The Zika mystery

Scapegoat or villain?

**Report:** Brenda Marsh

**From the beginning**... 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.

**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 the feverish monkey was taken to the Foundation’s laboratory and its serum inoculated intracerebrally into a handful of cases. Also obtained from febrile toddlers and a sick 10-year-old.

**1951-51: Evidence of human ZIKV infection was reported from Uganda,** T a n z a n i a, C e n t r a l 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 250 people 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 canine 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.

**Continued on page 2**
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 Bünger developed the programme ‘National Matching’ in collaboration with the Niederlausitz Hospital in 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 monitored 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 Bünger envisages an event where the employers meet participants. ‘We aim to promote deep excursions to hospitals and outpatient departments aims to promote deeper contact with the healthcare sector. However, this will not be easy. Brandenburg’s rural areas are not well equipped to deal with these challenges. These have little experience of migrants and, accordingly, are not usually exposed to migration and do not exhibit hostility towards foreigners. Bünger 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 this process include an expert panel assessment of specialist knowledge and professional experience, as well as participants’ social competences. This applies to refugees with and without evidence of their qualitative assessment, in a form that is not part of the job reference. Any participating refugees with false documents are immediately returned. The comprehensive assessment is also important if employers are considering the possibilities 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 to know and need to find out all of this if we want to achieve successful integration.’ Bünger points out. Currently he is testing an IT-based system to evaluate social competences that has already been used in Sweden. He also wants to adopt another initiative that investigates the issue 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 their work references. 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 to oversee the entire process of professional integration for a specific professional group, from start to finish. Presented to the general public at the beginning of March the programme will start this spring. Bünger is still seeking a sponsor. Once found, he hopes to begin 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.

Marco Bünger has been the chief executive of Adler Management Berlin since 2013, a regional recruitment company for the metal and electro-industry (BEIL). Commissioned by the Brandenburg Ministry for Health, he developed the National Matching concept in partnership with the Niederlausitz Hospital.

The Zika mystery

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Certainly not from the group of Argentinian doctors who blame a larvicide, Pyriproxyfen, for the rise in mosquito numbers. Although this larvicide has been added to people’s water tanks and introduced into male mosquitoes, he states. This protein has been found to cause microcephaly. Accidental leaching shows that farmed fish can be high in mercury for the broad-based research in aquaculture products. Much research 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 GX5134A is produced by Osxite Ltd, near Oxford, England. The firm’s description of various mosquito control methods found at http://www.osxite.com/health/dengue/information centre/vector-controlled/ is certainly worth a read.

Environmental issues

Amy Vittor MD, Assistant Professor of Medicine at the University of Florida’s Emerging Pathogens Institute, studies the interface between vector-borne disease and the human body. He explains that microcephaly is a brain disorder caused when the gene truncates the development of cells that form the brain, ears, 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 GX5134A is produced by Osxite Ltd, near Oxford, England. The firm’s description of various mosquito control methods found at http://www.osxite.com/health/dengue/informationcentre/vector-controlled/ is certainly worth a read.

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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 likely to be a major driver of this increase. The number of suspected cases is currently not assured. 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 could become part of regular 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 disease could 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 could become part of regular newborn screening. Only once the disease has been diagnosed can the appropriate treatment commence. ‘Every 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. Therefore, Lobitz believes, standard newborn screening is essential.

Sickle cell anaemia results from inherited changes to the haemoglobin in red blood cells. 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 a increased accumulation of metabolic products, which in turn can damage larger blood vessels. Along with these slow, but steady, 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, can 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 tenth 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 could become part of standard laboratory procedures. ‘German laboratories are usually not equipped with the devices that are 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 in this research group.

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

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.

Erythrocytes can be deformed

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 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.

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Impact on health

In the most severe forms of microcephaly has occurred ‘that a high incidence of milder forms.’ (Ref: Report by Health professionals who started to notify milder forms.

Sickling in the sickle cell patients with sickle cell anaemia is a reason that only those extreme cases, with small heads are diagnosed can the appropriate treatment become part of standard screening. Therefore, Lobitz believes, standard newborn screening is essential.

Sickling in the sickle cell disease can and should become part of newborn screening.

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Spain: 24 years on top of the world

With 4,560 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, Melinda Le Bouge, 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 just ask: you have to sell the idea. And our strategy 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. We can get them from any other medical specialty.

‘Presumed consent’ is a 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 the 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 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 transplanter 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 these 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.

