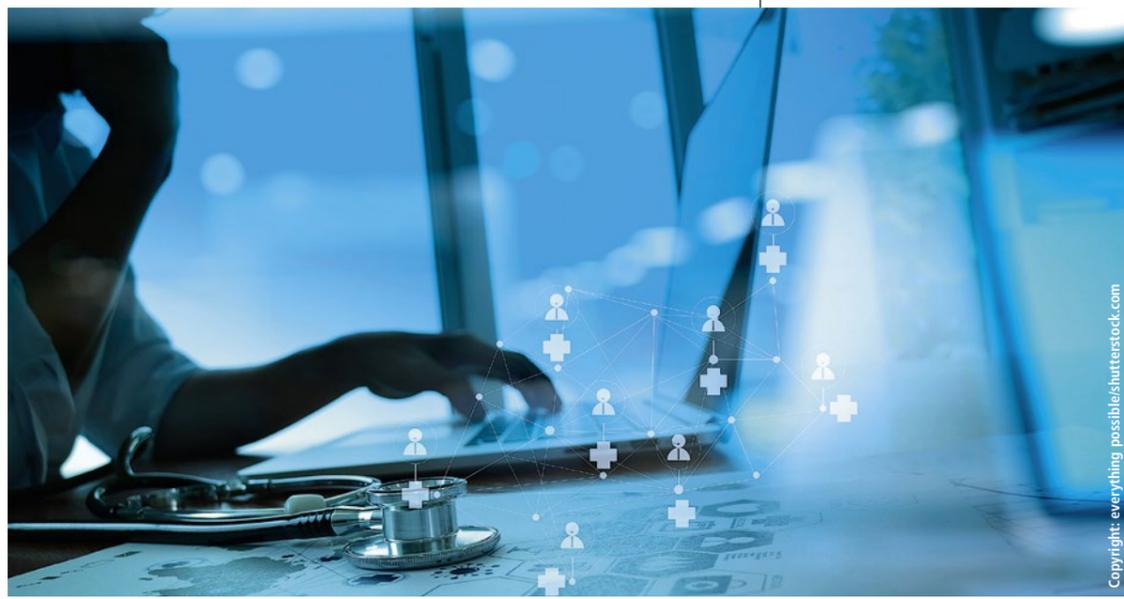
Federal healthcare is a highly regulated market with fewer degrees of freedom, in which existing funding models have no direct relation to innovation provision (no pay-for-innovation). Since the (healthy) insured present a "contribution preference" rather than a "performance preference" concerning their healthcare insurance, the relative contribution of additional funds is more important than a better package of services given by statutory health insurance. Digital innovations are also uncertain expenditures, withdrawing money from the system that is needed to treat the sick. Calculating the return on investment is not always straightforward.



Professor David Matusiewicz PhD, from the University of Applied Sciences for Economics and Management, Essen

If Digital Health is used as a competitive tool to attract and retain patients/insured people, the question arises as to whether the real target was missed.

Digital Health ranges between that mentioned euphoria among supporters and "German angst" among critics. Health economics evaluations will play an important role in the future. There is a lack of an overall strategy, which transfers lighthouse projects into standard care and integrates with the core business of health actors. A doctor will increasingly be a "transparent physician" and the patient will become an expert in his illness. The healthcare system will radically change in the next few years. Insurers and patients will vote with their feet. In the meantime, we can hope that there is no excessive brain drain by the (good) start-ups in health and they will all have migrated to the USA.



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Difficult to diagnose: interstitial lung diseases

A fan of pattern analysis

Good teamwork, a pneumologist's clinical data, and the use of HR-CT with very thin CT sections, high spatial resolution and specific algorithms for image reconstruction are essential ingredients for the successful diagnosis of rare interstitial lung diseases. Sylvia Schulz reports

Interstitial lung diseases (ILD) are rare – yet they are far more difficult to diagnose and highly variable. Professor Julien Dinkel, consultant at the Institute of Clinical Radiology, Ludwig Maximilian University Hospital in Munich, deals with these rarities and presents 'Systematic HR-CT Diagnostics, Part 1'. In October 2014, Dinkel was appointed as the newly created W2 Professor for Thoracic Imaging at the German Centre for Lung Research (DZL). 'There is a series of basic prerequisites to making a good differential diagnosis,' he emphasises. Those highly important prerequisites include clinical information provided by the referring pneumologist, he adds. Good teamwork is essential.

The second prerequisite is good technology. The technique used in this case involves HR-CT with very thin CT sections, high spatial resolution and the use of specific algorithms for image reconstruction. 'A section thickness of 1mm is almost always demanded in practice', Dinkel reports.

The radiologist particularly argues the case for acquisition of CT images both during inhalation and exhalation, because the examiner thereby obtains additional information to assess the pulmonary window and to reconstruct the core of the lungs. 'This is helpful, but not a must', he notes. Above all, there is no Europe-wide standard for the use of this method. 'One can obtain addi-

tional information on minor respiratory diseases; for example, whether bronchiolitis is present, which can be important for the differential diagnosis.'

Knowledge of microanatomy – especially with reference to the secondary lobule – plays a decisive role in interstitial lung disease diagnosis. The secondary lobule is the smallest anatomical structure in the lung that is fully surrounded by connective tissue and has a diameter of 1-2.5 cm. 'There is no chance at all of producing any images without high-resolution CT,' Dinkel points out.



Professor Julien Dinkel MD studied medicine at Louis Pasteur University, Strasbourg and gained his doctorate in 2010 from the Ruprecht Karl University of Heidelberg, based on research entitled 'Four-dimensional multi-slice helical CT of the Lung: Qualitative comparison and reproducibility of small volumes in an ex vivo model'. Since October 2014 the consultant radiologist has been W2 Professor for Thoracic Imaging at the German Centre for Lung Research (DZL), LMU Munich.

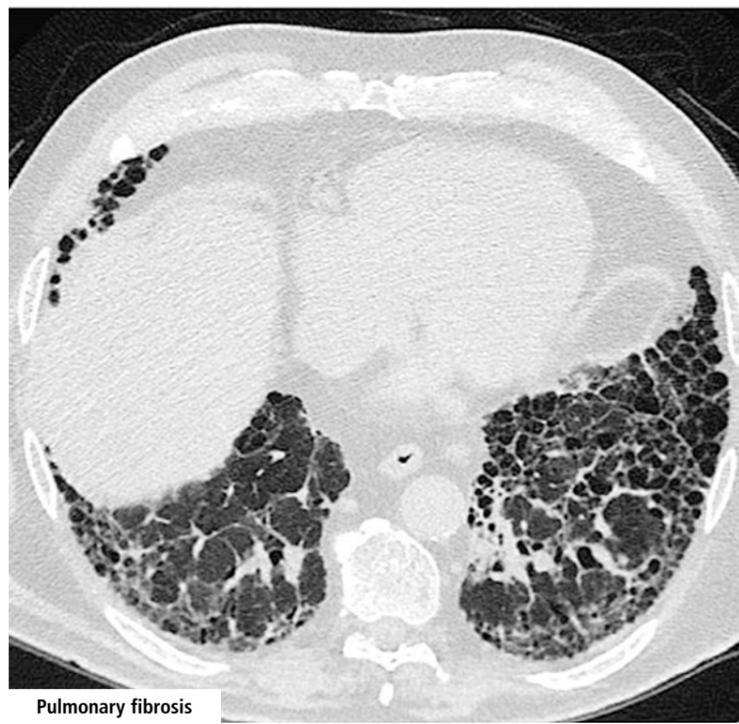
Normally, only a few structures can be assessed in the secondary lobule, most of which become apparent due to pathologies.

