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9-20

- Obama's billion-\$ war on drug resistant microbes
- ECCMID's 25th anniversary event
- Are medical apps a waste of time?



RADIOLOGY

21-24

- AB-MRI ideal for screening?
- Bonding radiology and NUC
- Eliminating barriers in patient communication



Cut prescriptions and choose treatments wisely!

Choosing Wisely
An initiative of the ABIM Foundation

The USA's cautionary campaign is hitting the global psyche

Report: Bettina Döbereiner

Prescribing antibiotics for a viral infection with fever, a cold and a cough? There is no point! This is the best-known example of over-use in medicine. There are also numerous examples of diagnostic procedures and therapies that are pointless, yet still being doled out in surgeries and hospitals – sometimes even harming a patient. This is set to change, according to the German Society of Internal Medicine (DGIM), which has launched 'Klug entscheiden', modelled on the USA's campaign 'Choosing Wisely'.

That country is not alone. Worldwide, Canada's campaign runs alongside the USA's version, and the Swiss, Dutch and Italians have also adopted the concept. A Choosing Wisely campaign is also planned for by Great Britain, Australia, New Zealand and Japan.

The German campaign consists of 3-5-point checklists per specialist medical discipline, aimed at alerting doctors and patients to typical examples of over-use. The attraction of the campaign: 'First, the doctors are encouraged to compile these check-points with patients and patients' representatives. Second, the lists are meant to be written in such a way that patients can also understand them,' explained Emeritus Professor Ulrich Fölsch, DGIM General Secretary and former Director of the Department of Internal Medicine I, at the Schleswig-Holstein University Medical Centre, when introducing the campaign in Berlin this February.

The model for the DGIM campaign was initiated as Choosing Wisely in 2012 by the American Board



Source: Shutterstock-Gajus

of Internal Medicine (ABIM), with which 60 specialist medical societies are currently involved. In line with the campaign's US motto – Five things physicians and patients should question – The North American Spine Society, for example, begins its checklist with the statement: 'Don't recommend advanced imaging (i.e. MRI) of the spine within the first six weeks in patients with non-specific acute low back pain in the absence of red flags.' Red flags signify, among other things, the presence of trauma history, unintentional weight loss or immunosuppression. However, the above-mentioned example does not

fall within the field of internal medicine represented by the DGIM. The German campaign is also still in its infancy. As recently as the beginning of 2015, Prof. Fölsch asked all eleven DGIM member societies representing, for example, cardiology, pulmonology and intensive care, to name three to five examples of over-use, but also under-use in their specific medical disciplines. This will be further discussed and consented in a conference prepared for early May this year.

The fact that so-called under-use will also be addressed is one of two differences between the German

campaign and American trailblazer. The second, more important difference concerns scientific safeguarding. Feedback from the different medical societies is to be checked for scientific verifiability based on existing, evidence-based directives before publication.

The first German organisation to engage with the Choosing Wisely theme, and discuss the relevance and methodical challenges in specific workshops, was the German Network Evidence Based Medicine (DNEbM). Daniel Strech, Member of the Board at the DNEbM, values the DGIM initiative as well as similar campaigns currently being initiated by other organisations. He appeals for the implementation of the campaign in a patient-oriented and science-based manner.

Professor David Klemperer, from the Regensburg University of Applied Sciences, and member of a working group within the Association of the Scientific Medical Societies in Germany (AWMF), which is focusing on the implementation of a Choosing Wisely campaign under the patronage of the AWMF, also hopes for good cooperation with the DGIM. Klemperer assumes that, in coming weeks, it will be possible to integrate the DGIM initiative into the efforts of the AWMF and to develop a joint campaign that all 168 specialist societies within the AWMF can join. 'Such comprehensive implementation of the campaign would be very significant, also in comparison with the American and Canadian Choosing Wisely campaigns,' says Klemperer, who is also a member of the 2014 established Choosing Wisely International Working Group.



Emeritus Professor Ulrich R Fölsch, General Secretary of the German Society of Internal Medicine (DGIM), based in Wiesbaden, Germany

Editor's note: The effects of such a campaign on volumes of laboratory, pharmaceutical, imaging and usage of a multitude of other medical supplies is inestimable, at this stage. In addition, ethical questions must be addressed and debated regarding what is or is not really essential – for example, dip into the debate on cancer treatments at <http://consumerhealthchoices.org/wp-content/uploads/2012/10/ChoosingWiselyCancerASCO.pdf>



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CONTENTS

| | |
|-------------------|-------|
| NEWS & MANAGEMENT | 1-6 |
| CARDIOLOGY | 7-8 |
| LABORATORY | 9-20 |
| RADIOLOGY | 21-24 |
| ULTRASOUND | 25 |
| IT & TELEMED | 26-28 |

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Cleaning up hospital design

'Hygiene begins between the ears'

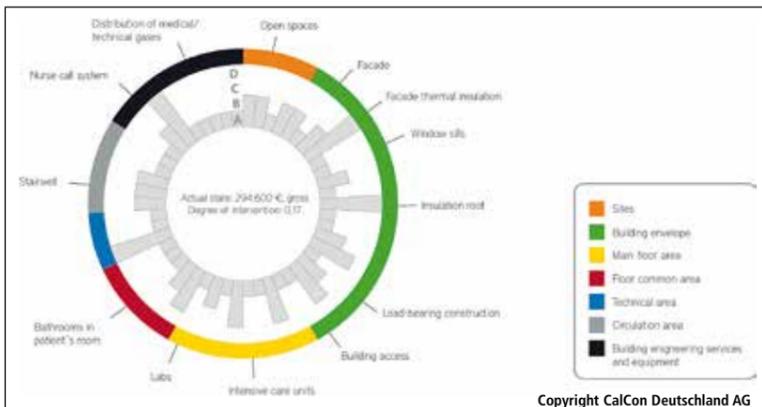
Report: Anja Berhringer

In terms of their architectural organisation, few buildings need to be geared towards their occupants as much as hospitals do. This insight is not new, but medical and technical developments call for different building conditions than those that might have sufficed ten years ago. The Nickl Architectural Practice, which specialises in the new build and refurbishment of hospitals, introduced the term 'healing architecture' for this kind of design.

Originating in the 19th century, the large hospital complexes in Berlin, Hamburg and Munich no longer meet the demands of modern medicine. Whilst the pavilion-type structures of the Rudolf Virchow Clinic in the grounds of Berlin's Charité Hospital may have been considered exemplary 150 years ago – being copied by hospitals worldwide – modern healthcare needs short distances and central treatment complexes. The Nickl Architectural Practice initially made its name with a new design for the University Hospital Hamburg-Eppendorf. Various pavilions were converted for different types of use and some of the old buildings were demolished to make way for the dominant, main new structure.

However, according to Professor Christine Nickl 'Many old hospitals are beyond a cure' because of contamination with pathogens, right down in the pipework and wiring and also due to built in materials such as asbestos, at the time of construction considered harmless.

Her architectural practice is now also in demand abroad. The new build and redesign of Frankfurt's University Hospital was undertaken based on the healing architecture



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criteria. The architects developed ten criteria, such as orientation within the building, which create trust in people; the architecture is never anonymous but always personal. There is a need for individual, one-bed rooms and the appropriate design logistics to connect these individual rooms with one other, creating adaptable spaces between them.

According to Professor Nickl, this is a current issue. 'We need the smaller spaces between rooms, which allow us to quickly react to changes in hospitals.' She therefore advocates modular design.

Modular for fast reaction to change

This must not be confused with the type of modular design presented by numerous firms at the specialist meeting on Design and Operation of Hospitals, held at the Management Forum Starnberg, in University Hospital Munich. Fast increases in capacity, refurbishment of old buildings or contingency rooms during renovations – numerous solutions are available at various levels of cost.

Requirements in this field are very individual. Finding a customised solu-

tion for restoration or modernisation initially requires analysis of the current building portfolio, so that appropriate investment decisions can be made.

The CalCon Group, founded in 1999 as a spin-off from the Fraunhofer Institute for Building Physics, has developed software called 'epiqr' for portfolio assessment. The software collects just a few geometric parameters from any building portfolio and assesses only the most important building blocks as to their condition. With the help of statistical projections the system then calculates the materials required and the cost of respective structural measures. An acquisition effort of only 20% achieves a data accuracy of 80%.

The results are displayed in the 'epiqr-diagram' so that the customer can see, at a glance, where building priorities should be. The structural measures and costs database integrated into the system then determines the respective costs the customer can expect once the structural measures have been selected from those stored in the database.

Once the structural measures commence everyone's attention should

be on the internal design. As the changed process logistics affect daily routines, infection prevention and control must be a priority during renovations. In the chaos that develops during assumed short-term construction works, medical equipment has been known to have been moved out of operating theatres and stored in hallways, or sterile equipment may end up next to cleaning agents in storerooms.

Building hygiene

Dr Ernst Tabori, Medical Director of the German Consulting Centre for Hospital Epidemiology and Infection Control (BZH), at the University Hospital Freiburg, specialises in building hygiene in hospitals and outpatient healthcare facilities, as well as surgical units. 'Infection Prevention and Control,' he says, 'is a matter of awareness and continuous education'. As far back as the 19th century, Ignaz Semmelweis was able to reduce maternal mortality rates in Vienna significantly through the simple measure of hand washing.

However, these days this appears to have disappeared from our consciousness, as the disinfectant dispensers visible on all wards do not reduce the contamination of door handles and other surface in the hospital with germs. Says Tabori: 'We have moved along the way a little bit but haven't quite arrived.' Why? Lack of time? Ignorance? Lack of staff? The hospital infection control specialist believes that, even in modern buildings, the hospital pathogens infection rate cannot be further reduced because two thirds of all these pathogens come from the patients themselves.

Therefore the term 'indirect contact infection' is imprecise and out-dated. One solution could be for their



Ernst Tabori MD has been Medical Director of the German Consulting Centre for Hospital Epidemiology and Infection Control at University Hospital Freiburg for the past 17 years. He is also a specialist in building hygiene for hospitals and outpatient healthcare facilities as well as for infection prevention and control in surgical units

general practitioners (GPs) to examine patients for pathogens before hospital admission, as carried out in the Netherlands. Alternatively, new admissions could be separated from other patients until the results of their infection status are known.

However, even small building-related issues can help, such as installing several, smaller wash basins in different locations rather than central washrooms with many basins for instance. Electronic water installations are susceptible to legionella, and the installation of elbow levers instead of water taps avoids contact with germs. There are many, detailed examples relating to water and air systems.

Specialists at the BZH can answer all enquiries on these subjects. As so nicely put by Ernst Tabori: 'Hygiene begins between the ears.'

Hospital construction and operation

Keep as few buildings as possible

Report: Michael Krassnitzer

Vienna is the perfect place for a symposium dedicated to 'hospital construction and operation because, over the next 15 years, the Austrian capital will radically transform its hospital landscape. In the facilities of the Municipal Hospital Association Vienna (Wiener Krankenanstaltenverband – KAV) 32,000 employees care for 400,000 in-patients annually, making KAV one of the largest hospital operators in Europe.

The new hospital master plan (Wiener Spitalskonzept 2030) is indeed stunning. Currently the network of 15 KAV sites will be reduced to seven; one new hospital will be built, three existing hospitals are to be demolished and entirely rebuilt on their sites and the three most recent hospitals, erected in the 1970s, will be modernised and expanded.

'The old hospitals date back to the days of the Austro-Hungarian Empire and are made up of many separate buildings – pavilions – some of them listed. Today, such a structure cannot be operated in an economically viable way', explains engineer Friedrich Prem, Head of the Technical Division at KAV, during last November's Best Practices symposium in Vienna. To

operate and manage the hospitals according to present-day standards, new buildings are needed, Prem added: 'The new buildings alone will reduce operating costs by 250 million euros annually. This means building costs are recuperated within two or three years, simply by the lower operating costs.'

A point of departure in the master plan is the concept of having 'as few buildings as possible', which spells an end of the decentralised pavilion system in favour of one central clinical building in a large public park. In line with this new concept, for example, the hospital in the Hietzing district, currently encompassing more than 100 buildings, will be reduced to 20 percent of its present floor area, and the listed pavilions will be converted into apartments.

As Prem explains, a compact central building has a number of advantages: small floor area, small frontage area and small gross floor area.

After the number of buildings is reduced, how would the remaining buildings be used? 'You separate the clinical from the non-clinical functions – that's a major step', Prem underlines. In Vienna, a separate administration and services building will complement each clinical centre, housing



services such as pharmacy, sterile supply, kitchen, laundry, supplies, waste management, facility management and procurement. Non-clinical buildings have very different operating life and functional life cycles than clinical buildings that must regularly be adapted to new functional require-

ments. To ensure that all clinical departments can be fully operational, even during construction work, the interior layout should be as flexible as possible – for example, few primary structures and flexible interior walls.

According to Prem, the clinical buildings must comply with a number

of strategic specifications, inter alia:

- separate access areas for people and goods/emergency access
- centralised people access (one entrance, one lobby) private and semi-private roomsthe highest possible degree of automation and orientation towards state-of-the-art information and communication technologies transparency and openness – with one exception: where privacy is needed it takes priority over openness.

Implementing such a master plan involves decisions that go far beyond architectural and functional questions. 'It's crucial to separate organisational issues – for example, the transformation of the existing operational structure into the new operational structure, separated from construction issues, the new buildings,' he emphasises.

Dr Klaus Offner, engineer and Technical Director of the Salzburg State Hospital, totally agrees. Since 2006, his facility has been permanently modernised while still fully functional: 'Such a project takes at least ten years – and in those ten years your hospital management will change and new management will introduce new ideas.' At his hospital,

Support in the transition from paediatric to adult healthcare

Coming of age with a chronic disease

Report: Bettina Döbereiner

During the transition from child to adult many teens with chronic diseases somehow slip through the healthcare cracks between paediatric and adult medicine. Compliance deteriorates, regular check-ups are missed – an international problem, as many studies indicate. A promising programme, launched in Berlin, helps teens to manage this difficult change.

The five-year pilot project began at DRK Kliniken Berlin-Westend; over a two-year period, to make the transition to adult healthcare, professional case managers accompanied adolescents with type II diabetes or epilepsy, who had been patients at various paediatric institutions in and around Berlin.

The successful pilot was turned into the permanent Berliner TransitionsProgramm (BTP), which targets teens in Berlin, and northern Germany, with six different chronic conditions. 140 adolescents are enrolled in the programme, 80 have already completed it.

One major issue is financing, since only a few of the statutory health insurers reimburse costs. This is 'a major limitation', says Dr Silvia Müther, BTP project manager and diabetologist at the Paediatric Diabetes Centre, at DRK Hospital Berlin. Müther would like to see BTP classified as a regular service covered by the statutory health insurers, so that all adolescents could benefit from the programme.

On an international level, the Berlin project is unique, Dr Müther

explains, because it targets several indications, is multidisciplinary and envisages reimbursement-based funding. Previously described transition projects have focused on one indication, are tied to a specific

institution, privately funded and temporary.

Thus BTP might serve as a blueprint on the national and even European level: expansion scenarios are being developed.



To make the difficult transition from paediatric to adult healthcare, for two years adolescents with chronic diseases are accompanied by case managers from the Berliner TransitionsProgramm (BTP) at DRK Kliniken Berlin-Westend. Communication is phone and internet based rather than face-to-face. Since teens tend to prefer new media, an app was developed to facilitate interaction between the case managers and their young patients.



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Photo: KAV/Lisa Lux

A graduate from the Higher Technical Federal Education and Research Institute, in 2006 engineer Friedrich Prem, left his job as head of the Technical Review Division of the Vienna Municipal Hospital Association (Wiener Krankenanstaltenverband – KAV) to lead KAV's Technical Division. His responsibilities there include overseeing the construction of several specialised hospitals, as well as their technical and property management. In addition to Prem's career in the public sector, he has been active in the private sector since 1999. He is a member of several expert bodies and author of a book on the management of large construction projects (Starke Bauherren – Komplexe Bauprojekte effizient und erfolgreich managen).

when new directors were appointed to the gynaecology and neonatology departments, process changes were needed. 'In this situation,' he points out, 'it's an enormous advantage if your organisational project is separated from your construction project.'

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Splitting a role makes a big difference

Successful TopSharing

In the late 1990s, management consultant Julia K Kuark and Swiss communication consultant Hans Ulrich Locher coined the term 'TopSharing' – as in job-sharing but, in this case, to describe splitting a senior management role. In Germany, Dr Ulrike Ley, who coaches female doctors, considers the TopSharing model, expanded over a decade by Kuark, is a valid management model for hospitals. TopSharing helps male and female physicians to achieve a work/life balance by showing the way to split and share various management and administrative tasks, thus also gaining more time for patient care. Bettina Döbereiner interviewed the two trailblazing women to find out how they made this work.

Female physicians, as well as their male colleagues, struggle to achieve a sound career/family life. Cardiologists Katrin Glass and Reina Dobberkau are among the lucky few who became successful 'TopSharers' in a senior clinical role. Since 2011 the two physicians have jointly headed the cardiology department at the private 80-bed Brunnenberg MediClin hospital, a German rehabilitation facility near the border with the Czech Republic.

The idea of sharing a senior management position

'At the same time as my predecessor retired I also wanted to return to the hospital after my extended maternity leave,' Dr Reina Dobberkau explained. 'Whilst the hospital was already struggling with a clinical staff shortage, I didn't want a full-time senior consultancy due to my family situation. Katrin Glass, whom I'd met during my medical training and with whom I had cooperated frequently, headed the cardiology department at a nearby clinic. Her institution also suffered a staff shortage and the workload was extremely high. We jointly developed the idea of sharing the management position and presented our idea to the group's top management. Their reaction was very positive.' What drew Katrin Glass in the same direction?

'I had always wanted to balance my career with my family life,' she explained. 'I live in a multi-generation house and, to me, my family

tasks are as important as my passion for my profession and my career.

Reina Dobberkau: 'The hospital group's top management gave their OK very quickly. For the group, having two permanent specialists represented a clear, competitive advantage.

'By law, the statutory pension insurers in Germany will only fund cardiological rehabilitation if two cardiologists are permanently employed in a facility. Consequently, our department was at risk of being shut down if we had not come up with our job-sharing scheme.'

Role organisation

Katrin Glass: 'We both work 80 percent of a full-time position, which means we are both there four days a week and are off one day. This is a fixed set-up, of which everyone in the hospital is aware.

'We discuss and jointly decide all important administrative and clinical issues and we both sign the patients' discharge reports. Obviously there are tasks we do not share, such as patient care and certain tasks assigned to us by the hospital management, clinical responsibility for nursing care, for example, or the psychology department.

'We split human resources issues, such as appraisals of clinical and non-clinical staff between us and, although we don't take verbatim minutes that contain each detail and each single word, we always document all relevant statements and decisions in a transparent and

comprehensible way. With a bit of experience, that works very well.'

Necessary preconditions for TopSharing

Reina Dobberkau: 'Cooperation is crucial. You can't just take any two physicians and ask them to share a position. While friendship, as it has developed between Ms Glass and me, is certainly not a precondition for successfully sharing a senior clinical management role, similar levels of clinical training are of utmost importance to ensure efficient clinical communication – after all, the two physicians have to stand in for each other. In addition, similar levels are necessary to avoid competition.'

Katrin Glass: 'Another important issue is the employer's support – he has to be willing to consider the idea of TopSharing in the first place; and you have to be able to convince him; you have to present a clear, well thought-out concept.

'Then, when you do share your job, you need to organise your work well and you need discipline. The latter includes the fact that decisions, once made, are accepted and not questioned. What else is important for TopSharing? Openness, trust and the willingness to negotiate compromises.'

Big TopSharing advantages

Reina Dobberkau: One major advantage is the fact that TopSharing opens up family time, your private life. When we're in the hospital



Source: MediClin Klinik am Brunnenberg

A specialist in internal medicine, with a focus on cardiology, **Reina Dobberkau**, studied medicine at Karl Marx University, Leipzig, and then became a junior physician at several hospitals in Vogtland, Germany. Her doctoral thesis (1996) focused on hygiene issues related to reprocessing endoscopes. In 1997, Dr Dobberkau joined Vogtlandklinik Bad Elster for cardiology training, as did Katrin Glass (right).

In 2001, she was appointed senior physician in the Brunnenberg cardiology department, where she became head of the unit in 2010 – and, in January 2011, joint head with Dr Glass.

we work long hours, which in fact means we work more than 80 percent of a full-time position – but we still have more time for the family. When we are off, we are off not only physically but also mentally, because we can be sure that our patients are well taken care of by the colleague.

Another issue, which I consider very important, is the fact that there is another professional with whom I can discuss and exchange ideas. We have our patients and when questions arise there is always the other cardiologist next door to turn to for feedback.'

Katrin Glass: 'One of the major advantages I see is that we share responsibility. Obviously, we do



Source: MediClin Klinik am Brunnenberg

A specialist in internal medicine with a focus on cardiology, **Katrin Glass** had studied medicine at Karl Marx University in Leipzig. Following training in internal medicine at several hospitals in Vogtland, Germany, in 1989 she joined the cardiology department of Vogtlandklinik Bad Elster where she was appointed senior physician in 1992 and department head in 2007.

Since January 2011 Dr Glass, alongside Dr Reina Dobberkau, (left) has jointly led the cardiology department at Brunnenberg MediClin hospital, a rehabilitation centre in Bad Elster.

There, the team of one senior physician and two junior physicians covers post-acute care of cardiovascular diseases.

have different opinions from time to time, but we always manage to find a consensus, and before we "go public" we've come to an agreement. TopSharing is, no doubt, not always easy. There are difficult days, but there are difficult days in any clinical environment, particularly when you have a tough workload. However, summing up, the advantages of our work model far outweigh the problems.'