The gruelling fight for trust

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.

Organ donation in Germany

Despite a ‘new record’ for organ donations the number in Germany has stabilised at a low level. The good news is 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 1.6% in 2015 – 10.8% donors per one million inhabitants. (2014: 10.7% compared to Spain with 28.7% 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 fell continuously over the following years. There are currently around 12,000 patients awaiting donor organ expectation of scarce organs, the current 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 patients and the media reacted: A number of fundamental changes to improve transparency and quality assurance have already 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 post-mortem conditions for organ donors, 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 employment 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. But young donors are at higher risk of complications during pregnancy. Further the DHG plans to coordinate pressures and pressure secretion in urine. As German Transplant Law stipulates ‘Spanish Model’, which led Spain from mid to low donation levels in the 1980s to world leader from 1992, with rates over 100 per million inhabitants. He predicts over the Spanish National Transplant Committee, and the EuroAmerican Council of Organ Donation and Transplantation, and advises the USA’s Institute of Medicine (IOM) and the WHO.

‘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% refused to donate. The Spanish donate far more in Spain, and this is also true for other communities living in Spain.’

‘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 increase in the US and Spain and to become the main expansion strategy in deceased donors.’
After last year’s success, congress – radiologist and nuclear physician – has shaped the face of the School at Umeå University, Sweden, as a representative of two professions: radiology and nuclear medicine, and will provide a framework for the future development of training, education and standards in hybrid imaging.”

"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.”

"Personalised medicine and personalised imaging means the personalisation 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 homogeneous 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 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 (ESHM). ‘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.’

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 precision imaging: myth or reality?’
Biomarkers increase impact

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

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 (HFMRC) at MedUni 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.

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 metabolite 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 imaging of kidneys (left); conventional morphological MR image (centre) and a coloured overlay of the sodium image over the anatomical image.

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.

In cell diseases the ion pump becomes impaired

The Trattnig team at Vienna's High-Field MR Centre works on sodium MR imaging, which is based on 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, biological 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 disease."

Krestin also believes the shift to personalised and precision medicine and imaging will be cost-effective. 'An unelected 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.'

In magnetic resonance imaging (MRI) - Trattnig's specialty, T1 and T2 relaxation times and the apparent diffusion coefficient (ADC) are measured. 'On the molecular level healthy and diseased tissues show very different diffusion characteristics,' Trattnig explained. 'The more cells there are, the higher the water diffusion and since a tumour consists of many more cells than healthy tissue, it means that the higher the apparent diffusion characteristics and thus pathological changes can be detected much earlier than in a merely morphological analysis.'

Establishing a European biomarker infrastructure

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 outlining their intention 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 drug 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 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
The European Imaging Biomarker Alliance (EIBALL)

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).

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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 provokes an oversupply 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 perspective, reimbursements 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 outpatient care going.

“Two-class” medicine is often quoted in this context. However, all German patients, regardless of the insurance cover, receive almost identical medical treatment, apart from some better comfort in hospital and quicker appointments. Therefore, it’s 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 affects the overall level of income among the general public is too low for patients to bear the cost of their services,” explains Dr. Dieter Maurer. In Switzerland the mean income is considerably higher and even an alternative healthcare model can still make a contribution that adequately covers costs. In Germany, because the quality and performance is known, 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 the change in the economic environment. Reimbursement for hospitalisation is too high. However, as a German, I am 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 consider increasing radiology as a cost factor that should ideally be kept low, meaning that the significant cost base of radiology at Swiss hospitals is being ignored. German hospitals don’t appear to value this, because the development of larger networked imaging systems is not envisaged. One of the key motivational factors is reimbursement for existing practices to minimise risks and cut costs through economies of scale.

I worry about the emergence of large practices and exclusions of profit-oriented investors who 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 life. However, the recruitment is still very heterogeneous, it’s important to find a “clear-out” process for smaller hospitals that cannot be run profitably in a “clear-out” process for smaller hospitals that cannot be run profitably.

Which country offers the brightest future for radiologists?

It’s becoming increasingly risky and unattractive for German radiologists to work in the public health sector, because the costs are particularly high. Increasingly, radiologists work on a payment-by-results basis, such as often discussed abolition of private health insurance, which would soon have existential implications for many private radiologists. Therefore, having their own practice is no longer attractive for many 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, which cut costs through economies of scale.

I worry about the emergence of large practices and exclusions of exclusively profit-oriented investors who...

