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EHFG 2011

'There are too many unnecessary operations!' ***Hans-Christian Pruszinsky*** **reports**

Participants at European Health Forum Gastein 2011 (EHFG) agreed: the tendency in Germany and Austria is to operate far too soon (particularly for hip, knee and disc surgery), and many surgical interventions are unnecessary, posing a particular and increasingly urgent problem especially in industrialised countries. '289 operations are performed in Germany per 100,000 inhabitants; in Austria the figure is 243 per 100,000, but in Poland, for example, it's only 39 per 100,000, and in Cyprus 15 per 100,000,' said EHFG President **Günther Leiner**. 'This is too striking a difference, and nobody can tell me that it is simply down to being a medical issue and that provision in other countries is worse. Medicine in Poland is outstanding, and the Poles are brilliant surgeons. Hence there must be another reason behind it – and, in most cases, it's economic.'

Private patients particularly risk unnecessary or early surgery because people can still walk with a joint problem for some time without a replacement, 'However, you can also opt for economic gain and tell the patient: "You need a new joint".' **Professor Helmut Hahn** of the Charité Clinic Berlin, pointed out.

Often, complaints can also be treated without surgical intervention, for example via physiotherapy: 'In some cases it's totally possible to do without surgery altogether,' Prof. Leiner said, 'but it's also possible to postpone it and not operate so quickly. Each operation is an intervention and entails additional risks for the patient.'

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Cause for concern: Diagnoses via teleradiology

Whilst the benefits of teleradiology as a diagnostic tool continue to grow, concerns have been raised about the lack of uniformity in reporting protocols across Europe. ***Mark Nicholls*** **reports**

Although **Dr Hans Billing**, Medical Director of the Telemedicine Clinic in Barcelona, Spain, sees enormous advantages in teleradiology, he also points out that the concept raises a number of issues of which radiologists should be aware in terms of the varying legislation, patient confidentiality and developing a good working relationship with end-user clinicians.

One of the key issues, he said, is the need for an EU-wide protocol for reporting from teleradiology because the legal position in Europe still lags far behind the technical capabilities, medical advances and patient benefits that teleradiology offers.

Whilst Scandinavian cases can be reported without any restrictions in the whole of EU, UK cases, he points out, cannot be reported outside the UK unless they are anonymised.

Confusion can arise with a patient of one nationality being scanned in a second country and reported on by a radiologist in a third location with all three covered by different reporting protocols. 'We must have some sort of common European healthcare legislation, but we still don't, even after all these years,' Dr Billing explained.

Presently, the Telemedicine Clinic – which has offices in Barcelona and reading in the UK and Sydney, Australia - opts for the strictest legal position, but it would welcome an EU-wide protocol for reporting from teleradiology. 'I feel that advances are being made but they are made from many different interest groups,' he said.

Hans Billing

The European Society of Radiology and organisations in the UK and Scandinavia have working groups on the issue but he stressed the need for different organisations to unite to establish uniformity to enable radiologists – and patients – to reap the full benefits of teleradiology. 'Even if it means we have to make our workload even stricter,' he added, 'it's important to have a common workflow from a legal point of view, everywhere.'

Teleradiology is a tool radiologists use daily to report from different locations, such as from home, providing the opportunity to use resources where they are situated and harness specialist expertise remotely. 'Today, it's even more important,' Dr Billing pointed out, 'to use specialist expertise and it will become more important in our clinical environment in the future. The amount of very specialised knowledge we can get from the current modalities is increasing, so today it's not enough to be a good radiologist in practice, you need to be able to put it into clinical context and that is where you need clinical expertise.

'Every hospital, even university hospitals, can't have all the subspecialists now required to cover every little niche of radiology; that's the most important benefit of teleradiology.'

With security less of an issue because of heavy encryption, teleradiology services can be offered effectively to remote geographical areas. It gives clinicians and patients access to specialists, but also offers the radiologist greater flexibility in where they work.

But when reporting teleradiology, Dr Billing believes it is important to be familiar with the needs of the clinician. 'In a hospital environment you are surrounded by your colleagues and clinicians who know you and the way you usually report. You are familiar with which type of surgery they perform and their exact needs.

'One of the pitfalls with teleradiology is that you are not only distant physically but also distant from a knowledge point of view from the end user. What is needed in teleradiology is to get to know the end user – the radiologist in radiology department and especially the clinicians - and know what their real need is and the setting in which they work.'

Further radiology reports: pages 14-27

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Patient safety in anaesthesiology

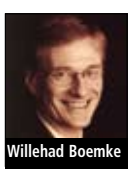
Step by step the Helsinki Declaration is being implemented: Great Britain and the Netherlands have made it law. In Germany, it is voluntary, ***Susanne Werner*** **reports**

Patients in Germany, the Netherlands and Great Britain can assume their safety of care when it comes to anaesthetics. Hospitals in these three EU countries are among those who, to a large extent, have implemented the 'Helsinki Declaration on Patient Safety in Anaesthesiology', as pointed out by **Professor Hugo Van Aken**, General Secretary of the German Society of Anaesthesiology and Intensive Care Medicine (DGAI), during the HAI 2011 congress of the DGAI in Berlin, this September – an event attended by over 5,000 specialists and nurses from Germany and neighbouring countries.

