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EUROPEAN HOSPITAL

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Fraudulent and faulty medical implants

Shaken by two medical implant scandals, France is scrambling to rebuild confidence in its system of medical products and medication surveillance, John Brosky reports

First came the discovery that up to 500,000 women in 65 countries received breast implants with sub-grade silicone gel made in La Seyne-sur-Mer by Poly Implant Prothese (PIP). The owner of PIP was thrown in jail and a new National Agency of Medicine and Health Product Safety (ANSM) was created, replacing the former French Agency for the Safety of Health Products (AFSSAPS). Never mind that it's the same functionaires with 'the same missions, rights and obligations,' according to the government statement.

Increased implants scrutiny turned up another scandal earlier this year, when health agency officials found non-certified hip implants made in Roissy-en-France by Ceraver were sold to around 60 French hospitals. Officials said there is no reason to believe patients are in danger from the experimental antibacterial surface coating, but all the same they confiscated 1,000 more of the company's artificial hips.

The scandals have raised more questions than answers about the regulatory process and also point to the shortcomings in the system.

Mathieu Cynober, health technologies practice leader for Tech2Market

Even the newly launched European Databank on Medical Devices (EUDAMED) can only show a fragment of the total universe of data on implants.

In the heart of France at an industrial centre for orthopaedic implants, an initiative is now underway to address the challenges of creating a bigger picture for medical implants with Big Data.

Launched at Medtec France in May, INNOVIMPLANT is a collaborative project among companies and partners in the I-Care Cluster. The Innovimplant programme is far from a reactive or defensive effort aiming only to track down failing products. The organisers believe there are opportunities for innovation to be found by mining information about implants that will improve both products and processes.

Coordinated by Pôle des Technologies Médicales in Saint-Etienne, the programme seeks to gather and then exploit data already available about medical implants that is widely dispersed along the entire value chain from the manufacture of the product to its use with patients and beyond in follow up clinical studies.

The Region Rhône-Alpes and the Saint-Etienne Metropole provide Innovimplant funding. Presented by Anne-Sophie Gouzy, Director of the Pôle, she highlighted the increasing demand for more information about implants, not only by regulators, but companies to better define opportunities.

The challenges today to the competitiveness of companies in a crowded market include the increasingly stringent regulatory system, but also decreasing reimbursement levels and greater expectations on the part of more exacting patients, she said, adding that a central source of data could indicate numerous opportunities for both industrial and clinical actors, as well as serving as a powerful lever for innovation.

In a first step, Innovimplant will identify sources, gather and structure the information.

The goal is to define by the end of the year a series of concrete and collaborative projects to be undertaken with funding from regional sources.

At Medtec France in Lyon a preliminary study showing the complexity of the programme and opportunities was presented by Mathieu Cynober, health technologies practice leader for Tech2Market. 'What we've found is how distributed and dispersed the information captured for implants actually is among vendors, regulators and hospitals with each stakeholder having a limited scope of data but no interoperability of data for sharing,' he reported. 'It sounds very conceptual, but behind this programme there is very specific information useful to all actors in the chain of utilisation.'

State insurance funds, for example, may have epidemiological information with patterns of use, causes and effects of implantations, patient quality of life after implantation, and post-operative symptoms that emerge.

Hospitals have data on how devices are stored, hygienic conditions and rates of infection, purchasing patterns and handling in the supply chain. Clinical data sources could help evaluate how products and technologies are used, identify best practices and show companies how to adapt tools and implants to facilitate better pre-operative planning and choice of products.

According to Anne-Sophie Gouzy, 'Innovation does not come strictly on the technical level. Ultimately, innovation results from better information that hopefully adapts technology for the health ecosystem in a more sustainable way.'

Integrate – from Day One

Integrated care in Europe is primarily offered in regional networks. An international symposium in Berlin showed that new forms of care require innovative ideas and a tenacious team, Susanne Werner reports

Two principles can spell success for integrated care (IC) in Europe. First, integrated care programmes need to address entire population groups rather than single medical conditions.

Second, integrated care should be implemented via incentives, not via regulation. Those major messages from the 13th International Conference on Integrated Care, we passed on to 220 international experts in Berlin this April, an event co-funded by the Robert Bosch Foundation and hosted by the International Foundation for Integrated Care, the AOK Federal Association and the German Managed Care Association (BMC).

Almost all European countries struggle with the same problem: the healthcare system is fragmented and isolated from other support systems with reimbursement models and cost pressure exacerbating this fragmentation.

IC experts have been searching for innovative responses to the key issue for some time. How can the different providers in the healthcare systems and beyond cooperate with other actors in social security systems to be able to offer uninter-

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EH 3/13

Gastein 2013 on resilience and innovation

Report: Michael Krassnitzer

'How can we make European healthcare systems resilient against crises and still remain innovative?' asks Professor Helmut Brand, President of the European Health Forum Gastein (EHFG), highlighting the core issues of this year's agenda of the renowned event (2-4 October). 'Cost saving and innovation are not really compatible,' he points out. 'We have to discuss where we draw the line; at which point does cost saving become dangerous for healthcare systems?'

As the current EHFG President, Professor Brand wants the event to be more focused. EHFG is a forum for politicians, civil society, scientists and healthcare providers to discuss European healthcare politics. 'We'll try to have representatives of the three upcoming EU presidencies to attend each year,' he announces 'because in such a setting issues are discussed that can inform imminent political decisions.'

However, EHFG is not only about Europe: this year exchange with non-European countries will receive much attention. Emerging economies, such as Brazil, Russia, India, China and South Africa (BRICS) have achieved economic success often at high environmental costs and are keen to learn how Europe managed to reduce air and water pollution at major industrial sites without harming the economy.

In turn, Europe wants to find out whether those countries do things in new and surprising ways that might also work in 'old' industrialised countries. 'Asia's reform movements are presently stronger than in continental Europe,' Prof. Brand says, explaining his interest in a dialogue with Taiwan. Indeed, European health economy is already watching the emerging countries. 'Indian and Chinese companies export products that were originally developed for their markets to Europe,' he points out. 'We don't always need the deluxe version of a product. In many areas a nuts and bolts version that does exactly what we need it to do is fully sufficient.'

Focus TAFTA

A further important EHFG issue will be the planned transatlantic free trade association (TAFTA) between Europe and the USA, which will have major impacts on healthcare. Will TAFTA, for example, mean that all medical procedures approved by the US FDA will automatically be allowed in Europe? 'In the US, genome analysis services are being offered that are not compatible with the European privacy and patient information regulation,' he explains. Another question, among many TAFTA raises, concerns applicable law: If US companies can offer their medical products on the European market, which law will prevail – European or US?

Cross-border healthcare is 'an entirely untenable situation that for a European citizen living in a smaller or poorer country it's impossible to obtain adequate treatment for certain conditions,' he emphasises. Many EU Member States fear that cross-border healthcare provision will lead to throngs of people from other EU countries inundating their healthcare systems and using up their own citizens' resources.' He does not share this concern. 'Nobody will voluntarily go to a foreign country to receive treatment that's available in decent quality at home.' In Malta, he says, for historical reasons many patients obtain medical care in the United Kingdom. Thus the Maltese government is actively trying to provide certain medical services domestically – and even establish the island as a European centre for rehabilitation medicine.

'You see, it can work both ways,' Prof. Brand concludes.

Professor Helmut Brand studied medicine at the universities of Düsseldorf, Germany and Zurich, Switzerland. In 2008 he was named Jean Monnet Professor of European Public Health, Head of the Department of International Health and Director of the Research Programme on Comparative Health at Maastricht University (Netherlands). He has been President of the European Health Forum Gastein (EHFG) in Austria since the beginning of this year.

* 2-4 October 2013. 'Resilient and Innovative Health Systems for Europe', Health Forum Gastein (EHFG)

Integrate - from Day One

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rupted and reliable care to patients with multiple or chronic diseases?

Professor Chris Ham, head of the non-profit foundation The King's Fund in Great Britain and a key speaker at the IC conference, recommends a step-by-step approach to IC projects. A common objective to which the partners commit, he emphasised, is an absolute must. The increasing number of patients with chronic diseases and the concomitant increasing need for coordinated measures require regional and population-focused programmes.

The professor presented the approach of the Knowsley district, where representatives of different professions and organisations cooperate intensively every day to ensure flexible and need-oriented care. 'That means everybody has to give up his independence to some extent and make compromises, which is not always easy,' he said.

Tighter integration of social security and healthcare systems

President of the International Foundation for Integrated Care, Professor Guus Schrijvers from Utrecht, uses three terms to describe the successful implementation of IC structures – local leadership, vision, and commitment – and observes 'useful approaches in many countries – the UK, Spain, the Netherlands and Germany, among others'. Nevertheless he warns: 'There is no "one size fits all" solution in healthcare since the conditions are far too heterogeneous.'

Prof. Schrijvers is like the incarnation of success in the Netherlands. Economist by profession and professor for Public Health, he helped establish new care structures in Almere, Leidsche Rijn and Zwolle. No doubt he had a major advantage, being familiar with the municipal structures in his home country: for 10 years he was a Utrecht City Council member. His approach: 'Create a network member of different partners in a town, for example a hospital, and several office-based healthcare providers, and then take this model to other towns.'

The professor also demands better education for members of non-medical health professions and urged their tighter integration in the IC programmes. The incentive system, he suggests, should be developed in the course of the cooperation and should consider the different points of view of the professions involved.

Share success – share gain

Helmut Hildebrandt, managing director of Gesundes Kinzigtal GmbH and co-organiser of the symposium, emphasises that the participants in IC need to agree on three objectives: to achieve a healthier population, create positive experiences with the care system and handle funds responsibly. In his organisation, based in south-west Germany, he tries to find answers to what he considers the key issue: how can we ensure that healthcare actors direct their intelligence towards these objectives? While Gesundes Kinzigtal GmbH has gained a reputation beyond German borders, Hildebrandt founded another company: OptiMedis AG Hamburg. Here he built a regional network with a local physicians' net for the clients of two health insurers. Other partners are, for example, care services, hospitals and physiotherapists.

The network not only aims to improve care but also to offer prevention services, such as weight control programmes designed to reach risk groups before a disease can develop. In Kinzigtal, he reports, some objectives have already been reached: the mortality rate decreased, there is less fluctuation among the insured between insurance companies and last but not least the income situation of the health insurers has improved.

Based on the 'shared gain' principle, health insurers and Gesundes Kinzigtal GmbH share the funds generated. A unique feature of Gesundes Kinzigtal: 80% of physicians participating in the network are also shareholders in this limited liability company and thus participate in its economic success.

Structuring a tumour board

Re-evaluating the multidisciplinary approach to cancer care

A 2012 study analysing the care of cancer patients in the USA in 138 Veterans' Administration hospitals (pub: Journal of the National Cancer Institute) questions the effectiveness of tumour board review. The study measured effectiveness by comparing the presence of tumour review boards with stage-specific quality of care and patient outcomes.

Report: Dan Conley and Anna Fenton-Hathaway

When first introduced, tumour boards promised cancer patients input from a variety of medical experts that might include social workers and palliative care specialists as well as surgeons, pathologists, medical oncologists and radiation oncologists. The goal of these multidisciplinary boards was to harness the expertise of different specialists to more accurately identify the stage of the cancer and to devise the most effective course of treatment. Bringing together experts from different fields of cancer medicine would presumably overcome the possibility of 'specialty bias', producing the most integrated care possible. However, a recent study suggests that this promise has gone unfulfilled. With this new information, the status of tumour boards in the USA has become the subject of increased scrutiny.

The study, designed by Nancy L Keating, of the Department of Health Care Policy at Harvard Medical School, and her colleagues, 'surveyed 138 VA medical centres about the presence of tumour boards and linked cancer registry and administrative data to assess receipt of stage-specific recommended care, survival, or use for patients with colorectal, lung, prostate, hematologic, and breast cancers'. The study examined the records of patients diagnosed from 2001 to 2004, using 27 measures of quality and outcome to analyse those patients' data through 2005. They ultimately found 'little association of multidisciplinary tumour boards with measures of use, quality, or survival'.

Titled Tumour Boards and the Quality of Cancer Care, the study does not recommend dispensing with multidisciplinary review altogether, noting that 'tumour boards likely vary in their efficacy' depending on factors such as the expertise of their members, their structure, and other functional components. 'Additional research is needed to understand the structure and format of tumour boards that lead to the highest quality care,' the researchers conclude.

The American College of Surgeons, whose Commission on Cancer sets the national standards for tumour boards, has already recognised this need. As their 'Cancer Program Standards 2012: Ensuring Patient-Centred Care' states, each board features a Quality Improvement Coordinator, whose role is to evaluate tumour boards' effectiveness in improving patient outcomes. These coordinators make an annual report presenting their research. They also have the power to 'recommend corrective action if activity falls below the annual goal or requirements'.

Other experts such as Tamar H Taddei, of Yale University School of Medicine's Department of Internal Medicine, agree that Keating's study does not foreclose on the promise of multidisciplinary reviews for cancer patients.

In his essay on hepatocellular carcinoma (HCC) in the Journal of Clinical Gastroenterology, Taddei also argues that multidisciplinary opinions could have special benefits in terms of treating this particular disease – 'the fastest growing cause of cancer death in the US'. Because HCC is a heterogeneous disease and 'aris[es] in a damaged organ', it poses 'unique diagnostic criteria and treatment modalities'. According to Taddei, this complex cancer requires 'a keen understanding of the benefits, risks, limitations, and trade-offs of potentially curative, bridging, and palliative therapies'. He asserts that a multidisciplinary team 'is an essential forum for each specialty to lend their expertise to the collective decision making involved in formulating a plan of care'.

Another group of physicians from Feinberg School of Medicine's Surgical Outcomes and Quality Improvement Centre at Northwestern University take up the cause of tumour boards in an invited critique in JAMA Surgery online (20/3/2013). Drawing on research by the Mayo Clinic's Nabil Wasif and colleagues, Feinberg's doctors Karen Sherman, Jeffrey D Wayne and Karl Y Bilimoria conclude from that study that 'all sarcoma patients should be managed by a multidisciplinary team with expertise in sarcoma to mitigate individual physician and physician specialty treatment bias'.

Taddei and Sherman et al. argue for the continued viability of multidisciplinary teams in terms of diagnosing and treating specific cancers. Yet Taddei also remarks of the Keating study that it suggests a need for more 'standardised processes', to institutionalise best practices across the board. In all of these cases, the practice of tumour board review does not seem to be in jeopardy, but its current function and structure invites room for improvement.

Finally, while most of the controversy seems to surround the relationship between tumour boards and patient outcomes, the debate has largely overlooked one of their early primary goals: to 'provide a forum for the continuing education of medical staff and health professionals', according to Cancer Care Ontario's 'Multidisciplinary Cancer Conference Standards in Review' 2006 report.

The educational aspect of these boards figured even more prominently in a 1988 report by the USA's Government Accounting Office on 'Encouraging the Use of Breakthroughs' in cancer treatment. One of the 'breakthroughs' the National Cancer Institute was considering support pertained to these boards' function as continuing medical education; the GAO cited a NCI finding concluding that the patient-focused tumour boards are the most extensive professional education program available to physicians,' (Cancer Treatment 1975-1985. Gaithersburg, M D US General Accounting Office, 24).

* More expert opinions on this subject will be published in EH issue 4/2013

Chemotherapeutics

The role of the immune system in cancer therapy

Apart from tumour immunologists themselves, for a long time oncologists have underestimated the role of the immune system in cancer treatment. Nonetheless, in recent years increasing attention has been given to this aspect of cancer. One eminent researcher, who has studied the dynamic interactions of tumour cells and the immune system for some time, is Dr Guido Kroemer. In his lecture 'Immuno-surveillance induced by cytotoxic anticancer agents - a necessary step for therapeutic success', given at the Max Delbrück Centre for Molecular Medicine in Berlin, he presented his latest discoveries. Bettina Döbereiner spoke with renowned cell death expert about the role of the immune system in cancer therapy.

His findings suggest that some particularly efficient chemotherapeutics can mobilise the host's immune system against cancer and thus significantly improve cancer treatment. 'The first results of our studies led us to believe that some conventional cytotoxic chemotherapies agents convert dying cancer cells into a sort of vaccine that stimulates an anti-tumour immune response thereby making therapy more effective,' said Guido Kroemer, introducing his lecture during Cancer Day at the Max Delbrück Centre for Molecular Medicine, Berlin. He and his team, co-directed by Laurence Zitvogel, could demonstrate in animal experiments with mice that anticancer agents like anthracyclines and oxaliplatines cause an endoplasmic reticulum stress response in cancer cells, resulting in the abnormal cell surface exposure of calreticulin, a protein that normally is hidden within the interior of the cell. Once the immune system has identified calreticulin, it attacks and kills tumour cells of different kinds, including a particular colon cancer cell line (CT 26).

However, this complex response only took place in immune-competent mice, meaning that chemotherapeutic regimes based on anthracyclines or oxaliplatin were less efficient in reducing tumour growth in immune-deficient mice. Moreover, only few of the conventionally used and commercially available chemotherapeutics were able to elicit an anticancer immune response. The reason why some agents cause this so called 'immunogenic cell death' is, according to Guido Kroemer, still poorly understood. Even chemically related agents like cisplatin, which works at a first sight exactly in the same way as oxaliplatin, do not cause the calreticulin exposure required for cancer cell death to elicit an immune response.

The role of cardiac glycosides in cancer therapy

After these first findings Guido Kroemer's team and Laurence Zitvogel also analysed whether any other drugs, used to treat other diseases, may cause immunogenic cell death in cancer cells. Thus they systematically tested 980 FDA approved drugs by means of a tailor-made fluorescence microscopy platform that allows for the automated detection of the biochemical hallmarks of immunogenic cell death. This approach led to the unexpected finding that several cardiac glycosides (CG) were among the most efficient inducers of the hallmarks of immunogenic cell death including calreticulin exposure. Cardiac glycosides, which include the components of the foxglove plant (digitalis) digoxin and digitoxin, have been used for many years for the treatment of heart failure and atrial arrhythmia.