PUBLICATIONS

Julia K Kuark: Together at the Top, the TopSharing model (2003)

TopSharing - Division of labour on the executive floor - is included in the Management Handbook for Female Doctors; Healthy Management in Medicine, Ulrike Ley, Gabriele Kaczmarczyk, Franziska Becker, 2013 (2nd edition)

Women in neuroradiology

More freedom, more respo

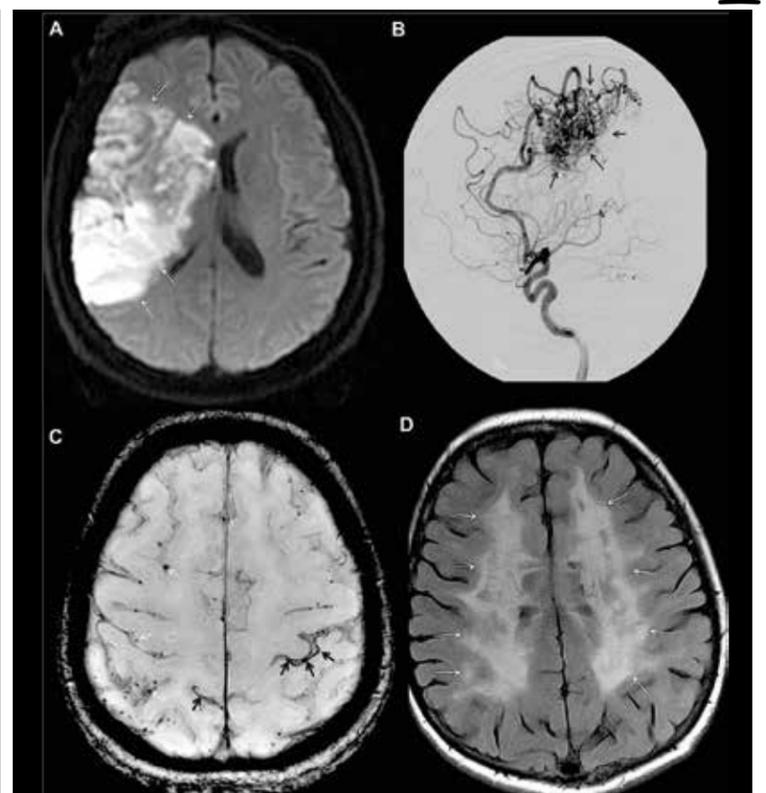
She is a neuroradiologist, professor, researcher and now the Medical Director of the Department of Neuroradiology at Dresden University Hospital. Her objectives are ambitious – be it in patient care, research or teaching. Professor Jennifer Linn MD wants to increase the quality of care, drive breakthroughs in research, ignite enthusiasm in students for their future profession and last, but not least, ensure job satisfaction for her team. Dr Linn is a rare breed: next to Professor Ulrike Ernemann, currently she is only the second woman in Germany to be a medical director of neuroradiology

Report: Chrissanthi Nikolakudi

As Head of Neuroradiology at Carl Gustav Carus University Hospital Professor Jennifer Linn has gained a much cherished opportunity to shape and further develop the neuroradiology department. 'As resident your responsibilities are limited to a certain area and you don't have to consider the entire department,' Linn explains. More freedom, however, also means more responsibilities and a greater willingness to negotiate compromises, particularly with regard to personnel and budget decisions: Technical but above all human resources are limited. The challenge I have to meet is to deliver top quality. That's quite a tightrope walk.' She does not intend to rest on laurels her predecessors earned. The

Dresden neuroradiology department is ISO-certified, patient care is considered very good and across the board referring physicians are satisfied. 'Although at a certain level improvements become more and more difficult, my overarching aim is to drive quality assurance, diagnostics and speed,' Linn explains. She knows that a hospital is always only as good as the staff. Increasing job satisfaction, ensuring quality education and a positive workplace climate – for her these are much more than empty phrases: 'I want my team members to know that they can rely on me.' Why is that important? 'You can reach for the sky but when the people around you are dissatisfied, when you don't manage to create enthusiasm, you will fall flat on your nose pretty quick-

Important causes of a stroke: A) 72-year-old patient with recent ischaemic stroke in the area supplied by the Arteria cerebri media (diffusion MRI, arrows) B) Digital subtraction angiography of a 34-year-old patient with intracranial arteriovenous malformation (arrows) causing intracerebral haemorrhage (not shown) C) 82-year-old patient with many microhaemorrhages (e.g. white arrows) and superficial siderosis (black arrows) and cerebral amyloid angiopathy (MRI with SWI sequence) D) 35-year-old patient with CADASIL syndrome, a hereditary form of cerebral microangiopathies, which is a major cause of ischaemic stroke in young adults and cause inter alia confluent white matter lesions (MRI with FLAIR sequence, arrows)



Korea's expanding medical & hospital equipment fair

The Far East's highly international event



Report: Ben Giese

KIMES, Korea's leading medical and hospital equipment exhibition, continues to expand internationally, shown this year in the larger number

of visitors from the greater Asia-Pacific region as well as buyers from, for example, far off India. Europe and the USA drive that continuing development. Exhibitors also reflect internationalisation – for example

a first-time German pavilion presented 12 participating companies that brought 'Made in Germany' to this market.

The Korean medical market has reached two major milestones: the

percentage of GDP spent within the medical sector is expected to top 8% this year bringing this closer to that of OECD major markets.

Additionally, the country's average age has risen to over 40 years. The demography mandates greater medical investment and also drives innovation on ways to provide top quality care. KIMES reflects those trends, reflected, for example, in the number of exhibiting companies from beyond Korea – 615 among the 1,145 total.

Asked if KIMES is the most important show in Asia, Thomas Kocher of HT Labor + Hospitaltechnik, Bavaria, said that a single leading exhibition does not exist, even in countries such as China. KIMES is growing and cannot be missed when needing to cover the whole Asian market. 'Personally, I would like to see this show become the leader due to the show's timing, the level of organisation and quality of contacts,' he said.

'As the search for quality continues to gain importance in Asia, we are positioning ourselves at the KIMES for future success,' says Cyrus Law from GCX, in California. 'We enjoy a strong market share providing mounting solutions to top-tier healthcare firms. As more manufacturers, especially those from Korea, continue an up-market shift, they also need the quality we provide to match their ever-improving solutions. We expect this trend to continue.'

Some people at the show had criticised scheduling – this year's event ran concurrently with the annual European Congress of Radiology. Asked about that conflict, Choong-Jin Kim, Vice Chairman of Korea E&E Inc, organiser of KIMES, assured,

'We are very aware of this situation,' he said. 'Next year will not force such a difficult decision on exhibitors and visitors. Both of these world class shows will have their own place on the calendar.'

onsibility

ly,' she explains her philosophy. With all these mundane tasks will research get short shrift? Absolutely not, Professor Linn is adamant. On the contrary: Expanding the department's and her own research work is top priority. 'The research profile of the neuroradiology department in Dresden can be sharpened. Whilst, in the past, the institute participated in four large multi-centre studies, I intend to increase the number of studies initiated and performed by the department itself,' Linn promises. She will continue and expand the team's research focus. Her predecessor, Professor Rüdiger von Kummer, was an expert in major ischaemic strokes; Linn is bringing her specialisation to Dresden: cerebral microangiopathies – pathologies of the small vessels supplying the brain, which cause strokes. 'The significance of these pathologies as stroke triggers is not yet firmly anchored in many physicians' minds since they do not cause major strokes. I would like to change that in our facility,' Linn explains. After all, from a certain age upwards almost everyone

suffers some kind of microangiopathies. The small vessels are damaged by risk factors such as age, arterial hypertension or diabetes mellitus. 'For a long time we have considered this as a 'normal' ageing process. However, more recent research has shown that microangiopathies can indeed cause stroke symptoms and above all impair cognitive capabilities.' Jennifer Linn wants to take a closer look at vascular dementia and find out more about the connections between vascular conditions and dementia: 'At this point, we do know that these diseases are connected but a lot of research remains to be done.'

The professor estimates that 60 to 70 percent of her students are female and most of them will indeed get a degree. However, at senior resident level only about 20 percent are women. Albeit, Professor Linn points out that this is not a health-care-specific problem. She is also the mother of a one-year old child and knows that it can be very difficult to find reliable childcare during working hours. 'Many women who



Jennifer Linn gained her doctorate from the Institute for Neurosciences at Munich's Technical University and habilitation at Ludwig Maximilian University, Munich, with a thesis on the differentiation of haemorrhagic stroke using modern cross-sectional imaging methods. In 2011 Professor Linn was invited to work at the Department of Neuroradiology of Johns Hopkins University in Baltimore and in the same year received the Kurt Decker Award of the German Society of Neuroradiology. After leading the MRI research group at the Department of Neuroradiology, Ludwig Maximilian University Hospital, Munich, since 2009, last October she was appointed Medical Director of the Department of Neuroradiology at Carl Gustav Carus University Hospital in Dresden.

face these difficulties give up too quickly. I firmly believe that children and a professional career can go hand in hand.'



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Consider your future care when young enough

Ambient assisted living systems

New technologies in health and geriatric care promise great benefits – and risks – all of which were aired this February during Evangelical Academy congress in Berlin. Interestingly, an instrument to check the ethical dimensions of new developments was also introduced, Bettina Döbereiner reports

If we believe the prognoses on demographic change, deciding how we want to be treated if ill, or in need of care, will not remain easy, unless society agrees on a decisive migration policy to help ensure medical care in Germany can be safeguarded for the future.

Along with the option of implementing selective, work-related migration, the technological advances, which have developed rapidly over recent decades, offer the potential to take the strain of nurses and carers, or even to replace them. Strongly affected by demographic change, countries such as Japan and Germany are making large investments in the development of these technologies.

AAL = ambient assisted lives

The talk is of Ambient Assisted Living Systems. These aim to create an “intelligent” environment that can adapt independently, proactively and situation-specifically to the needs of the elderly and those needing care in their own homes for as long and as independently as possible. The range of AAL systems already available along with those currently in development is huge – from hobs that turn off automatically after a period of time, to shoe soles equipped with GPS to help track dementia patients, to patients’ lifting systems, and even to robot nurses.

Four of these AAL Systems, primarily designed for use in geri-

atric care, were introduced at an Evangelical Academy congress in Berlin. Two are already in use, SAMDY and Care-O-bot 4, the others still in development.

Networked Living – SAMDY

SAMDY stands for Sensor-based Adaptive Monitoring System for behavioural analysis of the elderly and, following a development and pilot phase in 2013, is now used on a regular basis by the Social Network St. Georg, a regional care provider.

To help enable old people to live at home for as long as possible, their flats and houses are fitted with a range of sensors that register their daily movements and actions. These motion and contact sensors are fixed to external doors as well as to fridge and oven doors along with tracking systems and bed sensors. The latter can register movements during sleep and different depths of sleep, as well as monitoring the heart rate.

As soon as the sensors register a breach of the norm, specified as deviations from pre-defined, normal behaviour(s), a wireless warning system alerts members of the (nursing) care service to take immediate, appropriate measures.

Care-O-bot 4 – the Service and Care robot

Development of the 4th generation Care-O-bot, a robot developed by a Working Group at the Fraunhofer



Completed in 2008, this interactive Service Robot Care-O-bot 3 can collect and deliver objects, opening and closing drawers for this purpose. Its interactive touchscreen provides a multitude of entertainment and communication functions. Video telephony, for instance, facilitates communication with relatives and friends. The robot can also remind the user about appointments or, for example, taking a medication. If a user falls, the Care-O-bot can move towards them, simultaneously establishing a video link with an emergency control centre

Institute for Manufacturing Engineering and Automation in Stuttgart, was completed at the beginning of 2015. The system will be introduced in April, during The 8th AAL Congress.

As a mobile service and care robot its purpose is to assist the user in the household and, just like SAMDY, enable the user to live at home as independently as possible. Care-O-bot safely moves around people, recognises typical household objects, can grip them and take them to certain locations, can set the table or open doors and drawers. With respective programming, it also reacts when someone has fallen and is lying on the floor, immediately establishing contact with an emergency service provider.

How do we want to live?

As yet, advanced AAL technologies such as robots are not yet fully utilised worldwide, their development and testing is sufficiently advanced to expect them to be widely used. However, before this happens, we should ask ourselves: Do we want this? Do we want to live at home alone and surrounded by technology when ill or old? Do we want our every movement registered and passed on to third parties, as is required for the concept of the SAMDY system? Do we want a robot to bring us water? This is an individual issue as well as one for society as a whole, and all of us should think about answers here to ensure that we don't feel we have become overtaken by these devel-

opments. This is the firm opinion of Professor Arne Menzschke, one of the congress organisers, Head of the Department for Ethics and Anthropology at the Institute for Technology, Theology and Natural Sciences at the Ludwig-Maximilian University, Munich.

MEERSTAR – the ethical evaluation instrument

He developed a tool to evaluate AAL applications in the context of a study initiated by the Federal Ministry of Education and Research (Ethical Questions around Ambient Assisted Living Systems) that collects and evaluates the advantages and disadvantages of new technological approaches and developments and all their aspects (legal, economic, social and moral). Since 2012, there has been a recommendation that all AAL projects promoted by the Federal Ministry of Education and Research should carry out a Model for the Ethical Evaluation of Socio-Technological Arrangements (MEESTAR) in the form of two-day workshops.

Conclusion

Today, the fit among us should answer the question of how we would like to be cared in the future, and should establish procedures that will enable us to live a truly self-determined life to the end. ■

Date for the diary

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Personalised medicine in ophthalmology

Computerised tailor-made retinopathy therapy

Report: Michael Krassnitzer

Nowadays the concept of personalised medicine is usually applied to oncology. However, there are other clinical disciplines in which therapies tailored to the individual patient are within reach, viz. ophthalmology. In the researchers' limelight is intravitreal drug delivery since the outcomes of injections into the vitreous differ from patient to patient. Ophthalmologists in Vienna, Austria, are working on software to identify suitable therapy for each individual patient.

Intravitreal injections (IVI) are indicated for retinopathies such as age-related macular degeneration (AMD), diabetic macular oedema (DME) or retinal vascular occlusions. Antibodies are injected directly into the vitreous, which serves as a drug reservoir, and released to the retina over the course of a few weeks. Thus, for the first time retinal diseases can be treated directly – and successfully.

Thanks to intravitreal injections AMD is no longer the prime cause of blindness. However, there is a catch: In order to be on the safe side, the treatment must be repeated



An intravitreal injection (IVI)

every few weeks – for life. ‘This is de facto impossible,’ says Dr Sebastian Waldstein, ophthalmologist at the Department of Ophthalmology and Optometry at the Medical University of Vienna, who is also in charge of the research focus Macular Degeneration at Vienna Reading Centre (VRC). ‘First, most patients simply cannot afford the monthly treatment financially,’ he points out, adding that it is also too stressful for the patient.’

Indeed, only a minority of patients need monthly treatment, he says.

‘For about two thirds of patients much longer intervals are entirely sufficient – in fact, some patients need only a few injections.’ Even better, ‘The course of retinal disease and the best treatment strategy can be predicted with a probability of ninety-nine percent probability’ using optical coherence tomography (OCT), a diagnostic procedure largely developed in Vienna, that has revolutionised ophthalmology within a few years. In OCT, hundreds of scans are combined to produce a 3-D image of the retina, which in turn allows reconstruction of the macula within

seconds. However, the computing power behind this contactless procedure also poses a problem: the data volume generated in OCT is so huge that the ophthalmologist can no longer interpret it. To eliminate this quandary, Dr Waldstein is developing innovative computer-based methods to analyse large clinical image data sets.

To provide his research with an institutional framework, he initiated the Christian Doppler Laboratory for Ophthalmological Image Analysis, which he currently coordinates under the supervision of Professor Ursula Schmidt-Erfurth. The first results are already available: ‘The algorithms we developed need three exams to reliably predict the retinal status at the next scheduled exam and to predict whether the patient will suffer a relapse in the course of treatment,’ Dr Waldstein explains. These preliminarily tested methods must now be applied to large patient cohorts. ‘We delivered the proof of principle and expect prototypes for the large-scale evaluation to be available in one to two years.’

It may well be that the physician will not be able to comprehend the calculated results based on the algorithms. ‘The parameters that lead to the predictions might be highly com-



Based in the Department of Ophthalmology and Optometry at the Medical University of Vienna, ophthalmologist Sebastian M Waldstein also leads research on macular degeneration at the Vienna Reading Centre (VRC). Additionally, supervised by Professor Ursula Schmidt-Erfurth, he coordinates the Christian Doppler Laboratory for Ophthalmological Image Analysis, a publicly funded, interdisciplinary research group set up to develop innovative computer-based methods to analyse large clinical image data sets. A native of Salzburg, Dr Waldstein studied medicine in Innsbruck and Vienna. Subsequently he has received prizes and awards from international professional associations such as ARVO, Max Kade Fellowship and ESASO.

plex,’ Waldstein says. ‘The analysis of big data is often a black box method. In short: the prediction is correct, but we don't understand why.’ Dr Waldstein aims to provide software integrated into the OCT system, to offer a score or probability for the outcome that allows a physician to select the best possible treatment. ■

A blueprint for Europe?

Chest pain units in Germany

The German care system for patients with acute and unspecific/undifferentiated chest pain is unique in Europe, Bettina Döbereiner reports. The closely knit and countrywide network of accredited Chest Pain Units (CPUs) ensures fast and targeted diagnosis of acute cardiac events. The German CPUs may soon serve as a blueprint for other European countries. The German Cardiac Society (DGK) has already accredited the first institutions – others will follow suit.

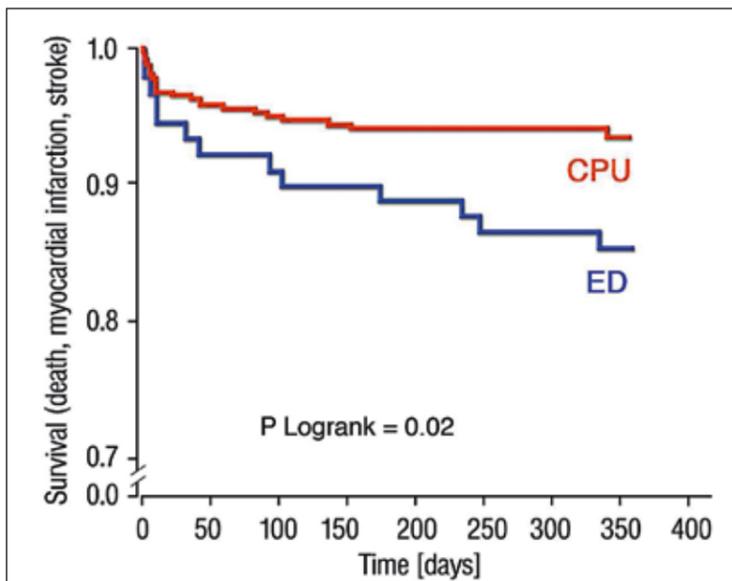
Trauma specialists in the USA pioneered modern chest pain care. In the early 1980s, the first Chest Pain Centre (CTC) was established in the emergency room at the St. Agnes HealthCare Hospital in Baltimore, Maryland.

The main objective was to increase survival rates of patients with acute myocardial infarction, unstable angina or acute coronary syndrome by offering fast diagnosis and targeted treatment. Today there are approx. 3,500 chest pain centers in the USA, 826 of them accredited according to the Society of Cardiovascular Patient Care (SCPC), the responsible body.

In Germany, Dr Thomas Münzel, professor and head of cardiology at University Hospital in Mainz, was instrumental in launching and driving CPU development and quality assurance. He and his team established the third German CPU at University Hospital Mainz in 2005.

In 2007 Münzel also initiated a task force within the German Cardiac Society to draft quality criteria for CPUs, develop an accreditation procedure and lay the groundwork for more CPUs in this country. Just one year later DGK accredited the first CPUs and today Germany has 215 accredited CPUs.

CPU standards have been continuously adjusted and improved, although the core elements have not altered. The foremost objective of a CPU is to provide a definite diagnosis and timely treatment for patients presenting with unspecific chest pain. The team is supported by internal medicine specialists and qualified cardiac care staff, led by a cardiologist. At least four monitoring units with ECG must be available 24/7, 365 days a year. In general, the CPUs are integrated in a hospital, because transport to the cardiac cath lab must be completed within 15 minutes to ensure speedy



Survival analysis. The Kaplan–Meier survival curves in patients with acute coronary syndromes for composite endpoint of death, myocardial infarction, and stroke within one year. CPU: patients treated in the chest pain unit; ED: patients treated in the emergency department.

coronary angiography and, if necessary, a percutaneous coronary intervention (PCI).

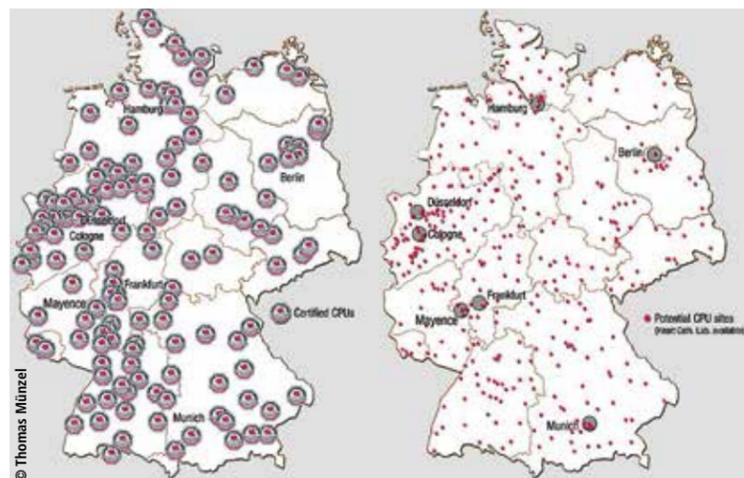
Whilst in the USA several randomised controlled studies have shown the effectiveness of chest pain centres, Germany has no such comprehensive studies on this. Nevertheless, results of the US researchers agree with the results of small-scale German studies, Münzel says. For example, a retrospective, single centre analysis at Mainz University Hospital indicates that, among myocardial infarction patients admitted to a CPU, the one-year survival rate is higher than among those admitted to a conventional emergency department (see illustration).

In 2008, DGK commissioned the Institute for Infarction Research in Ludwigshafen to set up a Chest Pain

Center register. The initial analysis of 30,000 patient data sets shows that Germany CPUs record a high number of self-referrals. Between 2008 and 2010, 32 percent of the admitted patients were ‘walk-ins’ and around 30 percent of them presented with acute coronary syndrome – mostly younger people who had a vague feeling that something was wrong, but for a variety of reasons did not call the emergency medical services. ‘Without CPUs, this patient group would not have received help in time but, because of the CPUs they have a better long-term prognosis,’ Münzel underlines.

Similar to the USA’s SCPC, Münzel and his DGK colleagues want to offer CPU accreditation internationally, above all in Europe, where many countries have comparable levels of care and comparable infrastructures. Thus, the recently updated DGK accreditation criteria will also be published for the first time in English (Clinical Research in Cardiology, 2015). DGK has already accredited two CPUs in Switzerland while hospitals in Austria, Turkey and Qatar expressed interest in the accreditation process.

Germany, however, is not the only European country to adopt the US model to set up chest pain facilities: Great Britain, Spain and France follow similar routes. However, unlike Germany, these countries have so far not managed to implement accreditation processes and create a nationwide CPU network. Why that is the case is a matter of speculation – although it is no speculation that Münzel’s personal and on-going commitment continues to be crucial to the German CPU success story.



Map, left: Accredited CPUs. Right: Cardiac cath labs (as per Dec. 2014). The maps indicate that not every cardiac cath lab is complemented by a CPU, with these ‘accreditation gaps’ particularly visible in east Germany. Currently, Professor Münzel and colleagues on the DGK accreditation committee proactively approach cardiac cath labs in those regions to find out why there are fewer CPUs – accredited CPUs – and how possible barriers to CPU accreditation might be removed.



Professor Thomas Münzel MD has been Director of Cardiology and Angiology at Johannes Gutenberg University Hospital in Mainz since 2004. He was instrumental in establishing the third German Chest Pain Unit (CPU) there in 2005. He has chaired the CPU Accreditation Committee at the German Cardiac Society (DGK) since 2009.