The third prerequisite for a good diagnosis is structured diagnosis. 'I am the biggest fan of pattern-based analysis', Dinkel states, with enthusiasm. In structured diagnosis, the dominant pattern is identified using pattern analysis. In this process, the relationship to the secondary lobule and involvement of the lung must also be considered, and the primary disease and secondary findings must be diagnosed.

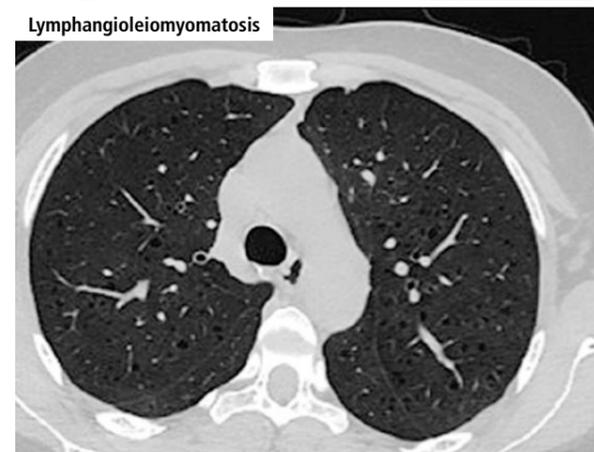
'Analysis of the HR-CT images is facilitated by consideration of four basic patterns: reticular and nodular patterns, cystic changes and densification of the lung parenchyma. Each pattern alone is not necessarily typical for a disease and they are commonly even present simultaneously. The dominant pattern, location and the clinical data are key to the diagnosis.'

Dinkel will report on reticular and cystic patterns in his ECR lecture. For example, reticular patterns are dominant in idiopathic pulmonary fibrosis, sometimes in NSIP (non-specific interstitial pneumonia), lymphangiosis carcinomatosa (LC) and in pulmonary-venous congestion. Purely cystic interstitial lung diseases, such as lymphangioleiomyomatosis or Langerhans cell histiocytosis, are recorded rather more rarely.

The professor is fully aware of the fact that some colleagues have



Pulmonary fibrosis



Lymphangioleiomyomatosis

other diagnostic preferences, some excluding the most common, whilst others the most dangerous diagnosis. 'People with lots of experience will not go through every single pattern systematically,' he points out. However, he recommends the 'safe approach' to those who are only rarely confronted with interstitial lung disease in practice. In such cases, however, a good differential diagnosis will only be possible at specialised centres.

ECR 2016
Friday 4 March
8:30-10:00 am. Room D1
Low dose and no-dose chest imaging: opportunities and limitations (RC 904)

The beauty of radiology

The trend in radiology is towards an increasing split into subspecialties such as interventional radiology, paediatric radiology or neuroradiology, which, with the growing complexity of this field, are becoming more independent of each other. Is the general radiologist a dying species? asks Professor Gerhard Mostbeck, Head of the Institute for Diagnostic and Interventional Radiology at the Wilhelminen Hospital, Vienna, in his lecture on the 'The Beauty of Radiology'.

Gerhard Mostbeck: 'The general radiologist? I couldn't find a concrete definition of this term. A general radiologist is obviously considered to be someone with no subspecialisation, i.e. someone who knows a little bit about everything.'

'However, when we look at personalised medicine, such as the treatment of breast cancer, a clinical specialist needs a clinically experienced radiologist specialising in breast cancer to work with, someone who knows about all aspects of this complex subject: from screening, mammography and ultrasound to the behaviour of tumours, biopsy and staging, evaluation of therapy response and process control. Specialisation is of utmost importance for successful treatment.'

'Unfortunately, though, the question as to whether we still need general radiologists cannot simply be answered with yes or no. Large university hospitals with 50 to 60 radiologists have several specialists in each area. In smaller hospitals, with fewer radiologists, the specialists have to be "multi-specialists". Not all specialties can be personally covered by one specialised radiologist throughout the entire day, during the night and over the weekends.'

'In my view, a general radiologist is someone who has had training and experience in all the basics such as ultrasound, CT and MRI. Building on this specialisation is then possible.' 'Pure subspecialisation is a form of organisation that works in large hospitals. In smaller hospitals general radiological skills are the basic requirements needed to work there.'

'In our hospital we encourage the development of a second set of skills alongside the general expertise that is structured based on specific modalities. Our colleagues are urged to train in several subspecialties. We then obviously expect that they also will work in these areas. However, we must also ensure that a paediatric radiologist or neuroradiologist can diagnose an accident victim on a Saturday night, for instance.'

'In rural regions, where it's not possible to have specialists in all subspecialties, teleradiology and teleconsultation offer new opportunities to ensure patient care. Each radiologist – even in a very small hospital – should have access to teleconsultation and therefore access to specialist knowledge.'

'Image data transfer for this type of exchange is already established in many areas. Only those patients needing interventional radiology, or the doctor, have to move location.'

Has radiology changed?

'Yes, especially for radiologists in private practice. Single-handed radiology practices are dying out whilst larger institutions and group practices are being set up to withstand economic pressures. Specialist and multi-specialist radiologists increas-

ingly staff group practices. This trend will grow, although we do not yet have the "public private partnerships" in Austria as are found in Germany. However, political change is already

evident and wanted.

'In my view, one thing applies to both radiologists in private practice and radiologists in the hospital: The trend towards subspecialists with

knowledge of only one organ, as seen in the USA, is absurd outside the setting of radiological research.

'My message: General radiology should be the basis of all specialisation. The beauty of general radiology is that we gain an overview and are able to assess many different areas; a designated super-specialist who only knows about one subject can really only be functional in university settings.'



Professor Gerhard Mostbeck heads the Institute for Diagnostic and Interventional Radiology at Wilhelminen Hospital, and the Institute for X-ray Diagnostics at the Otto-Wagner Hospital, Vienna.

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ECR 2016
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Radiology ten years from now:
where will it be?