Animal models: Cardiac glycosides induce immunogenic cell death of cancer cells

Although it is not new that CGs might have some positive impact on cancer – the first epidemiological report on the anticancer effects of CGs was published in 1982 by Björn Stenkvist – these new findings help to understand the mechanisms accounting for their anticancer effects, an effect that implies the induction of immunogenic cell death of cancer cells. Indeed, CGs could enhance the anticancer effect of drugs that alone are unable to induce immunogenic cell death, such as cisplatin, but only in immune-competent mice. The combined anticancer effect of CGs plus cisplatin was lost in immunodeficient mice, demonstrating that it was immune-dependent. Confirming these results, the researchers could also show that cancer cells succumbing to a combination of cisplatin plus cardiac glycosides could vaccinate syngeneic mice against a subsequent challenge with live cells of the same type.

Retrospective analysis showed effect of CGs in humans

Finally, Guido Kroemer and team analysed 435 computerised patient files from the Institut Gustave Roussy in a retrospective clinical study that was designed to determine, whether CG interact positively with chemotherapy. This study revealed that the administration of the cardiac glycoside digoxin during conventional cancer therapy, mostly chemotherapy or radiotherapy had a positive impact on overall survival in cohorts of breast, colorectal, head and neck, and hepatocellular carcinoma patients. 'We expected, of course, that patients affected by an underlying cardiopathy, arrhythmia or heart insufficiency, would die well before the control group, but we found the contrary. The overall survival of digoxin-treated patients was better than that of the control group.' This is not true for lung cancer and prostate cancer, as Guido Kroemer added. 'Perhaps because chemotherapy in the lung does not work anyway and because prostate cancer is mostly treated by chemical castration, not by chemotherapy.'

The results also revealed – as well as in the mentioned animal model – that cardiac glycosides only interact positively with chemotherapeutic agents that, given as mono-therapies fail to induce immunogenic cell death like, for example cisplatin. Therefore only this kind of per se non-immunogenic chemotherapy could be improved by cardiac glycosides. Guido Kroemer and Laurence Zitvogel are currently launching a clinical trial that will evaluated whether co-medication with digoxin may improve the current standard of care of locally advanced head-and-neck cancer, which are normally treated with cisplatin-based chemotherapy and radiotherapy.

Consequences for future research

Based on these results, which suggest a hitherto unexpected link between the success of chemotherapy and the immune system, Guido Kroemer proposed a new organisation of drug development and approval. He argued that most scientists still conceive cancer as a cell-autonomous disease, yet ignore the essential contribution of immuno-surveillance towards the cure of malignant diseases. This would lead to the premature launching of clinical trials that finally turn out unsuccessful. 'We should introduce a filter during pre-clinical evaluation to prevent the high attrition-rate of over 95 percent in clinical trials' he claimed.

Thus he proposed that, after identifying an agent that has some effects on tumour cells in vitro, the agent should be analysed with regard to its potential to induce immunogenic cell death or other positive effects on the immune system. 'Only once an agent has been tested in immuno-competent mouse models and has turned out to mediate satisfactory immuno-stimulatory effects, should it be introduced into clinical trials. Through this procedure,' he said, 'scientists would select immune-stimulatory molecules in mice before clinicians do so in patients'

In 1995, after gaining MD and PhD degrees at Innsbruck University, Austria, **Guido Kroemer** undertook post-doctoral training at the Collège de France, Nogent-sur-Marne. He was also awarded a doctorate in biology at the Autonomous University of Madrid in 1992, where he worked as a group leader at the National Centre of Molecular Biology (1990-1992) and at the National Centre of Biotechnology (1993). He later joined various research teams at the French National Institute of Health and Medical Research (INSERM).
Since 2007, he has directed the INSERM unit 848, covering research on apoptosis, cancer and immunity at the Institut Gustave Roussy near Paris.
Worldwide, Dr Kroemer is one of the most cited cell death scientists. Besides many honours and awards, he received in 2006 the Descartes Prize, the EU's highest scientific distinction, for his fundamental discoveries in apoptosis.

Hexaminolevulinate combined with guided blue light cystoscopy

Treating bladder cancer

Bladder cancer (BC) is highly challenging in terms of patient management and medical costs. As the fourth most frequent cancer in men and ninth in women in developed countries (Ferlay et al. http://globocan.iarc.fr, accessed 9/1/13), although BC is a common disease it is still under-represented in public awareness and in cancer research (Pezaro et al. Expert Rev Anticancer Ther. 2012 Jan;12(1):87-98).

Didier Jacqmin, Professor of Urology

Interviewed during the 28th Annual Congress of the European Association of Urology* in Milan, this March, Didier Jacqmin, Professor of Urology at Hôpitaux Universitaires de Strasbourg, France, and pioneer in BC since the 1980s, explained evolutionary changes in this field. 'As the industrial risk factors decreased over time we saw more cases of non-invasive bladder cancer in people who smoked,' he explained. 'We also saw high rates of recurrence of 60 to 70% in the first three years after being diagnosed with non-muscle-invasive bladder cancer.'

In terms of the financial impact, he added: 'In muscle-invasive cancer the costs can easily be calculated. You have an expensive surgery at the beginning, but after that the follow-up is quite simple. In other forms of cancer such as non-muscle-invasive bladder cancer you have very intensive follow-up plans, which are quite expensive.'

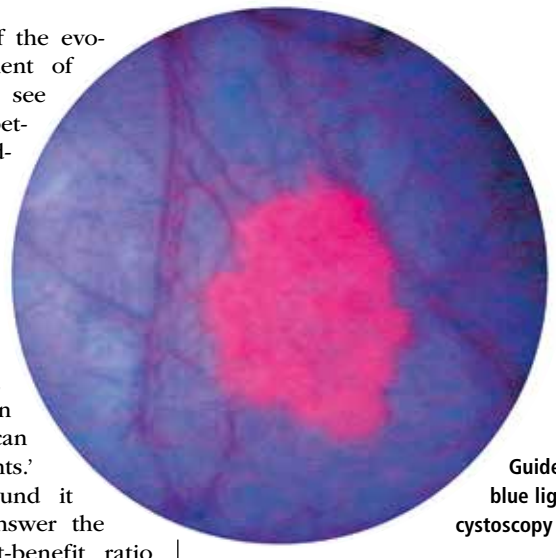
Over the last three decades he has seen achievements in patient management. 'First we improved surgery, knowing that in some situations we were able to replace the bladder. However this cannot be performed in all patients. After that, chemotherapy was developed. Bladder instillations like mitomycin in non-muscle-invasive cancers and systemic chemotherapy for muscle-invasive cancer showed good results.

'The next step was an improvement of the instruments from rigid to flexible and now to high definition video cystoscopes. The latest development for non-muscle-invasive cancer is the optical imaging agent hexaminolevulinate in combination with guided blue light cystoscopy. Since 1999, using this technique we can detect more lesions. Overall, the peak of the evolution in management of bladder cancer we see today is the much better detection of bladder cancer.'

Due to that use of hexaminolevulinate with guided blue light cystoscopy the rate of recurrence is decreasing. 'This,' he confirmed, 'has been shown in many studies and I can see it with my patients.'

The professor found it more difficult to answer the question of a cost-benefit ratio when investing in blue light-guided cystoscopy. 'It depends on the country you are working in and its associated health system,' he explained. 'However by reducing the recurrence rate, it reduces the number of hospitalisations and therefore the overall cost. It also has an impact on the quality of life of the patients.'

For those patients, there is a further plus to the system. 'With blue light-guided cystoscopy you have a very clear and easy to understand image,' Prof. Jacqmin pointed out. 'People like images, they tell you much more about the disease than words. The patients understand their disease much better when you show the pink colour of the tumour.'



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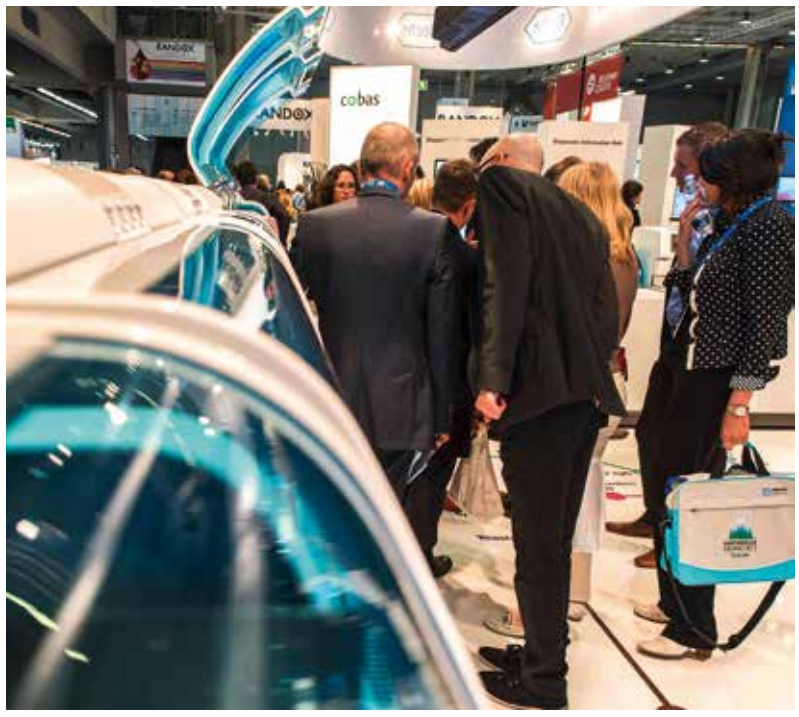
Guided blue light cystoscopy

* Sponsored by Ipsen

EuroMedLab 2013

Milan, Italy – The 20th European Congress of Clinical Chemistry and Laboratory Medicine certainly lived up to its claim as the EU's largest event of its kind – 2,407 visitors and 4,786 delegates from 101 countries plus 82 exhibitors fanned out or arranged themselves over the event's 3,500 square metres, Hanna Politis reports



More than 200 speakers presented technological advances that have resulted in detailed diagnostic findings for numerous diseases, among them the pattern of biomarkers that characterise diseases such as breast cancer or diabetes mellitus on a molecular level. This is made up of many different simultaneous measurements, which, thanks to new technologies, can be obtained with far more information than was available just a decade ago.

Also put forward: if a sufficient number of biomarkers is put into a meaningful context, diagnosing and treating a certain disease in a specific individual will become easier, safer and more precise, also bringing financial/budgetary benefits.

In addition, complete laboratory automation through integrated robotics and IT solutions show that lab processes can be simplified, manual activities reduced and patient safety increased. Discussions also showed that, helped by intelligent robotics, new systems can automatically prepare blood samples for immediate analysis and post-analysis processing. The risks of mix-ups with samples or contamination through manual handling by laboratory staff are reduced. Short and predictable cycle times also mean faster clinical decisions.

Cancer also can be ever more specifically diagnosed, with laboratory medicine enabling individual treatments. Tests are increasingly non-invasive and free of undesired side effects, and results can be evaluated more quickly. Future health risks, such as those for breast cancer or diabetes, can be detected through blood tests. Experts agree that evidence-based laboratory medicine should be introduced quickly to medical practice.

New in vitro diagnostic device

AB SCIEX mass spectrometry-based systems enter Europe

The firm's focus, explained AB SCIEX President Rainer Blair at a press event during EuroMedLab, is on meeting the medical, technological and compliance needs of clinical diagnostic laboratories and hospitals. 'The use of LC/MS/MS technology for clinical diagnostics has already been proven to deliver faster, more accurate results at lower cost compared to existing technologies,' he said. 'Now, we are bringing these benefits to Europe in a way that will simplify and accelerate adoption of this powerful technology.'

Daniela Zimmermann asked Markus Lusser, Vice President of Global Sales and Customer Support, and Fabienne LeFloch, Global Clinical Marketing Manager at AB SCIEX, about the value and role of mass spectrometry.

AB SCIEX has a very long history in this field, with well-established relationships with clinical researchers and many instruments installed for use by scientists with their own methods of running certain tests, Markus Lusser explained, however adding that, although well-established, the process needs simplification. 'We've introduced the first instrument, the 3200MD portfolio, which is a dedicated instrument for the clinical market. It has the potential to give hospitals access to the same technology with a standardised workflow, instead of being used to perform certain tests. For some specific applications it could replace existing technologies because of the many benefits that this mass spectrometry technique brings, especially in terms of getting better quality results. You really have a big win in terms of confidence, precision and repeatability of results for specific applications.'.

Fabienne LeFloch: 'Typically, in clinical research involving lower level testosterone analysis, immunoassay systems are used but they are well known to have cross-reactivity issues with steroids. As a result, they are not specific enough for such low level compounds as testosterone in women and children. This is something that we don't see with mass spec used in clinical research because the technology is different and very specific and does not suffer from interferences. We know the results are specifically for the compound you are looking at. It's not giving you a signal for something else; it's extremely selective.'

Does the new device partly replace existing equipment for testosterone and other tests, but is an add-on for others?

Markus Lusser: 'Let's clarify the term 'replace.' Immunochemistry assays have a very broad spectrum of tests on the menu. Some assays work very well and some have tremendous issues in terms of specificity – selectivity. We would replace those menu items. They could migrate to a better technology, such as mass spectrometry, and into higher quality, more precision, yet also decrease costs. If, for example, you want to analyse a whole spectrum of compounds, you have to run multiple immunoassays. With our instrument you can do it in one injection, with one sample, and get a precise result.'

So while initially this device only replaces immunoassays, could it finally replace everything?

'Well, let's say in a ten to fifteen-year vision it could, but we're not suggesting it can replace standard tests done in a very high quality, rapid way with existing immunoassays,' Markus Lusser replied. 'The vision we have is that it fits into the workflow and certain tests that are right now challenged with immunoassays or standard techniques will be replaced over time with mass spectrometry.''We are working from two sides. We're expanding the kind of tests we can do by working with researchers, and we're providing a ready-to-go solution that can be put into a lab and it works. These two angles make this approach interesting, because we can talk on both sides. 'Many hospitals have installed systems, but use them under a research-only agreement. They validate the workflow themselves, often they verify the immunoassay results with mass spec. It's almost like a validation of inconclusive tests, especially those that are very difficult to measure, such as low-level testosterone. They very often go back to mass spec to validate the result. If they'd done it within mass spec at the beginning, it could eliminate those in between inconclusive tests. It's a technology evolution. Markus Lusser: 'We also still have lots of research collaborations. They are investigating switching some assays that they do on other platforms over to mass spec, but it's still in the development phase. There's probably an interesting bridge – for example, talking with one customer who has a standard routine application. Today, to diagnose this particular indication, I need to do A, B, C, D, E, and F. Then, the regular result is spotted. 'If I do this in a mass spec setting, I could have a definite result in 20 minutes.'Mass spectrometry has tremendous potential, but it's really just the beginning. It's not fully automated, but we are getting there.'

Markus Lusser, Vice President of Global Sales and Customer Support, AB SCIEX

* Launched in about 15 European countries, shipment of the two 3200MD products begins at the end of June.

28 July – 1 August - Houston, Texas

The American Association for Clinical Chemistry 2013

Jacquie Michels reports on what to expect – and look for

According to Molly Polen, at the AACC, great opportunities lie ahead for laboratory medicine and, to seize them, 'meeting with colleagues and learning about new technologies is a critical first step. The 2013 AACC will provide these and other opportunities, such as informative sessions and live demonstrations of new technology.'

Scientific programme topics include the role of insulin in the brain; relevance of 'junk' DNA to human development; how much vitamin D is needed for bone strength, and the importance of patient-based therapeutic discoveries. The AACC is also collaborating with Texas Medical Centre – the largest medical complex in the world – with sessions highlighting some of its latest findings.

Conducted in Spanish for the first time, three sessions will focus on improving patient care, what vitamin D assays really mean, and biomarkers for Alzheimer's. An additional session will look at how clinical labs in developing countries can meet their unique challenges.

On the expo side, all attendees will receive an e-mail that lists contact information for the booths they visited. 'They no longer have to worry about keeping scraps or business cards,' Molly Polen pointed out. 'They can consider purchasing decisions in their own offices, with no chance of losing information.'

Worth attending is the AACC's annual New Product Review, which many companies use to reveal new findings and products.

'Attendees should look forward to visiting Houston, rated by the New York Times as one of its 46 places to visit in 2013,' said Polen. 'Expect excellent dining, and cultural opportunities such as the Museum of African American Culture, and the Asia Society Texas Center, as well as the Houston Museum of Natural Science,' she said. 'It promises to be a great meeting with something for everyone!'

Exhibitors you should visit in Houston:

SIEMENS

Siemens Healthcare Diagnostics (Booth 3449) will unveil its latest clinical diagnostics innovations, from new assays and automation to digital microscopy, and present a new workflow management solution for labs of all sizes and budgets.

greiner bio-one

Greiner Bio-One North America, Inc., (Booth 4511) from Monroe, North Carolina, provides product manufacturing, distribution logistics and product application support to clinical and research laboratories at universities, start-up companies, and to the world's largest hospitals, pharmaceutical and biotechnology corporations. The firm's products relate to collection of human samples and plastic labware specifically related to medical research.

BECKMAN COULTER

Beckman Coulter (Booth 4751) will showcase scalable laboratory solutions for labs of all sizes – the community hospital, core, reference lab – and also feature total lab automation solutions, small footprint solutions and newest portfolio additions, including recently acquired IRIS Diagnostics automated urinalysis products.

Roche

Roche Diagnostics (Booth 4049) will showcase its comprehensive solutions portfolio from labs to hospitals, clinics and patient homes. Visitors will have the opportunity of being introduced into a total automated modular laboratory solution. Two workshops on Tuesday, July 30th, will highlight best practices for improved cardiac testing workflows in the hospital and trends about diagnosis and treatment of Hepatitis C in the US.

In vitro diagnostics partnerships

China looks inward and outward

Report: Nathanial Whitney of Whitney Research

From the meetings between the Presidents of China and the USA came the slogan, 'A new model of cooperation'. One item discussed was the proposed $4.6 billion purchase of a US pork producer by a Chinese company, which affirmed: 'the acquisition won't affect the quality of the bacon on stateside breakfast tables'.