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Fast specialist care saves lives

Rapid Access Chest Pain Clinics

The United Kingdom's National Health Service (NHS) offers a two-pronged approach to care, diagnosis and treatment for patients with chest pains, Mark Nicholls reports

Many NHS hospitals in the United Kingdom have established Rapid Access Chest Pain Clinics (RACPC) to work in tandem with them in offering primary percutaneous coronary intervention (PPCI) – the gold standard treatment for heart attacks – 24 hours a day.

Patients who need instant, emergency treatment can access PPCI at the earliest opportunity, whatever the hour, yet those with previously undiagnosed chest pain can also receive timely assessment and onward treatment through the service provided by the RACPC.

The concept of RACPC can trace its origins back to the National Service Framework (NSF) for Coronary Heart Disease, published in 2000, which set modern standards for the management of patients presenting with angina symptoms and aimed to provide rapid investigation and symptom relief and reduce the risk of coronary events.

More recently, the guidelines led to the widespread development of RACPC to provide specialist assessment within two weeks' of GP referral, with RACPCs established in almost all acute trusts in England and Wales.

Most UK chest pain clinics have adopted an exercise electrocardiogram (ECG) model of approach, where patients are risk-stratified based on clinical history, examination and exercise ECG.

Within major hospitals, such as University College Hospital London,



The University of London's Rapid Access Chest Pain Clinic (RACPC) provides a quick and early specialist cardiology assessment for patients with new onset of chest pain

the RACPC provides 'a quick and early specialist cardiology assessment for patients with new onset of exertional chest pain thought likely to be angina, and for patients not currently under a cardiologist who have known ischaemic heart disease and worsening symptoms, who need urgent assessment.'

This consultant-led, one-stop clinic enables a rapid and definitive

assessment of symptoms and investigations and results in either treatment initiation or the swift reassurance of patients without pathology.

Through the RACPC system, all patients are offered an appointment within two weeks of a referral by their general practitioner (GP), with letters generally sent within 24 hours.

Viewed as a fast route of entry

into cardiology services for patients with suspected ischaemic heart disease, the system allows quick access to appropriate treatment, either medication or invasive procedures and to advice on risk factor modification and prevention and to rehabilitation services.

However, patients with suspected myocardial infarction (MI), or acute coronary syndromes, should go

directly to A&E and, where necessary, undergo PPCI.

At RACPC, patients will have an electrocardiogram (ECG), blood tests and chest X-ray with access to an exercise ECG test while a cardiac technician monitors pulse, blood pressure and heart trace. CT calcium scoring, CT coronary angiogram, stress echocardiogram, myocardial perfusion scan, 24-hour ECG and coronary angiogram are also available as required.

West Middlesex University Hospital NHS Trust RACPC provides a one-stop service involving clinical assessment and investigations to confirm or exclude coronary artery disease and also sets the patients onwards to evidence-based treatment (revascularisation).

Led by consultant cardiologists and nurse specialists, this clinic is regarded as such a success due to the partnership and collaboration between the GPs, A&E staff, physicians who refer patients to the service, and the specialist nurse who runs the clinic supported by the medical members of the cardiology team and diagnostics department.

Gloucestershire Hospitals states the aims of the service are to review all patients within two weeks of referral; make accurate diagnosis of exertional angina; eliminate cardiac cause from those who have non-cardiac pain promptly; perform risk stratification; instigate appropriate/stop inappropriate treatments promptly; refer for onward cardiac investigation as appropriate.

Referral criteria include typical cardiac chest pain; recent onset or recurrence (within three months); patient suitable to perform Exercise Tolerance Test; patients with a pre-existing diagnosis of IHD/ CAD, who have recurrence of chest pain.

Yet, for those suffering heart attack and requiring emergency PPCI, there is a wide round-the-clock network.

A typical example of the PPCI network expanding within the NHS is the investment in additional specialist staff which enabled the Lister's Hertfordshire Cardiology Centre to provide the service 24 hours a day over the last year.

Before that, the service at the hospital in Stevenage, north of London, was only available 9am-5pm, Monday to Fridays and, outside those hours, patients would have to be transported several kilometres to Papworth hospital in Cambridgeshire or Harefield in North-west London for PPCI.

The development of the service means that when someone has a heart attack within the hospital's catchment, they can always have emergency life-saving treatment locally.

Professor Diana Gorog, clinical director for cardiology, said: 'Having rapid access to a local PPCI service, rather than being transported to another centre around an hour away, will give those suffering from a heart attack not only a greater chance of surviving, but also reduce the amount of heart muscle damage and thus improve quality of life.'

Reports from the Royal College of Physicians shows that the Hertfordshire Cardiology Centre is ensuring people who have a heart attack obtain that specialist treatment quickly and is among the top 15% in England for treating patients within 90 minutes of hospital arrival.

Yet, for those who require ambulatory care, the RACPC is an effective service – and readily available. ■

TAVI: Only for hospitals with cardiac surgery and wards

Restrictive ruling on cardiac procedure

In the future, TAVIs can only be carried out in German hospitals with cardiac surgery departments and cardiac wards, as decided by the German Government's Expert Panel on Health (G-BA) last January. An interim arrangement in force until 2016 is anticipated for Heart Centres that currently carry out the TAVI procedure without cardiac surgery departments on site. The Federal Ministry of Health is still to confirm this decision, Bettina Döbereiner reports

The interdisciplinary G-BA justified a decision to restrict TAVI procedures to hospitals with cardiac surgery departments and wards by stating that complications following the procedure cannot be ruled out, and that in-patient aftercare provided by heart surgeons is therefore a necessity. The decision was taken in the context of a new G-BA guideline that sets minimum standards for minimally invasive aortic valve interventions in German hospitals. Heart surgeons have therefore asserted themselves over their cardiologist colleagues with a demand that TAVIs should only be carried out in heart centres with cardiac surgery on-site, as per recommendations

defined in the European Guidelines on Management of Valvular Heart Disease. In a position paper published last year, the cardiologists

had argued in favour of allowing heart centres without cardiac surgery departments on-site to continue performing these interventions under certain conditions and in the presence of a cardiac surgeon (see report in EH 2/14 www.healthcare-in-europe.com/en/article/11713-transcatheter-aortic-valve-implantations-tavi.html).

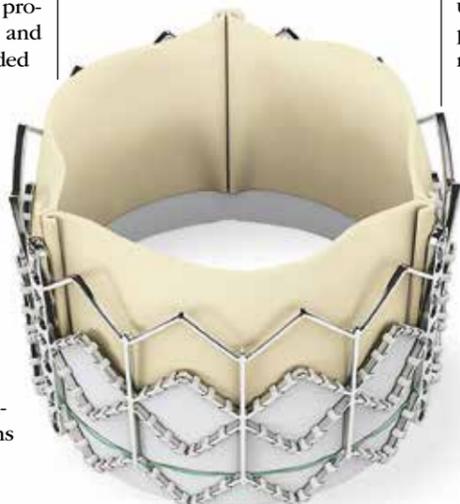
As expected, when the decision was announced Professor Jochen Cremer, President of the German Society for Thoracic and Cardiovascular Surgery (DGTHG), welcomed this move. Professor Christian Hamm, President of the German Cardiac Society (DGK) also views the G-BA guidelines, along with the mentioned quality criteria listed in the DGK posi-

tion paper, as a positive contribution towards quality assurance for TAVIs in Germany.

According to Hamm, there are currently 11 Heart Centres without cardiac surgery departments on site that carry out TAVIs - treating fewer than 5% of all patients undergoing this type of procedure. According to the definition of the G-BA interim arrangements, the centres are to continue with the provision of cardiac surgery through cooperation agreements until June 2016.

As for the indication for treatment, the new G-BA guideline confirms the guidelines as well as national and international recommendations currently in force. For patients with a low risk score, open surgery remains the procedure of choice; TAVIs should only be carried out for older patients and those classed as inoperable.

The Federal Ministry of Health is expected to pass the new G-BA guideline in coming months; only then will it be legally binding. ■



Source: Edwards Lifesciences

25th European Congress of Clinical Microbiology and Infectious Diseases

Keeping up with an ever-evolving science

Expecting 10,000 participants, prior to the 25th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Copenhagen, Denmark (25-28 April) its Programme Director, Professor Winfried V Kern MD, was keen to point out: 'The findings and recommendations that emerge from this vibrant platform each year have, in the past, had a tremendous impact not only on guidelines and best practices, but also on international policies.'

'With challenges like antibiotic resistance and infection outbreaks to tackle, it remains crucial that healthcare professionals – from clinical settings as well as those specialised in microbiology and epidemiology – attend this event so that we can jointly discuss and disseminate evidence of advances that will help us better prevent and control the spread of infectious diseases.'

Top-notch sessions

Among the one hundred and fifty keynote lectures, symposia, oral sessions, educational workshops, meet-the-experts session and around 2,500 poster presentations, '...microbiologists and clinicians will have the chance to exchange opinions and ideas on how to translate research findings into diagnostic tools, medicines, policies and education and thus effectively deal with the world's most pressing infection problems,' he predicts.

Healthcare organisations provid-



ing their expertise and validating ECCMID's significance are WHO Europe, the ECDC and national or disease-specific societies. Together with the WHO, ESCMID has also organised, ahead of ECCMID, the 7th International Day for Fighting Infection, which runs under the slogan 'Learning from the Past to Shape a Better Future'.

Prof. Kern: 'This year's Clinical Grand Rounds, co-organised with

the Infectious Diseases Society of America (IDSA) and chaired by international experts, will feature seven multifaceted cases. In another session, young professionals will also have the opportunity to discuss their ideas and projects with 20 renowned experts during round table discussions.'

Strong topics include stewardship and other strategies to deal with antibiotic resistance, and specialists

in antimicrobial susceptibility will also provide an update on breakpoints and methods for new agents, Kern adds. 'At the same time, there will be presentations on infections in more specific settings, including in the operating theatre and in long-term care.'

Resurrecting old antimicrobial agents

Also included will be a focus on the



ECCMID Programme Director Winfried V Kern MD is Professor of Medicine at the Albert-Ludwigs-University, Freiburg, and Head of the Infectious Diseases Division in the Department of Medicine, and Centre for Infectious Diseases and Travel Medicine, at Freiburg University Hospital, Germany. The professor gained his medical degree at Karl-Ruprechts-University in Heidelberg, and was trained in Bordeaux, in Erlangen-Nuremberg and Heidelberg, with postgraduate training, residency and fellowships (internal medicine, clinical microbiology, tropical hygiene, infectious diseases, and clinical immunology) in Heidelberg, Ulm, and Tübingen, as well as in Providence and San Francisco, USA. Today his main professional interests lie in bacterial multidrug resistance mechanisms and epidemiology, hospital antibiotic stewardship programmes, healthcare-associated infections including infections in the immune-compromised host. Dr Kern is a past president of the German Society for Infectious Diseases (DGI), co-editor of the German Antibiotic Use and Resistance Atlas (GERMAP), a member of the Drugs & Therapeutics Committee of the Federal Chamber of Physicians and he has worked within the EORTC Infectious Disease Group on clinical trials in cancer patients with infection.

challenges associated with successfully developing new therapeutic agents and updates will be provided on the potential of resurrecting old antimicrobial agents and the use

Continued on page 11

Planning for perfect clinical conditions

Made to measure laboratories



Claudia and Robert Karl, Managing directors of Kugel medical

In 1995 Claudia and Robert Karl risked self-employment in a sector already dominated by experts. Those manufacturers, however, sold standardised products. The Karls, with backing from a stainless steel producer, decided to produce tailor-made solutions to fit customers' needs. To that end they attended international medical equipment exhibitions from Dubai through to Malaysia. Today, Claudia Karl believes entrepreneurial thinking and attention to customers' needs established their success.

In the '90s a friendship with a pathologist from Nijmegen, the Netherlands helped to optimise their products. By 1996 their company, Kugel, based in Regensburg, Germany, fully equipped a newly built forensic centre in Budweis, Czech Republic. 'There was a lot of backlog demand after the Iron Curtain fell,' Robert Karl observed.

Their product range contains almost everything for a modern laboratory and the portfolio expansion continues to expand, with a focus on various tables. 'Our specialties are the integrated exhaust units for dissection and autopsy tables. We also offer a complete range

Continued on page 10



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New IVD regulation planned for Europe

'We will need a lot more regulators'

Report: Mark Nicholls

European Hospital has already reported on the consequences of the new EU draft IVD regulation (December 2014 issue). Now, the new Directive proposed for Europe looks set to have major implications for IVD manufacturers and laboratory-developed tests (LDTs). Replacing a current system that is inflexible, unresponsive and does not effectively protect patients, the new regulation will apply directly to all 28 EU countries and govern the manufacture and marketing of in vitro diagnostic devices (IVDs).

Speaking ahead of the Advanced Diagnostics for Infectious Disease Conference in Lisbon, Portugal (April 15-16 April), Dr David Barton said the purpose of the new regulation would not only be to ensure that IVDs are safe and effective, but also to create a single market throughout the European Union so that devices 'approved according to the rules and the regulation in one European country can be sold in all European countries'.

However, Dr Barton, who is Chief Scientist at the National Centre for Medical Genetics in Ireland, warned that at the present stage it remained unclear when the new regulations will be in place, because there are on-going negotiations between governments and the European Parliament. However, once they are complete, it could be a further four years before the directive is fully implemented.

Dr Barton will present the conference with an update and analysis of the pending regulations, which will be based on a framework proposed by The Global Harmonisation Task Force (GHTF), a forum of industry and direct national regulators. 'Under this framework,' he said, 'each IVD would be placed into a risk class from A-D with D being the highest risk class and A being the lowest, depending on the intended use of the device.'

Dr Barton explained that challenges might arise over the regu-

latory rollout in Europe; it sees a move from 'very light touch regulation to a much more structured and hands-on form of regulation'.

'Compliance with that will be a big burden for industry and also a big burden for the regulatory side,' he added. 'We're going to need a lot more regulators and they're going to need a lot more skills to carry out the new tasks they've been given.'

There are potential advantages of the new regulations, particularly for patients.

Dr Barton: 'Light touch regulation in an industry that does commercial IVD production is probably not in the best interest of patients. Clearly, just as with medicines, you want to make sure that your diagnostic devices are working well in order to protect the safety of patients.'

'From that point of view, more regulation should make things safer. We should also have a database of all approved IVDs, whether they are lab-developed tests or commercially approved IVDs.'

There will be more transparency, akin to the USA's system, he added, although there is no direct link between Europe and the US in this respect, as they are different jurisdictions, but there are interesting parallels.

In both cases the professional associations are making strong arguments for the continuation of the exemption of laboratory-developed tests, built in to the current European legislation.

As to how IVD manufacturers and clinical labs might prepare for the coming changes, Dr Barton concluded: 'We're hoping that, if the exemption for LDTs remains and is extended to all classes of device, the clinical labs won't actually have to do very much. There will be recording of which LDTs are in use and reporting of adverse events and that's quite proper.'

For industry, he foresees extra work and additional layers of regulation, inspection of their facilities, compliance, and production of clinical evidence in moving 'from a very

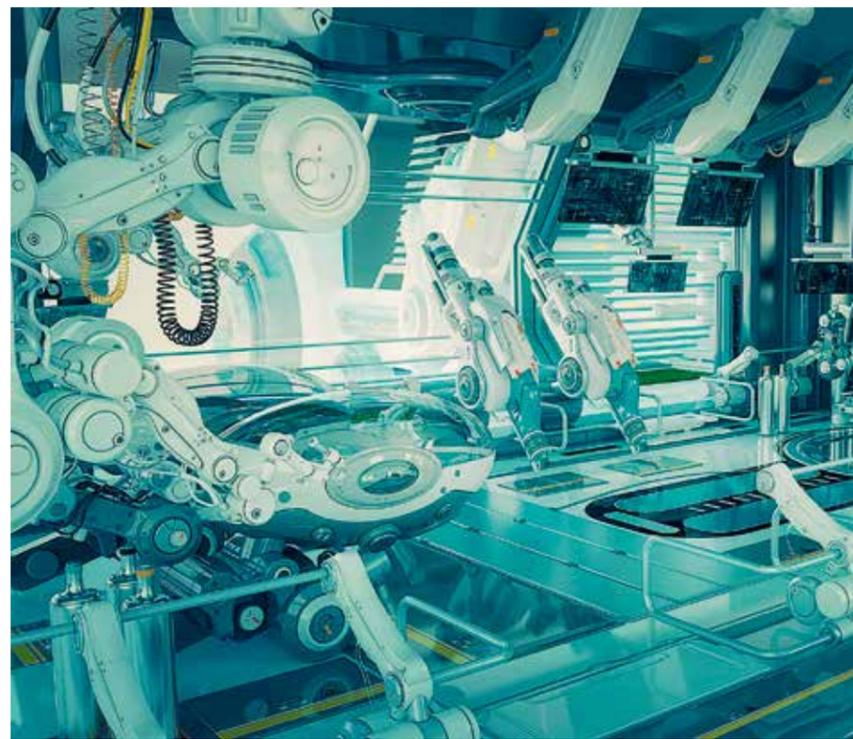


David Barton is Chief Scientist (Director) of the Molecular Genetics Laboratory at the National Centre for Medical Genetics in Dublin, Ireland, and Adjunct Associate Professor at University College Dublin. He trained in Trinity College, Dublin, and The Queen's University of Belfast and carried out medical genetics research at Yale and Cambridge Universities before setting up the NHS molecular genetics diagnostic laboratory in Cambridge. In 1995, he returned to Dublin to set up his current laboratory at the National Centre for Medical Genetics.

light touch regulation to regulation that's more aligned with global norms'.

Other topics at the Advanced Diagnostics For Infectious Disease Conference include the keynote presentation, 'A Paradigm Shift of Diagnostic Medical Microbiology: Will It Finally Happen?' by Dr Herman Goossens, Professor of Medical Microbiology at Antwerp University Hospital; the ESGMD/ESCMID Roadmap of Bringing New Technologies into the Clinic, by Dr Eric Claas, Associate Professor of Medical Microbiology, Leiden University Medical Centre; and Molecular Diagnostics of Antimicrobial Resistance at Point-of-Care, by Dr Till Bachmann from the University of Edinburgh.

Also on the agenda are point of care testing in infectious diseases, infectious disease applications of next-generation sequencing and mass spectrometry for infectious disease detection.



The role of laboratory medicine in clinical

IT communication fosters unified s

Interview: Walter Depner

Looking back, the founding fathers of laboratory medicine were doctors who carried out the historic medical practice of uroscopy in the Middle Ages, explains Professor Klaus Kohse MD, Director of the Institute for Laboratory Medicine in Oldenburg Clinical Centre at Oldenburg University Medical Faculty. 'They drew conclusions about a patient's state of health by analysing a person's urine – an easily accessible body fluid. The change to the use of blood for this type of analysis, along with improvements to analytics, was decisive for progress in this field, particularly in the last century,' he adds.

'This information carrier is transported to all organs via the circulation and carries out an intensive exchange of substances. Examinations were carried out with increasingly sensitive procedures and extended to more and more physiological and pathological substances with increasing complexity. The ability to determine concentrations on a femtomolar level is no longer sensational, and for cells or genome equivalents the number required for safe quantitative and qualitative analysis can be counted on the fingers of just one hand.'

Where we are today

'These days, the knack of laboratory medicine lies in the ability to process the enormous abundance of information from examinations. The 'omics', the entirety of genes, proteins, lipids, carbohydrates or metabolic parameters can now only be captured with bio-informatic methods. Traditional assessment criteria, such as longitudinal studies or transversal studies, soon reach their limits.

'Going forward, the aforementioned, complex information will facilitate individual assessments along the lines of the much-heralded 'personalised medicine' – but only if we also realise that we are dealing with dynamic organisms, with any samples taken only giving us a snapshot of a situation at this very point in time. Last, but not least, diagnos-

tics will be advanced through the integration of clinical-chemical information with imaging procedures – such as functional NMR, PET and so on.'

Having been a member of various national and international committees, associations and societies, among others the Executive Committee of the IFCC Task Force on Paediatric Laboratory Medicine. With roles also including treasurer of the European Communities Confederation of Clinical Chemistry and lecturer at the European Medical School Oldenburg-Groningen, the professor's experience is pan-European. How does he perceive this array of countries and cultures?

'The development of Europe from a plethora of different national states has obviously led to a multitude of developments during the establishment of our discipline,' he points out. 'Clinical Chemistry, Clinical Biochemistry, Clinical Biology, Clinical Pathology, and Laboratory Medicine are terms that tend to be used on a mix and match basis.'

'The scope of diagnostic activity is also extremely different. In one country the fields of haematology and microbiology are included, in another they are considered to be separate subjects. The medical degree courses also differ. There is human medicine on the one side and natural sciences, such as chemistry, biochemistry and pharmaceuticals, on the other. The basic problem of how to deal with this continues to be an issue for the 'community'.

'This prevails despite the fact that there are European committees such as the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Union Européenne des Médecins Spécialistes (UEMS), which have agreed on and compiled fundamental documentation and competency descriptions, such as the term European Specialist in Clinical Chemistry and Laboratory Medicine, based on a 'common platform' type of catalogue.'

'The differences don't stop at European borders, but have to be assessed differently as a matter of principle against the background

Made to measure laboratories

Continued from page 9

of stainless steel furniture, morgue refrigeration units and transport and storage equipment.'

Robert Karl is increasingly asked to take over the entire laboratory planning, so the firm is not only a supplier but also planner.

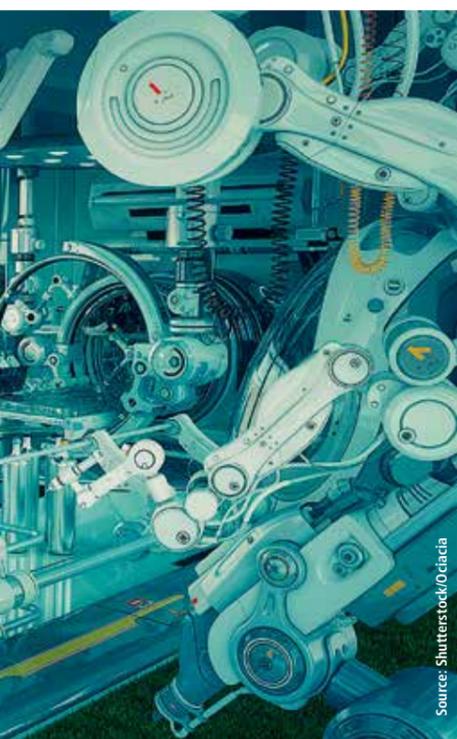
Kugel's customers include histopathology labs, forensic centres, universities, hospitals, anatomy institutes and pharmaceutical firms plus veterinary pathologists. The firm has 130 international partners and 85% of its products are exported to 72 countries, including those in Europe, the Middle East, Russia, Asia and Australia.

'This year, Kugel medical celebrates its 20-year anniversary – for which Robert and Claudia Karl issued a statement that it is 'an anniversary that we are very proud of and which motivates us even more

to develop and manufacture state-of-the-art solutions for our customers around the world.'