Electronic medical record (EMR) systems, with the capability for ordering diagnostic tests that CDS systems can interact with, in some cases can assist radiologists to choose 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 radiology

The ESR iGuide

The best place for radiologists

Report: Cynthia E Keen

Electronic radiology clinical decision support (CDS) systems are 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 can interact with, in some cases can assist radiologists to choose 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.

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 technology in 2001, have documented impressive, tangible benefits. But medical practice is a highly individual profession. The symptoms and presenting signs vary considerably from patient to patient, and are 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 require evidence 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 overhauled.

For several years, the ESR has worked to establish a foundation for CDS implementation for better imaging utilisation. After announcing a partnership with the ACR and its commercial CDS partner NexCure (Cardiac Drug Support Company) (NDCS) at ECR 2014, the ESR began to work on development of a common CDS framework for European harmonisation.

First, the ESR conducted a full revision of existing CDS 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 regions of interest. ESR CDS Committee conducted rounds of content reviews with specialist members. ESR discussed the changes members made 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 Guide 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 for use in a limited capacity, is currently being analysed. News for 2016 is that the ESR hopes to pilot programmes in hospitals in various European countries. Marcel Wigger, head of technology of NDCS Europe, explained that the ESR iGuide is designed specifically to meet the high level of customisation required for the numerous European healthcare systems.

The Guide 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 can be traceable to enable NDCS Europe to make localisations that enable healthcare professionals to use the ESR guide efficiently and provide automatic feedback to the ESR. These features will enable sites to adapt the guide-line 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 establish an ESR Guide 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 to CDS agreement rates. The degree of ‘sticking behaviour, measured against the referrals before the CDS system was deployed, will indicate how well the system is working. For analysis may be qualitative interactions with users, speed of through-put, reduced waiting times for exams, better scheduling, cost savings, and reduction in overall dose exposure through the avoidance of inappropriate
Spinal imaging

Last year, after the diagnostic imaging firm DMS Group acquired the French start-up AXS Medical, a French start-up developing diagnostic tools for spinal pathologies, DMS-Apelem’s position in diagnostic imaging was reinforced by offering stereo-radiographic imaging and 3-D modellisation tools for orthopaedics but also radiology, paediatrics, and ambulatory surgery.

BioMod SS combines optic information about back morphology with a classic radiographic image 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.

BioMod SS 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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Leading hospital installs new generation PACS and imaging biobank assets combined

Aad van der Lught, Professor in Neuro-radiology and Head-Neck Radiology at Erasmus MC, Rotterdam, Netherlands is director of the neuroradiological research programme. In 2003, 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 EPID (European Population Imaging Infrastructure), co-applicant of the BBRMo 3.3 (Biobanking and Biomedical Resources Research Infrastructure in the Netherlands) and responsible for Population Imaging in the Euro-Bioming (ESFR) project. He is also a member of the research committee of the European Society of Radiology.

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

A big update in X-ray and fluoroscopy equipment

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.

The main task 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 names 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 retrieval 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 retrieved, 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 learning algorithms could be used to automatically retrieve relevant structures and generate new information.

Leading hospital installs new generation PACS and imaging biobank assets combined

EUROPEAN HOSPITAL Vol 25 Issue 1/16

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Building on its 100+ years of experience, Agfa HealthCare develops innovations that offer the ease of use customers need to maximize the potential of their solutions, with designs that keep the user and customer in mind. With its strategy of one platform for IT and one platform for imaging, the company is doing exactly that: simplifying even while enhancing performance.

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On the wish list of scientist and academic researchers, 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 analyzable 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.

**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’.

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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 Giangiulio 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 closed-batch PACS.

Apart from the obvious economic benefits of sharing computational and associated clinical details is expected to be a perfect starting point for the automated training of computer-aided diagnosis algorithms based on deep-learning technology.’

‘Similarly, it becomes possible to directly use images to query for direct relevance 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 pipelines. ‘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, 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 reason-able privacy preserving boundaries, and, of course, much better computer-aided diagnosis algorithms and tools.’

Also during the session Professor Myraun Humink, Professor of Clinical 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’.

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 combines 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.'
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.

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 cloud 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 hospital’s 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 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; 95% 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.

Link to the survey: http://dx.doi.org/10.1594/ecr2016/C-0684

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

Most radiologists want to transfer images for consultations

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) health and Informatics Subcommittee and a Board member of the European Society for Medical Imaging Informatics (EusomI).