The concerns that keep Chinese IVD suppliers out of developed markets are not about breakfast tables, but operating tables. Bare bones, but at the cheapest price, doesn't make for a tasty breakfast any more than for a dependable IVD source and actionable test results.

The old adage, 'perception is everything in marketing', holds true for IVD; as does 'History repeats itself'. Japan of 50 years ago was perceived as selling cheap junk, no matter how good a product and support system an individual company may have designed. Just as with Japan at early development stages, Chinese companies lack homegrown innovation and attention to quality, and have concentrated on being the low cost producer – a strategy perhaps successful in most cash starved Chinese labs, but opening doors wide for foreigners in those large, rich Chinese hospitals who insisted on the best, and all hospital labs in the affluent, developed countries.

The large multinational IVD companies have dominated China's high-level hospital labs. They followed the strategy of American bank robber Willie Sutton, who, when asked why he robbed banks, was quoted as saying, 'Because that's where the money is.' China's healthcare system has been broken for generations, since the loss of government support and reliance on market forces, resulting in patients having no confidence in hospitals lower than the top tier. So, top hospitals are overloaded with patients and 60-80% of the IVD testing (and revenue) has been in those labs. The lower level labs could not generate enough revenue to cover costs.

Times are changing. Since China's healthcare reform began in 2009, modern healthcare infrastructure has been reaching the community health centres in cities, at county level, township level and, soon will reach village level. There are only 1,399 top level (class 3) hospitals, 6,488 Class 2, 5,636 class 1 and 7,861 community health centers in the cities, and 37,295 township level hospitals, 24,999 community health stations, and 662,894 village clinics. Compare this with the 5,724 total registered US hospitals. Is it surprising that the China IVD market has so much potential and has been growing at 30% annually since 2009?

Patient traffic is still not there at lower levels due to lasting perceptions and inability to pay, but local health insurance schemes are directing patients to these lower level facilities, and that is taking hold. IVD test volumes are increasing – still the domain of the local producers as foreigners have yet to develop an effective strategy to reach them.

Does this mean lower level facilities will be substandard in quality? Until recently, China's labs, especially those without expert clinical professionals, lacked the tools to judge 'value' over price. Manufacturers were very loosely regulated and sales were made more on personal relationships, than value judgments.

Some changes are bringing the Chinese IVD manufacturers up to world class quality standards. To pass China's FDA, all manufacturers must comply with ISO13489, requiring a documented and implemented quality system. Hospital labs in China are increasingly complying with ISO 15189, which requires routine internal quality control and external blind surveys. The Centers for Clinical Laboratory Management in each province have been taking blind samples to the hospitals and reporting comparative results. Now the hospitals can judge value, not just price, and it is playing a major role in separating the quality companies from lowest cost, poor quality manufacturers.

How is this impacting on Chinese manufacturers? Many Chinese IVD firms are becoming world class in quality, but still having trouble accessing the developed markets. We will bring over 75 Chinese IVD manufacturers with their quality products to the American Association of Clinical Chemists 2013. Clearly, they are reaching out.

Multinational IVD manufacturers are looking for partnerships, or M&A opportunities, to help them reach into the huge China healthcare system, and cash rich Chinese IVD manufacturers are looking to multinationals to bring them innovation and an understanding of the developed market culture and logistics support.

Look for increasing cross investments to bring both sides into the world IVD market, more as partners than competitors, maintaining quality while decreasing costs.

With over 45 years in the IVD industry and experience in China dating back to 1983 as Asia Technology Marketing Manager for the Medical Division of Corning Glass Works, and the former owner of a Chinese distribution (medical imaging) and consulting businesses with offices in Beijing and Boston, today chemical engineer **Nathaniel Whitney** owns and presides over Whitney Research. The firm focuses exclusively on the Chinese IVD market, developing profiles and tracking the performance of more than 355 Chinese IVD companies, as well as the top multinationals selling in China and providing general and customised market research for manufacturers, major research firms, investment groups and NGOs. The firm is also the Chinese agent for AACC Clinical Lab Expo, and also sole agent for the American Association of Microbiology for China, Taiwan, Hong Kong, Japan, Korea, Singapore, Malaysia, Indonesia, Thailand, Vietnam.

LEAN workflow analysis

The company's Power Link

This year's EuroMedLab and IFCC-EFLM Congress came at a time when all hospitals face ever-increasing healthcare costs, aging populations and patients and GPs demanding more complex and novel diagnostic tests. Hospital laboratories play a critical role in more than 70% of diagnostic decisions and productivity must to rise in line with workloads, with results improved despite the same or reduced staff levels.

The high throughput solution

Meeting customers at EuroMedLab for the first time in his new role as President of Beckman Coulter Diagnostics, Arnd Kaldowski said: 'When it comes to maximising the hospital laboratory's operations, choosing the right long-term solution, and the right trusted partner, is financially critical. Throughout seventy-five years, Beckman Coulter has singularly dedicated itself to the clinical diagnostic laboratory. Our commitment to customers has been to deliver innovative lab solutions to improve the overall return on investment in both diagnostics and disease management.'

Arnd Kaldowski, President of Beckman Coulter Diagnostics

Pointing out the growing trend to look for innovative ways to improve service delivery, he added: 'The concept of a LEAN workflow analysis has now become standard practice for a modern lab as part of a fundamental review of its workflow practices. The outcome of these workflow reviews has been to focus on partners who can provide high throughput systems with a consistent turnaround time (TAT) that can also offer standardisation of technology and reagents as well as results.'

The LEAN approach has also driven a move towards the consolidation of IVD laboratories, using an expanded workflow concept of a 'hub and spoke' model. This is becoming the template, in various manifestations, for hospital lab services throughout Europe, with a central core lab aligned to numerous regional or satellite locations.

For a successful partnership Arnd Kaldowski suggested customers demand standardisation of reference ranges and results, whether tests are performed in the core lab or regionally; maximum instrument uptime and availability; scalability to meet increasing workloads; reduction in time-wasting, manual steps; delivery of an improved and consistent turnaround time (TAT); on-going training and staff support.

The firm is recognised worldwide for its range of automated testing platforms, offering a flexible, scalable solution whatever the lab size. New automation solutions featured this year, e.g. the Power Link (a streamlined, integrated solution to link sample processing for immunodiagnostics and chemistry from a single sample entry point), further improve workflow by decreasing the reporting time of both routine and life-critical results back to clinicians.

For haematology customers, a critical step in the sample review process is being able to identify abnormal cells as quickly as possible, the company points out.

To ensure accuracy and the earliest possible diagnosis, an automated solution has first to deliver high levels of sensitivity and specificity when flagging abnormal or atypical cells. To meet this need, Beckman Coulter launched the new, small footprint UniCel DxH 600 Coulter Cellular Analysis System, a compact, bench-top for mid- to high-volume labs.

Quality control via round robin tests

If a parameter is determined with different test systems the results must still be comparable. This sounds simple, but is hard to achieve. The quality of medical laboratories is controlled via round robin tests, and is assured through the evaluation of results by the participating laboratory and the respective manufacturer – a process where reference institutions act as mediators. European Hospital interviewed Professor Ingo Schellenberg, Vice President of the Society for the Promotion of Quality Assurance in Medical Laboratories (INSTAND) e.V., about the long road from internal and external quality control to active quality management.

Clinical chemist **Professor Ingo Schellenberg** has worked on the quality assurance of laboratory-medical procedures for more than 30 years, beginning as a department manager in the clinical laboratory at Dessau Regional Hospital and as director of the regional laboratory for quality control of diagnostic test methods (BLQ) in former East Germany. In the '90s he trained Weights and Measures Inspectors and today directs the Centre of Life Sciences at Anhalt University of Applied Sciences in Bernburg.
Prof. Schellenberg leads the round robin *in vitro* allergy diagnostics test at the Society for the Promotion of Quality Assurance in Medical Laboratories (INSTAND e.V.) of which he is Vice President.

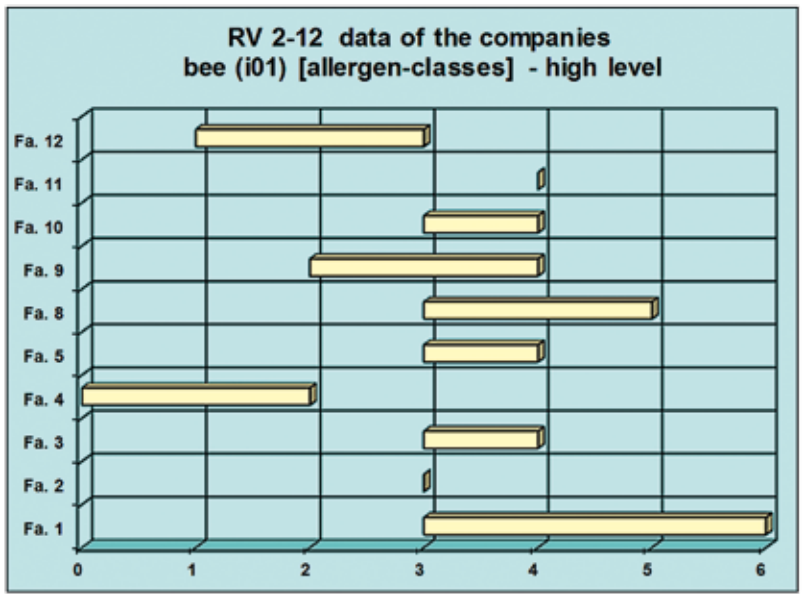
Report: Holger Zorn

Over 40 years ago (1971) the German Medical Association (GMA) issued the first guidelines on the implementation of internal and external quality control for clinical chemistry. The regulations were not implemented by the state but through medical self-administration. The objective was to focus different initiatives from the respective specialist associations for the implementation of laboratory-medical examinations and to establish an interdisciplinary concept for quality assurance in this area of medical diagnostics.

Those guidelines have been updated and adapted to new scientific and technical developments several times. The new aspect is that not only internal and external quality controls are obligatory but also the basics of a quality management system.

Achieving accreditation or certification as a clinical laboratory necessitates the compilation of a quality management handbook that shows day-to-day processes - up to the 1990s the responsibility of the National Measurement Offices in the federal German states, i.e. of governmental organisations. Presently, the German Medical Association has appointed two main organisations for external quality control, i.e. for round robin (or inter-laboratory) testing, The Reference Institute for Bioanalytics (RfB) in Bonn, a foundation outsourced from the German Society for Clinical Chemistry and Laboratory Medicine, and the German Society for the Promotion of Quality Assurance in Medical Laboratories (INSTAND) e.V., a specialist scientific-medical association.

Describing this special structure, Professor Ingo Schellenberg, Vice President of INSTAND, said, 'We have an interdisciplinary approach and, as a specialist scientific-medical association, work closely with medical associations. Not only chemists or laboratory medicine specialists are involved in the individual round robin tests but also the respective medical specialists. Endocrinologists contribute their specialist competencies to the planning, implementation and evaluation of hormone tests. The two most important specialist associations for virology, to name another example, have long appointed a joint head of round robin testing – leading virologist Professor Heinz Zeichardt of Charité Berlin, reports to a joint diagnostics commission four times a year.



A round robin test on bee and wasp allergy from 2012, with image showing allergen classes of a high-level control sample, tested in participating laboratories with systems from nine manufacturers. Had this control sample been from blood from a patient undergoing special immune therapy, the patient would be classed as successfully hypersensitised based on results from manufacturer number one, but as a non-responder based on results from manufacturer four. Things could become dramatic for the patient if the laboratory changed manufacturer during treatment. The value chart used for orientation by the treatment clinician may, in some circumstances, have suggested successful treatment – and a single sting could trigger an anaphylactic reaction type one, possibly fatal within minutes

'This commission not only evaluates round robin tests results but also determines strategies for the future. If, for example, there's a rise in the occurrence of hantavirus due to a major increase in travel, with the threat of an impending epidemic, it makes sense to make the appropriate test available as promptly as possible.' Prof. Schellenberg sees this as a competitive advantage: the customers – clinical laboratories – are not only offered a broad, but also up-to-date range of services.

Germany's politicians now also desire this competition. Previously, the country's market was shielded from European influence and the GMA only appointed national reference institutions. However, in the course of European developments, this will no longer be sustainable. Finnish as well as British round robin test organisations have already applied for licenses in Germany. In future it will only be suitable qualifications and capabilities and – an important requirement stipulated by the GMA – independence from commercial interests that count. Device or test sera manufacturers, whose natural interest it is to market their products, will be denied access.

'These days, participants in our round robin tests come from all over the world,' said Prof. Schellenberg. 'For instance, in the case of allergy testing, from France, Italy, Austria, Switzerland and Turkey. Those responsible for the tests no longer come only from Germany but also Switzerland, Austria and the USA. In virology, a large number of participants come from Russia and Poland and, he adds, 'even hospitals from Argentina and Chile participate which we didn't solicit; they found their own way to us. Quality assurance is mandatory there as well, and certification of an independent German organisation is highly regarded.' There are no logistic problems as all control samples are shipped lyophilised.

The primary objective of the round robin tests is to improve comparability. The doctor in charge of treatment, who wants a laboratory result, must be certain that the same parameters used would also have been used in the same way elsewhere. The round robin test, the shipping of the same control samples to all laboratories and the central evaluation of results determined there, ascertains a certain status. 'This is quality control, i.e. only an indicator,' the professor pointed out. 'Quality assurance is the reaction to this, and is carried out by the laboratories – and manufacturers. This is in their mutual interest: the laboratory wants to keep its accreditation and the manufacturer wants to keep its customer.

'We pass the anonymised results to all manufacturers who ask for them. If a laboratory fails a test the manufacturer will ask us if they can talk to the respective participant. We then inform the laboratory and, if they are in agreement, establish contact so that they can jointly work on the causes.' Testing, training and moderating, that's the service offered by INSTAND to ensure comprehensive understanding of quality assurance and quality management.'

Quality management i

A lot of information makes a lot of work, says Dr Markus Neumann

Quality management (QM) for medical laboratories shaped its footprint during recent years – it's a hot topic in papers, conferences and trade fairs. Although a bunch of IT products are available to help handle the numerous documents a laboratory must maintain (quality manual, quality system procedures, standard operations procedures), they normally lack the support of a special class of documents: a lot of information for reagents, supplied by the manufacturers for their analytical devices.

According to ISO 15189:2012: 4.2, 4.3, the lab must always control every document with content that could affect the quality of the laboratory outcome. As this is also valid for external documents, it is obvious that a lot of information supplied by manufacturers of analyser and reagents falls under this regulation. In terms of ISO 15189, controlling means that active documents must be authorised before use, identified (e.g. in a document register) and held available at the point of use. Furthermore, at the end of a document's lifecycle it must be removed from the point of use and at least one copy has to be retained for a specified time.

While a laboratory normally offers more than a handful of analytical tests to customers (depending on size and specialisation of the lab there could be considerably up to a thousand tests) the extent of resulting external documents may become innumerable. Fortunately manufacturers are switching to providing their documents electronically: the lab staff logs into a WEB environment and after being identified by their login credentials will be pointed to an updated list of rele-

Do-it-yourself scientific testing

Teenager builds DNA machine at home

Report: Mark Nicholls

A British teenager, 17-year-old Fred Turner, has won a major accolade for building a DNA testing analyser in his own home for a few hundred euros. His achievement has been recognised by leading scientists and helped him win the prestigious Young Engineer of the Year Award in the UK. Fred explained that he built a PCR (Polymerase Chain Reaction) machine to amplify a target DNA sequence along with equipment for electrophoresis to set up a home genetics lab. A key component of his award-winning project was to identify the gene mutation that gives his brother Gus ginger hair.

To build the PCR machine as cheaply as possible the parts were 'scavenged' from the electronics of old computers and a video player, while the microcontroller is an Arduino Mega, which is an open source and cheap microcontroller. He bought electrical components only when absolutely necessary, designed all the electronics and carried out the programming required for the touch screen and precise heater control using only the limited tools he had available at his home in Brighouse, West Yorkshire.

Total prototype cost was about £400 (€475), though now he has the completed designs he believes he can build another model for as little as £250 (€300).Fred said he learned how to build the PCR machine from the internet and also by taking apart a broken PCR machine that a university laboratory had discarded.

The desire to build the machine was triggered by a long-standing ambition to be able to read his genetic code. 'Investigating the genetic basis of my brother's ginger hair was another project I carried out as a "proof of concept" that the machine and my lab worked and because it was a test that I found personally interesting,' he said.

Fred Turner, a pupil at the Crossley Heath School in Halifax, Yorkshire, has recently completed his A-level exams. In October he will go to Oxford University to study biochemistry and already has ambitions after his studies to start his own business related to biotechnology/ synthetic biology.

He conducted the analysis by extracting DNA from buccal cells from his brother's cheek using an alkaline lysis technique with the DNA undergoing PCR in his machine to target the specific gene under investigation and increase the amount of DNA for the next stage of the process.

Fred added: 'Depending on the gene I'm investigating, there are two different analysis steps that can be used next. If I am investigating either an insertion or a deletion in a certain gene, I can run the PCR product on an agarose gel using electrophoresis on equipment I built. This allows me to determine the length of the DNA fragment that was amplified by the PCR and thus determine if the insertion/deletion is present. I can carry out this technique at home.'

However, for some genes where he is looking for changes in a single base pair, often referred to as SNPs (Single Nucleotide Polymorphisms), he has to send the DNA to a lab that carries out the sequencing reaction, as he cannot do this at home due to the expense of reagents and equipment.

To read the results of his tests, he built a transilluminator that allows him to see the DNA in an agarose gel using a fluorescent dye and 'read' the results when looking at insertions/deletions and allows him to estimate the length of the DNA fragment produced in PCR.

'When I get the results back from the sequencing lab I perform several different techniques on the computer to work out what the results mean,' he said. 'This usually involves doing a BLAST search (on the NCBI website) of the sequence, aligning the sequence to a reference sequence to look for mutations, or looking at the electrophoreogram to determine if there are any heterozygous SNPs.'