Illuminated Down-draft Grossing table with accessories such as a corian cutting board and a monitor holder





Source: Shutterstock/Olga

national (DIN), European (EN) and international (ISO) level also make significant contributions towards standardisation and harmonisation. They determine important specifications. For instance, one noticeable example is the definition of a unified standard for the competency of medical laboratories, which is implemented via accreditation with ISO-Norm 15189.

'All of this only works because these days we can communicate in unbelievably fast and efficient ways. Sharing activities in internet presentations, along with electronic communication, enables international discussions with colleagues.'

of non-conventional drugs for the treatment of pathogens, he points out. 'Very popular are also presentations on promising drug candidates in late-stage clinical trials, which will be the subject of oral sessions, poster presentations and a pipeline corner.'

In the pro-con debate on pneumococcal conjugate vaccines we expect a vibrant discussion of the advantages and disadvantages of an adult vaccination.

Other ECCMID highlights include

Keeping up with an ever-evolving science

Continued from page 9

the lessons learned from the recent Ebola outbreaks, strategies on how to control poliovirus, malaria, multi-drug-resistant tuberculosis and respiratory viruses, as well as recent news on the eradication of Hepatitis C, he says.

Clinical microbiology speakers will highlight developments in culture-based, PCR-based and rapid diagnostics as well as current and future challenges in forensic microbiology. 'Participants will also get updates on whole genome sequenc-

ing, on the detection and screening for resistant bacteria, the integration of molecular platforms into the laboratory and the use of digital imaging to assess colony morphology, Prof. Kern points out.

Although a quarter of a century 'old', clearly ECCMID remains a sprightly scientific leader and opinion shaper.

diagnostics

on standards



Klaus Kohse MD directs the Institute for Laboratory Medicine at the Oldenburg Clinical Centre, Oldenburg University Medical Faculty, Germany

of different legislations beyond the European Union.

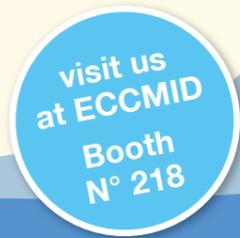
'The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the World Association of Pathology and Laboratory Medicine (WASPaLM) are also working towards the creation of job profiles that are standardised worldwide and with comparable competencies. Not all partners are always weighted equally, which is partly due to sheer size - the American Association of Clinical Chemistry (AACC), for instance, is only one of 85 specialist associations involved, but it has a huge number of members - and partly also for legal reasons.'

The future is not gloomy

In no way is the view towards international harmonisation gloomy, according to Prof. Kohse. 'When it comes to the contents of our activities, there are now hardly any national differences. There are procedures recommended by the international specialist associations and societies for the most important determination methods. The subject of quality assurance is basically handled in a very similar way the world over, although subtle differences will continue, due not least to different philosophies (such as target values for reference methods vs. consensus on target values for inter-laboratory test samples).

'Standards organisations on a

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Cancer diagnostics

New nanoparticle could enhance MRI scanning

Scientists in the UK have designed a new self-assembling nanoparticle that targets tumours and could lead to quicker diagnosis of cancer, Mark Nicholls reports

Researchers at Imperial College London report that a new self-assembling nanoparticle can adhere to cancer cells, thus making them visible in MRI scans and possibly eliminate the need for invasive tissue biopsies.

The nanoparticle increases the sensitivity and improves the efficacy of MRI scanning by 'specifically seeking out receptors found in cancerous cells' – a breakthrough the research team suggests has the potential to alter anatomic pathology's role in diagnosing cancer and improve doctor's ability to detect cancerous cells at much earlier stages of development.

Work is now under way to enhance the effectiveness of the newly designed nanoparticle as a tool to improve the sensitivity of MRI scanning, with a goal to test the design in a human trial within three to five years.

Under the process, the nanoparticle is coated with a protein that

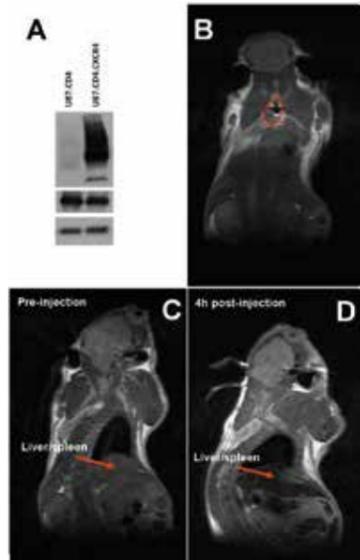


Figure. A: Protein expression in U87, CD4 tumours, as compared to U87.CD4, CXCR4 tumours, as evaluated by western blot (upper CXCR4 middle CD4 and lower -actin). B: whole body T-2-weighted MR image of mouse after injection of 0.75 mg Fe/kg of pre-aggregated targeted nanoparticles directly into the tumour (tumour area highlighted in red). C & D: Whole body T-2-weighted images of a mouse before (C) and 4 h (D) after the injection of 7.5 mg Fe/kg of targeted nanoparticles. Red arrows indicate signal loss in the liver and spleen due to accumulation of iron from the nanoparticles.

scanning against commonly used imaging agents and found that the nanoparticle produced a more powerful signal and created a clearer MRI image of the tumour.

Professor Nicholas Long, at the Department of Chemistry at Imperial College London, said the results show real promise for better cancer diagnosis. 'By improving the sensitivity of an MRI examination, our aim is to help doctors spot something that might be cancerous much more quickly,' he explained. 'This would enable patients to receive effective treatment sooner, which would hopefully improve survival

rates from cancer.'

'MRI scanners are found in nearly every hospital and are vital machines used every day to scan patients' bodies and get to the bottom of what might be wrong; but we are aware that some doctors feel that, even though MRI scanners are effective at spotting large tumours, they are perhaps not as good at detecting smaller tumours in the early stages.'

The aim is to improve the design so that doctors can more easily spot a tumour and surgeons can then operate on it. Long: 'We're now trying to add an extra optical signal, so that the nanoparticle would light up with a luminescent probe once it had found its target, so combined with the better MRI signal this will make it even easier to identify tumours.'

The next research stage will endeavour to fine-tune the size of the final nanoparticle, to be even smaller but still produce an enhanced MRI image. However, researchers are aware that, if the nanoparticle is too small, the body will secrete it before imaging, but if too big it could be harmful. 'Getting it just right is really important before moving to a human trial,' added Dr



Professor Nicholas Long is the Sir Edward Frankland BP Chair in Inorganic Chemistry and Head of the Catalysis, Sustainability and Applied Inorganics Research Section at Imperial College London. The Long Group has expertise in applied synthetic inorganic and organometallic chemistry and his research interests focus on transition metal and lanthanide chemistry for the synthesis of functional molecules, homogeneous catalysis and, in recent years, probe design and novel methodologies for biomedical imaging. He has published c. 150 papers, several high impact review articles and the critically acclaimed textbook, *Metalloenes*. He received the 2006 RSC Prize in Organometallic Chemistry, was a Leverhulme Trust Research Fellow 2009/10 and, in 2011, became a Fellow of the Royal Society of Chemistry.

Juan Gallo from the Department of Surgery and Cancer at ICL.

* Research funding came from Cancer Research UK, Engineering and Physical Sciences Research Council (EPSRC), the Medical Research Council (MRC) and the Department of Health.

Human resources

A pathology workforce fit for the future

Report: Mark Nicholls

The UK pathology sector faces numerous challenges as it strives to create a future medical laboratory workforce.

As in many divisions of the National Health Service (NHS), this area has an ageing population yet must evolve against a backdrop of fast-developing technologies, emerging science, financial constraints and the challenge of working in tandem with the private sector.

Neil Anderson, Clinical Director of Coventry and Warwickshire Pathology Services, highlighted how UK laboratory medicine is at a pivotal point. He is concerned that the ageing workforce profile could present a problem in the future. 'Pathology,' he explained, 'has an age profile that is tending to show the greatest number of staff in the 40-60-year-old category with not enough staff coming in at the 20-30-year-old category.'

While work has been conducted around workforce patterns, he suggested predictions were often flawed in the way they looked at simply replacing numbers, rather than analysing what type of workforce will be needed in the future.

It is about putting the right people with relevant skills in the posts available and in the right numbers,



Anderson said. His concerns centre on a potential de-skilling of the pathology workforce with recruitment of more medical laboratory assistants in lower grade pay bands at the expense of experienced staff.

'That is not just due to budget pressures and cost improvement targets, but also to the fact that to run complex machinery actually requires a range of staff who have different roles.'

'Loading and unloading machines are perhaps jobs more suited to lower staff grade and that could be perceived as a down-skilling, when we desperately need to up-skill staff, especially around the clinical interface, assays selection, interpretation and user engagement. We

haven't created the roles we need to respond to future challenges.'

Anderson believes a critical step in meeting those challenges lies with pathology becoming an 'integrated medical service' rather than being regarded as a support service, and establishing links with community and acute pathology sectors as it strives to provide 'more appropriate test selection and usage'.

'In addition, pathology in the United Kingdom needs to become a more coherent business function, needing to understand its costs and have a pricing strategy, articulate visions and, if required, work with the private sector.'

He also feels public sector pathology needs to be good in areas in

which the private sector excels, e.g. managing transition and change, and negotiating discounts with diagnostic suppliers.

One significant development is the 100,000 Genomes Project, which will sequence 100,000 whole genomes from NHS patients by 2017, set up a genomic medicine service for the NHS, enable new scientific discovery and medical insights and kick start the development of a UK genomics industry. 'The staff needed to support that are very different to those currently in place within most pathology laboratories,' he pointed out.

'It's not just about working towards the 100,000 Genome Project, it's what's done with those data that emerge from the 100,000 genome project, identification of new companion diagnostic tests, whether in cancer services or endocrinology and about developing those assays and turning those data into information.'

'The amount of data is rising exponentially and we're going to work to assimilate that to create information of value to patient care.'

Coventry and Warwick, one of the largest pathology organisations within the UK, is leading the way as it invests in the adoption of digital histopathology and molecular diagnostics to support cellular technology and virology, and is part of



Neil Anderson is Clinical Director of Coventry and Warwickshire Pathology Services and a consultant clinical biochemist. He addressed the *Frontiers in Laboratory Medicine* conference earlier this year in the 'Developing a laboratory medicine workforce fit for the future' session, when he examined how, given new and emerging technologies, modernising science careers and an ageing workforce, the evolving laboratory workforce can be fit for purpose today and in future.

an international trial looking at the verification of using digital histopathology in a routine setting.

'We are aware of the implications of the 100,000 genome project, the implications around rapid diagnostics through point of care testing and its applicability and we are engaged in transforming the way we deliver pathology,' he said. 'However, with increased demands on future staffing, we may have to look at alternative models, so that we can adopt new technologies more rapidly.'

Anderson also stressed that, to create a laboratory medicine workforce fit for the future, pathology needs to develop new service models, integrate into clinical teams, embrace specialist working and ultimately ensure the appropriate use of pathology.

Workers' safety and improved patient care

Labs need quality management systems

Report: Mark Nicholls

All laboratories should utilise quality monitoring systems and systematically work through their workflow processes to identify problem areas, according to Lucia Berte, who specialises in quality management systems in healthcare ancillary services through the Colorado-based organisation Laboratories Made Better. 'Laboratories in any country do not have unlimited financial resources,' she acknowledges. 'Therefore, it's in the laboratory's best interest to identify problematic processes that have high failure costs and then solve those problems to reduce the financial drain on the budget. Unfortunately, many administrators do not see the value of using money to prevent and measure activities that ultimately save money by reducing and eliminating failure costs.'

Under the title 'Understanding and Fixing Recurring Costs of Bad Quality in Your Laboratory', she told delegates at the recent *Frontiers in Laboratory Medicine* conference in Birmingham, England, '...this is an especially timely topic, as laboratories struggle with adding new methods and technologies while also being asked to reduce cost.'

Acknowledging that patients want quality care at the lowest reasonable cost, as do clinicians and administrators, she said applying the four types of quality costs – prevention, appraisal, internal failure and external failure – across all disciplines within the laboratory is a systematic way to manage a laboratory's limited financial resources. A key way to do this, rather than use expensive commercially available software programmes to manage quality cost data, is instead to systematically track failure costs using simple spreadsheet software. Prevention entails focusing on areas such as quality planning, work process training, preventive maintenance and quality management activities that help to ensure laboratory work process-

es function as intended. Appraisal includes conducting on-going competence assessment, performing and reviewing quality control data and conducting internal audits to ensure

that work already performed meets quality requirements.

Internal failure, she says, incurs costs that include anything from wasted blood components to insuffi-

cient or expired reagents or supplies or computer issues while external failures such as misdiagnosis, lost reports, reporting errors, lawsuits or customer complaints result in very

high failure cost. 'The laboratory can use quality measurement and monitoring data to identify problematic processes. These problems need to be prioritised according to the risks of severity and frequency they pose to patients. The prioritisation becomes a roadmap for laboratories to initiate improvement projects.'

Berte believes that laboratories must identify and quantify these costs and then tackle and remove the causes to begin to resolve problem areas that prevent labs from delivering high level services. ■

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With a 20-year history in healthcare management systems, **Lucia Berte** has a strong background in laboratory medicine, certifications as a medical technologist, specialist in blood banking, and a diploma in laboratory management. She has been a lab supervisor and manager, has experience in lab quality management and is a certified quality auditor and quality manager (in, for example, the medical laboratory, respiratory care, medical imaging, pharmacy, and rehabilitation). The author of numerous articles and books on quality management, she served for many years as a laboratory assessor, performing both readiness and conformance audits for laboratory and blood bank accreditation.

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U.S. aims to slow the rise of drug-resistant bacteria

Obama's multi-year, billion-dollar effort



U.S. President Barack Obama

The USA's President Barack Obama released a comprehensive plan in March to slow the emergence of drug-resistant bacteria, a multi-year, billion-dollar effort that includes getting doctors to stop over-prescribing antibiotics, developing new medications and rapid diagnostics, and real-time tracking of infection outbreaks.

'We're setting national goals for improving antibiotic use, and we're asking doctors and hospitals to help us meet them,' President Obama told Medscape in a March 27 interview about the plan. 'And we're going to help health departments across the country achieve these goals.' The overall goal is to reduce the most serious health threats, including carbapenem-resistant Enterobacteriaceae (CRE), methicillin-resistant *Staphylococcus aureus* (MRSA), and *Clostridium difficile*, which cause approximately 23,000 deaths in the United States alone, according to the USA's Centers for Disease Control and Prevention.

The plan will be overseen by a USA's Government Task force and includes several strategies:

- Getting doctors to prescribe fewer antibiotics and ensuring patients receive the right antibiotic at the right time.



Two plates growing bacteria in the presence of discs containing various antibiotics. The isolate on the left plate is susceptible to the antibiotics on the discs and therefore unable to grow around the discs. The one on the right has a CRE that is resistant to all the antibiotics tested and can grow near the discs.

- Developing at least two antibiotics, or non-traditional therapies, to treat bacterial diseases in humans.
- Developing tests that rapidly distinguish between viral and bacterial pathogens, and tests to detect antibiotic resistance.
- Creating a network of laboratories to detect strains of resistant bacteria and a specimen repository that can be accessed by researchers, and providing

incentives to healthcare providers to report antibiotic resistance and antibiotic use.

- Eliminating the use of medically important antibiotics for growth promotion in food animals and having veterinarians oversee the use of drugs for treatment, control, and prevention of disease in animals.
- Working globally — with foreign ministries of health and agriculture, and organisations such as

the WHO— to control the spread of antibiotic-resistant bacteria.

Obama has included the \$1.2 billion plan in his proposed 2016 budget. Infectious disease experts applauded the White House for taking the lead and offering practical plans for improved stewardship of antibiotic use in medicine and the development of new drugs and tests, but they worry that the effort doesn't go far enough to curb the use of antibiotics in animal agriculture.

Lance Price, a microbiologist at George Washington University, says the president's plan does not offer measurable goals for reducing use of antibiotics in animals raised for food, and also does not address overcrowding and other conditions that cause infections to spread among them.

'It's really weak on the animal antibiotics side,' Price says. 'You can't shut off one pipeline and expect the whole thing to be fixed without shutting of this other, huge pipeline.'

Europe has led the way in addressing the use of antibiotics in animals, says James Johnson MD, professor of medicine and an infectious disease expert at the University

of Minnesota. Using antibiotics to promote growth in animals has been banned in Europe since 2006. Johnson also points to recent efforts in the Netherlands where, in 2009, the government directed farmers to cut antibiotic use in meat animals in half, and to Denmark, which has been reducing antibiotic use in animals since the 1990s.

'I think the US has sort of moved into playing catch-up to Europe in handling antibiotic resistance,' Johnson says. 'I see the action plan as the US getting back in the game.'

Johnson also worries about what he considers the shortfalls of the White House plan, including the lack of an authority figure at the federal level to oversee efforts to curb antibiotic resistance.

'Pulling it all together and making sure it all happens — there has been a glaring lack of that in the past,' Johnson says. However, the healthcare community will likely embrace the effort, Price adds. 'It seems like the medical community is ready for a change here. I think, with reimbursement rules changing and these time-bound quantitative goals, this is going to have a benefit for sure, and the medical community will rise up to the challenge.'

CE-IVD certified molecular test added to Genspeed

One step C. diff testing



The Genspeed C. diff OneStep test, a CE-IVD certified molecular diagnostic test to detect nosocomial infections, has been added to the Greiner Bio-One portfolio. The manufacturer reports that the test identifies toxigenic *C. Clostridium difficile* by combining the detection of Glutamatdehydrogenase (GDH), Toxin A, Toxin B and binary toxin in a single, molecular test — and a complete analysis, including the detection on the Genspeed R2 Analyser takes under 100 minutes (* Time can vary with validated PCR-cycler used).

The new test addresses a leading threat to healthcare systems worldwide; *C. diff* infection (CDI), believed to be the most common healthcare-associated infection. The disease causes antibiotic-associated diarrhoea (AAD) that may lead to pseudomembranous colitis and even to death. In a 2013 published report, the Center for Disease Control (CDC) in the USA categor-

Genspeed R2 Analyser and Genspeed C. diff OneStep Test

ised *C. difficile* infections as 'Threat Level Urgent', the highest level available.

OneStep — one test — four results

The Genspeed C. diff OneStep test avoids the currently used, sequential, two-step diagnostic test procedures, which combine different test systems and assay principles for GDH and the *C. difficile* toxins. The new provides conclusive results without the need for confirmatory re-testing and enables inter-laboratory comparisons of test results, the maker reports. 'Ready-to-use reagents and automated dispensing minimise the number of manual process steps within the workflow.'

* All Genspeed products are currently available for sale in the EU and EFTA countries only.

Meet Mr Clean

They call him Mr Clean Hand. Professor Didier Pittet MD, Specialist in Infection Prevention and Control at the Hôpitaux Universitaires de Genève and Head of the Clean Care is Safer Care programme of the World Health Organisation (WHO), is known as the 'Father of Modern Hand Hygiene'. It was Pittet who, in the 1990s, introduced at his hospital the hitherto largest study on the subject of hand hygiene. It was he who defined the 'five moments for hand hygiene': before patient con-



Source: Heade & Dischinger KG



Source: Semmelweis

Didier Pittet MD directs the Infection Control Programme and WHO Collaborating Centre on Patient Safety at Geneva's University Hospital and is the External Lead of the World Health Organisation's (WHO) Global Patient Safety Challenge Clean Care is Safer Care and African Partnerships for Patient Safety. He developed the Geneva Hand Hygiene Model, and showed in a big study (1995–1997) the effects of this strategy on healthcare associated infections. He also led the development of the WHO Guidelines for Hand Hygiene in Health Care (pub: 2009).

tact, before an aseptic procedure, after contact with potentially infectious material, after patient contact and after contact with the immediate patient environment. Additionally, it was he who thought of the 'steps for effective hand disinfection: rubbing the palms, wrists, back of the hands, the spaces between the fingers, linked fingers, thumbs and fingertips with disinfectant within thirty seconds.

This March, during the First CEE Conference on Hospital Hygiene and Patient Safety (held in Vienna), Pittet spoke about healthcare associated infections (HAI) and the way to combat these with hand hygiene strategies. Such infections cost around 16 million lives worldwide every year. In developed countries these are the second most common cause of death, Pittet believes. 'However,' he adds, 'there's a simple remedy for hospital acquired infections — and this is hand washing.'

Unfortunately, however, there is one major problem: compliance, which is usually only around 40%.

Between 1994 and 1997 the hand hygiene model that he developed substantially increased willingness amongst Geneva doctors and nurses to carry out regular hand disinfection. The Geneva Model consists of two central cornerstones: an awareness campaign as well as monitoring and compliance confirmation.

At the time, funny cartoons of nasty bacteria and dirty hands adorned the corridors of the Geneva hospital, and all nosocomial infections had to be reported. As a study in *The Lancet* confirms, the success of this model was repeated between 2002 and 2005 in many other countries, including France, Belgium, the USA, Australia, Belgium, Great Britain and Switzerland. A recent adaptation of the Geneva Model helped to reduce infant mortality in hospitals in Vietnam by 80%, Pittet

Nosocomial infections kill 50,000 European patients annually

Microbes vs. viruses

Report: Walter Depner

In European acute care hospitals, on any given day, an estimated 80,000 patients – roughly six percent of all patients – receive antimicrobial treatment to fight a healthcare associated infection (HAI), according to the European Centre for Disease Prevention and Control (ECDC).

3.2 million victims a year

Between 2011 and 2012, the ECDC surveyed 1,000 hospitals with more than 231,000 patients from all EU Member States, plus Norway and Iceland. The results indicate that approximately 3.2 million patients acquire a nosocomial infection every year in the EU. The highest infection rates are reported in Portugal (11%), Greece and Spain (9% each). Germany, with its infection rate of 5%, ranks slightly below the EU average. In the United Kingdom the infection rate is almost 9% (England 8.2%, Wales 6.4%, Scotland 9.5% and Northern Ireland 5.4%). In France there are no reliable recent data, but experts discuss a prevalence of 3-6%. The same is true for Austria, where the percentages are considered to be roughly the same as in Germany.

According to the study, in Europe around 50,000 patients die from HAI every year – a figure, the ECDC underlines, which has to be used with caution due to differences in reporting procedures and incom-



parable or incomplete data. As in many comparisons and surveys of this kind the number of unreported cases might be considerable.

As far as Germany is concerned, the ECDC study estimates 400,000 to 600,000 new HAI cases per year and 15,000 deaths. However, during the German Congress for Hospital Hygiene in Berlin in March 2014, the German Society for Hospital Hygiene said it considers the ECDC figures to be 'doctored': According to the Society's estimates, in 2012 up to 900,000 people acquired HAI and up to 40,000 patients died from a nosocomial infection.

Last, but not the least, in the USA data (most likely from 2006, the exact time frame of the survey is

unclear) roughly 1.7 million HAIs were estimated (infection rate of 5.9%) to have caused or contributed to almost 100,000 deaths. More recent data indicate that infection rates are stable.