A 3-D Endocavity probe knocks for targeted prostate procedures

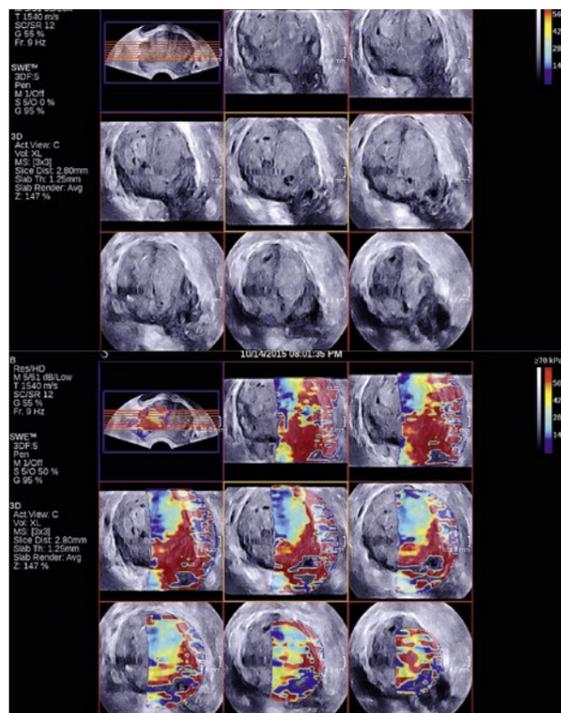
The prostate remains the only organ where random biopsies are performed to find cancer, notes Jean-Michel Correas MD PhD, from the Necker University Hospital in Paris. If we proposed this approach to a woman to search for breast cancer, it would be outrageous, he said.

This is mainly due to the limitations of prostate TRUS (Trans-Rectal Ultrasonography) using conventional ultrasound imaging (B-mode and Colour Flow), which detects less than 30% of cancer. While systematic biopsy techniques improve the detection rate, more than 20% of the cancers are still missed. Multiparametric MRI (mpMRI) is helpful for the detection of significant high-grade prostate cancer, but the vast majority of biopsies are performed under ultrasound guidance.

MpMRI with fusion to ultrasound imaging allows targeting of suspicious prostate lesion and should improve the biopsy detection rates; however, the overall cost of the procedure (mpMRI + TRUS + pathology) is high, and the availability of MRI is low in many countries. Moreover ultrasound-MR fusion guided biopsy increases by a factor of two the examination time.

At the European Congress of Radiology in Vienna, Professor Correas will present his recent experiences using a new probe from SuperSonic Imagine, which he says brings a significant improvement to prostate imaging with ultrasound and provides a true alternative to mpMRI imaging targeting for prostate cancer (SuperSonic Imagine's symposium, March 2nd, 12.30).

The SEV12-3 3-D Endocavity Transducer allows volumetric acquisitions of the whole prostate, and reconstructions of transversal, sagittal and coronal views not only in



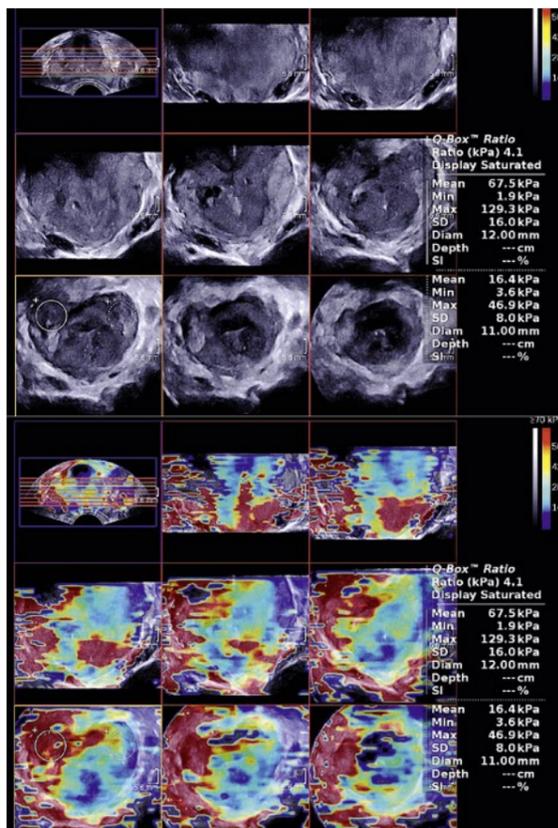
72 year-old patient with elevated PSA (42.3 ng/ml) with previous negative TRUS. Coronal views in Bmode (top image) and ShearWave™ Elastography of the prostate, reconstructed from one single 3D TRUS acquisition with the SEV12-3 probe, is showing one 45 mm single lesion at the left base with extra prostatic soft tissue extension into the seminal glands on both the Bmode and SWE with elevated stiffness greater than 70kPa. Targeted biopsies confirmed the presence of a large Gleason 9 adenocarcinoma.

sound based technique and perform targeted and systematic biopsies with the same imaging modality and probe,' Correas said.

The professor also emphasised that the SEV12-3 3D probe works equally as well as a 2-D transducer with excellent B-mode imaging, which remains a very important modality to guide systematically randomised biopsies, as well as the capability to detect low-flow

perfusion with a very sensitive Directional Contrast Power Imaging and with contrast enhanced ultrasound (CEUS).

Therefore, prostate lesion detection with TRUS, like for MRI, has become a multiparametric imaging technique combining several TRUS data to identify suspicious lesions. 3-D ShearWave Elastography (com-



62 year-old patient with 3.0 ng/ml PSA. Coronal views in Bmode (top image) and ShearWave™ Elastography of the prostate, reconstructed from one single 3D TRUS acquisition with the SEV12-3 probe, is showing one 10mm single lesion at the right lobe on ShearWave™ Elastography only with elevated stiffness greater than 70kPa. Targeted biopsies confirmed the presence of a 10 mm Gleason 7 (3+4) adenocarcinoma.

combined with B-mode) may be used for detection of lesion because of its high sensitivity (>95%)* while CEUS could be used to further characterise and biopsy the suspicious lesions.

In recent years, the concept of focal therapy has gained more and more interest. The aim of partial prostate ablation is to provide treat-



Jean-Michel Correas is Professor of Radiology at the Paris-Descartes University and vice-chairman of the Department of Adult Radiology in Necker University Hospital, Paris. He gained MD PhD degrees from the University of Tours and was Visiting Professor of Radiology at the University of Toronto department of Imaging Research. There he was headed several research projects on ultrasound contrast agents as part of his science doctorate on ultrasound contrast agents. He is deeply involved with the development of interventional urology, and particularly biopsy procedures and guidance as well as minimally invasive treatment of renal tumours.

ment to the index prostate cancer (lesion with highest grade) without removing the entire prostate because it would reduce side effects significantly by leaving untouched sensible structures, such as the neurovascular bundle or the urinary sphincter.

The limitations of partial therapy for prostate cancer are the multifocal nature of the disease, as well as the problem of correct identification and localisation of the prostate cancer lesions by prostate biopsy and/or imaging. 3-D ShearWave may help detect this index lesion and would enable partial focal treatment of cancers with, for example, RFA, HIFU or cryo-ablation, Correas concluded.

* Correas JM, Tissier AM, Khairoune A, Vassiliu V, Mejean A, Helenon O, et al. Prostate Cancer: Diagnostic Performance of Real-time Shear-Wave Elastography. *Radiology*. 2015 Apr;275(1):280-9. PubMed PMID: 25599156.