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.

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*ECR 2016 Wednesday 2 March 8:30–10:00 a.m. Room N Daily use of mobile devices in radiology.
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 new opportunities, its maturity 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 prognostic statements. Siemens is currently testing software that can differentiate between threatening and non-threatening coronary stenoses.

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 image source.’

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 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. That is the topic in which Siemens is also interested.

Currently, one of the main objectives is the development of a fundamental telecommunication base where comprehensive digital 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 will not only be served by doctors, clinicians and other health-care providers.

Customer data is anonymised, collated and processed, based on certain patterns. ‘One of the first applications we will offer with this new IT platform is the optimisation of dosing protocols,’ Peter Aulbach is a marketing manager at Siemens Healthcare

Software diagnostic advantage/disadvantages

Computers can now match clinicians’ performances, at least for isolated tasks. The most promising 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 is present, or not, depending on the need to extend and improve healthcare. I see radiologists struggling with the sheer amount of medical images they have to review. How long can this continue? Employing more radiologists seems unrealistic, given already explo- sing costs in high-tech medicine. Simultaneously, public awareness of the benefit of modern, image-based diagnostics increases the demand for this to offer a broader public. This is possible, but hardly imaginable.
EHR: 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?

Markus Harz: Because we have done it! At ECR 2016 we’ll show very specific use cases in which 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 a platform that is ready to be used, is already being used and is unique.

Healthcare systems are increas-ingly busy. Countries are chang-ing 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 technolo-gy. It’s happening because there are persistent, powerful, and important drivers. There is a strong belief on the part of payers, especially governmental payers, that this is going to help reduce costs and improve patient treatment.

Cost is a big pressure point and different countries are moving at different speeds, and with different blue-prints, it is something that’s really happening – already in England, France, and Belgium.

It’s very important to see how forcefully patients are becoming part of the process and a driver for this change. Today, it’s not very organised, varying greatly from diabet-ic patients to wound care manage-ment, 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.

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 coordi-nated way. The vertical management of healthcare is now going trans-forms, 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, so also view data such as a medical 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 com-pany 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 mess-aging between a patient and a physician. The patient can upload images and documents. Physicians can have peer-to-peer communica-tion 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 giving 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 to other data in different semantic formats, with Chinese to English.

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

EHR 2016, which comes after ECR, is the premier European meeting for radiologists and specialists in computer-assisted radiology. It is a major event where the latest developments in the field are presented and discussed. The meeting includes presentations, workshops, and hands-on sessions, providing attendees with a comprehensive overview of the latest advancements in the field.

EHC 2016 will see the introduction of the Agfa Healthcare Portal, a suite of capabilities that pulls data from any standards-based source, inte-grates 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.

EHC 2016 will see a capability to share images from anywhere to anyone involved in a patient’s care. EHC 2016 will see a capability to share images from anywhere to anyone involved in a patient’s care. This will enable healthcare professionals to access patient information from anywhere, at any time, and on any device, improving patient care and outcomes.

The Agfa Healthcare Portal is a platform that is designed to facilitate the sharing of patient information across different sources, including PACS, EMR, and EHR systems. It is built on an open architecture, allowing for seamless integration with other healthcare systems and devices. The portal is designed to support the exchange of images and other patient data, allowing healthcare professionals to view and share images from different sources.

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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 outlined how PET and amyloid imaging is not only 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, available only in centres with cyclotrons, to full commercialisation, with three fluorinated amyloid PET tracers (Florbetapir, Florbetaben, and Flutemetamol). "It 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-constructed, blinded 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 discuss "MR contribution to diagnostic and differential diagnosis" and Sebastiaan Engelsborghs, Professor of Neurosciences-neurochemistry at the University of Antwerp, will focus on "The neurochemistry of the Alzheimer’s continuum."

Making data management intelligent and stress-free

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. Infinit’s VNA, the Infinit Healthcare Platform (IHP), is not just an average vendor neutral enterprise storage solution, the manufacturer points out. It’s 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 API, allowing data integration from other systems possible."

A key that means 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 systems monitoring. Another advantage of the IHP is an accompanying zero-footprint viewer (Universal Viewer, Ulite), where both DICOM and non-DICOM 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."