In the meantime, the ECDC has developed a unified European protocol for so-called point prevalence studies (PPS) and urged all European countries as of 2011/2012 to conduct national PPS on HAI and antimicrobial use. (Bemke, M. et al, *Deutsche Ärzteblatt* 110 (38) September, 2013)

Another important issue has been making headline for about a year: Ebola, above all spreading in West African countries – Sierra Leone, Liberia and Guinea. The figures

are frightening – more than 8,200 people have died and about 25,000 people are infected with the Ebola virus. The number of unreported or undetected Ebola-caused deaths is most likely even more significant than the number of unreported or undetected HAI-caused deaths in Europe.

Fortunately there are worldwide initiatives, research and support projects, fund raising campaigns, emergency hospitals and volunteers to help contain the pandemic. In March 2015 a large-scale vaccination campaign was launched with more than 10,000 participants. While the campaign's success is impossible to predict, it will raise many questions – particularly if successful:

How quickly can pharmaceutical companies produce and distribute the vaccine? How can an uninterrupted cold chain be ensured during transport and storage? How can the necessary infrastructure be established? These are enormous challenges with uncertain results.

In Germany, the Robert Koch Institute (RKI) and other healthcare groups drafted 'Recommendations and Information' and established STAKOB, a network of competence and treatment centres in charge of infection control and of clinical Ebola management, which provide trained staff, specialised diagnostic equipment and dedicated wards. While there are no reliable figures on the financial and other resources being used in Europe and across the world for Ebola research, treatment, aid, infrastructure, etc. we are no doubt talking about billions of euros – and no one knows whether these funds are sufficient, insufficient or too much, or whether they are being invested in useful or superfluous projects.

HAI numbers differ widely

By no means do I want to create the impression that I am supporting a pro/con microbes or viruses – or vice versa – stance. Quite the contrary: I do want to underline the need to fight microbes and viruses with the same sense of urgency. Rather than comparing or offsetting 50,000 deaths in Europe with 8,200, or whatever number of deaths in Africa, we must treat both issues urgently, efficiently and intelligently.

Having said that, I do think we need to ask troubling questions, such as why, in Europe with its more or less comparable healthcare standards, does the prevalence of nosocomial infections differ so widely – at between 5-11%.

It is indisputable, however, that the efforts must not be influenced by media coverage or public attention. Every death due to a nosocomial infection, or Ebola, whether in a state-of-the-art ward, a European metropolis or an African camp, is one death too many. ■

Hand

reports. In developed countries the risk of healthcare associated infections is twenty times as high.

'An awareness campaign on its own is not enough. The key to success lies in the adoption of the entire strategy,' Pittet emphasises. This is what he tried to explain to everyone who, over the years, has asked for permission to use the cartoons displayed at Geneva's University Hospital. Regular self-assessment is essential to help achieve sustainable changes in behaviour. Hand hygiene is only one aspect of efforts to defeat nosocomial infections. 'Antibiotics management is just as important,' emphasises Prof. Herman Goossens MD, head of the Department for Microbiology at Antwerp University Hospital. There is a clear connection. 'The more antibiotics prescribed, the more resistance occurs.'

Hospitals are particularly prone to resistant pathogens. At the First CEE Conference on Hospital Hygiene and Patient Safety, Goossens reported on a campaign in Belgium that was introduced to reduce the high prescription rates for antibiotics. This included advertisements on posters, in newspapers, on radio and television as well as information brochures and a website. The key point was a metaphor describing antibiotics as swimming armbands, worn daily on buses or in streets, but which deflate as soon as the wearer actually falls in the water. The success: Around €500 million were saved between 1999 and 2010 because the prescription rate for antibiotics was reduced. ■

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Yes No

Yes No

How much influence do you have on purchasing decisions?

I can only present an opinion

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I can purchase from manufacturers directly

Yes No

Yes No

Yes No

Do you consider that your equipment is

out-dated

relatively modern

state-of-the-art

Yes No

Yes No

Yes No

Do you use/buy second-hand equipment?

If so, what do you use of this kind?

Yes No

Is your department linked to an internal computer network?

Is your department linked to an external computer network?

Is your department involved with telemedicine in the community?

Do you consider your department is under-staffed?

Are you given ample opportunities to up-date knowledge?

Do you attend congresses or similar meetings for your speciality?

Yes No

Yes No

Yes No

Yes No

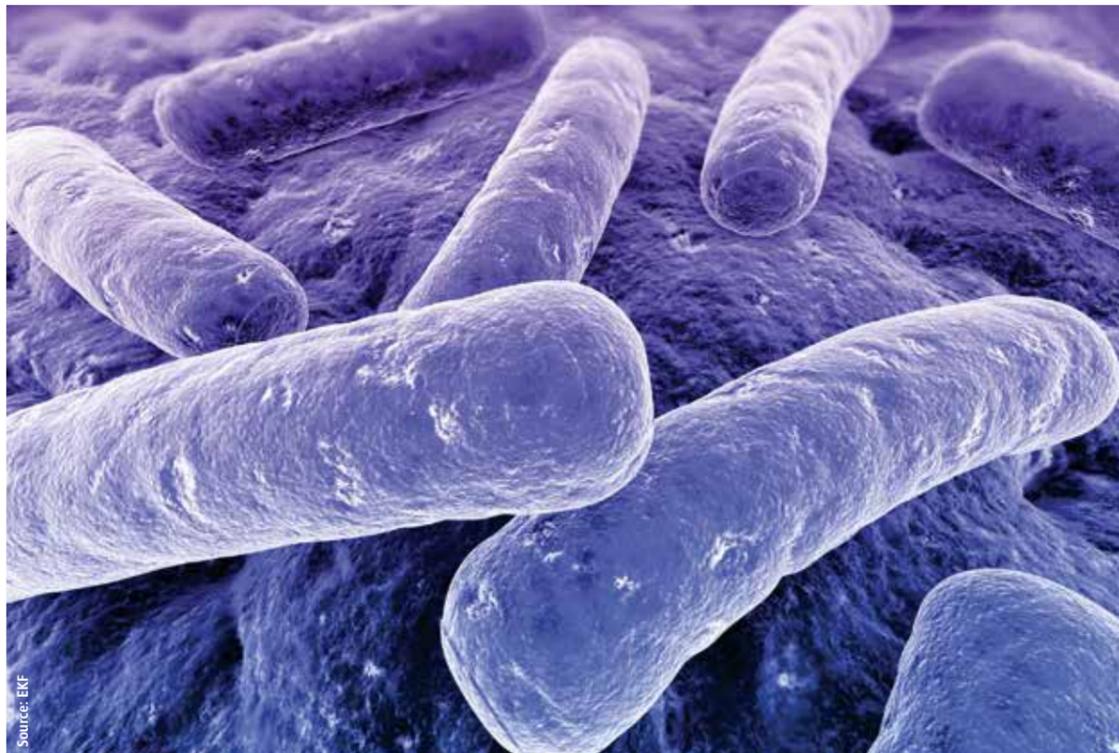
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EH 2/15

Fast, accurate and convenient

New test identifies early sepsis



A newly launched test enables the quantitative determination of PCT in serum samples, EDTA or lithium heparin plasma samples by latex enhanced immunoturbidimetric methodology. The Stanbio Chemistry Procalcitonin (PCT) LiquiColor Assay was launched by EKF Diagnostics, based in Cardiff, Wales, which explains: 'Procalcitonin is a marker for bacterial infection and sepsis and has been recognised as an important adjunct marker in the diagnosis of sepsis.'

'The new assay is fast, accurate and convenient. The test provides a precise result, which correlates well with established methodology, within 10 minutes and requires just 20 µL of sample. The reagents may be used on almost any liquid-based chemistry analyser with open-channel capability. In addition, the reagent kit, calibrator and control sets are all available separately.'

Commenting on the cost-effectiveness and convenience of the Stanbio Chemistry Procalcitonin (PCT) LiquiColor Assay, Al Blanco, Business Unit Director of EKF Diagnostics Central Laboratory, added: 'This assay can be performed on a customer's existing chemistry analyser with the same collection tube used for analysis of other chemistry tests. Therefore, it will provide optimised lab workflow by eliminating the need to split a sample, or have a dedicated off-line workstation. These features will provide any lab with a cost-effective solution for PCT testing.'

Products go worldwide

EKF Diagnostics Holdings plc., which includes the EKF Diagnostics, EKF Molecular, Stanbio Laboratory, Separation Technology Inc., DiaSpect and Selah Genomics brands, specialises in the development, production and worldwide distribution of point-of-care blood analysers to detect and manage diabetes, anaemia, lactate and kidney related diseases.

EKF Molecular Diagnostics, the firm's new molecular division, focus-

The EKF-Stanbio Procalcitonin LiquiColor Assay aids in viral and bacterial infection differentiation

es on technology used within the development of companion diagnostics, specifically within oncology.

Sold in more than 100 countries, the firm's analyser range is used in GP surgeries, pharmacies, blood banks, sports clinics, hospitals and laboratories for glucose, lactate, haemoglobin, haematocrit and HbA1c measurement.

Molecular diagnostics

In March 2013, EKF set up a new

division to focus on molecular and companion diagnostics following the acquisition of UK-based 360 Genomics. PointMan, EKF Molecular Diagnostics' technology, can detect mutant genes from tiny biopsy and blood samples and the firm has recently entered a partnership with the world-renowned cancer research centre at Massachusetts General Hospital, USA.

Details: www.ekfdiagnostics.com.

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www.healthcare-in-europe.com

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Subscriptions

Janka Hoppe, European Hospital,

Theodor-Althoff-Str. 45, 45133 Essen, Germany

Subscription rate

6 issues: 42 Euro, Single copy: 7 Euro.

Send order and cheque to:

European Hospital Subscription Dept

Printed by: WVD, Mörfelden-Walldorf, Germany

Publication frequency: bi-monthly

European Hospital ISSN 0942-9085

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Many uncertainties in breast cancer biopsy diagnoses

Ambiguity calls for a second opinion

Report: Cynthia E. Keen

Each year, approximately 1.6 million women in the USA have breast biopsies to diagnose or rule out cancer. Pathological diagnosis is considered the gold standard – how accurate are these diagnoses?

A recent study published in the Journal of the American Medical Association that generated national media headlines has shaken the faith of American women and their doctors. 115 pathologists, working throughout the country, independently interpreted biopsy samples of 60 cases. Whilst their diagnoses of invasive breast cancer were nearly 100% accurate, one in five pathologists made incorrect diagnoses relating to ductal carcinoma in situ (DCIS), and half misdiagnosed the presence of atypia – abnormal cells.

Accurate diagnosis of atypia is important. Although 87% accurately diagnosed benign tissue samples without atypia, the fact that 52% of atypia cases were misdiagnosed is disconcerting. With a diagnosis of atypical ductal hyperplasia on a core needle biopsy, further surgical excision of the site is recommended to ensure that a cancer is not missed as a result of a sampling error. Over-diagnosis of atypical ductal hyperplasia may lead to unnecessary surgery and under-diagnosis of atypia may miss a cancer in adjacent tissue.

The study consisted of sending a set of 60 cases with a single tissue sample to each of the 115 pathologists. The 60 cases were a subset of 240 cases: 10% were tissue samples of invasive carcinoma, 30% DCIS, 30% atypia, and 30% benign. Diagnoses were made independently and subsequently by consensus of three expert breast pathologists.

Nearly half of the cases were from women aged 40-49, 28% from women aged 50-59, 12% aged 60-69, and 11% age 70 and over. Breast density categories from mammograms included all categories, with heterogeneously dense and extremely dense representing 40.4% and 10.4% respectively. Samples were obtained from both core needle and excisional biopsies.

Principal investigator Dr Joann G Elmore, an affiliate investigator at the Fred Hutchinson Cancer Research Center of the University of Washington in Seattle, and colleagues, reported that over-interpretation of atypia was 17% and over-interpretation of benign tissue without atypia was 13%. DCIS was diagnosed as invasive carcinoma in 3% of cases. Under-interpretation was 4% for invasive breast cancer, 13% for DCIS, and 35% for atypia.

'We were surprised by the amount of disagreement among pathologists,' Elmore said in a JAMA website video interview. Should she have been? The individual diagnoses of the three expert pathologists were in agreement only 75%. Only after they concurred with one another did they reach the consensus diagnoses used to compare the diagnoses of the 112 pathologists.

'The key finding [of the study] was that the overall concordance rate of diagnostic interpretations

with the reference diagnosis for participating pathologists was 75.3%, identical to the initial level of unanimous agreement between the three expert pathologists,' wrote Professor

Nancy E Davidson MD, director of the University of Pittsburgh Cancer Institute and Professor David L Rimm PhD*, director of pathology tissue services at Yale School of

Medicine in New Haven, CT, in an accompanying editorial. They stated that 'the accuracy of the pathologist's diagnoses is relatively understudied and represents an important knowledge gap at a time when medicine is becoming more evidence-based'.

However, they pointed out factors that may have influenced the inadequate performance. Pathologists only had a single slide to work with, and did not have the option to consult with others. In daily practice, they work with multiple slides and have the ability to consult with colleagues about challenging cases. Additionally, the case mix of slides included a large number of chal-

lenging cases that were atypical of what a pathologist would encounter on a day-to-day basis.

However, because pathologists were in low-volume practices and less experienced pathologists made more errors than more experienced pathologists in the cohort, Davidson and Rimm recommended that pathologists should consult with more expert colleagues about challenging cases – and, in cases of ambiguity, a second independent opinion is recommended.

*Davidson NE and Rimm DL. Expertise vs. Evidence in Assessment of Breast Biopsies. 2015 JAMA 313:11, pp. 1109-1110.



SIEMENS

Business Case
Leiden, NL

What if you could reduce manual working hours in molecular pathology by 50%?

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For a better understanding of the pathology of cancer cells, medical researchers around the world are using biomarkers. However, before a biomarker test can be performed, the genetic information has to be extracted from the solid tissue and the nucleic acids have to be isolated as carefully as possible. This has been a critical and highly manual step, so far. At the Department of Pathology at Leiden University Medical Center, tissue samples can now be processed twice as fast thanks to a fully automated workflow. This not only saves costs, time, and source material, but most of all accelerates and improves diagnostic testing for cancer patients.

For the complete business case, visit www.siemens.com/healthcare-leiden.

The statements by Siemens' customers described herein are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist (e.g., hospital size, case mix, level of IT adoption) there can be no guarantee that other customers will achieve the same results.

Leiden University Medical Center

| | |
|-------------|---|
| Location: | Leiden, Netherlands |
| Innovator: | Molecular biologists at the Department of Pathology |
| Specialty: | Molecular diagnostics |
| Technology: | Siemens Tissue Preparation Solution |

Answers for life.

Scottish NHS group endorses auto

It's thumbs up for Siemens Healthcare Diagnostics' Aptio Automation, following a two-year deployment by Dundee-based National Health Service (NHS) Dundee, the first north European healthcare organisation to use the system to consolidate formerly siloed biochemistry, immunology, haematology and haemostasis testing onto a single automation track.

Tayside now processes 7,000 tubes per day – a 20% increase in its main laboratory workload, with no additional staff. Total decreased turnaround time (TAT) brought a 61% improvement in TAT for add-on tests – all with high-quality results.

Three labs into one

Serving 480,000 people through 22 hospitals/infirmaries and 69 general-practices, Tayside relies on two laboratories. In the Blood Sciences Laboratory at the 900-bed Ninewells teaching hospital, Aptio Automation merged three former individual labs onto a single track, fully providing pre- and post-analytical sample-processing modules along with comprehensive analytics.

By crossing traditional disciplinary boundaries and standardis-



Aptio Automation is a unified solution developed expressly for the changing workload and expanding needs of today's clinical laboratory. It provides unlimited potential for lab optimisation by combining peak performance, adaptability, and intelligent technology with Siemens' signature automation workflow expertise. With Aptio Automation, labs of all sizes can transform their operations to harness change and drive maximum performance and efficiency

ing and streamlining flow of information, samples and data back to patients, Dr Bill Bartlett, NHS Tayside Joint Clinical Director of Diagnostics, concludes, lab services are transformed from cost centre to value investment.

The new system can track and manage 3,600 specimens an hour just in circulation. At the touch of

a CentraLink system screen, we can also retrieve and drive testing on up to 15,000 more samples stored in the Aptio refrigeration module.'

Thus Ninewells lab could take on 73% of testing formerly conducted at the 260-bed Perth Royal Infirmary (PRI), enabling that smaller laboratory to focus on acute admissions and in-patient testing. Ninewells

now handles 100% of the general-practice testing in the entire region.

Results

The Ninewells Blood Sciences Laboratory processes up to 7,000 tubes a day on the Aptio Automation track, 1,700 tubes an hour at peak times. Despite volume increases of around 5% per year since 2012, samples no longer back up. Median TAT is 41 minutes, with 95% of the work completed in 67 minutes. 'Our input potential has increased 246%, without the additional capacity of the Input Output Module, which is reserved for STAT samples and used heavily for sorting,' Bartlett points out.

The 75-foot track employs a variety of modules to reduce manual samples handling, ease test re-runs and add-on testing, and speed all TAT, all enabling Tayside to up-level biomedical and clinical scientists responsibilities.

Customising workflow management

The CentraLink Data Management System drives Aptio Automation. With end-to-end touch points, the CentraLink system consolidates

information from the LIS, track, and instruments to automate workflows in a lean, multidisciplinary laboratory that can handle routine and emergency testing on one track. The CentraLink system customises and standardises workflows across automation, analysers and IT. Additionally, when add-on orders arrive, the CentraLink system finds the tube on the track or in refrigerated storage, coordinates de-capping and/or aliquoting, sends it to the right analyser and uploads results. Shirley McKay, associate services manager at the Ninewells lab: 'We can drill down and look at each individual sample, the route it takes, and re-route as needed.'

The lab can also use auto-verification for approximately 90% of its workload, she adds; such high volumes could not be processed if validating everything manually. Logic rules in the CentraLink system can be test- and site-dependent, for example, so that renal ward rules can differ from those of the paediatric ward.

Bartlett recalls that, after a 90-minute fire drill, staff returned to find the Aptio Automation Rack Input Module and track empty, with

Clinical chemistry is broad ran

The field is neither tedious nor monotonous; it's fascinating every day, Professor Katharina Rentsch emphasises, when explaining the need to attract students to this often overlooked but intriguing and varied discipline

The discipline of clinical chemistry in Switzerland comprises the biochemical and immunological analyses of substrates, hormones, metabolites, proteins, drugs and drugs of abuse in blood and other body fluids, mostly using highly automated instruments. In bigger laboratories more sophisticated chemical techniques are also used, such as atomic absorption spectroscopy to quantify heavy metals in blood, urine and tissues, chromatography coupled to mass spectrometry e.g. to quantify drugs, and electrophoresis to separate proteins. Unlike other countries, coagulation tests, blood cell count and blood smears, are not part of clinical chemistry.

A Masters degree in medical and pharmaceutical sciences, biology, biochemistry, chemistry or a comparable natural science is needed to become a clinical chemist. The Swiss Academy of Medical Sciences issues the curriculum to specialise in laboratory medicine. The Swiss Association of Medical Laboratories, FAHM, represents the commercial labs that perform over 1,500 different analyses of blood, urine, stool or other patient samples, for doctors and hospitals, and it also organises education in clinical chemistry.

After passing an entrance exam that covers all disciplines of laboratory medicine (clinical chemistry, haematology, immunology, medical microbiology and human genetics) the course to qualify as a clinical chemist lasts four years, during which FAMH candidates work in a routine laboratory and attend several block courses in topics such as

man management, quality management and change management etc. At least one of the four practical years must be spent in a public hospital laboratory. After the final oral examination, the clinical chemist can take full responsibility in a lab.

The Swiss Federal Office of Health regulates reimbursement for laboratory tests, including all clinical chemistry tests. One list of analyses is positive, containing all lab tests reimbursed by the health insurers linked to one price. Since autumn, there has been one excep-



tion to this general rule: point-of-care (POC) tests performed in doctors' offices have higher prices than the same test performed in professional laboratories. The price of a lab test is a so-called technical activity. Therefore, lab directors usually don't have any private income for performing medical activities, for example for patients with private insurance. This contrasts with German laboratories.

Due to these circumstances, and a common education, pharmacists and natural scientists have equal

rights to bring lab tests to account. Each test has one or several suffixes, which indicate its laboratory medicine discipline. If a lab wants to be reimbursed for analytes that belong to different disciplines it needs a FAMH lab medicine specialist for each discipline.

In 2012, Switzerland had 206 acute somatic hospitals and specialised clinics, according to H+, the organisation that represents Swiss hospitals. The Swiss health system is organised in a non-centralised manner and each of the cantons has its own health law and hospitals. The size of the 26 cantons varies considerably (~16,000 – 1,425,000 inhabitants) and consequently also hospital sizes vary substantially. Depending

laboratory medicine specialist is needed, as already mentioned. There are also several private laboratories responsible for lab testing, mostly in smaller public or private hospitals. Private laboratories always need FAMH laboratory medicine specialists for each discipline performed in their premises. Switzerland's five big medical faculties are all linked to a university hospital with a clinical chemistry laboratory. Unfortunately, there are only three ordinary professors for clinical chemistry (Zurich and Geneva) or Biomedicine (Lausanne) appointed to the respective medical faculties. Basel and Berne university hospitals, and the Zurich's Children's University Hospital, have associate professors. Nevertheless, with their co-workers, they are heavily engaged in teaching medical and pharmaceutical or natural science students. In all university hospitals MD and/or PhD students perform lab work to gain a doctoral degree from the respective faculty.

Highly specialised medicine is offered in all university hospitals in different areas of expertise. Usually, different research groups of clinical colleagues carry out research on these fields and often also the clinical chemistry department has research activities in these topics, to allow specialised and unique progression in diagnosis and/or monitoring of therapy or disease progression/remission.

Ten years ago, the different disciplines in laboratory medicine were mostly separated in the big hospitals, but since then organisational units have been created or are in development. They usually consist at least of clinical chemistry, diagnostic haematology and clinical immunology. The clinical chemist is usually experienced in managing a very high number of patient samples, covering a wide diversity of analyti-

cal techniques. Therefore, in many hospitals, the clinical chemist has taken over the position of head of these organisational units and therefore is finally responsible for the organisation of most, if not all, of the laboratory tests performed in his hospital.

In Switzerland the number of young scientists studying clinical chemistry is small, perhaps because the profession is not publicly visible – adolescents are not usually aware that the profession exists and medical and natural science students rarely have contact with those from this profession. In Switzerland only pharmacists have mandatory courses in laboratory medicine, mostly given by a clinical chemist. To offer positions for a Master or PhD theses for all these university courses is therefore an absolute need, because this is the best chance to draw students into the laboratories.

In my opinion clinical chemistry is the most fascinating discipline of laboratory medicine. Many different analytical techniques are used for patients from all medical disciplines. The discipline is so broad that a young, active clinical chemist can choose a field of expertise. This might be on a more organisational level if he's interested in automation processes, or lab organisation or, on a basic research level, focusing on a very specialised topic. The expertise of Swiss clinical chemistry researchers lies in biomarker research, cardiovascular research, metabolomics and toxicology. Besides being active in the Swiss Society of Clinical Chemistry, they are all very actively involved in national and international scientific societies.