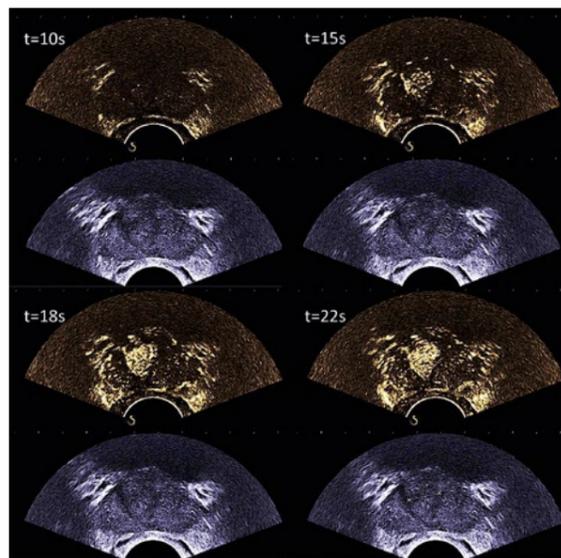
SuperSonic Endocavity Transducer reveals, for first time, true volume of prostate cancer lesions

B-mode but also in colour Doppler and in ShearWave Elastography. Volumetric ShearWave Elastography enables measuring stiffness everywhere in the prostate in a very rapid manner (full volumetric SWE acquisition of the prostate obtained in a minute or less).

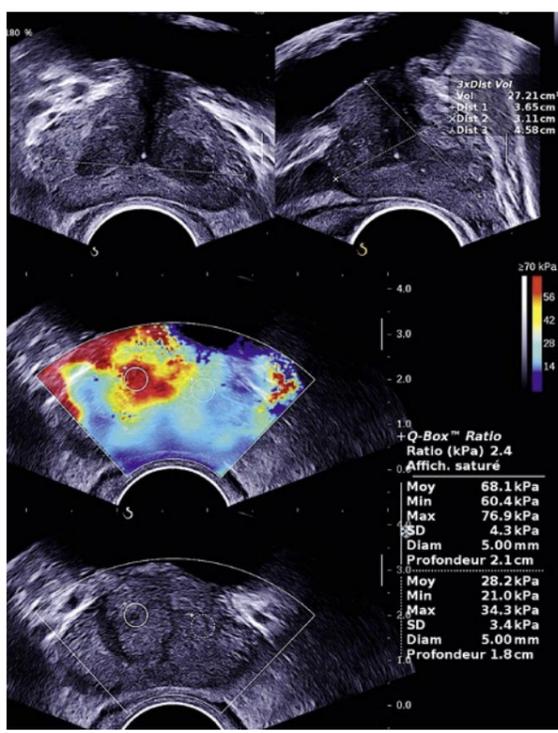
In a recent study performed by Correas with 2-D ShearWave Elastography on a population of 184 patients with biopsy proven cancers, it was shown that prostate tissue with higher stiffness (>35kPa) measured with ShearWave Elastography are at higher risk of malignancy*.

Another improvement with the new transducer is that ShearWave is now possible across the entire transversal view of the prostate, allowing the visualisation of tissue stiffness on both lobes and therefore enabling the comparison of stiffness of both lobes in 2-D or 3-D.

With 3-D ShearWave Elastography, for the first time, we can clearly identify and target suspicious regions of the prostate with an ultra-



CEUS at different time in the same suspicious area after the bolus injection (1.2 ml of SonoVue). 3 targeted biopsies in the suspicious area showed 22 mm adenocarcinoma with Gleason 8 score while systematic biopsies came back with no cancer. Patient was referred for radical prostatectomy.



72 year-old patient with elevated PSA (6.3 ng/ml) stable for 1 year (no previous data). MRI not possible due to non-compatible PaceMaker. Previous TRUS examination was performed but no suspicious area was found. Suspicious area found with ShearWave™ Elastography in the transition zone (isochoic lesion on Bmode) with a stiffness of 68kPa.

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Datasets like TCGA are 'the ultimate commodity'

Benefits from The Cancer Genome Atlas

Report: Lisa Chamoff

Last year, scientists at the University of California San Francisco (UCSF) revealed that by measuring the proportion of both immune and cancerous cells in tumours, or 'tumour purity,' clinicians could more precisely predict the success of certain precision therapies. A key aspect of the discovery was access to over 10,000 samples constituting 21 different cancers.

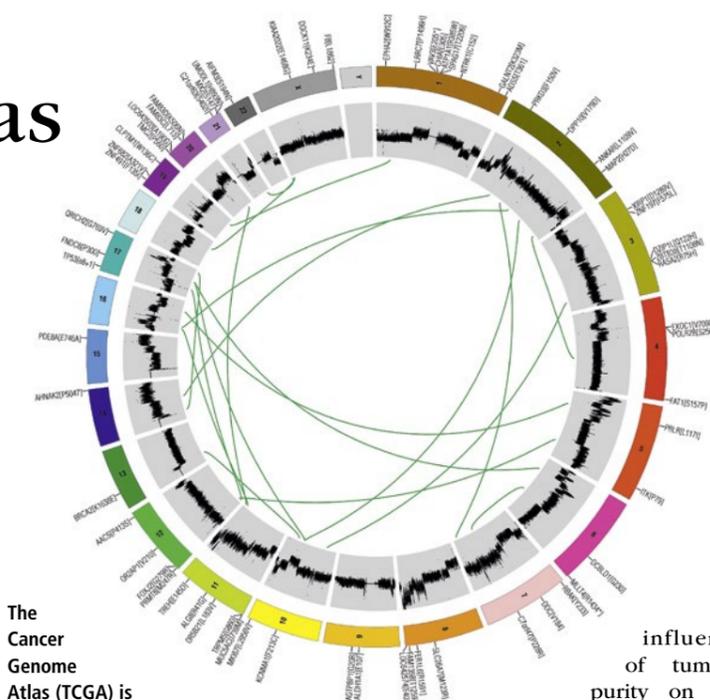
This wealth of data came from The Cancer Genome Atlas, a vast public resource, which is a joint initiative of the National Cancer Institute and the USA's National Human Genome Research Institute. The database contains genomic profiles of over 10,000 cancer patients, including mutations, copy number variations, gene expression, DNA methylation and proteins profiling, as well as pathology slides and full clinical information.

'There's no equivalent to this resource with so many "omics" character ratios for so many patients,' says Dvir Aran, a research scientist in the laboratory of Atul Butte at UCSF's Institute for Computational Health Sciences. Aran will discuss the team's use of the database

in his talk, 'Studying the Tumour Microenvironment with Big Data', at the Cambridge Healthtech Institute's Liquid Biopsy Summit (June, S.F.) For the study, published in the 4/11/2015 issue of Nature Communications, the team combined four previously developed algorithms to estimate tumour purity. They found 'immense differences' in tumour purity levels among cancer types and among patients with the same type of cancer, which may be a major factor when analysing gene expression, Aran says.