As for his analysis of the ginger gene, he found that his brother has a deletion of a single A at position 85 of the gene MC1R (Melanocortin 1 receptor) which causes a frame shift mutation, producing a non-functional receptor and leading to his ginger hair.

Fred's Genetics at Home project – which won him the UK's Young Engineer of the Year award in the National Science + Engineering Competition organised by the British Science Association - highlighted how anyone can carry out basic genetic tests for a fraction of the cost of existing technology. The panel of judges included Hadron Collider physicist and TV presenter Professor Brian Cox, renowned space scientist Dr Maggie Aderin-Pocock and Nobel Prize winning biochemist Sir Tim Hunt.

Norway leads in POCT quality control

Professor Sverre Sandberg urges central laboratories to improve communication with POCT users

Report: Brigitte Dinkloh

Increasing demand for Point of Care Testing (POCT) devices leads to an increasing number of nurses and physicians working with unfamiliar equipment. Laboratory-quality test results are available in doctor's surgeries, out-patient clinics and hospital departments. However, how can a high and comparable quality standard for POCT be guaranteed?

In Norway that concern was addressed very early on. In 1992, the country introduced NOKLUS, a quality improvement scheme for laboratory services in primary healthcare. The government and medical association wanted to ensure that laboratory analyses outside hospital are ordered, carried out and interpreted in accordance with the patients' need for evaluation, treatment, and follow-up.

'The possibility of errors is generally bigger in the use of POCT instruments than in semi- or totally-automated analysers', explains Sverre Sandberg, professor in the Department of global public health and primary care at the University of Bergen and a director of NOKLUS. In his eyes, one of the main difficulties in very many countries is that the responsibility for POCT is not clearly defined: 'Who is responsible for the testing? Is it the laboratory, the general practitioner the clinical ward?'

Another difficulty in these settings is that members of the staff not accustomed with laboratory work are handling the POCT instruments and equipment. 'Inexperienced hospital or general practitioner's (GP) nurses and co-workers make mistakes more often, also because they think it isn't difficult. They think this is a small instrument and so it is easy to do it; they are often too self-confident and don't know about all the errors that could occur,' Professor Sandberg explains.

Various studies show the kind of errors that can occur, and it can also be shown that enrolment in an external quality assurance programme can improve quality. In Bergen University Hospital, for example, nurses are regularly trained in glucose measurement and must attend certain courses before they are accepted as operators of the instruments.

In addition, training is not only assured for hospital wards. Along with the provision of an external assurance quality programme for GPs, laboratory consultants are engaged all over the country to offer help to general practitioners surguries, in the form of visits and courses in laboratory work. Advice is also given concerning what point of care tests to have at the GP surgery and how to use and interpret the results.

Two decades ago, when the Norwegian government and Norwegian medical association launched this programme the quality was very low; errors in glucose samples, for example, were high, about 15% of participants showed a poor performance, where now the error quote is about 1%. Participation in NOKLUS isn voluntarily and 99% of GPs in Norway take part in the organisation. Noklus is also expanding to nursing homes, oil platforms, military installations etc.

Sverre Sandberg is director of the Norwegian quality improvement of primary care laboratories (NOKLUS) *(www.noklus.no and www.skup.nu)*, director of the Norwegian Porphyria Centre (NAPOS) *(www.napos.no)* and a professor at the University of Bergen. He is chair of the Scientific Committee of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and president of the European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM).

Thus, today, the country is seen to have introduced an 'extended' external assurance quality in a most excellent way because, compared to other countries, it also offers a laboratory consultancy that can help each GP's offices.

'In practice there should be an alliance between laboratory medicine and the GP, so that they can help the GPs in some way and handle the difficulties. It is important that the GPs and their employees should have someone to talk to anmd someone to get advice from. The laboratory should have the overall responsibility, at least for training the personnel who are doing the analysis and they also should ensure the quality of the instruments, that high quality instruments are used by the GPs. As a laboratory profession we should be more clear to give concrete advices on, for example, e.g. which instruments to buy ' Prof. Sandberg advises.

He underlines that laboratories should take greater responsibility for what is going on beyond the hospital and central laboratory. 'We have to move ourselves outside a little bit more. A lot of measurements are carried out in pharmacies, so we have also to go into this debate and take responsibility for all the testing that's going on, not only in the central laboratory.

'POCT is different from central lab testing, so we can't transfer the routines we do in a central laboratory, for example, internal quality control routines, into POCT because the world outside the central laboratory is different.'

Details: http://www.noklus.no

n medical laboratories

vant documents. These documents are downloaded by the user and must undergo the above stated process of authorising and distribution.

While the manufacturers part in the game is almost available, it's time to propose a manageable IT supported procedure to simplify the quality management (QM) manager's life in the lab. The most crucial part of process automation is the availability of a primary document ID that must be unique over system boundaries. Assuming a manufacturer will deliver this ID with the downloadable document, it will be easy for the lab to track further changes and updates of this document more easily – a local version of this document becomes obsolete and could be automatically replaced by the QM software. Furthermore, the software will initialise the authorisation and distribution processes and finally the archiving of the obsolete version.

Although so far the process will deliver significant benefit to the laboratory, it is still affected by manually conducted steps: the user has to display any new document to map its content to a position in the laboratory's document tree before importing it to the local system.

Consequently the next step for the manufacturer is to provide additional information on the document (document type e.g. a lot of information, affected analyser, test, lot-number etc.) in machine-readable form (metadata). After setting up a proper mapping the laboratory's QM software would be able to determine the correct position of any document in the document tree and the task of the user is limited to the decision regarding whether the document should be included in the local document collection.

This will finally deliver an improved and automated process for receiving new and relevant documents for the lab. As stated, existing but updated documents will be imported directly and start the local control process. Any new document will be presented to the lab staff, together with its desired position in the tree, that they can finally decide what to do with it. This decision will be added automatically to the audit trail.

As leading manufacturers have just taken note of this idea, it is time for the QM supplier to create the infrastructure to facilitate the QM work of a laboratory.

Following his analytical chemistry studies at Bochum University, Germany, under Professors William S Sheldrick and Gerhard Bergmann, **Dr Markus Neumann** gained his doctorate for work on nuclear resonance spectroscopy. He held various roles with well-known laboratory information systems (LIS) manufacturers before, in 2006, establishing Dr Neumann & Kindler Ltd. & Co. KG. with Heiko Kindler, the firm's Executive Director. Dr Neuman's focus is on quality management and IT-strategies in the medical laboratory.

Innovative concepts in the lab

Faster sample analysis for UK and EU hospitals

Run by Sheffield Teaching Hospitals NHS Trust, the new automated Medical Laboratory at the Northern General Hospital has drawn a previously fragmented service into a purpose-built centre.

With facilities for haematology, microbiology, clinical chemistry, immunology and virology testing, samples for analysis arrive via a vacuum pipe network running across the main hospital campus, or by courier from other district general hospitals or GP surgeries across the Yorkshire region and hospitals across the UK and Europe.

Lead contractor Roche provides the hospital with a comprehensive managed laboratory service package, which means that in addition to installing key components of the automated testing equipment, the firm oversees procurement of anything from agents to sample tubes as well as having a company representative onsite.

Left: Andrew Lumley and Jennifer Cooper, both BMS (haematology)

Right: Billy Hall BMS (clinical chemistry)

Medical laboratory directorate manager Peter Blair explained that the new centre and automated equipment can process more than 10 million tests a year with urgent A&E samples turned around in 40 minutes and results delivered electronically to the requesting clinicians, while GP results are available overnight.

He also added that the technology helps with tests for Norovirus where the automation and rapid turnaround means a suspected outbreak can be confirmed or ruled out more quickly, as well as faster identification of MRSA and clostridium difficile.

Automation and IT connectivity play a major role in Roche's product development and solution offering, according to Roland Diggelmann

In addition to blood sample analysis, tests are conducted on wound swabs, urines and STD screens, and the centre offers a high security sealed environment for samples that may be, e.g. TB or swine flu.

'The automation means we've been able to deploy the more highly qualified staff to where they are needed and expand the range of services we offer,' said virology department manager Duncan Whittaker. The installation has seen Roche provide the automated track system at the Northern General Hospital campus, which sees samples loaded onto the Roche pre-analytics module for decapping, centrifugation and aliquoting. The system features three high volume cobas 8000 for chemistry immunology and serology testing along with the cobas p 701 Post Analytic Unit for recapping, storage of up to 32,000 samples and retrieval of samples for further investigation.

Roche has also installed systems for cardiac, heart failure and bone disease testing.

The managed laboratory service sees all Roche and third party equipment managed and maintained by Roche along with consolidation of purchasing, supply, stock management and procurement, covering more than 120 suppliers. 'This approach of managing a complete lab is rather unique to the UK market and its specific parameters,' explained Roland Diggelmann, Chief Operating Officer at Roche Diagnostics. 'We help reduce the overall operating costs of running a lab, and provide maintenance and service as a one-stop shop.'

Roche Diagnostics Ltd managing director Christopher Parker added that Roche is responsible for managing all supplies, 'everything from glass slides to reagents for the various instruments in the laboratory' and the firm also has a person in situ to tend the equipment.

Left: At the opening ceremony, from left: Tony Peddar, Chairman of Sheffield Teaching Hospitals NHS Foundation Trust, Sir Andrew Cash, Peter Blair and Branko Perunovic, clinical director of laboratory medicine

Right: Hannah Breen, trainee biomedical scientist in microbiology

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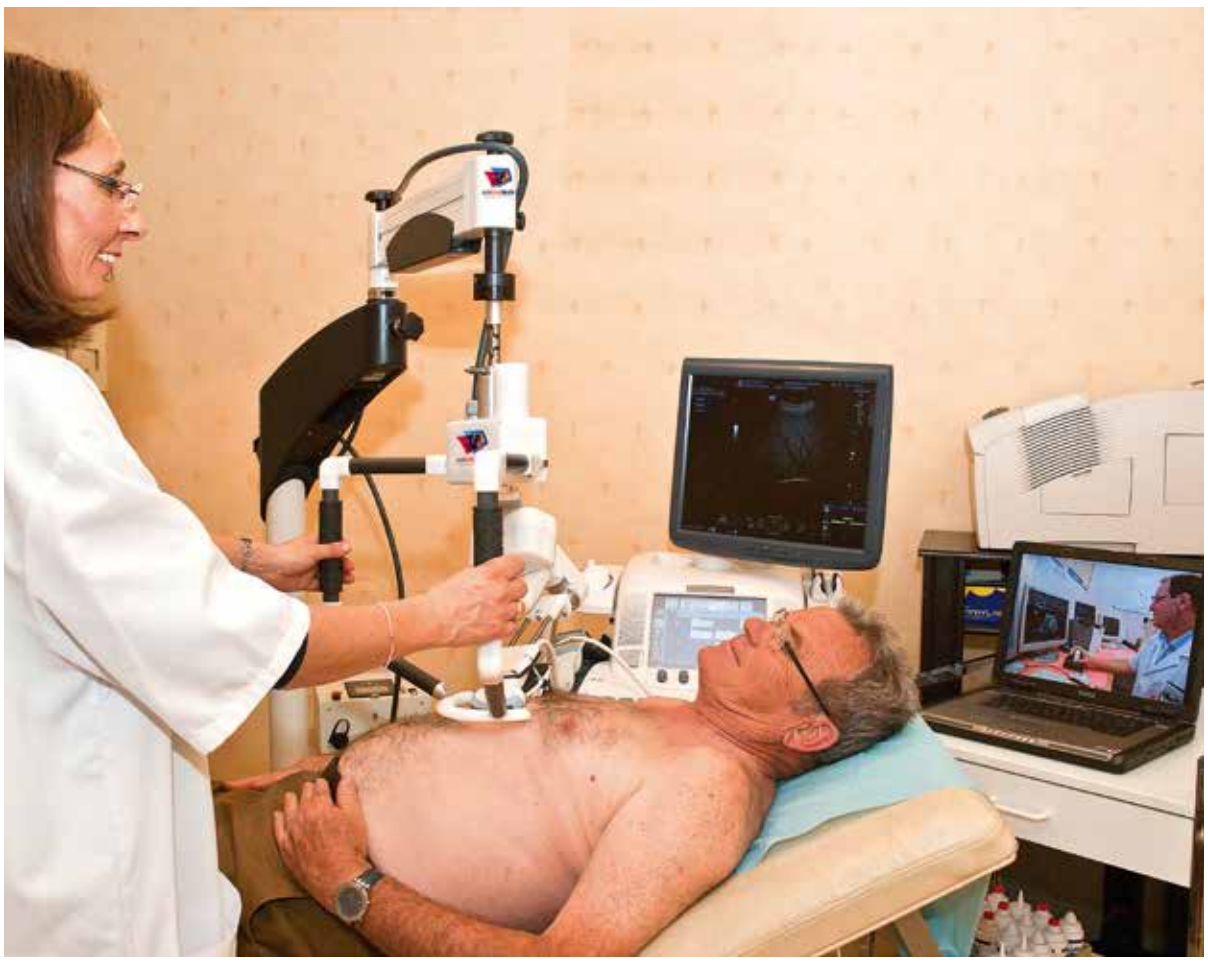
Space: US exams come down to earth

Remote US examinations is not science-fiction; they are now available for real-time diagnostics, *John Brosky reports*



Dr Lefebvre views an ultrasound exam in real-time and is simultaneously connected by video conferencing with the operator at the secondary centre

The first hospital on Mars will be equipped with ultrasound. But the radiologist will be earth-bound, conducting the exam by using a robotic arm to move the ultrasound probe.

CT or MRI scanners are far to heavy to be launched into space, so medical imaging of astronauts and cosmonauts, whether orbiting the Earth in the International Space Station or exploring distant planets, will necessarily be performed using a lighter and far more portable ultrasound system.

The results of such exams are famously operator-dependent, so rather than sending radiologists into space, the European Space Agency (ESA) and the French National Centre for Space Studies have helped to fund the development of a robotically-controlled exam operated by an ultrasound imaging expert.

This is not science fiction. The Melody robotic tele-echography system received a CE mark in January 2013. In May, Melody captured the Innovation Trophy 2013 at the combined congresses for Health Information Technology and Hospital Expo in Paris.

Developed by AdEchoTech from Huisseau en Beauce, France, the company has down-to-earth commercial plans for the technology, offering the system to hospital imaging centres for patient examinations in remote facilities. Thus the system responds to the unmet medical need of patients in rural areas lacking expert diagnostic, and one can imagine other applications, such as for workers on oil drilling platforms in the North Sea, or guests on a cruise ship. So far the Melody remote diagnostic system has been used on hundreds of patients in France, Cyprus and Guyana.

The Melody technology is based on the pioneering research of Professor Philippe Arbeille MD, from the Trousseau Hospital, part of the University Hospital Centre-Tours (CHU-Tours), where he is the director for nuclear medicine and ultrasound.

Over 15 years, Prof. Arbeille worked on projects encouraged by, and at times financed by, ESA. He also was the physician who, for 520 days, followed the six astronauts in the Mars 500 programme to test endurance in space, capturing and analysing effects on the cardiovascular system of confinement and simulated space flight.

Eric Lefebvre MD, a colleague from CHU-Tours, who believes 'the potential is colossal and we expect to sell thousands of systems', founded the company in 2008. Using the Melody Patient system, a trained operator at the patient's side in a remote centre places a frame over the anatomy of interest to the expert physician and applies gel to the targeted zone. The robotic arm can accept any ultrasound probe and plug into any ultrasound platform for the exam, according to Nicolas Lefebvre, business manager of AdEchoTech and son of Dr Lefebvre.

Connected by high-speed landline or satellite transmission, the Melody Expert system at a remote medical centre controls the movement of the probe.

The expert, who is simultaneously connected by video conferencing with the operator at the secondary centre, views the ultrasound exam in real-time.

One megabyte per second for both uploading and downloading is sufficient capacity for the transmission of the exam as well as for the video conferencing, according to the business manager.

Among the 400 monitored exams 15% were considered inconclusive due to an incomplete view of the targeted organ. Neither false positives nor false negatives have been reported among the completed exams.

A strong selling point for Melody is that the technology's price is quickly offset by not needing to transport fragile patients during an emergency.

Initial interest has come from developing countries, with vast regions to cover with medical services and a pronounced lack of expertise, such as hospitals in Cyprus and Guyana that have purchased the Melody system.

Another selling point for Melody, according to Lefebvre the younger, is the real-time assessment of an ultrasound exam by the expert who performed the exam.

Whereas in teleradiology an expert reader can remotely assist in diagnosis by assessing the images from MRI or CT scanners, the quality of an ultrasound examination is highly operator-dependent. In other words, the physician must move the probe to know what is being seen.

'Our goal is not to replace ultrasound experts with remote readers, which is sometimes the case in teleradiology,' he said. 'The goal is to make available ultrasound diagnosis for centres and facilities that do not have a 24/7 coverage or have no experts at all.'

The company is currently working with the Telemedicine Centre Aachen (Germany) to create an Advanced Robotic Tele-echography Integrated Service to provide a connecting centre for a satellite based tele-consulting network providing 24/7 support for diagnostic problems or challenging therapeutic decisions.

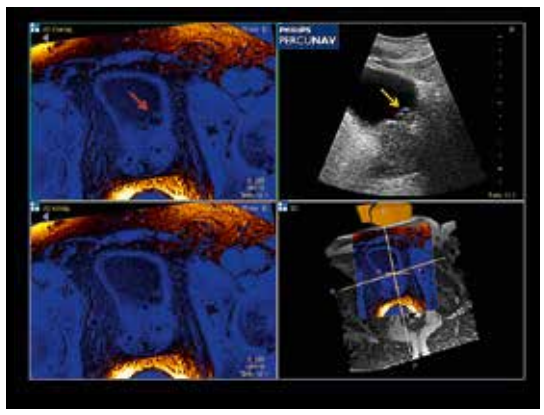
Meanwhile, AdEchoTech is continuing development of next-generation systems, including research that will ultimately support the ESA goal of equipping a hospital on Mars.