Nevertheless, in daily routine we are all confronted with different aspects of lab work that demands a broad knowledge of medicine, besides experience in organising processes to optimise lab turn-

overturning processes to optimise lab turn-

overturning processes to optimise lab turn-

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Automation



Bill Bartlett, NHS Tayside Joint Clinical Director of Diagnostics, U.K.

multidisciplinary Aptio Automation track enables secondary, cascade testing. Tayside's clinical and lab teams are collaborating to develop simple user interfaces – powered by complex algorithms – to enable liver disease investigation. Far from automation reducing staff, Bartlett points, out, knowledge and skills are re-directed to augment care.

Expert guidance

Bartlett says the project's success is down to Siemens' expertise and consultative approach. 'We relied

on them to evaluate workloads recommend the optimal mix of instruments to support peak loads. They not only saw what happens in this lab, they have a lot of experience in labs elsewhere and understand the environment.'

Members of the Siemens team chaired meetings with biologists and biochemists and its consultants helped people formerly working in silos to understand how their actions affected downstream workflows for others, and vice versa. It also gave support in the transi-



The CentralLin Data Management System is a proven data management solution that empowers labs to deliver timely, accurate results efficiently.

tion period to the new track, said McKay: 'On occasion, they even helped with sample processing!'

Two years later the consultants still support Tayside with services and strategic consulting for process engineering.

specimens processed and in their storage units, and the CentralLink system validating the data.

New tests reduce costs

'We received the first new immunoassay funding in five years by demonstrating how to generate 38 antibiotic-free days per month in the ICU by introducing procalcitonin testing at the starting or stopping of antibiotics,' Bartlett adds. Although no big drug saving, cutting one night's ICU stay saves around £1,200.

The CentralLink system's ability to take data from systems on the

Enging



ETH Zürich promoted Katharina Rentsch Dr. sc. nat to professor in 2003. She currently heads the department of clinical chemistry and laboratory medicine at University Hospital Basel, Switzerland. From 2009 Prof. Rentsch was also President of the Swiss Society for Clinical Chemistry and Molecular Diagnostics (SSCC).

around-time – also in situations where not all the instruments work properly.

Being the clinical chemist on duty in a big laboratory will soon confront me with topics concerning analytical techniques and their interferences, telephone calls from physicians asking for an interpretation of a result, coming from, for example, special endocrinology, therapeutic drug monitoring or protein analysis, and often usually at least one of the great many internal quality control results will be out of the accepted range. He, or she, will switch very rapidly between analytical details of the different assays, pathophysiological processes and management of challenging situations needing organisational experience.

This amplitude of topics prevents the clinical chemist job from becoming tedious and monotonous and makes it a fascinating task, every day.

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Pros and cons

Are medical apps a waste of time?

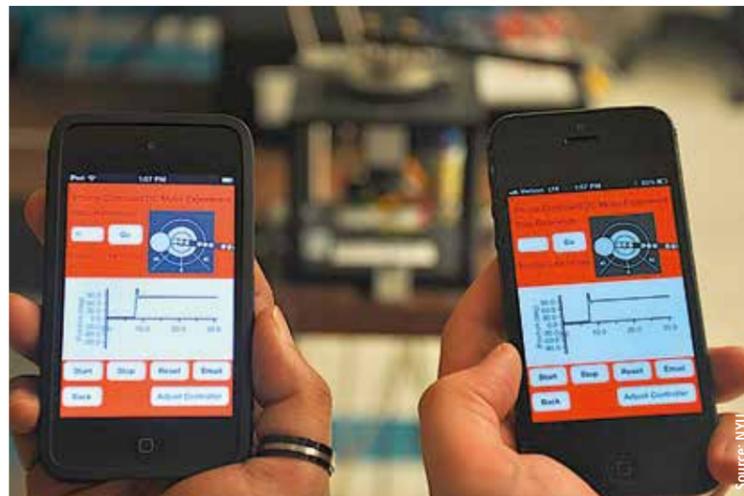
Among 28.8 million mobile telephones sold in Germany in 2014, 82% were smartphones. For this reason, the medical apps market has also increased exponentially. A survey by health insurer IKK showed that 22% of Germans already use these apps and a further 24% intend to install them on their smartphones or tablets. We asked Professor Norbert Gässler, Head of the Centre for Laboratory Diagnostics at the St. Bernward Hospital, Hildesheim, whether medical apps on private smartphones are worth having

Interview: Walter Depner

The most popular apps are those which provide quick information on diseases and their symptoms, or those with different types of reminder functions, such as for taking medication, doctor's appointments etc. Of particular interest are the medical-diagnostic apps used to control blood pressure, body weight, body temperature, pulse, blood sugar levels and other laboratory results,' laboratory diagnostics expert Professor Norbert Gässler believes. 'For skin diseases, such as malignant melanoma, photographic documentation is very helpful to assess the progression of the disease.

'There are also apps available for these types of diseases that calculate probabilities to predict malignancy with the help of algorithms. However, various studies have proved that these apps actually deliver false negative results in up to a third of cases.'

Depner: This implies they are not (yet) suitable as diagnostic tools. However, could they be used differently, for example, if a plastic foil could be put over the phone and blown into to check your alcohol level before driving home? Prof. G: 'Yes, this has already been trialled, but the blood alcohol content shown on the display is not precise enough, so we can only advise against this. Generally, the advice should be not to drive at all after alcohol consumption. Your conclusion that "diagnostic" apps are not (yet) suitable should be looked at with a little more differentiation. Simple measurements of blood sugar and lactate levels are already becoming quite precise. However, unfortunately these apps were not compared or validated with the methods used in precise laboratory medicine.'



Urine testing

Cystitis is a very common problem. An app currently available makes it possible to take a picture of a urine test strip, which can be purchased in pharmacies. The display then detects the disease based on the different colours and patterns of the different test fields. Would this not be useful?

'And then maybe another app for medication? No, this approach can only be described as negligent. Clinical symptoms and scientifically sound diagnosis of pathogens are the fundamentals of precise medical treatment. 'Out of the more than 100,000 apps that promise medical benefits there is only a small number of medical applications with measuring functions. These, however, make up a large percentage of the turnover of these apps (in 2012 it was around €350 million worldwide). As shown using the example of the diagnostic procedure for cystitis, additional products such as urine test strips are often required. Some apps don't require additional products and can be directly used with the smartphone functions. This includes hearing and eye tests to determine responsiveness.'

External sensors

Certain external sensors can be connected to the smartphone, for instance to measure electric currents in the heart via ECG; measure blood pressure (with BP cuff); pulse (with finger cover); current blood glucose concentration, as well as more specific diagnostic markers. The latter include measuring TSH to diagnose thyroid problems, measuring HIV to diagnose AIDS, and measuring syphilis to diagnose sexually transmitted diseases. What do you think of this development?

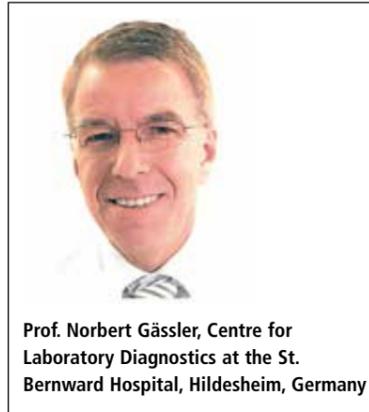
'The portfolio of such apps seems to be unlimited. In the USA, a first prototype to measure blood sugar concentrations without taking blood was introduced in February 2015 in the shape of a tattoo that can be applied to the skin. The continuously measured glucose concentration levels are wirelessly transmitted to the smartphone and then documented. The boom in these medical apps is mostly occurring in the USA and Asia, but we must assume that this rapid growth will soon also reach Europe.'

Security

Should we not scrutinise the issues of data security, patient protection, ethical and legal problems and many more at this point?

'Yes, correct! These apps are often heavily promoted, but with how much reliability the provider delivers the diagnostics, or other services, remains a bit of a grey area. Can we also trust them to safeguard our personal data? This requires more than a mere call for more legal guidelines.'

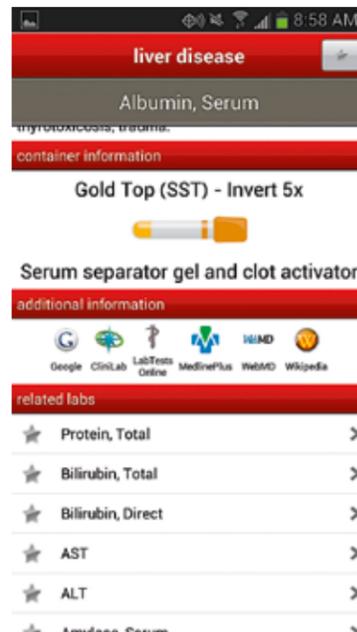
'On the other hand, certain apps really can be very useful for special applications and situations. Specialists in tropical diseases, for instance, have been working for years on using smartphones with special camera add-ons as microscopes. There is currently a field trial in Tanzania, where a modified smartphone is being used as a detection system for parasites, and particularly worms, in stool samples. The earlier mentioned detection of HIV, but also of Malaria and other diseases, could be a major argument for the use of such apps in third world countries or other areas with a lack of infrastructure.'



Prof. Norbert Gässler, Centre for Laboratory Diagnostics at the St. Bernward Hospital, Hildesheim, Germany

So, there's a plea in favour of apps after all?

'Users and manufacturers of these apps should definitely work together with medical specialists and diagnosticians on the development of "useful" apps. Furthermore, interdisciplinary teams should develop sensible workflows from the capture and transmission of measurements to the resulting diagnostic and therapeutic consequences.'



Point of care diagnostics

This market will boom

The turnover in POCT diagnostics will continue to increase substantially according to participants in an 'In Vitro Diagnostic Products' meeting held in Toronto, Canada last October. Sponsored by the German Institute for Standardisation, the event included participation by the DIN Standards Committee Medicine (NAMED; NA 063) and the Working Committee on Point of Care Testing (POCT) (NA 063-03-11 AA).

In 2013 in the USA, turnover for products used to diagnose glucose levels, infections, heart disease and cancers, to name the most important conditions, was around US\$25.2 billion. The forecast for 2018 is estimated at US\$27.5 billion, an increase of around 9.3%.

Robert L Michel (Editor-in-Chief of The Dark Report) spoke of the



particularly poignant diabetes occurrence in the US. 29.1 million Americans are diabetics, i.e. roughly 9.3% of the population. 21 million people were found to have diabetes following a specific diagnosis. 8.1 million people had no diagnosis. 75 million people are estimated to have

pre-diabetic symptoms already.

The number of POCT tests and their applications is growing exponentially. Many experts in Toronto particularly saw technological progress leading to distinct changes. Classic areas of application, such as chemistry, toxicology, haematology and microbiology, are using more and specific test procedures for Point-of-Care. For example, the latest trends include additional modules for smartphones, such as those used for glucose and thyroid stimulating hormone (TSH) diagnosis. The number of Point-of-Care DNA tests being used, some highly complex, is also increasing. Another interesting trend revolves around 'smart' nappies with an integrated, specific urine test for babies and other patients.

Based on examples from Australia and Canada (more specifically from the Ontario region) diagnostic networks to treat HIV, and also cardiac disease, were introduced at the event. This emphasised the clear advantage of comprehensive POCT diagnostics, particularly regarding their analytical quality.

Ana Stankovic, Vice President of Becton Dickinson (BD) opened the event with a detailed overview of POC diagnostics workflow, emphasising the issue of potential error sources and relevance of timing for these tests.

In conclusion, the importance and usability of POC tests can no longer be questioned. Frequently, they are on a par with tests used in conventional laboratory diagnostics, whilst clearly easier to use – and faster. Provided the critical points, such as error sources, are given enough consideration, this form of testing will continue to boom and grow.



Want to be a photographer or doctor?

Radiologists are doctors first

Delegates were asked an increasingly vital question during ECR 2015: do they want to be photographers or doctors? 'This is probably one of the most interesting sessions of this meeting and, after the congress, maybe even your career,' declared Jim Reekers, professor of interventional radiology at the University of Amsterdam, the Netherlands, when he faced a packed auditorium and kick started the eponymous Professional Challenges session.

Medical imaging practice has changed profoundly and extremely rapidly, and this has had huge consequences for radiologists, interventional radiologist Professor Jim Reekers explained. 'In the old days, we were called the photo department, still something that sticks today. A survey made by the ESR, which was never published, asked patients whether they thought the radiologist was a doctor or not... and they had no idea,' he said. 'So the question of this session really is: how to stay relevant for the future of radiology?' he added.

According to Nicola Strickland, a consultant radiologist at the Imperial College Healthcare NHS Trust, Hammersmith Hospital, London, UK, radiologists must first realise they are not future proof: 'We can only protect ourselves by making ourselves indispensable to patient care and to our clinical colleagues,' she said.

Radiologists must show their additional value to the team by emphasising that they are doctors first. 'We are both photographers and doctors, but we are doctors first. Compared with non-medical people, such as radiographers or nurses, we, as radiologists, can add value by showing we understand the pathology, physiology, and disease processes affecting that particular physiology, and apply that value to the clinical scenario,' she said. 'We can tailor our report to a particular clinical scenario.'

Any doctor can read an image nowadays. To maintain their lead in image interpretation, radiologists must remain at the forefront of knowledge in clinical intervention, imaging modalities and digital informatics and software, Strickland added. 'We have to maintain our clinical expertise, and keep abreast of technologies and rapid changes in our specialty. We must remain ahead of the game, and be as good as, and in fact better than, our clinical colleagues. For instance, I have to be able to interpret an ankle scan better than an orthopaedic surgeon,' she stressed. Inevitably, there has to be some subspecialisation and, she recommended, it is vital to attend multidisciplinary meetings on a weekly or daily basis.

Reekers wondered if subspecialisation could be the answer in the following presentation. Most specialties have an undisputed place in clinical practice, he argued. However, that is not the case for radiology. 'There is no surgeon who will do his or her own anaesthesia, so there is really this undisputed knowledge. Radiology is not undisputed and this is the problem.'

He quoted a survey unveiled at RSNA in 2009, in which 90% of interviewed clinicians said they were comfortable interpreting X-rays in 55.3% all of the time and 35.8% some of the time. Half of the interviewees felt equally competent at interpreting CT exams and, depending on the type of exam, 40% admitted they did not read the entire radiology report.

Imaging has become the most

important diagnostic tool over the past few years and many medical specialties now include it in their curriculum.

'We have to be aware that we are not alone on the planet anymore. Image interpretation without clinical knowledge is not possible

anymore, you have to know the whole package,' the expert said. The radiologist 2.0 should be part of this decision-making and be an active clinical partner with up-to-date knowledge about a medical specialty. Reekers recommended joining different medical specialty societies to acquire further skills. 'You have to have broad knowledge



Source: ECR

Jim Reekers, Interventional radiology, University of Amsterdam, The Netherlands

otherwise you will not be seen as an expert anymore,' he concluded. ■



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Breast cancer screening

AB-MRI could be the ideal screening tool

MRI is increasingly relevant to cancer management, especially to detect breast carcinoma. Professor Christiane K Kuhl from the department of diagnostic and interventional radiology at the University of Aachen, Germany, strongly advocated in favour of MRI in breast cancer screening during a dedicated Satellite Symposium organised by Bracco at ECR 2015

Report: Mélisande Rouger

'If one thing has been proven by screening mammography, it is that early diagnosis of a malignant disease does indeed translate into improved survival. This concept justifies the use of screening in general and specifically for breast cancer. We have indeed seen a decrease of mortality rates over the past decades,' said radiologist Professor Christiane Kuhl, opening

actual life-threatening condition.

Early publications on over-diagnosis through mammographic screening claimed that one out of three breast cancers represented over-diagnosis. However, it is currently, and probably more realistically, estimated that about 10% of breast cancers do belong to that group, Kuhl pointed out.

Mammography in fact has technology-inherent bias to detect slowly growing cancers. 'What we really

depicts pathophysiological changes that reflect regressive changes such as hypoxia, necrosis, fibrosis, calcification and architectural distortions.

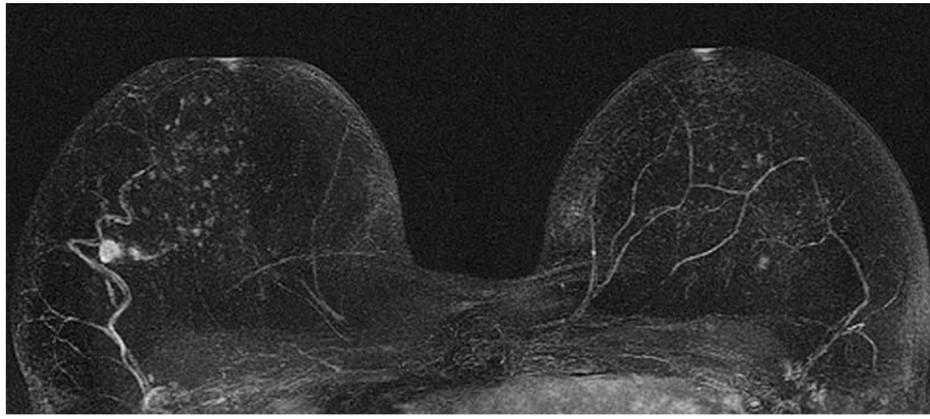
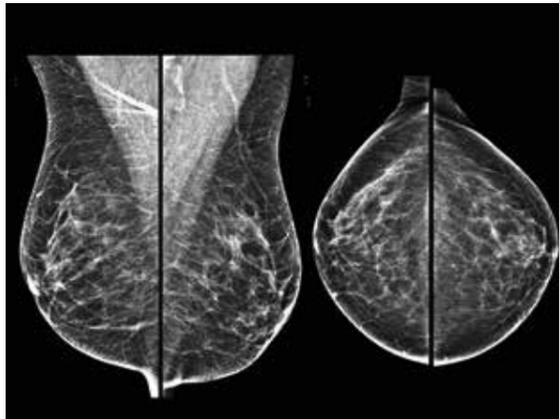
Another challenge with mammography is under-diagnosis. 'Surprisingly enough, this is not discussed so much by the scientific community, although it's clear that mammography screening has a limited sensitivity for prognostically relevant disease,' she pointed out. Despite decades of studying breast

ity. Their updated results, in 2005 and 2010, reported the exact same data. Moreover, the EVA trial, which was conducted in four different sites in Germany, confirmed that MRI had higher sensitivity than ultrasound or mammography in women at increased risk of breast cancer.

Interestingly, other publications that reported lower sensitivity of MRI compared with mammography found opposite results a few years later, stressing the importance of the user's experience with MRI, Kuhl explained. 'This evolution curve is represented in many studies. If you see variable results for MRI for screening use, this usually reflects a



Christiane K Kuhl is a professor in the diagnostic and interventional radiology department at the University of Aachen, Germany



her presentation during a Satellite Symposium at this year's ECR.

However, regardless of the benefits, a number of issues still call for improved cancer screening methods. Mammographic screening, just like PSA screening for prostate cancer, may pick possibly irrelevant diseases, which even if left undiagnosed would never progress to an

Patient with a small carcinoma in the right breast that is only visible in the MRI image (right). In the MIP image (left) it cannot be seen

pick are calcifications and architectural distortions. So triple negative breast cancers, which grow rapidly and don't calcify, are likely to go unnoticed by mammography,' she explained. The detection of breast cancer through mammography

cancer in epidemiologic studies, it continues to be the leading cause of cancer death in women and the most common cause of death in women under 50. 'Over-diagnosis is not our main problem. If it were, no one would die. Both over and under-diagnosis are shortcomings of mammographic screenings,' she said.

Other screening candidates have been studied, starting with digital breast tomosynthesis (DBT). A study that was conducted in over 400,000 women and published last year in JAMA showed that DBT presented with a 30% increase in detection rate compared with mammography alone. Another side effect was an improved PPV, in other words a higher specificity in distinguishing pathology alterations and benign changes.

In 2008 another study, also published in JAMA, compared the use of hand-held ultrasound with mammography and found an additional cancer yield of 4.1 per thousand. Acquisition time, on the other hand, was considerable, as it took over 20 minutes to complete a bilateral screening examination. Two years later, the authors published an update, in which they compared a single round of screening MRI with mammography. They found a 14.6 per thousand additional cancer yields with MRI.

Kuhl is a strong advocate for MRI in breast cancer screening. Fifteen years ago, she and her team published the very first paper on the topic, in which they highlighted MRI's high sensitivity and specific-

learning curve that radiology or the radiological community has to take in every area, not only for breast MRI but also possibly for prostate MRI.'

Kuhl also set out to tackle critics about MRI's supposedly high false positive rates in her presentation. 'MRI has often been reported to offer low specificity, which is certainly not true. Again, that is something that can be avoided with experience. More recent multi-centre trials, such as the EVA trial, showed that MRI had higher specificity than mammography,' she confirmed.

MRI can also be used as a screening tool for women at average risk. In an upcoming paper, Kuhl will show that, in those women, MRI has a 20 per thousand detection rate and an acceptably high PPV.

Finding more cancers with MRI should not be a problem, the researcher believes: 'More diagnosis is not more over-diagnosis, because, even today, too many women die of breast cancer. We still have a problem. We don't have to detect all the cancers but we should detect the ones that kill.'

The main issue facing MRI today is that economic considerations are driving its use for screening. One reason for high costs is the fact that the same (extensive) pulse sequence protocols have been used for breast MRI screening as the ones that have been used for diagnostic purposes.

To make breast MRI a real screening tool, Kuhl introduced the concept of abbreviated breast MRI (AB-MRI). 'AB-MRI means to strip down the pulse sequence protocol to its very essence,' she explained.

Her corresponding study (pub-

Journal of Clinical Oncology, 2014) used such an abbreviated protocol, which consisted of one pre- and one post-contrast acquisition, equaling a magnet time of about three minutes. Conducted between 2009 and 2010, the study compared the diagnostic accuracy and cancer yield of this abbreviated protocol against that full breast imaging protocol. Kuhl found that this was sufficient to help diagnose the same number of additional cancers, with similar diagnostic accuracy. Moreover, she found that the radiologists reading time of just three seconds was enough to exclude the presence of breast cancer with a negative predictive value of just under 99%. 'Establishing absence of breast cancer on a negative MIP image is done in the blink of an eye,' she said, 'and, in a screening setting, the vast majority of women have no cancer. By comparison, for a negative screening ultrasound study, a radiologist needs to work for 20 minutes.'

Accordingly, AB-MRI actually has the potential to make breast MRI a real screening tool, she argued. 'AB-MRI offers an additional cancer yield of 18.3 per thousand in women who have been pre-screened by digital full-field mammography and physician-performed breast ultrasound. It may be the ideal screening tool for women because it is conceivable to conduct on a population-wide scale, has high sensitivity for biologically relevant cancers and high diagnostic accuracy – and there's no radiation involved.'