'For example, we measure an expression of a gene that's expressed only from the cancer cells, but one of the samples is 90 percent pure and another is only 50 percent. A naive interpretation might suggest that the first sample is activating this gene, while this is only a result of the difference in purity,' Aran explains. 'Our analysis showed that this biases interpretations and leads to false conclusions of many bioinformatics analyses, such as constructing co-expression networks, clustering tumours to molecular subtypes and finding genes that are (differentially) expressed in tumours compared to normal samples.'

The estimate has an impact on tests



The Cancer Genome Atlas (TCGA) is a project to catalogue genetic mutations responsible for cancer, using genome sequencing and bioinformatics

used to predict the effectiveness of checkpoint inhibitor drugs, a popular cancer immunotherapy, the researchers found. When immune cell infiltration was measured, predicting the likely success of this expensive treatment was much more accurate.

'In this study we showed that the

influence of tumour purity on the results of genomic analyses is much stronger than previously appreciated, and ought to be included as a covariate in any future analysis,' Aran says. 'Tumour purity differences resulting from sampling variation exceed intrinsic individual differences. Lower purity samples, by influencing genomic data, may make precision medicine efforts more challenging. We urge cancer researchers and clinicians to take tumour purity in



Dvir Aran, laboratory of Atul Butte, UCSF's Institute for Computational Health Sciences, USA

to account when analysing genomic data from patient samples.'

Studying the tumour as a whole, including the non-cancerous cells that are part of it, was not possible before TCGA was available, Aran points out. Researchers previously used genomic data from cell lines, which characterise only the cancer cells, and not tissue from real patients.

Announcing the study, Butte said datasets like TCGA are 'the ultimate commodity. Unlike oil or water that can only be used once, data continually generates new insights.'

The data, which is completely free, can be downloaded from the TCGA data portal. For the study, Aran and team combined DNA, RNA, epigenetic and pathology analyses to create a consensus measurement of tumour purity, which is the percentage of cancer DNA in the sample, and studied the measurement in the context of the patient's clinical information.

'For bioinformaticians like me, this is a goldmine,' Aran says.

Severe infection evaluation needs cooperation between many laboratory disciplines

Calculated therapy is the objective

At a recent focus meeting held in Berlin by the Association of Accredited Laboratories in Medicine, Dr Andreas Weimann, managing director at the Laboratory Berlin - Charité Vivantes Services, spoke of the challenges that laboratories working with hospitals face due to the management of pathogens and the diagnosis of infections.



Andreas Weimann is Managing Director of Laboratory Berlin - Charité Vivantes Services

'We are clinging to red tape. Instead of prevention, our focus is on those who are already ill,' Weimann explains, in the "Five Bad Habits of Healthcare" drafted by the World Economic Forum 2012. Demographically, the focus is increasingly on older, multi-morbid patients who are particularly exposed to infectious agents due to their complex clinical pictures. Weimann refers to patients who have had organ transplants as an example. There are no reference values for this group. 'Can you spontaneously state the reference value for liver function tests in a 75-year-old, immune-suppressed liver transplant patient? We don't know it!' Yet it is precisely these kind of questions that clinicians want laboratory medics to answer.

Is an infection local or is it sepsis? Is it bacterial or viral? Should I administer effective, anti-infective chemotherapy or not? What is the severity? Can I make a prognosis? Weimann emphasises that, particularly in the field of intensive care medicine, one should be realistic enough to anticipate that some patients will not survive. Effective screening of pathogens and the effectiveness of medication with regards to selected biomarkers can help doctors in their decisions as to whether treatment should be continued or whether life-preserving measures should cease - from a cost perspective, as well. Such screening should '...buy

the intensive care medic time to actively wait,' Weimann points out. Sometimes, such a comprehensive, sufficient diagnosis also allows the doctor to 'do nothing for a day'. It also makes significant contributions towards cost efficiency, allowing better control over the development of multi-resistant pathogens.

With these multi-resistant pathogens in mind, Weimann talks of the current practice of antibiotics prescriptions in Germany: 85% of all antibiotics are administered in veterinary medicine. Of the 15% prescribed in human medicine only 0.5% are used in intensive care medicine. Weimann calls this a 'topsy-turvy world'.

One large problem in anti-infectious therapy is the high rate of wrongly prescribed antibiotics, i.e. unnecessary prescriptions and those inappropriate for the respective pathogens. 'The current best practice appears to be to shoot sparrows with cannons,' Weimann says wryly.

Over the last ten years, in cooperation with medical company Sysmex, the Berlin Laboratory, at the Charité, has been developing the sepsis 'Intensive Care Infection Score' (ICIS), which is based on cellular values and aims to facilitate a better

prognosis.

A combination of 10 readings, evaluated and scored, could then for instance be displayed over an intensive care patient's bed. This would allow doctors to quickly orient their strategy based on the respective prognosis. The ICIS is available 24/7/365 in all locations in the hospital, but requires specific staff training as to the score values used in on-going treatment.

Weimann quotes an example from the Charité. When a sepsis patient is treated with antibiotics it needs sufficient drug monitoring. In the case of multi-morbid, intensive care patients particularly, the doctor will usually prescribe not just one antibiotic but a combination. The objective of therapeutic drug monitoring (TDM) is sufficient control of pathogens, as well as the prevention of toxic effects. Weimann points out that affected patients are typically not 'male, aged around 20 and with a weight of 70kg, such as described in text books' but 'old and sick', with several potential sources of infection arising from various access ports to the body.

Furthermore, the interactions between various different types of medication that most people are prescribed due to multi-morbidity must be taken into consideration. 'Nobody can do this. But what we can do is determine the concentration from the serum.' This means different concentrations and different effective dosages in different patients. Sufficient drug monitoring and close cooperation between clinicians and laboratory staff enables the development of a personalised TDM record for each individual patient.

Calculated therapy is the objective. The development of a 'house standard, adapted to the existing mix of patients' is the method of choice.

The interdisciplinary working group ABx has developed a web-based programme of recommendations (www.dgai-abx.de) to treat infections in intensive care and emergency medicine. The ABx programme offers evidence-based recommendations while taking into consideration the national and international guidelines for calculated antimicrobial therapy.