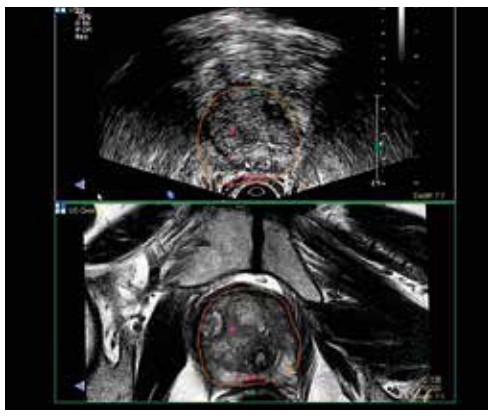
Specialising in ultrasound for more than 25 years, **Eric Lefebvre MD** estimates he has performed almost 200,000 examinations in nearly every practice area at the University Hospital Centre in Tours, France.
The author of four reference books and 15 articles in the field, he is a recognised expert in echography, participating regularly as a speaker at international congresses. In 2008 he founded AdEchoTech to apply the technology developed for robotic-assisted exams to advance the potential for remote diagnoses using the Melody robot.

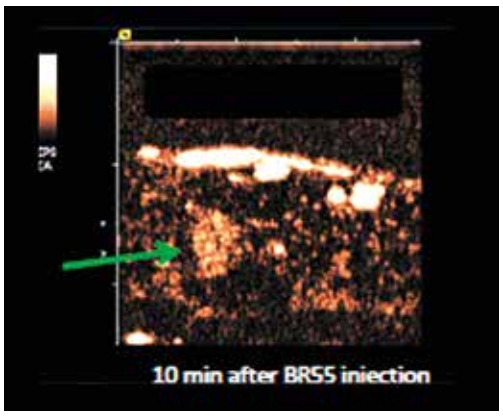
Contrast-enhanced transrectal ultrasound and MRI

A clever(t) fusion for prostate diagnosis

Statistically speaking every fourth older German man suffers from prostate cancer with the mortality rate being 60,000 patients annually. So what's more obvious than trying to improve diagnostics by combining the different modalities, asks Dr Dirk-André Clevert, ultrasound expert and Director of the Interdisciplinary Centre at the Institute of Clinical Radiology, Munich University Hospital.







1: Trans-abdominal image fusion of the prostate and bladder with bladder carcinoma visualised with MRI (red arrow) and the conventional b-mode image (yellow arrow)
2: Transrectal image fusion of the prostate combining high-resolution b-mode image and MRI
3: The Dunning tumour in rats is the standard model for the study of prostate carcinoma in humans. After application of the target-specific VEGF-2 receptor contrast agent, the late phase shows increased enhancement (green arrow) in the tumour compared with the surrounding tissue (Source: Bracco Research S.A., Geneva)

In his opinion the combination of contrast-enhanced transrectal ultrasound and MRI offers many advantages. Nevertheless, he adds, there is room for improvement in image fusion and he urges industry to take up the challenge. There is always a certain risk that a prostate tumour remains undetected since certain areas of the gland are very difficult to image. MRI and ultrasound, the most frequently used imaging methods, have advantages as well as drawbacks. However, using the strengths of both technologies, Dr Dirk-André Clevert emphasises, can spell progress: 'The advantages of contrast-enhanced ultrasound or even elastography pair excellently with high-resolution MRI.'

So far, the good news; now comes the bad. There are not enough suitable high-resolution transrectal transducers that can be used for image fusion. Moreover, medical imaging lacks target-specific contrast agents, i.e. micro-bubbles. These agents, which are currently under clinical development, dock only onto VEGF-2 receptors that are overexpressed in tumour vessels, such as prostate carcinoma. The target-specific contrast medium attaches via the receptors on the vessel walls where its characteristic luminescence makes it easily visible.

The receptors, as such, are not tumour-specific but, due to increased angiogenesis, the high receptor density in the tumour makes the diagnosis with micro-bubbles unambiguous. 'It's like flicking the light switch and suddenly some corners are illuminated,' Dr Clevert explains. The method allows detection of several lesions in one go. Not surprisingly these advantages help with a decision immensely. 'Most men who are given the choice between having a contrast medium injected and a prostate biopsy,' he points out, 'will opt for the contrast medium. Obviously a biopsy is required if the contrast-enhanced ultrasound yields a positive finding. Nevertheless, we can avoid a very unpleasant exam for many patients.'

Private docent **Dr Dirk-André Clevert** began his medical career at the MRT-Diagnostik-Institut Westend in Berlin and the Department for Internal Medicine at Waldkrankenhaus Gransee. After a three-year residency in the Radiology Department at Passau Hospital, in 2003 the Berliner moved to Munich, heading the Interdisciplinary Ultrasound Centre – the focal point of all ultrasound activities in Munich University Hospital in Grosshadern – since the centre's opening in 2004. Dr Clevert has designed, organised and taught many national and international ultrasound training courses. He is also Vice President of the European Society for Clinical Haemorheology and Microcirculation.

There is indeed hope that current studies will show that fusion imaging can entirely avoid false-positive findings, which would mean near-100-percent diagnostic accuracy.

Several renowned manufacturers are exploring the market and have launched products; Bracco's research lab in Geneva, for example, is at work on micro-bubbles. 'As far as I'm concerned,' Dr Clevert concludes, 'optimising prostate cancer diagnostics is a useful and overdue objective because particularly this organ has remained a major challenge,'

* Based on an article in 'RöKo HEUTE 2013', the official publication of the German Radiology Congress

Click and learn ultrasound

Self-guided study of more than 6,000 ultrasound exams are at your fingertips thanks to an eight-year voluntary effort by a Dutch radiologist and technical support provided by Hitachi-Aloka.

Report: John Brosky

Taco Geertsma likes to get down to cases. After finishing his regular work at the Gelderse Vallei Hospital in the Netherlands, this self-described ultrasound enthusiast turns to building new teaching files to post on the website he created at *www.ultrasoundcases.info*. 'More and more ultrasound examinations are being performed by a broad range of people, radiographers, for example, or general practitioners and physiotherapists, almost everyone but radiologists. A problem this creates is on-going education, which is the reason I started the website,' he explained, noting that clinicians and care givers can turn to books to complement their training, but the space for illustrations in books is limited and 'not everyone involved in ultrasound has access to the latest books, while many of them have access to the internet'.

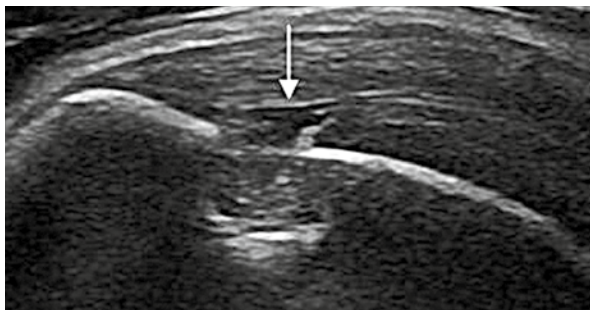
Marking his 30th anniversary as a radiologist, **Taco Geertsma MD** heads the ultrasound department at Gelderse Vallei Hospital in the city of Ede, in the Netherlands. A specialist in this practice since 2000, he is an internationally recognised authority on ultrasound, a regular speaker at conferences, and passionately dedicated to continuing education.

Dr Geertsma started the website in 2004, following a series of teaching courses in Eastern Europe that he conducted for the Aloka company. 'After each course I would get a lot of requests to see the images again,' he said. 'I could provide the presentation, of course, but this was only a part of a much larger database I had collected over the years.'

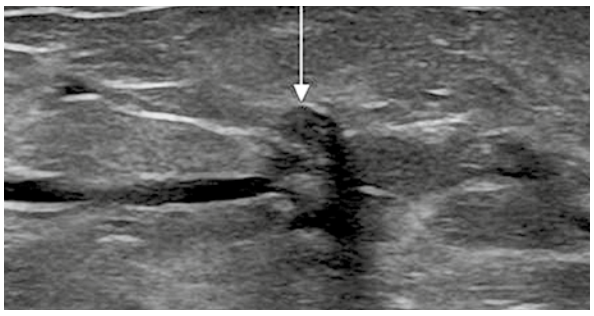
Providing access over the internet was the obvious answer.

'I have no idea of how to build websites,' he said, especially one that could quickly display the high-quality images from more than 2,500 cases he had collected to that point.

Impressed with the material and his dedicated effort, Aloka decided to build a website to support what it saw as an independent resource for continuing education in ultrasound. After a year of work integrating the collection, the site was launched in 2005.



Shoulder image: Small articular sided partial supraspinatus tendon rupture with cortical irregularity



Breast image: Small infiltrating ductal carcinoma with extension within and outside a mammary duct

Today, visitors can browse more than 40,000 images supporting 6,000 cases, as well as video clips of MRI or CT sequences to provide complementary views of the same pathology from a different modality.

Where possible cases are correlated with clinical information, endoscopy results, surgical findings and pathological reports.

When Hitachi-Aloka was created in 2011, the technical support for the website continued, as well as the complete independence for Dr Geertsma to manage the site as he thinks best for educating a new generation of ultrasound operators.

At a time when we are seeing an increasing specialisation in ultrasound exams, the straightforward website at www.ultrasoundcases.info becomes a rich resource for self-guided learning.

While modestly described as 'an overview of the various ultrasound presentations of common pathology, as seen in a general Dutch hospital', there is an abundance of material available on the site instructive for examinations across a range of pathologies. For example, Dr Geertsma offers a deep database of cases from his specialised studies in paediatrics and a surprising richness in studies he led for developmental dysplasia of the hip in neonates.

The Gelderse Vallei Hospital has also earned a reputation for musculoskeletal imaging and contributions by the radiology group enrich the website with sections dedicated to joints and tendons, and then bone, muscle, nerves and other soft tissues. Other sections include cases for abdomen and retroperitoneum, urinary tract and male reproductive system, gynaecology, head and neck, breast imaging, thorax, and peripheral vessels. 'The whole choice of content is up to me,' he explained, adding that whilst Hitachi-Aloka hosts the site on its servers and provides technical support, the company does not influence the cases selected nor special features applied for examinations.

The integration of Aloka with Hitachi has been welcome because he continues to work with the same people, and there are greater possibilities in working with a larger company.

An upcoming challenge for the website is Dr Geertsma's retirement in a few years. Several ideas are being considered, including cooperation with a professional society and expanding the inclusion of other modalities.

Right away, management of the site by a larger group would mean establishing a committee with rules and requirements for posting cases, he said, adding that his personal choice would be to hand over the work to a younger radiologist equally enthusiastic about ultrasound.

The first wireless ultrasound transducer

This spring, when Siemens Healthcare launched the world's first wireless ultrasound transducer, the Erlangen-based company ushered in a development that might make mobile scanning in, say, 20 years' time, as commonly used as mobile phones are today. For now, this wireless transducer is compatible with the Acuson Freestyle, bringing to the system more freedom and – almost more importantly – enabling sterile procedures, thus significantly lowering infection risks.

Peter Hildebrandt, Director for Ultrasound in the General Imaging Segment EMEA at Siemens Healthcare

Something already used in taking X-rays also will be possible soon for ultrasound, thanks to mobile detectors – wireless transmission of image data to the system console. Siemens has developed a new technology specifically to transmit large data volume from the transducer to the system. 'The ultra-wideband (UWB) is 75 times faster than Bluetooth,' explains Peter Hildebrandt, Director for Ultrasound in the General Imaging Segment EMEA at Siemens Healthcare. 'It works at a frequency of eight gigahertz and can transmit 20 frames per second and even higher picture rates. By comparison, the fastest consumer smartphone currently works with four gigahertz. The new UWB can therefore transmit twice as much data – the higher the frequency, the higher the data transmission rate. Communication between the transducer and the system works via antennae. A user interface allows remote control of the system via the transducer. In a similar way to an iPad, several menus can be selected to adjust depth and brightness. The examiner has an ergonomic advantage as they do not have to trail a cable and there is less strain on the arm muscles during longer scans.'

However, for him, the sterile environment is even more important 'Be it in anaesthesiology, interventional radiology, emergency medicine or intensive care, procedures often have to be carried out close to cuts and orifices under ultrasound guidance, and all these procedures must clearly be sterile.' Sterilising a transducer and cable had been complex, error-prone and time-consuming. 'Now you can drop the transducer into a bag, seal it and start scanning,' he explained.

The advantages are considerable. Almost all ICU patients today are catheterised and catheter-related infection costs an additional €40,000 per patient. A non-sterile transducer poses a big risk, which can be eliminated when using the new wireless transducers. Not only can they be placed in disinfectant or sterilised with gas, they make it possible for each doctor and, in theory, even each patient to have their own transducer. 'The system console is installed in the ICU, the doctor goes to the patient, presses two buttons to connect transducer and the system and can scan immediately. This is certainly a concept with a future,' explains Hildebrandt.

Whether or not it establishes itself will, as always, also depend on the price, with the wireless transducers for the Acuson Freestyle unlikely to be considerably above the usual budget. Three different transducers are currently available: a low-frequency linear model for deeper regions, a high-frequency linear version with good resolution for superficial structures and a curved array model for the abdominal area.

Ultrasound of the fatty liver

Of echoes, triangles and quadrants

Medicine is not immune to prejudices. In the past, the 'fatty liver' diagnosis was often accompanied by the hasty conclusion that the problem was surely caused by alcohol abuse. Today, non-alcoholic fatty liver disease, or non-alcoholic steatohepatitis (NASH), receives increasing attention. It is, inter alia, associated with diabetes, detrimental eating habits, adverse reactions to medication or problems in the fat metabolism. About fifty percent of the patients of Professor Günter Layer, Director of the Central Institute of Diagnostic and Interventional Radiology at Ludwigshafen Hospital, Germany, show liver fat changes. Prof. Layer knows how to detect them and how to avoid the diagnostic pitfalls.

Whilst fatty liver is quite common, in Professor Layer's experience it is mostly an incidental finding. Since the centre he heads at Ludwigshafen Hospital focuses on oncology, fatty liver disease is often diagnosed during tumour restaging. 'Thus we see in many cases the disease is an adverse effect of cancer medication. Today, we are aware that cancer patients are at risk to develop diffuse liver parenchyma diseases, primarily steatohepatitis,' he explains.

Nevertheless, with regard to metabolic syndrome, an increasing problem in the Western world, poor eating habits, lack of physical exercise and resulting overweight remain the most important risk factors. As steatohepatitis may lead to liver cirrhosis, the professor expects the introduction of targeted screening for non-alcoholic steatohepatitis sooner or later.

Such a screening is possible due to the widespread use of ultrasound. However, as a primary diagnostic tool, ultrasound yields very inconsistent results. Study conditions play a major role, Prof. Layer points out. In obese patients sensitivity and specificity of ultrasound decreases by fifty percent while in normal-weight patients accuracy is somewhere between 80 and 90 percent, which is pretty close to the current gold standard – biopsy.

A typical feature of the fatty liver is increased echogenicity. However, dense subcutaneous fatty tissue, which attenuates penetration of the ultrasound beam, make an accurate diagnosis much more difficult.

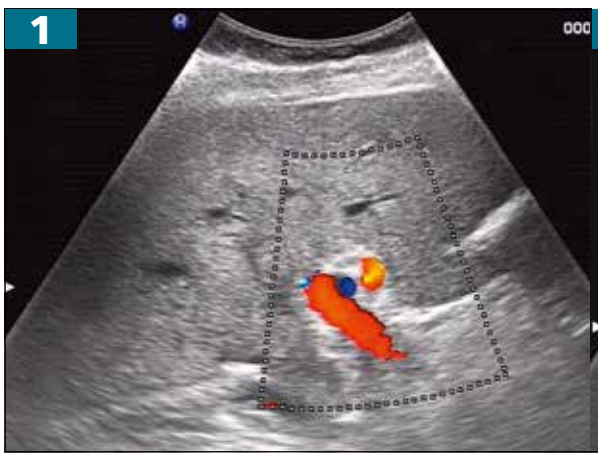
MRI is a second imaging method to confirm or rule out fatty liver. 'While liver MRI does provide precise quantitative data, in most radiology offices or clinics this procedure is not part of the standard study portfolio,' Prof. Layer explains, adding that MRI 'requires special fat quantification techniques, be it special sequences or spectroscopy, which are being offered by very few facilities.'

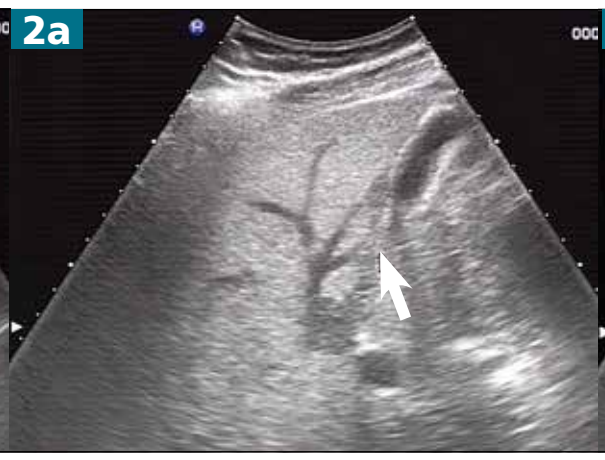
In ultrasound, operator experience can highly impact on the evaluation of fatty liver or liver fibrosis because these diffuse tissue changes are much more difficult to delineate and quantify than focal liver lesions such as tumours or metastases. 'Moreover, the fatty regions can be distributed very unevenly throughout the liver, which increases the risk of mistaking fat for tumours or vice versa. Therefore,' he advises, 'it's important to be familiar with the typical distribution patterns of steatoses and non-steatotic conditions.'