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...
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: Mélissande 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 even earlier age, increasing lifetime exposure to the risks. The percentage of morbidly obese patients – who have a body mass index (BMI) above 40 or 55 with co-morbidities 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 deaths in a war zone. (Ref: How the world could better fight obesity, Richard Dobbs, Corinne Sauers, Fraser Thompson, James Manyika, Jonathan Woetzel, Peter Child, Sorcha McKenna, and Angela Spitharius. 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 groundbreaking 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 (gastric 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 deeps, 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 for the Treatment of Obesity. Clifford R. Weiss, MD, Andrew J. Gussen, MD, Charles Y. Kim, MD, Ben E. Paxton, MD, Hans K. Reitblattmann, UMD, PMK, Arepally Arvind. 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.

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.

Daily reports and alerts, in case of exceedance of in-house and legal reference values, which are sent automatically via email to the responsible radiation protection officer

Configurable dashboards providing information about the patient, X-ray facility, exam types and protocols with the respective evaluations and charts of dose values and parameters

Integration with existing information systems e.g. KIS, RIS and PACS

Referring Community

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**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.

Emergency care depends on standards and experience

‘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 based on the actual issues such as radiation exposure.’

‘Actually, the diagnostic workflow 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 underestimating 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 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 unenhanced 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 workflow. 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.’

**Rewarding China-USA research**

If you are taking note of any break-through 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 – meaning during patient handover underestimating 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 immediate standardised whole-body CT is recommended.

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\[...\]
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 MRI 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 in a treatment decision required that will be influenced by the result of the emergency MRI 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 three 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.

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 25T 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.

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.”
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 are more adapted to children than others due to the child’s size and difficulty to obtain adequate paediatric contrast. 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: is it 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?

There will be four main points in my presentation:

1. A description of elastography and its potential applications in children.
2. A discussion of the challenges and considerations involved in using elastography in paediatric patients.
3. A presentation of preliminary results and case studies demonstrating the use of elastography in children.
4. A conclusion and future directions for research and clinical application of elastography in paediatrics.

In my presentation, I will focus on the clinical applications of elastography in children, highlighting the unique needs and challenges of paediatric patients. I will also discuss the importance of establishing normal values for children and the potential implications for diagnostic and therapeutic decision-making.

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 Ključevski, 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 Ključevski 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 embryonic development 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 for example, individuals younger than 18, and also young adults in the case of rare chronic diseases (e.g. some storage diseases, 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 environment 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. 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 principle (as low as reasonably achievable) numerous devices for the child’s protection (lead protection, immobilisation auxiliary 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 UCAs 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 Piskounowicz. Only one severe anaphylactoid reaction in a child following the intravenous administration of UCAs has been described, so far. In some children some minor transient adverse reactions (aritra 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 of 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.

Interview: Sascha Keutel
The precise emergency strength portable

Ultrasound speeds to the point of care

Consultant paediatric radiologist Damjana Ključevšek MD graduated from the Ljubljana medical faculty in 1989 and earned 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 intravenously or intrathecally.

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 intravenous application of UCAs there is a 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.’

The SonoSite iViz ultrasound system

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 applications 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 private 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 months 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 propriety medical-grade system that is fully integrated and fully protected 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.’

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

Torsten Walther is Country Manager for Germany

Mihorak 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 depart 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 sonoeastography. 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’ll 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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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.

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

MRI/ultrasound-fusion biopsy improves prostate cancer detection rate

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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 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 merits 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 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 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 registered, you can move the transducer through the MR images in the same way you’d move a computer mouse through an animated sequence: The MR 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 bunts to the 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 scan to the clinic to have them used during prostate biopsy.

Ultrasound Centre at his institution.

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Interview: Daniela Zimmermann

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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.

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, fibromatosus 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.’

In contrast, 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-echoic 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 4 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 axillary 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.

To provide the best care for your patients, you need tools that go beyond your expectations. The Philips Affiniti ultrasound system delivers the right balance of elegance and precision engineering. Its exceptional image quality gives you the results you need to stay ahead. And with easy-to-use tools such as image fusion for targeted prostate biopsies, it all adds up to a breakthrough in user-focused, patient-focused care. Philips Affiniti brings high-quality imaging to your practice.

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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.

’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-echoic 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 4 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 axillary 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.

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Up to now, no statistically different 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 mammography 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, assuming 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 mortality in the population. Instead, she suggests waiting for the follow-up analyses of the trials before we see where DBT actually has an effect on the interval cancer 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.