'Why are we making these huge efforts?' the expert asks at the end

of his lecture, before concluding: Antimicrobial Stewardship Concepts (AST) are integral to sepsis treatment. Consistent AST appears to reduce time spent in the hospital, reduces antibiotic prescriptions and lowers the cost per intensive care patient. 'The evaluation of severe infections requires cooperation between many different laboratory disciplines - methodically as well as organisationally,' Weimann confirms

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Analysing tumour tissue to establish a molecular profile with tumour cell characteristics

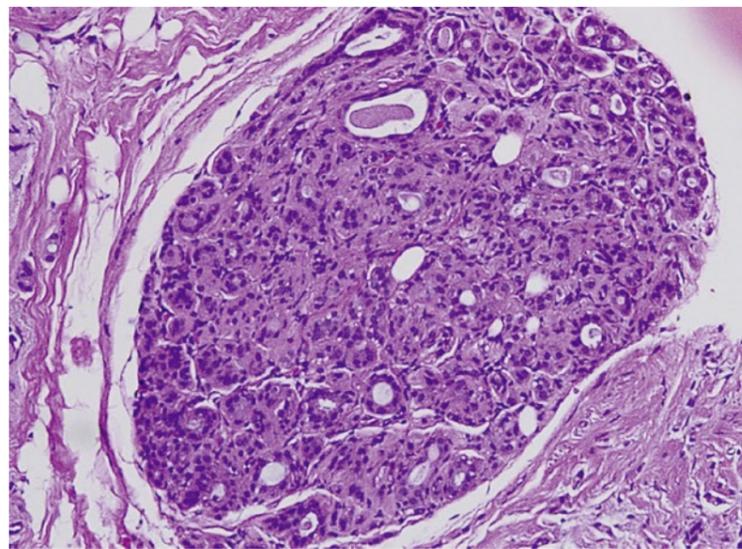
Revealing cancer at a minuscule level

Report: Michael Krassnitzer

Since the introduction of targeted therapies in oncology the task of the pathologist has expanded beyond histological diagnostics: today, the pathologist analyses tumour tissue samples to establish a molecular profile with tumour cell characteristics – which in turn become the targets of medication. This procedure lays the foundation for breast cancer therapy, explained Professor Sigurd Lax, Director of the Institute of Pathology at Landeskrankenhaus Graz Süd-West (Austria), prior to the autumn congress of the Austrian Society of Pathology – Austrian section of IAP (ÖGPath /IAP Austria): ‘Pathology plays a crucial and indispensable role in the diagnosis, early detection and interdisciplinary therapy management of breast cancer,’ he pointed out. ‘The definitive diagnosis of breast cancer and its precancerous stages is established by pathologists.’

The usual procedure

If suspicious lesions are detected in a radiological study, a biopsy is performed to collect tissue samples. ‘In more than 95 percent of cases, the pathologist can provide a conclusive diagnosis on the basis of those samples,’ Professor Lax points out.



Histopathologic image from ductal cell carcinoma in situ (DCIS) of the breast.

Moreover, highly sensitive digital systems check the biopsied lesion samples for the molecular biomarkers oestrogen and progesterone receptors, as well as human epidermal growth receptor 2, the so-called HER2/neu. Procedure results define the further diagnostic or therapeutic path:

- A majority of breast lesions contain oestrogen resp. progesterone receptors and show slow or

moderate growth. Most of these so-called luminal A tumours are surgically removed.

- Luminal B tumours are hormone receptor positive with an increased growth rate; they usually respond better to chemotherapy.
- 15 to 20% of tumours are HER2 positive; medication treatment targeting HER2/neu is available.
- Triple-negative (also called basal-like) breast cancer con-

tains neither oestrogen and progesterone receptors, nor HER2/neu; they grow rapidly and are very aggressive.

Prior to surgery, patients with HER2 positive and triple negative carcinoma usually undergo chemotherapy, which completely destroys the cancer cells in up to 66 percent of all cases.

After surgery, the pathologist analyses the removed tumour bed tissue to determine therapy has been successful and prepares a report providing data on tumour type, histopathological differentiation, tumour stage and resection margin status. In addition, the resection sample is checked again for oestrogen and progesterone receptors and HER/neu, as well as Ki67, a tumour growth marker.

The results of these histological studies inform the adjuvant therapy – either hormone therapy, targeted radiation therapy, chemotherapy or anti-HER2/neu therapy.

‘In the past 15 years molecular tests were developed that allow us to determine a broad range of molecular changes in tumour tissues,’ Lax reported. While these tests cannot predict tumour response to a specific therapy, they do have a certain prognostic value, albeit, he



Born and educated in Graz, Austria, Professor Sigurd F Lax MD established the Institute of Pathology at Landeskrankenhaus Graz Süd-West (Austria) in 2002 and today is still its head. Since 2004 he has also served as Speaker (Chair) of the Working Group on Gynaecological and Breast Pathology of the German Society of Pathology. In 2013-14 he was President of the Austrian Society of Pathology – Austrian section of IAP (ÖGPath /IAP Austria). He is a member of several national and international professional societies, including the American Association for Cancer Research (AACR) and the International Society of Breast Pathology. Authorship includes around 135 research articles and contributions in 25 books.

said, ‘due to the high costs, their use is still very limited.’

Such a molecular test is Endopredict, which provides information on the probability of tumour recurrence at the original site in hormone receptor positive HER2/neu negative patients. Lax expects to see ‘new therapy targets that promise higher survival rates specifically for patients with HER2/neu negative tumours.’

In the future, Lax is sure his discipline will contribute essential knowledge to cancer therapy: ‘The success of a targeted therapy will rely to a large extent on high quality molecular pathology studies.’

Triggers that could cause tumours

Can cancer be contagious?

No self-respecting TV crime series is without a pathologist – but the fictitious pathologist who incessantly solves crimes has little to do with reality. ‘More than 95 percent of our time is dedicated to living people,’ explains Professor Gieri Cathomas, Medical Director of the Institute of Pathology at Kantonsspital Baselland, Switzerland. Today, pathology is a clinical pillar of tumour management, from diagnosis through to therapy decisions to prognosis. But the specialty is not only tumours: ‘It’s important to mention that pathology also deals with infectious diseases,’ the professor adds. ‘We can contribute significant knowledge on the role of pathogens in general human diseases, including tumour development.’

Interview: Sascha Keutel

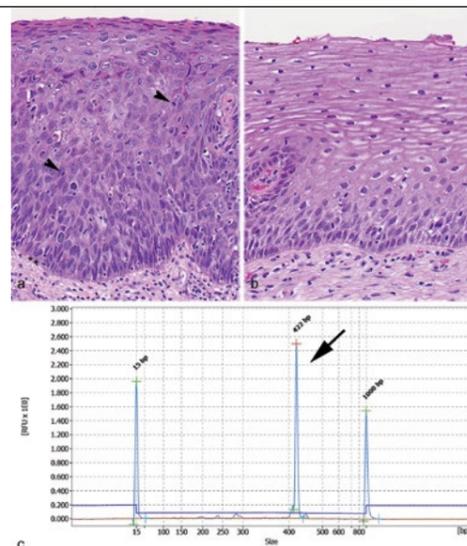
‘Cancer is a genetic disease and the result of an accumulation of genetic changes in our cells,’ explained pathologist Professor Gieri Cathomas, when asked how cancer develops and what role pathogens play. ‘Infections are involved in about 15 percent of all tumours that develop – with significant regional differences. The most important pathogens are viruses, such as the human papilloma virus that can cause cervical cancer or the hepatitis B and C viruses that cause chronic liver infection. Moreover, there are certain bacteria and parasites that play a role in tumour development. However, in most cases a viral infection alone won’t trigger cancer and fortunately most people who do get infected won’t develop a tumour. It is only a long-term infection that may lead to genetic changes that then cause tissue degeneration.’

Infection-associated tumours? Could cancer be contagious?

‘Cancer is not a contagious disease. Thus a person who cares for a cancer patient won’t ‘catch’ the disease.