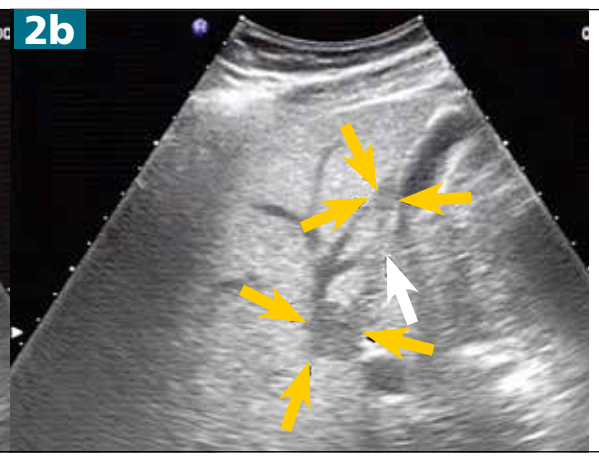
Focal low-grade fat accumulations that define liver steatosis frequently present as triangular changes near the gall bladder and as square-shaped changes in liver segment IV near the falciform ligament. The different degrees of fatty degeneration are believed to be caused by local changes in organ blood supply. How much experience precisely does a sonographer need to be sufficiently confident in diagnosing fatty liver? Professor Layer: 'Speaking from my own experience I'd say that you need to perform such abdominal exams several times a day for about a year to gather enough experience and be really confident.'

Based on an article in RöKo HEUTE 2013, the official publication of the German Radiology Congress

Following medical studies at the universities of Heidelberg and Zurich, **Professor Günter Layer** trained as a radiologist in Professor van Kaick's team at the German Cancer Research Centre and as assistant to Professor Reiser in Bonn. Since 2001 he has directed the Central Institute for Diagnostic and Interventional Radiology at Klinikum Ludwigshafen. The professor is, inter alia, a Member of the Board of the German Roentgen Society (DRG) and founder as well as current head of the Chefarztforum at DRG. His work focuses on abdominal diagnostics and oncological diagnostics and therapy.







1: Slightly inhomogeneous fatty liver in a patient with diabetes mellitus: Clear hyperechogenicity of the liver parenchyma; diagnosis is not affected by obesity

2a/2b: Fatty liver with two regions of delineated non-steatosis: triangular region near the gallbladder fundus, square-shaped region in liver segment IV

Exploring how the human brain operates

rfMRI reveals mind moving matter

Report: Michael Krassnitzer

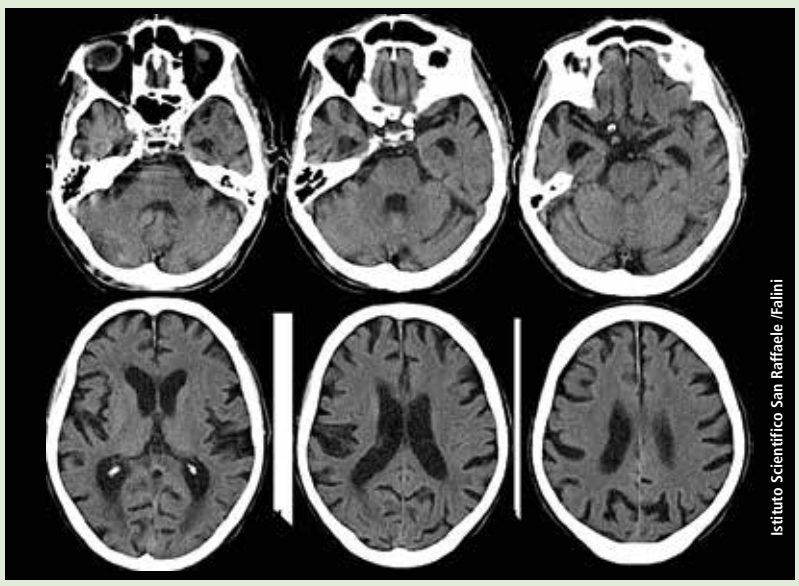
'We finally have tools to non-invasively study the human brain in normal subjects and diseased patients,' says Professor Stefan Sunaert, Head of Translational MRI at the Department of Imaging & Pathology, Leuven University Hospital (Belgium). The technology that enables us to perform such ground-breaking studies is functional magnetic resonance imaging (fMRI) or, more precisely, resting fMRI (rfMRI), the most recent further development of fMRI that visualises brain function.

rfMRI can show and quantify the brain regions involved in a certain process. 'But how the brain works exactly is something we still need to discover and learn in order to understand disease,' points out Prof. Sunaert, who chaired the New Horizons Session *Imaging of the mind at ECR 2013*.

Resting brain activity is identified by visually examining changes in brain perfusion. The MRI procedure uses the different degrees of magnetisation of oxygen-poor venous and oxygen-rich arterial blood to create a blood oxygen level dependent signal (BOLD). Based on this signal, brain activity can be visualised and displayed in a colour code. Every activity of the brain is associated with a BOLD signal. Thus, the functional organisation of a brain and its changes caused by disease can be examined. Unfortunately, the signal is buried under 'noise'. 'It took us a long time to prove that the noise is not only artefacts but that it covers the BOLD signal, which indeed correlates to certain brain activities,' Prof. Sunaert explains.

The research on resting-state functional connectivity unearthed a number of networks, of patterns of synchronous brain activities: the executive control component, sensory/motor component, auditory component, up to three different visual components, two lateralised frontal/parietal components and the temporal/parietal component. The elements of these networks are located in different brain regions and, in a healthy person, these are always simultaneously active.

A network that is already particularly well understood is the default mode network (DMN), a web of brain regions that becomes active when a person is awake but in a state of calm. It is activated by reflection, remembering or daydreaming and it correlates negatively with other networks involved in the visual perception of the outside world. The DMN activity changes over time. 'With age, the network connectivity decreases. And that is also what happens in Alzheimer's disease,' explains Professor Andrea Falini, Head of Neuroradiology at the Istituto Scientifico San Raffaele in Segrate near Milan. Falini's research focuses inter alia on the differences between natural ageing processes and the development of Alzheimer's – which all occur in the DMN – aiming for early diagnosis of Alzheimer's. 'Early diagnosis is mandatory for new therapeutic strategies,' the Italian neuroradiologist stresses.



Some neuroradiologists are apprehensive about possible abuses of rfMRI; for example, ECR chairman Prof. Sunaert mentioned several applications he finds personally very disconcerting: In one fMRI-based study the neural responses of children in connection with markers were examined. Results confirmed that food logos activate some brain regions in children known to be associated with motivation.

Professor Sunaert also pointed out that a US company claims to be able to use BOLD signals to tell lies from truth, a modern version of the lie detector. 'That's really scary,' the professor said, shuddering. 'Would you undergo an fMRI exam if the technology were able to identify lies or erotic thoughts?' he asked the audience. Not one participant raised a hand.

Looking good: Automated breast ultrasound technology

Breast imaging

Report: Cynthia E Keen

Over the decades of breast imaging numerous studies have shown that radiation free and inexpensive ultrasound can detect some subtle cancers not visible on a mammography exam. However, its use is time-consuming and skill- and operator-dependent – and for the latter reason, it is not easily reproducible.

Automated breast volume ultrasound systems are changing this, being less time-consuming and easily reproducible because they are independent of individual operators. They are designed to improve the conspicuity of cancers. This can result in better diagnosis and fewer false positives.

Automated breast ultrasound technology adoption has been stimulated by numerous studies proving that the use of ultrasound following mammography in dense breast women finds an average of four additional early stage breast cancers per 1,000 women than mammography alone. In the USA its adoption is surging in states whose governments legislate the reporting of breast density notification laws.

The SonoCiné Whole Breast Ultrasound System was the first product to receive 510-(k) clearance from the US Food and Drug Administration in 2008, for its use as an adjunct examination following mammography screening. Subsequently it received Health Canada Class 2 clearance and CE Mark approval.

In March 2010, Siemens Healthcare became the first company to receive CE Mark approval for an automated 3-D breast volume ultrasound scanner. (ABVS). A very early user, radiologist Dr Frank Stöblen, at the Diavero Diagnostic Centre in Essen, Germany, stated: 'this technology will play a major role in early detection'.

The automatically acquired, 3D volume images of the new breast scanner provide physicians with data about the entire breast. A typical examination takes less than 15 minutes, a considerably shorter period than when performing a manual ultrasound exam of the breast. The system acquires a coronal view, previously not available with conventional ultrasound systems. Coronal display of breast volume images provides an even better overview of the anatomy and architecture of breast tissue than earlier techniques. The 3-D images can now display the coronal view – from the nipple to the breast wall – in slices.

Additional to automated functions, the Acuson S2000 ABVS allows for all types of manually performed, conventional ultrasound examinations, e.g. biopsies and colour Doppler acquisitions, and elastography imaging with the Siemens eSieTouch. Last year, the firm introduced syngo ultrasound breast analysis software with image processing and reporting tools designed to enhance breast ultrasound quality and workflow. In addition to the S2000 ABVS, this is used with the Acuson S2000 ultrasound system.

In April 2012, U-Systems of Sunnyvale, CA, received pre-market FDA approval of its somo.v.ABUS Insight system and 510-k clearance in September. It also received the CE Mark and Canadian approval, according to GE Healthcare, which purchased the company in November 2012. The ABUS system is intended for use in dense breasts cases with negative X-ray mammography results and now previous invasive procedures.

When a somoVIEWer Advanced 3-D workstation is utilised for interpretation, 3-D volumes are displayed in a patented, two millimetre (mm) thin coronal view slice from skin to chest wall using proprietary pattern recognition software. According to U-Systems, experienced physicians can review a 3-D image set within three minutes or less.

One major drawback with automated 3-D ultrasound system is the time-consuming nature of reading images. Researchers from the Diagnostic Imaging Analysis Group in the radiology department at Radboud Nijmegen Medical Centre, in the Netherlands, are developing a computer-aided detection (CAD) system to identify suspicious lesions in automated 3-D breast ultrasound images. The prototype is being tested using images acquired from both the Siemens and U-Systems products.

'Reading ABUS screening exams is more time-consuming than reading mammograms. A CAD system may help minimise the workload impact that increased use of this modality will cause,' said biomedical engineer Tao Tan, a PhD candidate in the Diagnostic Imaging Analysis Group. Tan is part of the university team that participated in the Highly Accurate Breast Cancer Diagnosis (HAMAN) project on the automated detection of breast cancer in 3-D ultrasound.

The HAMAN project was coordinated by the European Institute for Biomedical Imaging Research (EIBIR) and, at the university, led by Dr Nico Karssemijer, professor of computer-aided diagnosis, who also headed the research of computer-assisted diagnosis software for mammography exams that commercialised as Image Checker from R2 Technology. This was the first successful mammo-CAD product, now sold with many later software version improvements by Hologic.

The ABUS-CAD software, said Tan, is still very much a work-in-progress, but the researchers hope that someday it will be used worldwide in conjunction with automated breast ultrasound systems. Forty to fifty percent of women have dense breasts. This tool might more easily and efficiently identify breast cancers that cannot be seen on even the best digital mammography images.

Multiple sclerosis

CNS damages are more complex than believed

Report: Michael Krassnitzer

Multiple sclerosis (MS) – the inflammatory condition in the central nervous system (CNS) – leads to scarring, with several scars forming lesions, also called plaques. Although long assumed that only white matter is involved, this is increasingly questioned.

'Today, it seems clear that multiple sclerosis is a diffuse disease of the CNS causing damages that are far more complex than previously thought,' explains Professor Majda M Thurnher of the Clinical Department of Neuroradiology and Musculoskeletal Radiology at Vienna Medical University, speaking during a session on recent developments in MS research at the European Congress of Radiology (ECR 2013) in Vienna in March.

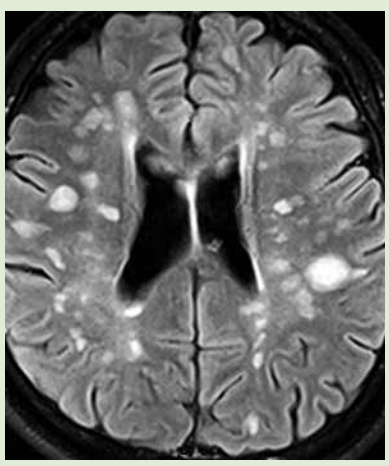
Magnetic resonance imaging (MRI) systems with higher fields, such as 3-Tesla or more, can detect relapse-caused lesions in grey matter. Particularly difficult to discover are juxta-cortical plaques, meaning those lying in-between white and grey matter. However, plaques can also form in the spinal cord as Prof. Thurnher explains: 'Studies indicate that ninety percent of all MS patients show focal lesions in the spinal cord and that in thirty percent of MS patients the lesions are exclusively to be found in the spine.' Spinal plaques are important because they allow an unambiguous diagnosis of the diseases.

'Five to ten percent of patients below 50 years old show lesions in the white matter,' explained Dr Frederik Barkhof, Professor of Neuroradiology at the Vrije University Medical Centre in Amsterdam (Netherlands). Those lesions, however, are caused by other pathologies, namely ischaemia associated with diabetes, hypertension or simply aging processes. They are restricted to the white matter and do not appear in the spinal cord. 'If it is unclear whether a lesion in the brain is MS-related or ischaemia-related, take a look at the spinal cord,' he advises. He believes a 3-T system is well suited and recommends T-2 weighted and proton-density weighted protocols.

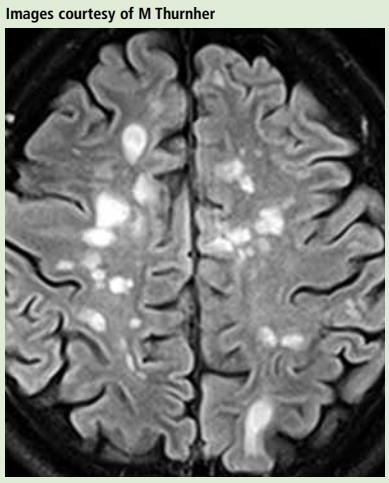
MRI is a crucial modality not only in the initial MS diagnosis but also for therapy monitoring purposes. 'New therapies particularly need to be closely monitored,' he says. Case in point: Natalizumab is a drug that can significantly reduce inflammatory processes, lower the number of attacks and slow the disease. Unfortunately, 242 of the 96,000 patients who received natalizumab developed progressive multifocal leukoencephalopathy (PML), a potentially fatal viral infection that often occurs in immunosuppressed patients.

Eighty percent of all adults carry the JC virus, which the immune system usually keeps under control. While the clinical presentation of PML and an MS relapse are very similar, 'MRI can distinguish PML lesions from focal MS lesions, which means PML can be diagnosed early,' the neuro-radiologist explains.

MRI also allows earlier diagnosis of MS itself. 'MRI shows the dissemination of the lesions in the brain and the spinal cord in time and space,' the professor points out. In 2010, the so-called McDonald criteria to diagnose MS were revised and today the dissemination in time can be shown with a single scan he reports, adding: 'This facilitates the diagnosis of MS.'



Images courtesy of M Thurnher



A new era of patient care

Paramount to reduced costs and a shortage of skilled professionals, improved quality of care and patient satisfaction are the leading priorities in healthcare today. In the US, e.g., this is reflected by new pay-for-performance measures that tie hospital reimbursement to patient satisfaction. Additionally, with about 1 in 4 people talking about their health experiences on social media, healthcare providers want potential patients to perceive them in a positive way.

With this increased focus on patients, providers need to step up their game. Perceived quality delivered is pivotal, therefore satisfying patient needs comes first. Interactive technologies can play a key role in service differentiation, bringing a host of services to the patient's fingertips.

Interactive patient care: the new drug

Interactive services include high-quality entertainment and communication options –including TV, radio, movies on demand, games, Internet, telephony, and chat – which have become commonplace at our homes. Now, these services are available at the bedside – through leading-edge technology and intuitive software interfaces.

With the emergence of these interactive tools, we've entered a new era of patient care. Interactive care not only provides patients with high-level communication and entertainment options at the bedside, it also allows them to play a more active role in the care process. Healthcare providers believe that facilitating patient participation – through education and feedback options – significantly improves quality of care and helps position themselves for success.

Tools providing educational videos on health-related topics, pain management, and medication help increase patient understanding. With high health literacy linked to lower rates of hospitalization, interactive patient education has proven to improve outcomes. Healthy patients are happy patients.

Patient needs under scrutiny

At the same time, interactive care includes extensive feedback tools, allowing providers to continuously capture and monitor patients' needs. Offering a deeper understanding of how patients perceive the care they receive and allowing providers to act upon results in real time, interactive patient care supports service improvements while further increasing patient satisfaction.

Gaining a competitive edge

There's a growing awareness that the benefits of high patient satisfaction also translate into economic gains, making providers go the extra mile to cater to their patients' needs. Initiatives to measure patient satisfaction are being implemented in hospitals worldwide.

In the US, the HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey provides a standardized methodology for measuring patients' perspectives on hospital care. These scores directly impact reimbursements from insurers and give providers a competitive edge.

Beyond doubt, patient satisfaction has become a measurable and focused target for healthcare organizations today. Interactive patient care supports the goals of personalizing the patient experience while enhancing quality of care. It even allows seamless collaboration with all hospital applications for a patient-centric workflow. More on this in our next issue.

Michael Reiter

Breast tomosynthesis helps a small radiology centre to compete and grow

Dr Martínez Miravete didn't set out to change breast imaging in Spain when she first adopted breast tomosynthesis. The sole radiologist at a small diagnostic imaging centre in Zaragoza, Spain, was looking for new imaging technologies that would help find breast cancer earlier, when it was more treatable, and save women the anxiety of unnecessary recalls.

'I'm the only radiologist in my practice and I began questioning my ability to make good diagnoses based on the analogue mammography images I was reading. I decided I needed a new technology to give me more confidence in my diagnoses,' Dr Miravete explained. The first time she saw tomosynthesis in practice, Dr Miravete knew this was the answer. In 2011, she installed the Hologic Selenia Dimensions breast tomosynthesis system, becoming just the second radiologist in Spain to adopt the technology.

Dr Martínez Miravete credits tomosynthesis with helping her make more accurate diagnoses.

'We don't have a technique that can diagnose 100% of breast cancers, which is what we aspire to do,' she points out, 'but tomosynthesis can help diagnose smaller lesions and I believe it's of fundamental help for the radiologist and for early diagnosis, which is what we are looking for.'