Kuhl pointed out that, just like prostate MRI, breast MRI is relatively blind for low-grade disease, especially low-grade DCIS. 'Replacing mammography by breast MRI, rather than adding MRI to mammography, may therefore be the way to proceed,' she said.

Radiologists must understand that the aim of breast cancer screening is not to detect all breast cancers and their precursors by all means, she insisted. 'Rather, the goal must be to develop imaging methods that combine a maximum sensitivity for prognostically relevant disease with a desirable lack of sensitivity for disease that is prognostically unimportant.'

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A new powerful partnership

Driving proton and carbon therapy worldwide

A global collaboration to expand access to advanced particle therapy worldwide was agreed this April between Belgian firm IBA (Ion Beam Applications S.A.) and the Toshiba Corporation.

In Japan, Toshiba Medical Systems Corporation will distribute Proteus ONE, IBA's compact single-room proton therapy solution, and IBA will be the agent for Toshiba's Carbon Therapy Solutions outside Japan. The two companies will collaborate on activities such as customer education for both systems. Additionally, the collaboration will enable both organisations to gear up their Operation and Maintenance (O&M) services.

Proton and carbon therapy

Proton Therapy is considered an advanced and targeted cancer radiotherapy treatment due to its superior dose distribution and fewer side effects, IBA reports. 'Protons deposit the majority of their effective energy within a precisely controlled range, directly within the tumour, sparing healthy surrounding tissue. Higher doses can be delivered to the tumour without increasing the risk of side effects and long-term complications, thereby improving patient outcomes and quality of life.'

'Carbon ions not only have similar physical characteristics as protons, they have also a higher radiobiological effect compared to photon and proton, which could lead to shorter treatment courses and improved patient outcomes.'

Olivier Legrain, Chief Executive Officer of IBA, which produces universal full-scale proton therapy centres as well as compact, single room systems, sees the partnership as important to take both therapies worldwide. 'Carbon ion therapy is particularly suitable for treating radio-resistant tumours and allows for dose escalation, which is recommended in a number of clinical applications.'

According to Satoshi Tsunakawa, Chief Executive Officer of Healthcare Company, Toshiba Corporation, pro-

ton and carbon therapies are '... among the most exciting technological advancements in the treatment of cancer.' Quoting the firm's motto "Committed to People, Committed to the Future" he added that the collaboration 'will give both our

companies an enhanced set of tools to provide the best cancer treatment technologies'.

Proteus ONE, IBA's compact single-room proton therapy solution



PICTURE CREDIT: Source IBA

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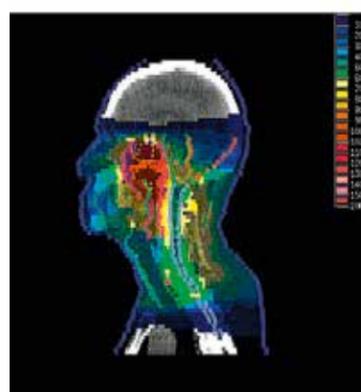
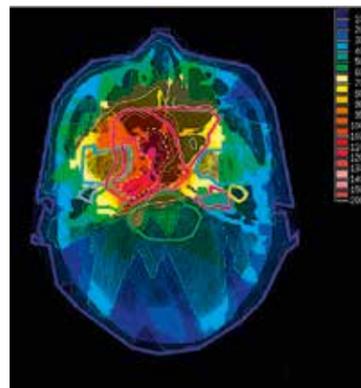
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Communication with the neurologically impaired

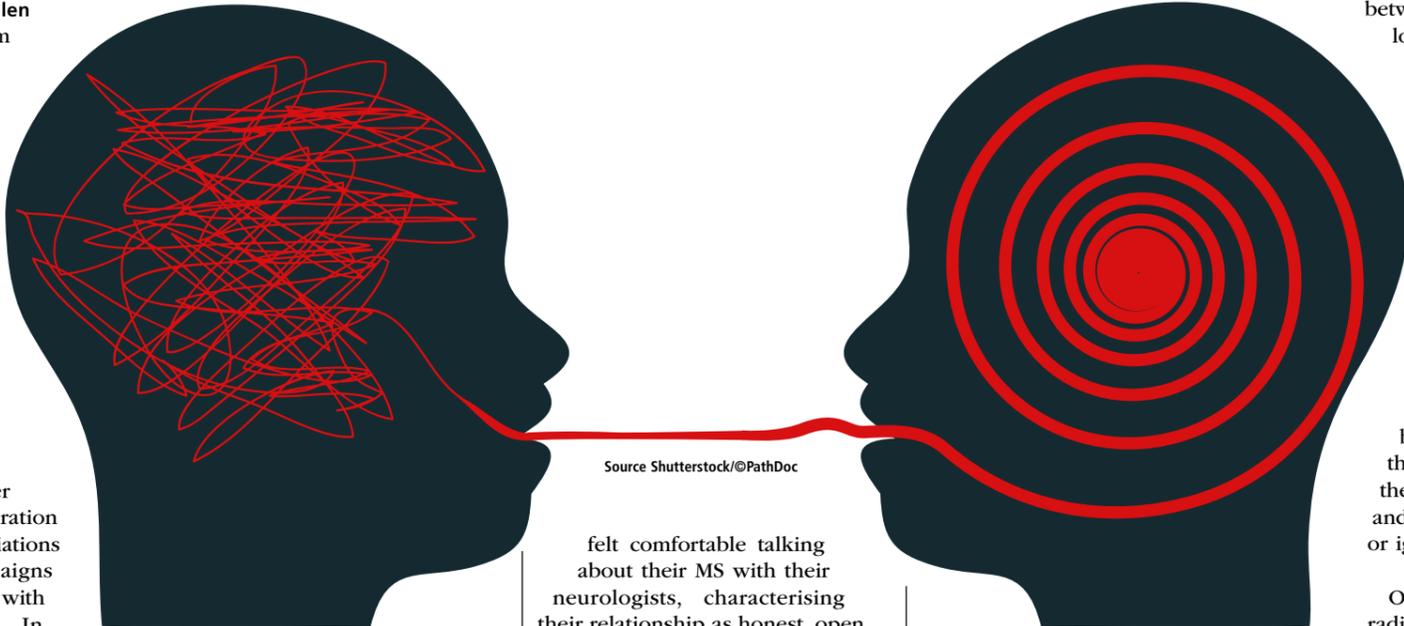
Tips to eliminate barriers

Manuela Messmer-Wullen

awoke in her hotel room one morning, during a business trip, and realised she was hemiplegic. There were also cognitive impairments and she could not articulate. Diagnosis: Stroke. 'In the very first period after the stroke, contact with radiologists was very strange and mysterious for me.'

Messmer-Wullen became a board member of the European Federation of Neurological Associations (EFNA), which campaigns on behalf of people with neurological diseases. In March, at the European Congress of Radiology (ECR 2015), she spoke during a session of the ESR Patient Advisory Group, which focused on particular communication problems between radiologists and patients with neurological diseases.

'Communication between the radiologist and patient can be quite challenging – and is even more complicated if the patient has a brain disorder,' explained Donna Walsh, Executive Director of the EFNA. Neurology patients can suffer language disorders (aphasia), motor



Source Shutterstock/©PathDoc

speech disorders (dysarthria) and difficulties with coordination (dyspraxia). Communication with the patient is made even more difficult when they have problems with their short-term memory or personality disorders, such as aggressiveness or paranoia.

A survey amongst patients with multiple sclerosis and their neurologists has shown that both groups are surprisingly pleased with their communication. More than eight in ten patients who saw a neurologist in the past year said they

felt comfortable talking about their MS with their neurologists, characterising their relationship as honest, open, comprehensive and helpful. Nearly all neurologists (96%) felt that they had an open dialogue with their patients, and 90 percent indicated that they have a good understanding of all aspects of a patient's disease. When asked if his or her neurologist is accessible and spends enough time with them, close to three-quarters of surveyed patients responded positively.

However, the survey also uncovered some less positive facts: 47% of doctors stated that they did not have enough time for communication

with their patients. Interestingly, though, only 21% of patients shared this view. Doctors were also more cautious when it came to the subject of communication barriers: 15% felt there were no barriers with patients at all, whilst the figure rose to 37% among patients. 'But that means 60% feel barriers exist,' Walsh emphasises.

'How do I know if my patient is satisfied with communication?' she asks, quickly following with her answer: 'Ask!' She also offers three more tips for communication

between doctors and neurological patients:

Give the patient at least 30 seconds to speak uninterrupted and during that time minimise note taking and maintain eye contact.

Touch the patient; touch makes them feel that the conversation is about something real.

Involve family members – but don't ignore the patient. The patient is the person you are treating and should not be dismissed or ignored.

Often this is not easy. 'The radiologist is usually considered to be a poor communicator,' admits Dr Lorenzo E Derchi, Head of Emergency Radiology at San Martino University Hospital in Genoa (Italy). 'It's possible that some medical students choose radiology because they're afraid of close contact with patients.' Derchi believes there should be more emphasis on communication in medical training.

Drawing radiology and nuclear medicine together

'Let's work as a team!'

Report: Marcel Rasch

Dr Gerald Antoch, professor of radiology and chairman of the department of diagnostic and interventional radiology at Düsseldorf University Hospital and active member of several scientific societies, delivered

the prestigious Wilhelm Conrad Röntgen Honorary Lecture at ECR 2015 on 'Hybrid imaging: Let the two worlds of radiology and nuclear medicine come together'.

'A hybrid in medicine has nothing to do with hybrid cars, hybrid bicycles or hybrid golf clubs,' Professor

Antoch emphasised by way of introduction. 'It is the combination of two imaging modalities, such as PET/CT or PET/MRI, adding that a good imaging system is basically nothing more than a good computer. 'PET/CT technology, developed to show tumours and metastases

that went undetected before, has seen many enhancements since the first system was installed in 2001. However, while in the early days clinicians would say "PET is easy: where it's light, it's bad", today we know that it is not that easy.'

Read image data accurately

The best technology is useless if not supported by people who can read – interpret – the images generated by the technology. 'You need as much morphology as you can get, but you also need the expertise to read these images,' Antoch stressed. 'This expertise has to be available not only for the morphological but also the functional side,' he added, to avoid misinterpreting findings in different images, because 'accurate hybrid imaging is a question of knowledge'.

The term 'Theranostics' describes the combination of therapy and diagnostics, which requires accurate hybrid interpretation by specialists as a basis.

New standards and comprehensive training

For 'Theranostics' to be implemented properly, Dr Antoch said, it must

The combination of PET to visualise the biological processes of life and the anatomical imaging capabilities of CT, provides finest resolution. Nuclear medicine physicians and radiologists need an elaborate training with detailed knowledge of all facets of PET/CT to interpret hybrid images accurately



Dr Gerald Antoch, professor of radiology at the department of diagnostic and interventional radiology, Düsseldorf University Hospital, Germany

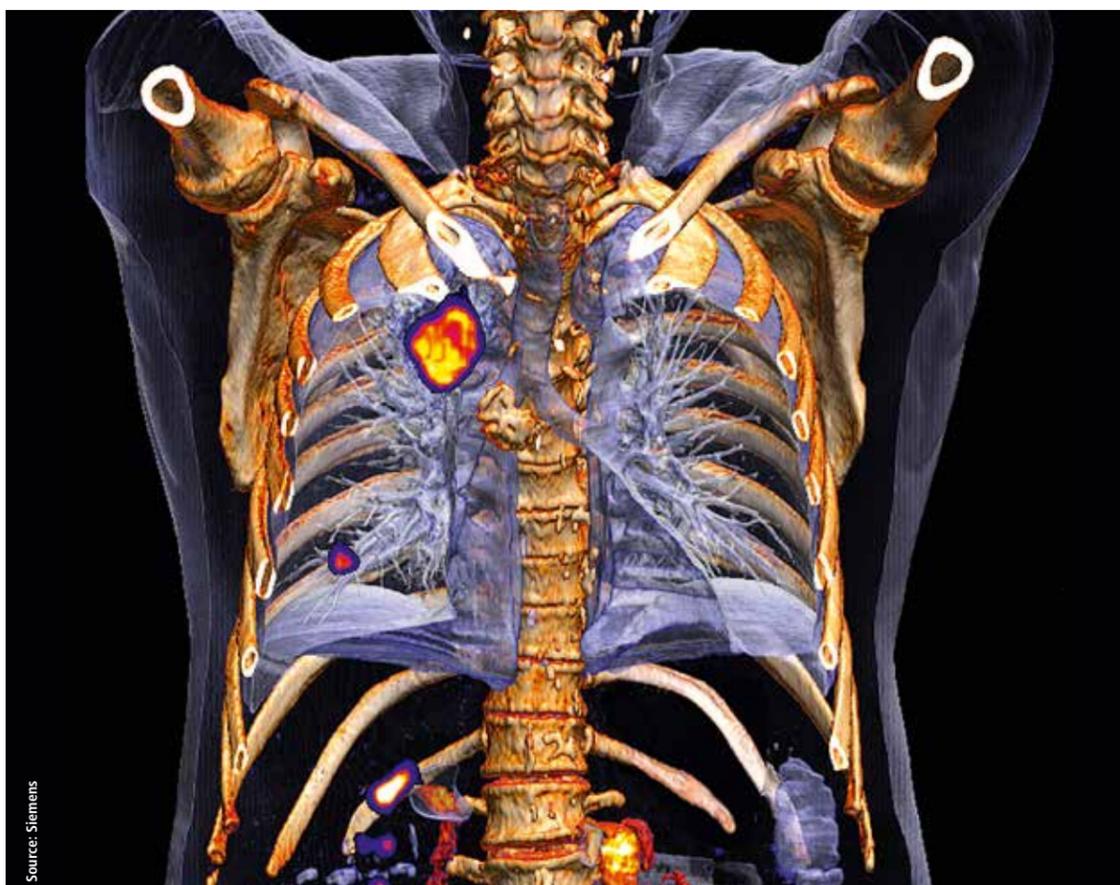
be clear who is responsible for scans and who provides them but, even more importantly, 'who reads and interprets hybrid F-FDG PET studies'.

Often, today, two specialists – a radiologist and a nuclear medicine physician – cooperate on each scan and to ensure that the images were read correctly and to avoid misinterpretation.

'We need to adapt the workflow to real life,' Antoch said – with 'real life', meaning 'limited resources'. He proposes the implementation of new training programmes where nuclear medicine specialists familiarise themselves with necessary radiology knowledge and vice versa, depending on the local or country-specific regulations.

What we need for the future

Antoch's vision for the future is very clear: 'We must move from separate departments towards one imaging centre. We need new training programmes, a flat organisation, interlinked reimbursements and no turf battles. Let's work as a team.'



Source: Siemens

Assessing chemotherapy

Ultrasound presents an alternative to radiation



Nathalie Lassau, from the Ultrasound Unit, at the Institut Gustave Roussy, University Paris-Sud, France

Injecting toxic chemicals into the body to kill cancer cells is a physically and mentally brutal experience for patients. The treatment cost is equally brutal for healthcare systems.

Yet, often after six months of difficult treatment, patients may hear that the chemotherapy did not stop or kill the cancer.

There is now a way to find out, in just 30 days and at a cost of just €183, whether the treatment is doing any good. A further plus: the exam does not expose a patient to radiation.

This three-minute exam, with an injection of a contrast agent, microscopic air bubbles illuminate blood circulation for ultrasound probes and can expose tumours.

Proven effective through clinical studies and recommended by WFUMB and EFSUMB – the World and European and federations for ultrasound in medicine and biology – the dynamic contrast-enhanced ultrasound exam (DCE-US) can determine whether chemotherapy is working and help the oncologist to decide whether treatment should be stopped, continued or even increased.

Nathalie Lassau MD, from the Gustave Roussy Institute for cancer research in Paris, has been working with clinicians and ultrasound

companies for 10 years to carefully advance this disruptive procedure through demanding requirements for clinical validation.

Having won approval and recommendations for the technique in Europe, she says her goal is now to win approval in the USA, where the contrast agent has recently been approved.

'We can provide the oncologist with the results of the assessment in

real-time – no one is able to do this with either a CT or an MRI Scanner.'

Key to her work has been a collaboration with Toshiba Medical systems that was the only ultrasound system manufacturer to provide the raw linear data essential to create the calculations and analysis of tumour response to chemotherapy.

Today, all major ultrasound manufacturers have opened their systems to enable this breakthrough tech-

nique.

It has also attracted the interest of pharmaceutical companies, as keen as patients to know if their therapies are effective.

'Cancer has become a chronic disease,' said Lassau. 'And today there are many drugs to treat carcinoma. It's possible that a patient will start with one drug, then be switched to another drug, and so on. In my institution, a single patient may be tested across six different drugs.'

'If a patient's doctor is following the current international standards, then the doctor will perform a Response Evaluation Criteria In Solid Tumours (RECIST) evaluation, which uses CT. This means the patient is being exposed to radiation to evaluate the effectiveness of the chemotherapy,' she pointed out. 'There is a strong association, supported by articles in leading medical journals, where they show there is a risk for inducing a secondary cancer through the radiation of patients with CT.'

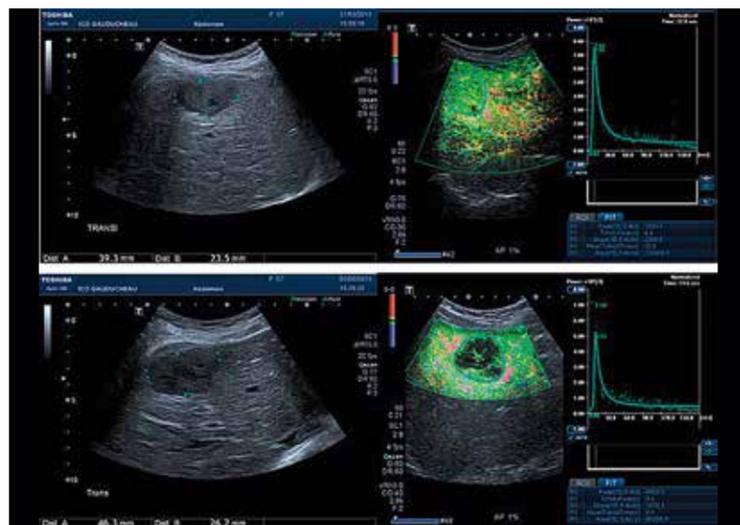
Performing a CT perfusion exam to see whether chemotherapy is working means exposing the patient to 20 millisieverts (mSv) of radiation for each exam. 'I don't know about other countries, but I know that, in France, 20 mSv is the maximum dose allowable for one patient dur-

ing a full year. With cancer patients there is a risk of scanning them every two or three months,' Lassau explains.

Some people might say that if a patient is dying from cancer, then the risk of creating a second cancer with radiation is not as important. 'This is a cynical view,' according to Lassau. 'There has been significant progress made in chemotherapy for many types of cancer and the life expectancy of patients is greatly increased.'

Patients are especially concerned about the risks of radiation exposure, and she said patient advocacy groups are helping to increase the awareness that there is now an alternative way of learning if chemotherapy is working.

Lassau continues to advance the DCE-US, currently leading a new multi-centre clinical trial to demonstrate the technique's effectiveness and reproducibility of results. The next step, she says, is to develop the system using ultrasound imaging in 3-D. 'All ultrasound companies now offer 3-D probes and we want to show a full acquisition to be sure we are studying the total tumour.'



Hepatic metastasis before (upper images) and after 42 days of anti-angiogenic treatment (lower images). B-mode and contrast-enhanced ultrasound image with time-intensity-curve analysis

Easing ultrasound operation

Touch system customises to user needs

Carestream Health, the medical imaging and healthcare IT specialist, presented its latest innovation, the Touch Ultrasound System at this year's ECR. This system offers a configurable all-touch control panel, a powerful processor, plus other innovative tools. Daniela Zimmerman and Mélisande Rouger, from European Hospital, interviewed Andrew J Hartmann, the firm's General Manager of the Global X-ray & Ultrasound Solutions division, to explain how the new platform promises to improve user experience

EH: Carestream's long love affair with film is part of its Kodak legacy. What drove the firm towards creating innovations in ultrasound?

Andrew Hartmann: 'Film is a big part of our legacy and an important component of our business. We sell in over 180 countries and our business is expanding; but, beyond film, we are also a leader in digital X-ray, both CR and DR, as well as healthcare IT, printers, and dental solutions. We are a growing company and our customers are looking to us to expand into other modalities. Ultrasound is one of the fastest

growing healthcare modalities and is a six billion dollar market today. It's certainly an area where we felt we could innovate and answer our customers unmet needs, while leveraging our existing sales and service infrastructure. Ultrasound is a logical step forward.'

What do you think makes Touch so special?

'One of the key differentiating features is the sleek, modern, all-touch control panel. The only button on the system is the Power button. The primary controls have the tactile feedback of traditional keys, via distinct etched patterns, while the unique design has the additional flexibility of configurable soft controls.'

'We like to think of ultrasound as a modality in which the user and the procedure define how the system should be set up – a little like adjusting the driver's seat in a car. When I log into Touch's system, it knows the way I like to drive it. This customisation will really simplify workflow.'

'We also tackled the issue of sterilisation. The Touch's smooth, sealed surface makes it effortless to clean. 'The Touch cart has been designed

with ergonomics in mind. There are multiple user adjustments to help minimise injury risk factors and also increase the user's efficiency and convenience.'

Of course, image quality is of primary importance and the Touch system will have extremely high image quality driven by graphic processing units (GPU's) for fast response and low noise.'

'Voice of the customer played a key role in our system design. We developed the system based on their daily challenges. We saw an opportunity to innovate.'

Do you listen to customers differently from your competitors, with their longer history in this field?

'Not having legacy products allowed us to start with a clean slate and look at what's challenging in departments from a use-of-ultrasound perspective. What are the features and functionalities people are looking for, but cannot be found in today's solutions.'

'If we introduced a product that was the same as everybody else's and wanted to become an ultrasound supplier, we could have just bought any of the small companies that have products.'



Andrew J. Hartmann, General Manager, Global X-Ray & Ultrasound Solutions, Carestream Health, Inc, Rochester USA

'When we step into a modality our intention is to become a major player. When we presented our mobile X-ray system, the market was saturated and dominated by two or three vendors. We now own 25-30% of the market share – because we innovate and do things differently.'

Along with radiology, ultrasound is used in internal medicine, cardiology and other medical disciplines. Does Carestream have a position in those?

'Our first entry will be for a premium product for general imaging in radiology. We have plans to expand the portfolio using the same architecture and same user interface for more value tier systems as well as other disciplines.'

When purchasing for a hospital, economic constraints often have the last word. How do you address this issue?

'The economic component is certainly a big part of the conversation. Carestream intends to design a family of systems from premium high-end to point of care, covering a variety of disciplines.'

'All will use the same transducers and have the same user interface and the same architecture. This will allow facilities to maximise their return on investment by lowering training costs, as well as being able to share transducers across equipment and across departments.'

'We are also developing a service strategy that will reduce overall cost of ownership and will make it easy for the facility to have high uptime and low maintenance costs.'