The cancer, as such, is not contagious. This has to do with the fact that the viruses in the tumours have undergone changes and cannot proliferate. However, pathogens, like all infectious agents, are transmissible. Therefore we may indeed call certain tumours infectious.’

Which pathogen pathways and mechanisms could trigger cancer



development?

‘Sexual transmission and transmission by blood products are the two most frequent viral pathways, but certain pathogens can also spread by everyday human contact. In an infected human the infection has to last very long, and most of the time our immune system keeps infectious agents from taking hold. In a per-

sistent infection, viral genes interact with cell genes, to be precise: the genes that regulate cell proliferation are activated or deactivated. This causes genetic instability of the cell, which in turn triggers an accumulation of genetic changes that lead to the development of cancer. Another mechanism is a chronic inflammation caused by the pathogen, such as chronic liver inflammation after a hepatitis B and C infection. These chronic inflammations frequently lead to the damage and loss of liver cells. Consequently, new cells have to be produced incessantly and at a sometimes enormous speed which leads to genetic defects and tumours.’

How do we benefit from knowledge about infection-associated tumours?

‘This knowledge helps us with regard to prevention, early detection, diagnosis and therapy of pathogen-associated tumours. Let’s take the human papilloma virus in cervical cancer. The so-called Pap test is a very sensitive test for the early detection of cervical cancer.’

‘Prevention is the best therapy – that saying also holds true for tumours. If the cause, such as a virus infection, is known, it can be prevented by vaccination, as has been shown in vaccination against hepatitis B and liver cell carcinoma. I do hope that further vaccines, for example against hepatitis C or helicobacter, will be developed.

This helps each of us to reduce the risk of such tumours.’

You mentioned viral infections as tumour triggers, what about bacteria?

‘Bacteria are a more complex issue. Every human being is colonised by many, many bacteria, be it on the skin, the mucous membranes, or in the intestinal tract. There are more bacteria in our colon than cells in our body. These colon bacteria, however, are highly desirable ‘residents’ since they contribute to our health. Other bacteria are ‘undesirables’ since they can cause acute and chronic diseases. Point in case: helicobacter colonises the stomach. During an infection tissue can be damaged and needs to be regenerated. As with the production of liver cells mentioned before this continuous and rapid process may cause a genetic instability, which triggers increased cell growth and a degeneration.’

In your crystal ball – what do you see happening over coming years in terms of pathogen-associated tumours?

‘Vaccination is a very efficient and long-term method to prevent infection-induced cancer, as can be seen in the case of papilloma virus and cervical cancer or hepatitis B virus and liver cell carcinoma. I do hope that further vaccines, for example against hepatitis C or helicobacter, will be developed.

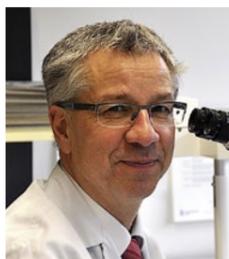
‘Another possibility is targeted therapy aiming at the pathogen itself.

The China Watch

Starbucks coffee and foreign medical devices: 'Will the addiction continue?' asks Nat Whitney

Every time I go into a Starbucks in China I'm amazed by the long, slow line of coffee drinkers, mostly young and low to middle wage earners. A cup of coffee in Beijing is more expensive than in the USA. When Starbucks first came to China, I could not imagine how coffee could compete with 'all the tea in China'. Is it the taste or the caffeine addiction? As Starbucks' CEO clearly stated when I ran into him in a Beijing Starbucks: 'We don't sell coffee, we sell atmosphere.'

So what has Starbucks to do with the future of medical device sales in China? It is a good bell-weather for spending that will continue to go on despite the slowdown in the parts of the economy that have strongly influenced GDP growth. Namely, these have been real estate, infrastructure building and exports, but the party has stated that the future of the economy will be based on internal consumer spending. No longer will personal savings, held out of the economy, be encouraged or required. With major China Healthcare Reform in 2009-11, the 12th five year plan priority of the healthcare system and medical insurance programmes, and the promised goal of universal healthcare coverage by 2020 (they must have been listening to Bernie Sanders) the result should be to free up a glut of family savings that has been kept under mattresses for medical emergencies.

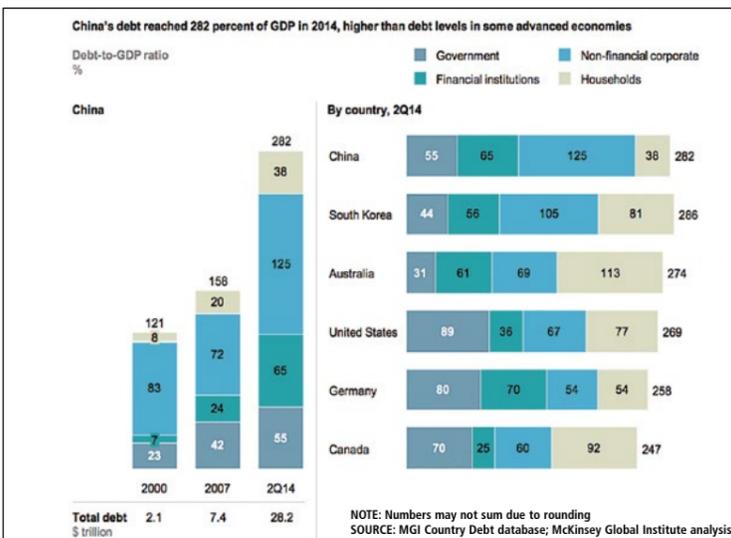


Professor Gieri Cathomas is Medical Director of the Institute of Pathology at Kantonsspital Baselland, Switzerland. In 1987 he received his doctorate from the Institute of Medical Microbiology at the University of Basle for his dissertation comparing different methods of electron microscopic virus diagnostics. His habilitation thesis in general and special pathology, submitted in winter 1998/99 to the University of Zurich, dealt with the role of virus detection in bronchial lavage and tissue for the diagnosis of cytomegalovirus and herpes virus 8 infections and diseases in immunosuppressed patients. His research focuses on the pathology of non-tumorous and tumorous lesions of the gastrointestinal tract, infection-associated tumours and the diagnostic detection of pathogens in tissue.

Today, modern technology, such as deep sequencing, allows us to read very large numbers of genes and their composition very quickly.

'Recent research has indicated that the composition of our enteric flora influences the development of colon cancer.

'This knowledge might enable us to identify people with an increased risk of colon cancer. In the medium to long term, we might be able to reduce the cancer risk by changing our individual diets.'



What makes medical device sales different from coffee is that the government has been targeting healthcare as a high priority in spending to stimulate the economy. This expectation and addition to high quality healthcare will keep hospital spending growing in China.