Today, Dr Miravete is a frequent speaker at radiology conferences in Spain and is regularly asked to share her experiences with radiologists thinking about making the transition to tomosynthesis. 'After performing 5,700 mammograms with tomosynthesis, we saw a 33% increase in sensitivity,' she reports. 'I've made many more diagnoses than I would with conventional mammography. We are finding small lesions in women with dense breasts and implants as well as malignant pathology in younger women that we would not have seen before. These are the cancers we need to find, the ones that can hide and grow and threaten a woman's life.'

Dr Miravete credits tomosynthesis with helping her practice to grow. The small imaging centre was competing against larger, more established radiology centres and radiologists who were initially sceptical regarding the benefits of the technology. 'At first other radiologists said tomosynthesis was not proven, so I had to struggle a lot in that respect. But the patients and gynaecologists soon realised that we were diagnosing cancer earlier, when it's smaller and the treatment is less aggressive. 'For me, tomosynthesis sells itself', she concludes, adding: 'News of the 3-D technology is spreading through Spain by word of mouth, and more women are coming to my centre because of it.'

A further reason for Dr Miravete's use of tomosynthesis is that she works alone. 'I don't have a colleague I can ask to look at something I think might be troublesome, so I need a technology that helps me find things I might miss. If I help even a single woman, or find even one additional lesion, it's very important to me, it's an achievement.'

* Source: Hologic. For specific information on what products are on sale in a particular country write to womenshealth@hologic.com.

* Hologic, Dimensions and Selenia are trademarks and/or registered trademarks of Hologic and/or its subsidiaries in the USA and/or other countries.

Ultrasound in mamma diagnostics

Breast surgeons have endorsed ultrasound for decades

Report: Cynthia E Keen

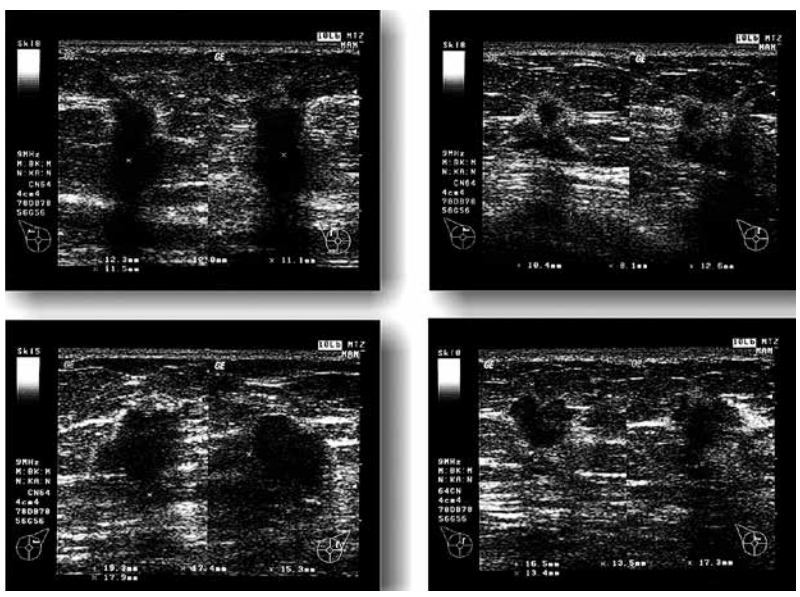
Ultrasound may be used during breast conservation surgery, to locate tumour lesions or to place localising wires; it can also guide a lumpectomy and perform a specimen exam to ensure a lesion has been excised and to evaluate surgical margins. Its versatility as a guidance tool also extends to cyst aspiration, core needle biopsy, needle localisation, and placement of brachytherapy devices. Intra-operative ultrasound does not require the sophisticated equipment needed for diagnostic ultrasound because it functions as a guidance tool during surgery.

More breast surgeons in Europe use ultrasound than those in North America. The American Society of Breast Surgeons (ACBrS) estimates that 60-70% of its 3,000 members perform ultrasound, but the society has only certified 300 members. However, according to Dr Sara Fredrickson, ASBrS Chair of breast imaging technologies, 'More and more surgeons are recognising the value of utilising ultrasound in their practices. Diagnostic ultrasound can evaluate palpable abnormalities, mammographic abnormalities, breast pain, and nipple discharge.'

She also pointed to real benefits for patients. 'A patient with a palpable mass can have a physical exam and an ultrasound in the same visit. This eliminates the need to make an appointment for the exam at a radiology department. If the surgeon identifies a cyst from ultrasound images, the cyst can be aspirated in the surgeon's office. This is just one example, but it saves the patient time and lessens the patient's anxiety. It is also more cost efficient.'

For many years, women undergoing breast conservation surgery for early stage breast cancer who had a positive sentinel lymph node biopsy also had axillary lymph node dissection. These recommended guidelines changed dramatically in 2010 due to results from the American College of Surgeons Oncology Group (ASCOG) Z0011 randomised prospective clinical trial. This compared outcomes of nearly 900 women who had a cancerous sentinel lymph node. Cancer recurrence was the same for women who only had a sentinel node dissection and those who had multiple lymph node dissection. The women had been followed for a median of six years when Dr Armando E Giuliano, the trial's principal investigator, announced the results. (Annals of Surgery, Vol.252:3, pp.426-433, September 2010).

Thus for a segment of women with breast cancer whose surgeons follow the ASCOG Z0011study recommendations there is less long-term pain and underarm discomfort and a lower risk of developing lymphoedema. Costs of surgery and follow-up care are also lower.



Ultrasound of breast cancer

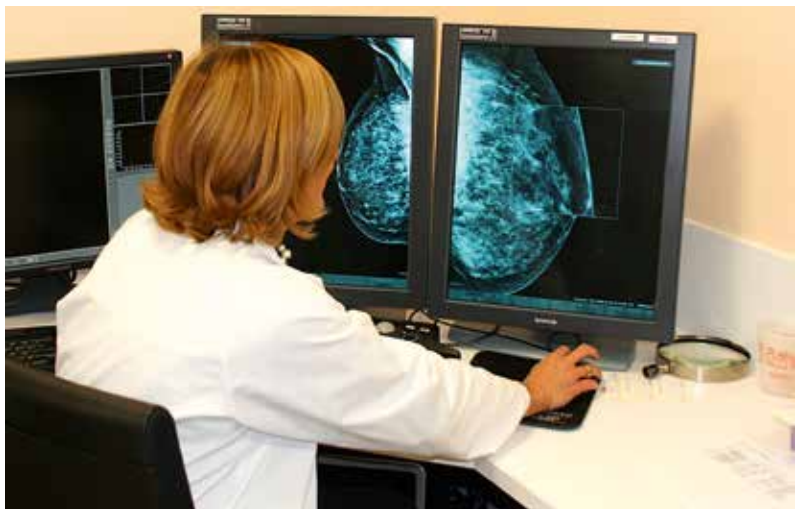
In 2011, researchers from Maidstone Hospital in the United Kingdom determined that contrast-enhanced ultrasound could identify and localise sentinel lymph nodes prior to breast biopsy. This capability offers the potential to produce more accurate biopsies and allow a patient's cancer and positive lymph nodes to be removed in a single surgery. The study's lead investigator Dr Ali R Sever, at the Department of Radiology, said that as many as 35% of patients require additional surgery following sentinel lymph node excision biopsy. (AJR, Vol. 196:2, pp251-256, Feb. 2011). Findings from a study at the Mayo Clinic in Rochester, Minnesota, recently presented at the American Society of Breast Surgeons (ASBrS) annual meeting, reinforced the role of ultrasound as a precise, non-invasive diagnostic tool to identify axillary metastases. The study showed that only 2% of patients with negative axillary might need to be considered for additional dissection after sentinel lymph node biopsy. (J Am Coll Surg. Article in Press 26 April 2013.)

'Applications for pre-operative auxiliary ultrasound (AUS) have been increasing over the last several years. Although its utility has not been universally accepted by breast surgeons, more studies are now being published about its benefits,' said co-presenter Dr Irada Ibrahim-Zada PhD, now affiliated with the University of Arizona's Department of Surgery. 'Our study, involving 1,140 women, confirms the very high sensitivity of pre-operative AUS as a diagnostic tool to detect lymph node metastasis. Its time has come. It can decrease surgery time, which contributes to better use of operating suites. It can eliminate frozen-section analysis, which also reduces treatment costs. And some breast cancer patients benefit by being able to avoid invasive surgical procedures.' Additionally, at RSNA 2012 Finnish researchers from Kuopio University Hospital reported that ultrasound-guided axillary lymph node core-needle biopsy is a more effective diagnostic procedure than fine-needle aspiration in the pre-operative staging of invasive breast cancer patients. The prospective, comparative study of the accuracy of both procedures involved 120 women, and was the first such study to do so, according to presenter Dr Suvi Raultiainen.

As breast cancer treatment becomes individualised with the tendency to avoid treatment that may not benefit a specific patient, ultrasound is expected to play an even more important role.

UK sees cases rise sharply in under 50-year-olds

Breast cancer



Report: Mark Nicholls

The charity Cancer Research UK reports that the number of breast cancer diagnoses in under 50-year-old women each year in the UK has exceeded 10,000 for the first time.

According to new figures, with the total number of new cases now approaching 50,000, the latest data reveals that a fifth are in younger women. 7,712 women under 50 were diagnosed with the condition in 1995 but by 2010 that had risen to 10,068 women, with the corresponding incidence rates rising by 11%.

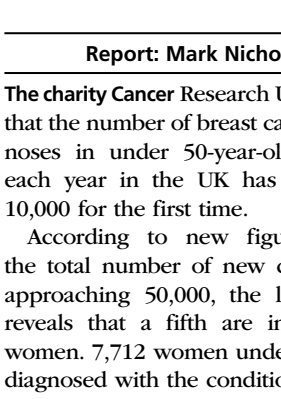
The rise reflects an overall steady increase in the numbers of breast cancer cases diagnosed in women of all ages in this country – an 18% growth in incidence rates over the same time period, up from 37,107 women of all ages diagnosed with the disease in 1995 to 49,564 women in 2010.

Jessica Harris, at Cancer Research UK, said: 'Breast cancer rates are rising in all age groups, it is not just in under 50s, and eight of 10 cases are still in women over 50. But it's important for us to bring this to light because there is a significant minority of woman who are being diagnosed at younger ages.'

The reason is not clear but, according to the charity, increasing alcohol intake and hormonal factors, e.g. having fewer children and later in life, and an increased use of the contraceptive pill may play a role. 'Things we'd suggest for people to reduce the risk are to cut down on alcohol, keep a healthy weight and also be physically active,' Jessica Harris said. 'Women should get to know their body and what is normal for them and if they should get breast cancer at any age they will be more likely to spot symptoms and have them checked out early.'

However, nowadays fewer than ever women under the age of fifty die from the disease – down 40% since the 1990s. In the early '90s, nine per 100,000 women in this group died. By late 2000, this had fallen to five women in every 100,000. The five-year survival rate for those diagnosed with breast cancer in England between 2005 and 2009 was 83.5% for females aged 15-39 and 89.1% for females aged 40-49.

The steadily improving outcomes is largely due to better treatment and research, but also '…likely to be down to a combination of different factors rather than one particularly big breakthrough – part likely to be related to people's awareness and how confident they are in noticing signs and symptoms and going to see their doctor and developments in the health service, meaning women can be quickly referred, quickly seen and diagnosed, and,' she adds, 'continued research.' Finally, she adds, health professionals should not assume that breast cancer is only an older woman's disease. Sara Hiom, Cancer Research UK's director of health information, added that her organisation's work in the laboratory '…is behind many important drugs, such as tamoxifen and herceptin, and our trials of drugs called aromatase inhibitors paved the way for the development of anastrozole – all of this is helping to give women with breast cancer more treatment options.'



Jessica Harris, a senior health information manager with Cancer Research UK, coordinates the charity's prevention and early diagnosis messages, keeping up to date with scientific and newly published evidence about risk factors, screening and signs and symptoms and translating these into meaningful information for the public.

Healthcare economics

A study from the United Kingdom raises questions over the cost-effectiveness of breast screening

Report: Mark Nicholls

Research using an analytical health economics model has suggested the current system of screening within the UK's National Health Service (NHS) is only moderately likely to be cost effective. However, Prof. Paul Pharoah and team, from the University of Cambridge, also highlighted the lack of relevant data currently available to reach clear conclusions and indicated significant further primary research will be needed for cost effectiveness studies to provide definitive data to inform policy.

The study followed last October's report from the Independent UK Panel on Breast Cancer Screening, which highlighted the need for a cost effectiveness study.

Using a life table model to generate an imaginary cohort of women, researchers simulated what happens to women year by year from the age of 50 over a period of 35 years, factoring in screening history, breast cancer diagnosis and mortality and mortality from other causes to compare the two and examine benefits and costs.

Professor Pharoah: 'The model depends on a whole series of input parameters, such as how effective breast cancer screening is in reducing breast cancer mortality and what the size of the over diagnosis is. All those parameters are estimated with some uncertainty so in a sense there is no single result of the model but part of the purpose of doing this was to try and get a feel of how important that uncertainty actually was.'

Their base case scenario estimated that breast cancer screening resulted in a small gain in quality adjusted life years (QALY) at a cost of £20,800 per QALY gain, marginally above the National Institute for Health and Clinical Excellence (NICE) threshold of £20,000 of QALY as representing good value for money.

New trials for long-term effects needed

Results suggest there were 1,521 fewer deaths from breast cancer and 2,722 over-diagnosed breast cancers but, over the 35 years, the model found the gain in survival was 9.2 days per person and 2.7 quality-adjusted days per person screened.

However, the study highlighted a 'surprising lack of good data' on the effectiveness of breast cancer screening using modern digital mammography, or on the long-term effects on the quality of life from screening.

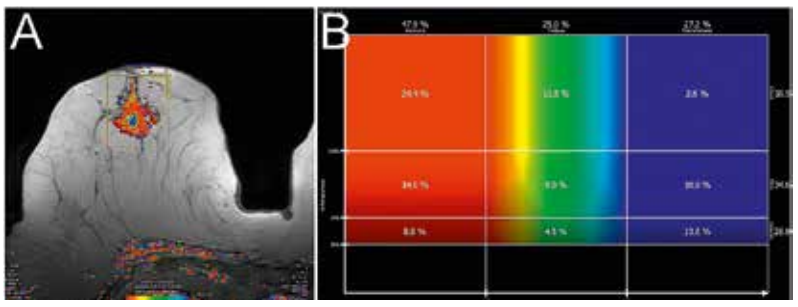
Paul Pharoah, Professor of Cancer Epidemiology at Cambridge University, qualified in Medicine at the University of Oxford in 1986. Following a series of internal medicine posts, in 1996 he became a research fellow in the CRC Human Cancer Genetics group. Gaining his doctorate in 1999, he won the Cancer Research UK Senior Clinical Research Fellowship, enabling him to develop an independent research programme. Major research focus: common genetic variation and breast and ovarian cancer susceptibility, the role of germline genetic variation in determining clinical outcome after a diagnosis of breast or ovarian cancer, and the molecular pathology of breast and ovarian cancer.

Professor Pharoah said most screening trials were conducted 20-30 years ago using old techniques with little carried out using modern mammography, surgery and treatments. 'We also have absolutely no idea what the long-term quality of life is of somebody diagnosed with breast cancer aged 50 who has had radiotherapy and a mastectomy. One of the problems of screening is over-diagnosis, so if you are over diagnosing breast cancer, how that affects long-term quality of life is important.'

The work, he added, highlights the fact that more information is needed and the study raises several questions. 'You can't say that screening is definitely a highly cost-effective intervention. Based on our results you'd not say it's absolutely a "must" from a cost-effectiveness point of view, but you wouldn't say it's ridiculously expensive either.'

While screening does identify breast cancers, Professor Pharoah believes the NHS should offer women more information about the issue of over-diagnosis so they can make an informed choice about whether to opt for screening or not. 'My view is that, because the randomised controlled trials of breast cancer screening are so old and based on old technology, a new and very large randomised controlled trial of breast cancer screening should be carried out.'

He thinks it unlikely that such a study will be conducted in the UK and while acknowledging his latest cost-effectiveness analysis may not in itself be a "game changer" he hopes it will help towards women being better informed about wider issues surrounding screening.



MR mammography of a 73-year-old with poorly differentiated (G3) invasive ductal carcinoma in the right breast. CAD analysis shows (a) the coloured overlay of the wash-in-wash-out ratio and (b) a summary of the volumetric analysis. The summary highlights tumour heterogeneity, with the larger part of the entire tumour volume (9.6 cm) showing wash-out kinetics (47.9%) or even a combination of a quick wash-in (>100%) followed by a wash-out (24.4%). Such CAD-based values indicate a highly aggressive tumour and in the future may be used for prognostic purposes

CAD evaluation of MR-mammography

With the help of a commercially available CAD (computer-assisted diagnosis) programme, MRI can provide prognostic data on the development of distant metastases in the further course of breast cancer. Not only is CAD as precise as conventional procedures, the combination of conventional methods and CAD increases predictive accuracy significantly by 10% to reach 87%, according to a study conducted by Dr Matthias Dietzel and Dr Pascal Baltzer at Jena University.

Working in the Neuroradiology Department at the University Hospital, Erlangen, researcher and private docent Dr Matthias Dietzel focuses on advanced MRI techniques and vascular as well as cancer imaging

'Today, MRI is frequently the standard modality in primary breast cancer staging. The blood supply parameters - meaning vascularisation - measured in MRI indirectly provide important information on the patient's risk of developing distant metastases later on,' explained Dr Dietzel (now based in Erlangen).