Health-tracking platforms as part of daily routine

Bring-your-own-device to the doctor

Report: Sascha Keutel

Many of today's smartphones have sensors, such as pedometers and pulse monitors. Wearables are a new class of device that are moving into sensitive areas i.e. being permanently worn on the body and always switched on to ensure a continuous data stream. In her lecture *From Sensor to Health-Tracking Platform – Technological Concepts for Online-Provision of Health Data*, Monika Pobiruchin, research associate at the GECKO Institute for Medicine, Informatics and Economics at Heilbronn University, tackled issues surrounding innovative technologies, uninformed users and the slow legislative process.

There are currently different types of health-tracking platforms on the market - for instance interfaces such as 'Google Fit' and 'Apple Health Kit' - platforms on which Developers and manufacturers run their own products on (such as tracking-apps).

Platforms such as 'dadadoo' take this a step further. The issue here is not just around pure fitness, i.e. tracking the distance covered, calories burned and pulse rate. 'These are in fact fitness and health platforms. The user can have his health score calculated on a scale between 0 - 1,000, which states how healthy they are,' Pobiruchin explains.

A very different approach is taken by the EU-subsidised research project DAPHNE, which aims to inte-



grate wearables and other device classes to record and display data. Here, safe data storage and data protection are a priority.

Ethical and legal implications

Health-related data are very personal and deserve particular protection. However, apparently every third person is currently prepared to make their data available in return for bonuses, vouchers or other benefits. Quite rightly, this makes one wonder: 'Where is the point in protecting data when patients themselves make the data available online?' In the first instance, health informatics specialist Pobiruchin does not see a problem: 'In prin-

ciple, I think it's great that people are doing this. Everyone should be at liberty to post their data on the internet.' The advantages of wearables, apps and smartphones are obvious: Why should a patient keep a diary of symptoms on paper when they can do the same thing with a smartphone - which they carry with them at all times, anyway? Everyone can also use apps to make their emergency contacts available, so these can be accessed as and when needed. Furthermore, patients can also make data available directly to their doctors (GPs) by showing them their smartphones and saying 'Take a look at this. I've measured my blood pressure and pulse - what do you say?'

However, this scenario also has a downside: there is no guarantee that the doctor will actually accept this information. 'Data measured with smartphones or wearable devices are not trusted in the same way as a blood pressure monitor used in a surgery, for instance,' Pobiruchin explains. She also has an eye on another danger - because many users don't know exactly what happens to their data and where it ends up. 'Users lack the specialist knowledge because these technological developments could not have been foreseen five or six years ago. Most of them have completely different ideas as to what can or can't be done with their data.'

According to Pobiruchin the legal implications need to be given particular consideration: 'A German provider of a fitness-app who wants to store their customers' data in a storage facility in the cloud provided by a third party is only permitted to do so if they have specifically entered into a data processing contract with the third party. However, the decisive question is: Where is the third party based and what are the laws on data protection in this location? In the USA, for instance, data protection is dealt with in a different way to how it is regulated in Germany or the EU. There is quite a lot of friction between global data management and regional legislation.' The expert also points to ethical aspects: 'Through the integration



A research associate at the GECKO Institute for Medicine, Informatics and Economics at Heilbronn University, **Monika Pobiruchin** received her Diploma in Health Informatics from Heidelberg University in 2010 and is currently writing her doctorate at the Medical Faculty of Heidelberg University. Focus: The automated generation of health economic disease models based on routine clinical data. In 2014, she became one of the co-founders of the project group Consumer Health Informatics within the GMDS e.V.

of the data I've made available I make myself identifiable. What happens if I have a rare disease, or rare blood group? Even without my name being mentioned, this might make me potentially identifiable. What happens if, for example, insurers can then process this data? Will I receive a bonus if my behaviour is perceived as health-conscious, or will I be turned down if it is not?'

These are the issues Pobiruchin is dealing with, and this expert would like to see an intensive discussion on this subject: 'Informatics is not meant to stoke fears but to throw light on what can be done with data and to encourage a dialogue about dealing with it. We missed out on creating this dialogue with the development of smartphones and should not repeat this mistake with the wearable devices that are currently trendy.'

Improving medication adherence via a patient-centric platform

The Connected Care Framework

'The core idea behind the Connected Care Framework,' nephrologist Dr Stefan Becker explained, 'is to develop a patient-centred communication infrastructure that serves as a basis for value-added services. These services can then be integrated into mainstream healthcare delivery. We focus on medication adherence of chronically ill patients, because this is a big challenge. Studies identified that only one-third of patients who have undergone transplantation adhere to their medical regime. Non-adherence, on the other hand, can jeopardise the success of the procedure.'

'We developed the Connected Care Framework including an app for patients, which is designed to help them to better comply with the medication regime and hence increase patient outcome.'

'The framework uses technology and data security concepts already implemented in the electronic patient record as an interface between physicians in the out- and in-patient field and their patient. It's a system that allows adapting its

single modules to patients' needs. We created a personalised app that



Stefan Becker MD MBA is a senior nephrologist and transplant officer at Essen University Hospital, where he also manages its Institute for Drug Safety. Recently, he spoke with Cornelia-Wels Maug, for European Hospital, about his involvement in e-health projects in the field of connected care that he carries out with interdisciplinary teams, including the Fraunhofer Institute for Software and Systems Engineering (ISST), and particularly the Connected Care Framework launched this April.

permits doctors to give feedback in an unstructured way, such as asking 'How are you? Do you feel good or bad?' Medical data is processed using a token-based system, permitting the patient to authorise those users with whom he or she wants to exchange information.'

How does the apps benefit patients?

'It involves the patient in the treatment process. Via a memory function, for example, it reminds patients to take their medication, or measure their vital parameters at a designated time. It also allows patients to record their moods as well as to look at the medication plan compiled by a doctor.'

Where is the app used?

German health insurance Techniker Krankenkasse (TK), the leading public state health insurer by number of insured, is the first to deploy the app in a newly created adherence program, which supports telephone coaching. Apart from the insurance field, the app will be rolled out in



the nephrology department of Essen University Hospital and, sometime later, in an out-patient practice. We are also preparing further use cases for pharmaceutical companies.'

What further developments are planned?

'The communication infrastructure behind the app was developed as a prototype to be rolled out in diverse settings: either in terms of use cases, such as general practitioners, rehabilitation, or in terms of functionality by adding modules to support certain modifications of behaviour as needed. 'We'd also like to explore

the app as a communication tool in the pharmaceutical industry and are already in talks with some companies. The intention is to offer a complementary service to selling drugs, giving pharma companies a competitive edge. By increasing medication compliance, pharmaceutical firms can leverage drug sales. We've seen the first advances in this direction with pharmaceutical companies sponsoring telephone hotlines for individuals who have just received an organ transplant. Nephrology associations are especially very interested in this topic.'

Hospitals face advanced persistent threats to security

Hacking into healthcare records can kill

Report: Mélisande Rouger

Is your network safe? This loaded question made delegates shiver during Inforsalud 2015, the annual meeting of the Spanish Health Informatics Society, held in Madrid this February.

In a fast-paced, hectic presentation, Dr Jesús Díaz Barrero, systems engineer at Palo Alto Networks (PAN), highlighted how hospitals are increasingly the target of advanced persistent threats (APTs) – from groups with both the capability and intent to determinedly and effectively targets a specific entity.

Over the past few years, an increasing number of cases have been reported in which hackers modified the parameters of an insulin bomb, or a defibrillator to deliver random shocks to a patient's heart from the Internet. Recently, a report in MIT Technology Review and CNBC stated APTs from the Chinese army stole millions of personal data from US hospitals in the USA.

The reason is simple: it is incredibly easy to hack a hospital. Millions of players can access a hospital's

network, either outside or inside the facility. For instance, patients can consult their reports and interact with their doctors from home.

These new means of communication increase the possibility of APTs, according to Díaz. 'Each time we open a door, we find a problem,' he said.

The growing use of telemedicine in Spain, especially in remote areas such as the Balearic Islands, also increases this risk. So does access to the network by external clinics, delegations, manufacturers, pharmaceuticals and insurance companies, lawyers, etc.

Within the hospital or campus, many teams are connected to the network – labs, examination rooms, patient rooms, and so on. Even the private wide area network (WAN), which connects all medical systems such as PACS and information exchange systems, can be a target.

'Having all these channels means that the opportunity for an APT is very high. I don't want to scare you, but this is the reality of the healthcare setting today, all around the world including Spain. We are used

to thinking that bad things only happen elsewhere. You'll see how it is far from being the case,' he said.

He presented studies conducted near three randomly chosen healthcare facilities over a year. These demonstrated how vulnerable those facilities were. All of them emitted malware from their own network without being aware of it.

Malware, short for malicious software, is hidden within standard web content and designed to exploit vulnerabilities on Internet-enabled applications, such as browsers and browser plug-ins. Its aim is to disrupt computer operation, gather sensitive information, or gain access to private computer systems.

Researchers placed external waves to monitor web traffic at those facilities. Results show that not only did scanners, modems and web cams emit malware, but also radiology systems and, most surprising of all, firewalls. 'Firewalls are supposed to protect hospital systems against malware, but they were actually the main source of malware. More alarmingly, the staff responsible for the system security did not know

what was going on,' Díaz said.

PAN gathered information over the past five years at a large number of facilities and healthcare companies in Spain. The firm found out that all of the amenities had malware in their systems. They all shared the same problem: their security systems did not work together, Díaz pointed out. 'The facilities failed because of dispersion. Traditionally, we've put punctual solutions that work independently and are not related to each other. Therefore, when I have an incoming threat, I'm lost in this mess. It's also crucial to distinguish which threat is important and which isn't. Moreover, most security systems need manual intervention, which is time consuming,' he said.

Díaz recommends that hospitals correlate information between their systems and identify what applications they have in their networks – and decide whether they are safe or not. Information should be segmented and access to the server should be granted strictly and according to the visitor's needs.

Hospitals should also apply the



Jesús Díaz Barrero, systems engineer at Palo Alto Networks (PAN), Spain

Zero Trust principle, in which two critical machines cannot share the same level of security. Access from one to the other should be protected, for instance by passwords.

With the explosion of smart phones and tablets use, one should also adapt these measures to the mobile world. Finally yet importantly, a security platform should be able to counter both known and unknown APTs.

Many firms currently offer protection platforms against all sorts of APTs, including Dell SonicWALL, NETGEAR, WatchGuard and PAN. The product PAN-OS is considered an industry leader but recently scored lower on independent NSS Labs test.

Is PACS ready to expand beyond radiology images?

'Not yet,' says IT medical systems expert

Report: John Brosky

Nine out of 10 hospitals in Western Europe have a fully-operational picture archiving and communications systems (PACS) to manage and exchange medical images. The integration has become so routine that other physicians are now asking why they cannot as easily share with others the images they generate with non-radiology devices.

It would appear that vendors of PACS systems are ready to tackle the assignment, thanks to the introduction of vendor-neutral archiving and zero-footprint viewers.

'Not really, not yet,' cautions Marco Foracchia, the IT Medical Systems Manager for Santa Maria Nuova near Parma, in Italy's Reggio Emilia region.

He is less confident that a system built for rigidly structured radiology exams is ready to take on all the types of medical images from specialties such as dermatology and endoscopy, or orthopaedic videos.

'One physician is a small problem, but when you add them up, it becomes a big headache,' he explained as he presented a case study for the Healthcare Information and Management Systems Society Europe at the European Congress of Radiology (ECR).

After an inventory at the Santa Maria Nuova hospital, Foracchia said he found 534 imaging and data sources to be added to the traditional radiology network. Of these, 13% create images that are what he called properly managed, and 8% are clearly improperly managed. The remaining 79% of exams are not managed or stored at all.

Unlike radiology exams, he said, image acquisitions on these devices are not scheduled but made on the fly, and reporting is not sequential following the acquisitions, as is the case in structured PACS management. Instead, physicians, surgeons and specialists often do their reporting during the exam itself.

DICOM, the bedrock standard for image exchange on the radiology PACS, is rare among over 500 of the devices physicians in his hospital want to connect.

'Radiology PACS is a proof that management and sharing is clinically meaningful, and on paper it is the solution,' he said, but added that there are so many anomalies that a system built for radiology does not apply to extra-radiology systems.

In an effort to determine the readiness of European hospitals for evolving PACS systems the European Society of Radiology and HIMSS have announced a partnership that

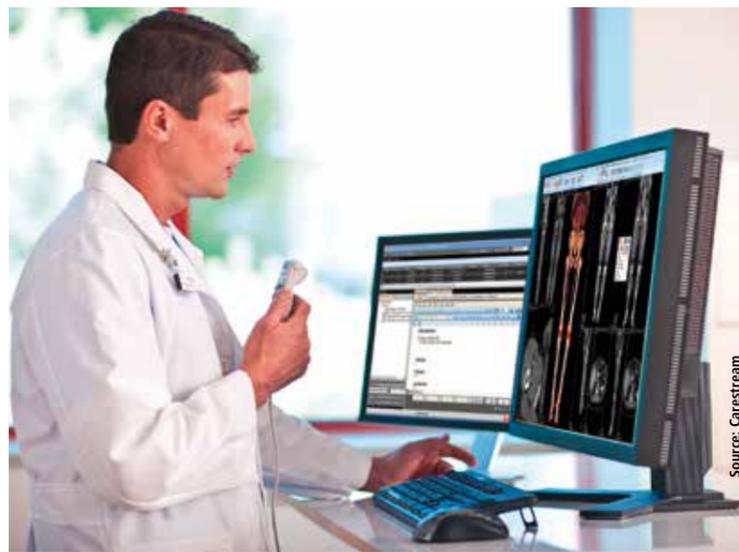
will, during, evaluate the maturity of health information technology systems with a report expected at ECR 2016.

'Radiology is already more closely tied with information technologies than any other medical discipline,' said ESR Past President Guy Frija MD, who described the scope of the partnership as embracing big data, business intelligence, as well as archiving and structured medical reporting to ensure future applications and challenges for radiology will be met.

'We also hope our partnership with HIMSS Europe will create a greater awareness especially among IT companies for the innovative potential that has always been inherent in radiology and which will continue to shape the discipline,' Frija stated in the joint announcement.

In a first step for establishing an imaging IT maturity model for the joint project work group, HIMSS senior consultant for analytics Jorg Studzinski presented an evaluation compiled from a survey of six major western European countries, with the notable exception of France, where, he simply explained, 'we just don't know'.

He also noted the maturity of Nordic countries in health informatics is so advanced that the data for



Source: Carestream

the Netherlands serves as a mirror.

Starting with the fundamental radiology information system (RIS), more than 90% of all hospital systems in Italy, Germany, Spain, the Netherlands and the United Kingdom reported a system in place, with Austria being the low end of the scale at 85%.

Radiology PACS is nearly as well implemented with Italy and Germany trailing at 80%.

A dedicated cardiology PACS has caught on with the UK reporting such a system at 80% of facilities, Spain and Austria pushing above half of hospitals, while Germany and Italy were at 24% and 14%, respectively.

Pointing towards the upcoming assessment is a newly created cat-

egory for an imaging data centre (IDC) that is meant to measure overall image management capabilities, though in the current evaluation it remains less clearly defined, and evaluation results are highly varied, from 97% in the Netherlands to 41% in Germany.

In announcing the partnership with HIMSS that initially will aim to establish an imaging IT maturity model for Europe, the radiology society said the on-going collaboration with the joint project group will help ensure that a broad agenda of IT topics are linked to radiology and that they are regularly addressed at the European Congress of Radiology, including e-health, data mining, dose watch, structured medical reporting and enterprise-imaging.

Digitising the operating theatre

The entrance of PACS-Surgery

Picture Archiving and Communications systems (PACS) are well established for managing radiology images. Could this robust and mature technology now become the backbone for creating the digital operating theatre?

In a hospital, the OT is perhaps the most expensive and labour-intensive area and it is expected that standardising procedures with the help of computer assistance will help to control costs better, as well as ensure that patients benefit from an optimal surgical interventional and treatment.

Yet, the operating room is also one of the most complicated areas in a hospital with complex information processing among as many as 30 to 50 medical devices, many of which do not share data with other systems.

In Barcelona, at the end of June, the Computer Assisted Radiology and Surgery (CARS) Congress will bring together experts from radiology, surgery, engineering, informatics and healthcare management to focus on a range of interconnected fields to shape the smart operating theatre of the future, an OT with state-of-the-art image processing and visualisation and with model-guided interventions supported by surgical navigation and robotics.

Heinz Lemke, a founder of the CARS congress and the Chair of the CARS Organising Committee, is a leading researcher and authority in the field of computer-assisted medi-



cine. 'Speaking about surgery generically is not useful,' he told European Hospital. 'We need to speak about specific surgical interventions, each of which has a characteristic workflow.'

The schematic approach that outlines each step in a surgical procedure is the fundamental logic for PACS systems, a way of organising the process for a computer.

By comparison, PACS for radiology is extremely simple, he pointed out. 'There are typically five steps of activity for a radiology workflow, and between each step you can go and have a coffee. For one specific surgical intervention we have identified 28 steps. Looking at another, there are 35 steps. For an intervention as complex as mitral valve

replacement, there are as many as 480 steps. There are hundreds, even thousands of specific workflows for specific surgeries, each of which needs to be modelled,' he said.

The goal with PACS-Surgery is not to have all information always available, as it is to have visualisations driven by the steps in the workflow, to only display what is specifically relevant to the specific activity at a specific moment.

According to Elisabeth Beckmann, consultant for IT and PACS at Lanmark, the challenge is more complicated than transferring images from radiology to surgery. 'Many other forms of information are needed, such as a pathology report at a specific moment,' she said. 'And, in a next step, the question becomes not

only when to integrate this information, but how it should be presented in different ways to different types of people.'

Intraoperative mapping is at the heart of the approach being taken by the Innovation Centre Computer Assisted Surgery at the University of Leipzig where Prof. Lemke is senior adviser on research strategies.

Funded by the German federal government, to date the Leipzig group has modelled more than a thousand workflows, he said, collaborating with research teams in Japan and the United States and coordinating an international effort to advance the digitisation of the operating theatre.

'My role, in working as a chair for the IHE (Integrating the Healthcare Enterprise) Surgery Domain, is to bring these three projects together around the table with a focus on developing integration profiles that will serve as the basis for an international guidelines,' he explained.

Once integration profiles are established to standardise workflow for surgical interventions, it creates an opportunity for manufacturers of medical devices to implement the profiles in order to assure their diverse devices in the operating room will work together.

The CARS meeting in Barcelona will see the first conference on the human machine interface in a session called Medicine Meets Virtual



A professor of Computer Science, Heinz U Lemke PhD teaches and supervises research on Computer Assisted Medicine at the Technical University of Berlin. He is also Research Professor of Radiology at the University of Southern California, Senior Adviser on research strategies at the Innovation Centre Computer Assisted Surgery (ICCAS), University of Leipzig and Visiting Fellow of the Institute of Advanced Studies, Technical University of Munich. He has been the organiser of the Computer Assisted Radiology and Surgery (CARS) congresses since 1983, and editor-in-chief of the International Journal of CARS and executive director of the International Foundation for CARS.

Reality, jointly organised by the NextMed group and the International Foundation for Computer Assisted Radiology and Surgery (IFCARS).

The international scope of work on the operating theatre of the future is reflected in the CARS congress, with dedicated sessions for the European Society of Medical Imaging Informatics, the International Society for Computer Aided Surgery and the International Society of Optics and Photonics.

Huge telehealth study reveals mixed value, but...

England's Florence looks like a winner

Report: Cornelia-Wels Maug

Given the increasing focus on telehealth and telecare services aimed at improving long-term patients' living conditions and save costs, numerous pilots in various countries have been conducted for proof of concept purposes. Among these, the United Kingdom's 'Whole System Demonstrator' (WSD) programme is the largest randomised controlled trial. Set up by the English National Health Service (NHS) this aimed to find out the effects of remote care.

A core consideration for the design of the WSD programme was to have a sufficiently large sample size, because past studies' samples were either too small (often focused on under 100 patients), not allowing any generalisation, or they did not meet robust evaluation criteria. Hence, a large sample incorporating 64 sub-studies with nearly 6,000 patients – affected by seven different health conditions – and 660 caregivers was drawn. The 47 studies that focused only on effects of telehealth included individuals suffering from heart failure/stroke

(22 studies), diabetes (22 studies) and chronic obstructive pulmonary disease (COPD) (3 studies) and took place at three sites in England (Kent, Newham and Cornwall).

Launched in May 2008, the UK programme ran until December 2009 and was followed up by a lengthy evaluation phase, with the final assessment only becoming available in 2014. The evaluation measured how telehealth affected the use of secondary healthcare (such as emergency room visits), mortality, quality of life and cost effectiveness, and investigated the patient, professional, and organisation factors related to its implementation. In its presentation 'What impact does telehealth have on long-term conditions management?' the King's Fund, an independent charity working to improve health and healthcare in England, came quintessentially to the somewhat disillusioning conclusion: 'The evidence for the positive impact of telehealth is promising but mixed, and mainly limited to specific conditions such as diabetes and heart failure. Significant benefits have yet to be

proved...'. Additionally, it provided some disease-specific insights:

- 15 out of 22 studies on heart failure proved that remote monitoring reduced hospitalisation
- from the 18 studies on diabetes patients that examined effectiveness of care, 11 reported a positive effect,
- research on COPD showed that telehealth cuts hospital admissions, but offered mixed results in terms of clinical effectiveness and care experience.

All's well that ends well

As disappointing those results may sound, Dr Charles Lowe, Charles



Source: Shutterstock/naka-stockphoto

Lowe Consulting, who led the bid for Newham to partake in the WSD programme, calls it 'a visionary approach to kick-starting the use of telecare and particularly telehealth to improve patient outcomes and reduce costs'. He reckons, 'partly as a result of the trial, equipment cost and functionality have changed so much, and we have learned so much more about how best to deploy and prove the benefits of the technology. Indeed, in spite of published material, all three WSD sites decided subsequently to mainstream telehealth, which is as good an indication as any of its value.' And Richard Stubbs, Yorkshire and Humberside and North East Coast and North Cumbria Academic Health Science Network (AHSN), who worked with Lowe at the time, remembers: 'As our clinical staff could support four times as many people with telehealth than they could without, there was a clear efficiency case to be made.'

Outlook – health apps as game changers

Since the time the WSD programme

was conducted, equipment costs have fallen extensively and functionality has improved considerably. The biggest game changer in the provision of telehealth, however, has been the arrival of apps. The fact that they are downloadable onto smartphones both significantly curtails upfront cost and installation time.

By setting up 'Florence', England's NHS came up with a simple telehealth strategy based on text messaging to manage patients with long-term conditions. Encouraged to become more involved in their own well-being, they text their vital parameters and receive personalised advice about managing their condition, or are asked to contact their clinician if their readings or symptoms are beyond a certain predefined threshold. There is no longer the need to involve specialist telehealth hardware.

Starting out in Stoke-on-Trent, the Florence has been used by over 70 health and social care organisations and more than 12,000 registered patients. It is growing daily.

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