Tomosynthesis on D2RS redefines the remote controlled table stan

**Digital breast tomosynthesis**

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**Mammography fusion**

**Contrast enhanced 2-D and 3-D mammography**

**PET/MRI impaired breast cancer screening**

**Launching a new field of investigation**

**Tomosynthesis** is an advanced application that allows a multi-slice acquisition and provides a reconstruction of a volume. Several applications at low dose are acquired with a single sweep of the X-Ray tube around the region of interest.

**Algorithm**

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 diagnos

**Contrast enhanced 2-D and 3-D mammography**

A new EU-funded project HYPMED is developing a method for more accurate detection of breast cancer.

**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 radiology 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.

**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.**
- **3 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.**

**ECR 2016 Digital Breast Tomosynthesis**
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.

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/MRT 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 transferable to other clinical applications, such as prostate cancer detection and hybrid cardiac imaging.

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

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The acquisition parameters, adjustable for the anatomical body part, offer the best image quality at low dose, Stephanides adds. After the reconstruction, you will have the possibility to navigate into the volume, or to decompose 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.’

PET/MRI improves breast cancer diagnoses

A new EU-funded project HYPMED is developing a ground-breaking imaging method for more accurate detection of breast cancer and a better, more personalised, understanding of its response to therapy.

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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.

EH: We are witnessing a wave of consolidation and new partner- ship dynamics in medical imaging. Industry: Guerbet acquired Mallinckrodt’s contrast business, Toshiba seeks to sell 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 even 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 intervention- al 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 medium 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 patterns within and across diagnostic data sets. These tools are already selectively available today to support the diagnostic workflow 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 exposure 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 radiology diagnostics companies can benefit from this opportunity, or whether outside IT companies, such as Google and the like, will conquer this new domain.’
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 CTA perfusion measurement techniques were launched that predict which lesion will cause a vessel occlusion 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 offers 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 voxel under development. ‘These detectors allow us to look at each voxel in 80,000 examinations worldwide, reduced average radiation dose by 1.4 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 do now,’ he believes, ‘is to enhance our diagnostic expertise.’

Tissue characterisation, dual energy, single photon detectors – these are some of 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.’
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 for about 30 years yet, with the introduction of CT and, to a certain extent, MR, we are beginning to acquire 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 bouncy 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 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 these findings affect the clinical management of these patients? ‘That’s a good question. The clinical management of these patients? Do those findings affect the clinical management of these patients?’

Next-generation CT aorta angiography challenges 30-year-old definitions

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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 Euroassis, a pan-European platform for "Researchers in Motion" in which 40 European countries are currently participating with more than 500 Euroassis service centres. Here, professionals offer personal 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. Euroassis 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 their workflow, Toshiba explains. ‘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 clinical routine.‘

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 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 compared to 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 infants 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 new protocols and applications, 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 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.
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 clinical pathways in hospitals), the digitisation of processes (e.g. online information, to evaluation and control of the health-care system).

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 profitability of initiatives 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 health-care system.

Additionally 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 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 health-care 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.

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 light house 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.

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 1 mm 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 additional 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.

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 pneumonitis), 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 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 specialized centres.

Difficult to diagnose: interstitial lung diseases

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.
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 Beauty of Radiology’.

Gerhard Mostbeck: ‘The general radiologist is often named in 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 “multispecialists”. 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 radiologists cannot simply be “multispecialists”. 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, 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.’

ECR 2016
Friday 4 March
8:30–10:00 am. Room E1
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 in 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 systemic biopsies techniques improve the detection rate, more than 20% of the cancers are still missed. Multi-parametric 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 lesions and should improve the biopsy detection rates; however, the overall cost of the procedure (mpMRI + TRUS + a pathology) is high, and the availability of MRI is low in many countries. Moreover, ultrasound-MRI 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 pros- tate cancer, like for MRI,

The SEV12-3 3-D Endocavity transducer allows volumetric acquisitions of the whole prostate, and reconstructions of transversal, sagit- tal and coronal views not only in 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*.

Moreover ultrasound-MRI fusion based technique combining several TRUS procedures and guidance as well as parametric MRI (mpMRI) is helpful for detection of lesions 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 treatment 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 multifac- torial nature of the disease, as well as the problems of correct identification and localisation of the prostate cancer lesions by prostate biopsy and/or imaging. 3D ShearWave may help detect this index lesion and would enable partial focal treat- ment of cancers with, for example, RFA, HIFU or cryo-ablation, Correas concluded.