Those government incentives have stimulated healthcare infrastructure spending, mostly in lower level facilities and under-served locations, which have been strongholds of the local manufacturers. Not surprisingly, we have seen many Chinese manufacturers' revenue grow disproportionately to the foreign brands. Not only have they expanded manufacturing facilities to keep up, they have also, sometimes, been successful in distributing foreign brands with their marketing and sales focus on these, lower level markets. The former #2 IVD manufacturer, Shanghai Kehua, last year attributed 50% of their revenue to sales of the Japanese Sysmex

imported product. The downside of this sales explosion for the domestic companies has been the taking on of considerable corporate debt for expansion. China's debt reached 282% of GDP, higher than some advanced economies, including the USA's of 269%. Different from the US debt, household and government debt is a much smaller part of the debt picture. Most of the debt in China is corporate debt.

The state own banks have prioritised loans to state owned companies, leaving private or public companies to borrow from the shadow banking system. Today, the corporate debt load has grown to the point where fewer funds will be available and debt servicing of local medical device companies will become a large burden. A meltdown of the Chinese economy is unlikely, but the burden on the Chinese medical device companies will likely affect any expansion plans.

Experts cannot agree on just how

big this shadow banking is. The Brookings Institution estimated last year that it could be between US\$769 million to US\$7 trillion. Brookings concluded that the shadow banking industry is still small enough to be a low risk to any financial crash similar to what happened in the USA in 2008. China still has very large reserves to offset any meltdown in the industry, so it seems the overall Chinese economy will remain healthy. But, the country's device manufacturers will be affected.

It remains to be seen if these companies can continue to grow as they have. We see an increase in M&A and partnerships between Chinese and foreign medical device companies and that continues to be ripe, with China trying to gain the technology, innovation culture, and management expertise, and foreign companies gaining access to the fastest growing medical device markets.

The addiction to foreign made goods, in the past, has been due to the lack of innovation and poor quality and service of locally made products. Also, similar to Starbucks, 'face' is also important to the decision makers. Those with foreign equipment to tout in their published studies, and brag to their colleagues, are regarded as being on the leading edge.

In the past few years, many Chinese companies have made dramatic strides in quality. Despite popular perceptions that China's Food and Drug Administration has been unfair to foreign manufacturers and gone easy on locals, this has not been the case at the national level. As a result, Chinese medical device companies have been, kicking and screaming, forced to upgrade, document and follow their formal quality systems. Even so, the lure of famous foreign brands has remained.

In 2014 and 2015 medical device



Nat Whitney is President of Whitney Research, Inc., USA and China

spending did slow down some from its peak growth years. Much of these slowdowns were caused more by the crackdown on corruption than on the slowing economy.

President Xi Jinping, since taking the reins of government, has made anticorruption a cornerstone of his legacy and instituted policies to prevent official corruption. He is not letting up. The impact has been more on drugs than devices, but it appears that the effect on all medical products will be felt until it all evens out and the purchasing influences become more like those in the developed world.

Despite the factors slowing down revenue growth for foreign medical device companies (we expect IVD sales to grow by 15-20% in 2016), the positive influences of healthcare reform, patient payment improvements, and innovation in the industry, will maintain the growth. Foreign IVD leaders are not shying away from the opportunities. Roche had been predicting that China would become their #3 revenue generator by 2015, up from 10th highest in 2010. Roche revenue from China exceeded US\$1 billion in 2015 and they will invest US\$463 million in a new diagnostic manufacturing facility in Suzhou.

So, the medical device market for foreign companies will continue to grow in the higher level city facilities but, to be successful in the faster growing lower levels, some cream and sugar may have to be stirred into the old ways of doing business.

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The European IVD market

Report: Walter Depner

The European Diagnostic Manufacturers Association EDMA (*) presented 2014 market data, and some countries, such as Germany, also provide estimates for 2015, based on Q1 through Q3 2015.

In its statistics, the EDMA differentiates between the so-called 'old' EU 15 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, the UK) and the twelve 'new' Member States (Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia). In addition, the EFTA members Switzerland, Norway and Iceland are included as well as Turkey.

The countries mentioned above – forming 'Europe' – reported a total turnover of €11,032 billion in the IVD market, an increase of 1% compared to 2013. While in the old as well as in the new EU countries, the market shrank by 0.2% and 0.6% respectively; EFTA countries recorded an increase of 0.8%, Turkey even of 6.5%.

Germany continues to be the largest single market with sales totalling €2,189 billion, a slight decrease of 0.1 % compared to the previous year. For 2015, VDPGH (Verband der Deutschen Diagnostica-Industrie e.V.**) predicts an increase of 1.1% to €2,212 bn based on the Q3 2015 figures. The next largest markets are France, which recorded a turnover of €1,785 billion (a decrease of 0.1

% compared to 2013), and Italy with €1,656 billion (decrease of 0.7 % compared to 2013).

Greece saw the largest decrease in turnover among the old EU Member States (close to 7%), while Sweden reported an increase of more than three percent.

Among the new EU Member States, Romania (7.5%) and Poland (7.0%) saw the biggest growth, whilst, in Bulgaria, the IVD market has to digest a decrease of 6.3%.

Switzerland and fellow EFTA member Norway reported an increase of 7.2% and 1.8% resp. while 'non-aligned' Turkey recorded a whopping 6.5% increase.

Even more interesting than these absolute figures are ratios. The IVD spend, as a percentage of the gross domestic product (GDP) in the individual countries, no doubt provides an insight into the status of the healthcare systems. Only seven European countries spend more than 10% of their GDP on IVD:

Sweden holds top position, with 12.9%, followed by France (11.6%), Switzerland (11.4%), Germany and Austria (11.3% each) and Belgium (11.1%).

Switzerland (11.4%), Germany and Austria (11.3% each) and Belgium (11.1%).

All other countries spent less than 10% on IVD. At the bottom of the table are Romania (5.3%),

IVD SALES 2014	
	MIO.
Germany	2.189
France	1.785
UK	812
Spain	972
Netherlands	297
Greece	198
Portugal	221
Belgium	362
Sweden	191
Austria	254
Denmark	145
Finland	107
Ireland	93
Luxembourg	--
Poland	305
Romania	100
Czech. Rep.	150
Hungary	62
Bulgaria	30
Slovakia	45
Lithuania	26
Latvia	24
Estonia	13
Cyprus	2
Malta	2
Switzerland	370
Norway	171
Iceland	11
Turkey	394

Lithuania (5.7%), Estonia (5.7%) and Turkey (5.6%), all reporting less than 6%.

The total population of Europe, including Turkey, is 592.8 million people. This translates into an average of 10% of the GDP being spent on IVD.

By way of comparison: The global IVD market records a turnover of US\$56,773 billion = €50,514 billion, with Europe accounting for €11,032 billion.

* By its own account, EDMA represents approx. 85% of the overall European IVD market.

** By its own account, VDPGH (Verband der Deutschen Diagnostica-Industrie e.V.) represents approximately 90% of the German diagnostic products industry.



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MEET US ALSO



New EU-law is about to come

The negotiations between the Commission, the European Parliament and the Council under the presidency of the Netherlands on the safety of medical devices and in vitro diagnostics (IVD) in the EU go after more than 40 months consultations in the decisive phase. A conclusion is expected before the summer break. At the end there is probably a new European medical device law with two separate regulations for medical devices and in vitro diagnostics.