The prognostic tools the researchers used were no intricate pharmacokinetics but some basic parameters such as the initial contrast enhancement and wash-out – a strategy that increases the applicability of the method. 'Patients at risk of developing distant metastases usually show fast initial contrast enhancement in the tissue followed by quick wash-out. While benign tissue tends to take up the contrast agent in the delayed phase after the initial 90 seconds and intermediate tissue shows a plateau take-up in malignant tissue the contrast agent is washed out as quickly as it is washed in. The advantage of CAD is the fact that not only vascularisation can be measured by mouse click, but also that the distribution pattern of each voxel is easily recognisable. This method is of high prognostic value particularly when assessing tumour heterogeneity,' explained Dr Dietzel. These distribution patterns in the volumetric analysis are a crucial element of the MRI approach. Another major advantage of the procedure is the ability to measure the volume of a vital tumour in 3-D in situ – which is potentially more accurate than 2-D ex vivo analysis of biopsied and maybe fragmented samples.

The team's initial results were collected in a feasibility study based on 60 patients. In a second study, with 250 patients, the team wanted to learn more about the precise relevance of the data acquired by MRI and to find out whether these data provide an additional benefit to non-CAD sources, such as the Nottingham scores, used to determine tumour aggressiveness. 15.8% of patients partaking in the study had developed distant metastases in a median follow-up period of 55 months. These results showed a 79% agreement with the data provided by the CAD evaluation and 80% with conventional methods. 'These, by themselves, are very good percentages. However, if you combine both methods the agreement is 87%. This is statistically significant – no doubt,' Dr Dietzel said. The therapy benefit is obvious: thanks to a verified diagnostic biomarker, women with an increased risk of developing distant metastases can receive a tailor-made therapy that could positively affect the overall prognosis.

Based on a report in RöKo HEUTE 2013, the official publication of the German Radiology Congress

Telemedicine for heart failure patients

Device transmits to mobile phone without patient's input

Report: Michael Krassnitzer

Heart failure (HF) has a worse prognosis than many cancerous diseases. HF patients who have to be admitted to hospital because of an acute worsening of the disease have a one-year mortality rate between 27% and 47%. 'It wouldn't have to be that way if the affected patients were treated by specialists early enough and for the long term,' explains Professor Bukert Pieske, Director of the Ludwig Boltzmann Institute for Translational Heart Failure Research (LBI HF) in Graz, Austria, and President of the Austrian Society of Cardiology.

Whilst telemonitoring could bring some relief, studies have not sufficiently documented the use of telemedicine for HF patients. With the Austrian Institute of Technology (AIT), the Medical University of Graz, Bayer HealthCare Pharmaceuticals and T-Mobile Austria, the LBI HF has therefore begun the as yet largest study of telemedicine in Austria.

Heart failure is characterised by recurrent deterioration, so-called decompensation. European Society of Cardiology (ESC) Heart Failure Association (HFA) therefore recommends that HF patients measure and record blood pressure (BP), pulse rate and body weight on a daily basis and that they should inform their GP about these measurements at the next appointment. 'The disadvantage of this method is obvious: The doctor may only find out about possible critical changes weeks or months after their occurrence,' according to Professor Friedrich Fruhwald, Key Researcher Telemedicine at the LBI HF. Higher pulse rate and BP as well as rapid weight gain (due to oedema) actually point towards a decompensation, which has to be reacted to immediately – otherwise the patient may have to be admitted.

Although a first study carried out in Graz (MOBITEL) confirmed a significant improvement in treatment results, many patients stopped their participation in the study because they had to manually enter their measurements into a mobile telephone. The study, INtegrated TElemonitoring and Nurse Support Evaluation in Heart Failure – INTENSE-HF, began at the beginning of 2013. The transmission of data from the measurement device to the mobile telephone is possible without the patient's input. The technical solution that makes this possible is known as Near Field Communication (NFC). It allows the transmission of data without contact over short distances of up to 10 cm. The patient is given a telemonitoring set equipped with BP gauge, scales, mobile telephone, symbol card, and receives training. Then, only the mobile phone needs to be next to the BP gauge and scales, and the vital parameters are automatically transmitted to the phone. From there the patient transmits the data to the monitoring centre and simultaneously confirms that s/he has taken the prescribed medication. 'An essential objective of this treatment is to counteract any possible recurrent deterioration of the disease in time and to thus to avoid repeated hospital admissions,' Prof. Pieske explains.

The automatic monitoring of individual critical values results in an e-mail or text message to the doctor in charge of treatment if measurements exceed these values or fall short of them respectively. The doctor can access the patient's data at any time and adjust treatment if need be. Also, if necessary, the patient can be referred to the responsible hospital. The doctor can also compose a personal feedback message via a special interface and transmit this to the patient's device. A read-receipt reassures the sender that the patient has received the message. In case of missing measurements the integrated reminder function alerts the patient to take his medication.

A novel type of software analyses the data and provides the doctor with recommendations as to further improvements in HF treatment. Should the pulse rate be increased for five out of seven consecutive days, for instance, the doctor is sent a suggestion that based on ESC guidelines an increase in the beta-blocker dose should be considered. The same applies to blood pressure with ACE inhibitors and for body weight, where the objective is a fast reaction to any fluctuations within two days. Whether or not the doctor follows these recommendations is his decision, but in any case he needs to document it.

'Experiences with telemonitoring show that patients understand and accept the advantages of a closed monitoring cycle, which reflects in improved treatment adherence,' Prof. Pieske concludes

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Internal medicine specialist, cardiologist and head of the Clinical Division of Cardiology at the Medical University of Graz, Austria, **Professor Burkert Pieske MD** is also President of the Austrian Society of Cardiology and head of the Ludwig Boltzmann Institute for Translational Heart Failure Research (LBI HF) in Graz, an extra-mural research facility comparable to Germany's Max-Planck-Institute. Born in Heidelberg, he studied in Munich and Paris and worked and researched at the Universities of Freiburg and Göttingen, with research stays in Tokyo, Harvard and Chicago, before his Graz appointment. He is Chairman of the Heart Failure Association of the European Society of Cardiology (ESC) and a Member of the Board at the International Society of Heart Research. His own research publications number more than 150.

Minimising radiation for some patients

Reduced dose breakthrough for coronary CT imaging

Report: Mark Nicholls

Researchers in Germany have suggested that, for certain patients, newly developed coronary CT angiography techniques can provide good quality images with very low dose radiation. Using a combination of prospectively ECG-triggered high-pitch spiral acquisition, with low tube voltage and current, combined with iterative reconstruction, the team from the Department of Cardiology at the University of Erlangen was able to achieve coronary CT angiography with sufficient image quality at an effective dose below 0.1mSv.

While CT coronary angiography is a promising test to detect and rule out coronary artery disease, it has been criticised for high radiation doses, prompting researchers to try to develop ways to lower the radiation exposure.

Researcher Dr Annika Schuhbaeck explained that CT coronary angiography five years ago typically had an effective dose of 12 mSv (and even up to 30 mSv in some cases), while diagnostic invasive angiography has about 2-3 mSv. Natural background radiation is in the range of 1-3 mSv/year.

When looking to achieve quality images in coronary CT angiography, the researchers also recognised that several factors need consideration, such as the used scanner technology or reconstruction algorithm, patient-specific characteristics such as body weight or heart rate before the examination. Guidelines from the Society of Cardiovascular Computed Tomography are also available for radiation dose and dose-optimisation strategies in cardiovascular CT.

Annika Schuhbaeck is a clinician in the Department of Cardiology at the University of Erlangen, Germany

In a previous study, the University of Erlangen team had shown that coronary CT angiography can be performed with a consistent dose below 1 mSv using prospectively electrocardiogram-triggered high-pitch spiral acquisition combined with filtered back projection, but was keen to press ahead and show that a combination with a new reconstruction algorithm might further reduce radiation dose in selected patients.

Their latest research was a feasibility study demonstrating that coronary CT angiography with a sufficient image quality can be achieved using prospectively high-pitch spiral acquisition combined with iterative reconstruction in a selected patient group with body weight below 100kg and a heart rate below 60 beats per minute (BPM).

The team showed that radiation dose could be minimised by using its protocol, but perhaps not in every patient. They acknowledge that larger studies will need to confirm their data as the patient cohort was small and only a few patients presented with atherosclerotic plaque. Results might be different in a study cohort of patients with a higher prevalence of coronary artery disease, Dr Schuhbaeck said, adding: 'As our data demonstrate, diagnostic image quality was limited in patients with a body weight > 75kg. But cardiologists have to consider that coronary CT angiography, using our protocol, is possible in selected patients and might be an option in patients of young age and low to intermediate risk for coronary artery disease, and in individuals who need to undergo coronary CT angiography for reasons other than stenosis detection, for example, the analysis of coronary anomalies, or non-coronary cardiac CT.

'It really depends on patient characteristics such as body weight and size, heart rate and others, whether such an extremely low-dose protocol can be used. Also, while the coronary artery lumen can be visualised, it may not be reliably possible to detect smaller plaques. But we now know that radiation dose can really be minimised in some patients and this is important information when considering a diagnostic test.'

The team's research is continuing in this area with their next step to find ways that imaging at this very low dose below 0.1mSv can also be applied to other patients who may not be as ideally suited for cardiac CT imaging.

Seoul: The 29th KIMES

Technology enables a happy life – and pulls in thousands, Michael Reiter reports

Through recent decades, the Republic of Korea in East Asia has developed into a society with an advanced economy. To Europeans, the culture and cuisine are certainly very different – and highly attractive to tourists. However, in terms of business things look similar to our western lives. The per-capita GNP generated by the 50 million inhabitants compares well with the better positioned member states of the European Union.

Every year, the Korea International Medical & Hospital Equipment Show (KIMES) provides a showcase for the country's medical technology achievements, whilst also attracting international manufacturers naturally interested in this dynamic healthcare market with around 90% of its hospital beds privately managed.

Cutting-edge equipment, ubiquitous healthcare, as well as digital medical information systems were among the highlights of the 29th KIMES *(www.kimes.kr)* last March, when around 65,000 South Koreans came to Seoul's COEX Conference Centre, mingling with 2,800 buyers from beyond the country, including numerous delegations.

During four days, nearly 500 South Korean exhibitors presented products and solutions, among them flagships such as Alpinion, BIT Computer, DK (Dong Kang) Medical, HDX, JW Choongwae, LG+, Listem, Samsung, Medien International, and UB Care. Regional governments support the industry; at KIMES 2013, pavilions showcased companies from Daegu, Gyeonggi-do, and Gyeongsangnam-do provinces as well as Wonju Medtech Valley.

Among the 1,000+ international companies were Fuji, GE, Hitachi, Philips, Shimadzu, and Siemens. Seven country pavilions grouped together products from China, Germany, Hungary, Japan, Taiwan, Pakistan, and the USA. A representative of the event's organiser, Korea E&EX, said exhibitors reported a very positive response, and the market in general, with investments in particular, is moving at a fast pace.

More than 100 management and academic seminars informed firms and care providers on key trends and topics, including government policies impacting on the medical devices market and how to address the global market aimed at industry representatives. Collaboration options between academia and industry was also geared at both groups.

Successful Seoul

Korea's Ministry of Trade, Industry and Energy selected KIMES as one of the four leading shows presenting the country's industry to the world, a KIMES rep said proudly. The government judges the med-tech industry to be a key sector propelling Korean economy in the future and will provide financial and political backing for the industry. Those accolades suggest that KIMES will again attract key healthcare players in 2014. Make a date: 13-16 March in the attractive city of Seoul.

Hygiene: Fighting infections

The motive was clear. Lowering Germany's comparatively high nosocomial infection rate – the reason for an amendment to the Hygiene Act passed in 2011 – called for improved hygiene management within the hospitals. Since March 2012, the law was also drafted at a federal level. Focusing on its implementation into healthcare, at the 2nd Berlin Hygiene Symposium in May, experts confirmed one issue in particular – the acute current and foreseeable lack of infection prevention and control staff, EH correspondent Bettina Döbereiner reports

According to statistics from the Initiative for Infection Prevention, around half a million people contract nosocomial infections in German hospitals every year, with a fatal outcome for around 15,000 people. An estimated 4,000 of these fatalities could be avoided through improved hygiene. That is not only tragic but also causes high costs for all involved. Therefore, the tenor at the symposium which was organised by the Initiative for Infection Prevention and a Healthcare Training Institution was clear: Even though the amendments to the act present great challenges for many hospitals, all speakers on the podium welcomed the new law.

The biggest challenge is the staff issue: All hospital representatives present stressed the major difficulties involved in supplying specialist infection prevention and control staff by 2016 as required. The regional hygiene guidelines envisage that each hospital should have at least one doctor specialising in hospital hygiene – and for hospitals where the number of beds exceeds 400, this specialist should be employed specifically for this purpose on a full-time basis – along with qualified infection prevention and control nurses. However, so far, many of these prospective specialists have not even been trained – neither doctors nor nurses.

Dr Claudia Brase, Managing Director of the Hamburg Hospital Association, emphasised the difficulties of recruiting appropriately qualified staff: Although more provision has been made for continuing education in Hamburg, for instance, it is not necessarily easy to attract enough applicants with the right competencies, particularly regarding communication. These specialist nurses must organise and control hygiene and hygiene measures across hospital wards in cooperation with a specially trained doctor.

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The panel, from left: Moderation: Prof. Claus Bartels MD, Managing Director of MedAdvisors GmbH (Hamburg), Dr Claudia Brase, Managing Director of the Hamburg Hospitals Association, Prof. Axel Kramer MD, Director of the Institute for Hygiene and Environmental Medicine at the Medical Faculty, Greifwald University, Dr Andreas Weigand, Head of Medicine at the Rhön-Klinikum AG, Dr Jan Helferich, Advisor to the Board at DAK-Health, Heiko Thomas, Health Spokesman of the Coalition Alliance 90/The Greens in the State Parliament of Berlin

The symposium was funded by the US firm Becton Dickinson Company, which develops, manufactures and sells medical supplies, devices, lab instruments, antibodies, reagents and diagnostic products, which also supports the Infection Prevention Initiative.

Clinicians from other German federal states, such as Prof. Axel Kramer, Director of the Institute for Hygiene and Environmental Medicine at the Ernst-Moritz-Arndt University of Greifswald, see the main problem in the ability to recruit doctors appropriately qualified in hospital hygiene.

The background for this shortage: 'Over the last two to three decades Germany has abolished 15 academic chairs for hygiene.' Currently only 12 remain. Aiming to provide the necessary qualifications, additional training for specialist was quickly developed last year – although, strictly speaking, those posts were only supposed to be filled by specialists in hygiene and environmental medicine or microbiology – even this additional specialist training will not be enough to employ the nationally required number of at least 450 hygiene specialists by 2016, Prof. Kramer believes.

This is also to do with the doctors' motivation or, rather, lack of it. 'If someone has trained to become a surgeon they want to work as a surgeon; the same goes for anaesthetists and so on,' he explained. A specialist is only likely to opt for this type of further training in great exceptions. Therefore, he is looking into high quality, interim solutions, such as a concept where doctors specialising in hygiene initially look after several hospitals at the same time to begin with, even if these have more than 400 beds.

'In the long run, it will be indispensable to reinstate the academic chairs for hygiene in order to teach specialist hygiene skills to medical students, as well as to expand scientific research into hygiene issues. Therefore, the professor clearly appealed to governments of the German federal states and the universities to preserve and promote hygiene as a subject.

Hospital Build & Infrastructure Europe

Around 2,800 visitors are expected at this year's international Hospital Build & Infrastructure Europe (HBIE) fair, where presentations will include 'pioneering healthcare strategies, prudent facility management and new approaches for the sustainable operation of hospitals' as central themes. Conference Manager Aleksandra Kreplin: 'The special feature of HBIE is that investors, construction planners, architects, hospital operators and hospital equipment suppliers have the opportunity to meet and discuss completed, on-going and also planned projects.' Along with colleagues, she focuses on inviting exhibitors and speakers who can report on the very latest projects. 'We want our participants to learn about new construction and renovation projects as early as the planning phase,' she explained.

Speakers from over 15 countries and visitors from 48 countries participated in the 2012 event and, so far this year, speakers from India, Russia, Denmark, Germany, the Netherlands and Switzerland have confirmed their attendance. Top hospital representatives will present new strategies under the theme 'Leaders in Health Care'. A second series of presentations will question how process optimisation and astute facility management can reduce costs and modernise hospital buildings in the long term.

In a third series of presentations – *Design, Build, Upgrade* – leading experts will report on their successful hospital constructions, 'projects that combine modern design with practical elements,' Aleksandra Kreplin explained. 'The participants will discover how interdisciplinary approaches can enable effective and lower-cost healthcare provision through the examples of some truly outstanding hospital buildings.'

One approach is the use of sustainable building practices. As a member of the German Sustainable Building Council, the Regional Association of Rhineland-Palatinate (LVR), which operates ten hospitals, is working on a certification system for the modernisation of existing building stock. Architect Markus Sauer, Head of the Sustainable Building Department at LVR, commented: 'Sustainability represents the future viability of the company – the goal is to orientate our actions towards ensuring that we bequeath stable ecological, economic and social conditions to future generations.' This has involved LVR viewing construction costs across the whole life cycle of the building and making the binding decision to introduce passive house standards to new buildings. Markus Sauer will discuss latest developments and future perspectives for his work at the event.

The private hospital operator Asklepios Group dealt with the sustainability concept at an early stage. Three years ago it began a 'Green Hospital' programme in which the ecological handling of energy in the construction and operation of hospitals has been promoted at selected hospital locations. One of the pilot locations for the programme, its hospital in Schaufling, for example, began to operate a new solar power plant in October 2012. The first phase construction investment was €340,000. Due to the rehabilitation clinic's enormous daily energy needs, the Asklepios Group expects the power plant to have paid for itself in about six years.

Dr Wolfgang Sittel, Head of Architecture and Construction at the Asklepios Group and a speaker at HBEI, has noticed that sustainability has become the focus of a broad-based discussion in Europe and the USA due to worsening environmental problems. He particularly attributes the changing environmental behaviour of those involved in healthcare to the certification of environmentally friendly construction and operation methods in real estate. HBIE will also include round table discussions and workshops, and around 90 exhibitors will present solutions for hospital construction, improved infrastructures and clearer processes.

Details: www.hospitalbuildeurope.com