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

72 year-old patient with elevated PSA (62.3 ng/ml) with previous negative TRUS. Coronal views in 3D SWE. 3 targeted biopsies in the suspicious area showed 22 mm adenocarcinoma, with a stiffness of 70kPa. Targeted biopsies confirmed the presence of a large Gleason 9 adenocarcinoma.

72 year-old patient with 3.0 ng/ml PSA. Coronal views in Bmode and ShearWave™ Elastography of the prostate, reconstructed from one single 3D TRUS acquisition with the SEV12-3 probe, is showing a 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 10 mm Gleason 7 (3+4) adenocarcinoma.

72 year-old patient with elevated PSA (63.5 ng/ml) with previous negative TRUS. 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 9 score while systematic biopsies came back with no cancer.

Patient was referred for radical prostatectomy.
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 genes found in tumours, health professionals could more precisely predict the success of certain treatments. A key aspect of the discovery was access to over 10,000 cancer patients, including 11 different tumours, to understand how genes are differentially expressed in tumours compared to normal samples.

The estimate has an impact on tests 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 interdisciplinary working group AIBs has developed a web-based program of recommendations (www.dija-axb.de) to treat infections in intensive care and emergency medicine. The AIBs program 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 antibiotics 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.
Revealing cancer at a minuscule level

Since the introduction of targeted therapies in oncology the task of the pathologist has expanded beyond histological diagnostics: today, the pathologist not only examines tissue samples to establish a molecular profile with tumour cell characteristics – which in turn becomes the targets of medication. This procedure lays the foundation for breast cancer therapy, explained Professor Sigurd Lax, Director of the Institute of Pathology at Landeskranzentrum Graz Sid-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 of at least some precancerous stages is established by pathologists.’

The usual procedure

If suspicious lesions are detected in a radiological, breast ultrasound, or a biopsy performed to collect tissue samples. In more than 95 percent of cases, the pathological evaluation provides an extensive diagnosis on the basis of those samples,’ Professor Lax points out.

Moreover, highly sensitive digital systems check the biopsied lesion samples for the molecular biomarkers oestrogen and progesterone receptors, as well as human epidermal growth factor 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 hormone 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/neu positive; medication treatment targeting HER2/neu is available.

- Triple-negative (also called basal-like) breast cancer contains 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 60 percent of all cases.

After surgery, the pathological analysis removes the remaining 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 HER2/neu, as well as HER2, 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 differentiate 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 said, due to the high costs, their use is still very limited.

Squamous cell carcinoma (SCC), like basal cell carcinoma (BCC), or malignant melanoma (MM) are other tumours the pathologist can provide a conclusive diagnosis on.

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 Baselstadt, Switzerland. Today, pathology is a clinical pillar of tumour management, from diagnosis 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. B is only a long-term infection that may lead to genetic changes that then cause tissue damage.’

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?

- 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 persistent 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 generated simultaneously and at a sometimes enormous speed which leads to genetic defects and tumours.

How do you 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 – this saying also holds true for certain cancers. If the cause, such as a virus infection, is known, it can be prevented by vaccination. An example has been shown in vaccination against hepatitis B and human papilloma virus. A further – individual – strategy to prevent infectious tumours is personal hygiene, particularly with regard to sexual intercourse, such as safe sex.

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 this bacteria 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 deterioration.

In your crystal ball – what do you see happening over coming years in the field 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 cancers. Vaccination against 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 pathogens 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 medical emergencies? No longer will personal savings, held off the economy, be the only source of capital to finance the healthcare system and medical insurance programmes, and the promised goal of universal healthcare coverage by 2020 (they hold the promise of China’s economic growth). The future of medical device sales in China may well be based on internal consumer spending. No longer will personal savings, held off the economy, be the only source of capital to finance the healthcare system and medical insurance programmes, and the promised goal of universal healthcare coverage by 2020 (they hold the promise of China’s economic growth). The future of medical device sales in China may well be based on internal consumer spending.

What makes medical device sales differ from coffee is that the government has taken on a new priority in spending to stimulate the economy. This expectation and addiction 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 Kenuba, 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 260%. 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 provided 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 are available and debt servicing of local medical device companies will become a 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 a 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 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 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.
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 0.1% 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 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 6.5%. 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.

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%).

All other countries spent less than 10% on IVD. At the bottom of the table are Romania (5.5%), Lithuania (5.7%), Estonia (5.7%) and Turkey (6.6%), 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 approximately 85% of the European IVD market.

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