The professor emphasised that Germany is the leader in Europe – with hospitals already implementing almost all the declaration recommendations in practice – despite the fact that those responsible for its implementation in that country made it voluntary, whereas in Great Britain and the Netherlands the implementation is now law.

Hugo Van Aken

Claudia Spies



Willehad Boemke

Anaesthesiology considered key to patient safety

Around 230 million people worldwide undergo some type of surgery annually. In around seven million cases complications arise, resulting in mortality for around one million patients, figures making European anaesthetists prick up their ears in recent years.

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Patient safety in anaesthesiology

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Anaesthesiology is considered a key element of medicine to see patients safely through a surgical intervention and best prepare them for the healing process. Therefore, leading representatives of the national anaesthesiological societies in Europe therefore developed and passed the 'Helsinki Declaration on Patient Safety in Anaesthesiology' in 2010.

The paper describes seven steps of a process for more patient safety, ranging from internal hospital decisions for more safety and quality in anaesthesiology to concrete guidelines, such as the labelling of syringes with standardised stickers, down to annual reports about measures taken and their results.

Experts estimate that in industrial countries the anaesthesia-related mortality rate of around one in 100,000 is relatively low. Safety of patients during operations under anaesthetic has improved over the years in Germany, said Prof. Van Aken, who is Director of the Clinic and Policlinic for Anaesthesiology and Surgical Intensive Care Medicine at the University Hospital of Münster.

The DGAI and the Professional Association of German Anaesthesiologists (BDA) recommends the use of 'check lists and other anonymous error reporting systems', he pointed out. Hospital doctors could avoid many undesired incidents if they adhered to certain safety steps. The specialist societies have made it their task to monitor the implementation of the guidelines on a national and European level: 'The national specialist societies deliver regular status reports to the European society which in turn has made patient safety in Europe a topic at its annual conference,' he explained.

As the arrangement in Germany is voluntary, as yet there is no hard evidence on the status of the implementation. 'To my knowledge, all university hospitals, as well as hospitals that are part of the Helios chain, work with many of the recommendations from the Helsinki declaration in anaesthesiological practice,' he said.

Further concrete figures result from a Berlin university medical study published on the occasion of the HAI 2011. This indicates that 28 hospitals in Berlin and Brandenburg are implementing the European recommendations on patient safety in anaesthesiology to a large extent. **Professor Claudia Spies**, Director of the Clinic for Anaesthesiology at the Charité in Berlin and co-author of the study, as well as conference president of the HAI 2011, emphasised: 'In a European comparison we are at the very top.'

Survey of 43 hospitals in Berlin and Brandenburg

There are around 115 hospitals in Berlin and Brandenburg. For the study, the team lead by Prof. Spies and **Professor Willehad Boemke**, head of the study and also Professor at the Clinic for Anaesthesiology at the Charité in Berlin, wrote to 43 hospitals that are part of the 'Innovation Alliance for Anaesthesiology Berlin-Brandenburg' (INABBRA). Representatives of 28 hospitals answered these questions in detail.

Based on these answers, 93% of hospitals have a special recovery room and 60% regularly analyse complications in so-called morbidity and mortality conferences. The Helsinki declaration also specially recommends utilising the World Health Organisation check list: 'Safe Surgery Saves Lives'.

Prof. Van Aken pointed to a study from the Netherlands: Data were analysed from six hospitals that had introduced the check lists at different times. The results were published in 2010 (N Engl J Med 2010; 363:1928-1937 November 11, 2010, internet: *http://www.nejm.org/doi/full/10.1056/NEJMsa0911535*. They showed how efficient working with the check list is: The overall rate of complication fell from 27.3% to 16.7%, and the ratio of patients with at least one complication decreased from 15.4% to 10.6%. The mortality rate in the hospitals fell from 1.5% to 0.8%.

The standards on a European level serve for orientation, said Prof. Spies. In her view, it is decisive how the recommendations from the Helsinki declaration are adapted to and modified for the respective processes in individual hospitals. For example: According to a current study from Berlin and Brandenburg, none of the hospitals surveyed works with the original checklist, but 82% are using a modified version. According to Prof. Spies, still a good sign because it shows that the operating theatre teams are proactive, talk about the actual processes in their respective hospitals and jointly improve the quality of their work. 'Communication and exchange are important,' she explained. Anaesthetists often still work in a somewhat isolated way, without being integrated into hospital teams.

Error reporting systems must become more established

The expert views another result of this study more critically: Only 60% of hospitals surveyed in Berlin and Brandenburg apparently work with a so-called Critical Incident Reporting System (CIRS). 'In my view this has not yet become established enough,' she explained.

The CIRS system envisages that doctors and nurses report critical incidents that could endanger a patient's health or actually have endangered a patient's health in an online form and therefore disclose mistakes. The reports are anonymised and uploaded to an internet platform (*https://cirs-ains.de/*). Employees in other departments or other hospitals can read these and learn from the experience, mistakes and near-mistakes made by colleagues. The use of a CIRS is very effective and a usage rate of 60% in the hospitals surveyed is clearly too low. Prof. Spies: 'Based on previous studies the existence of a CIRS alone reduces the error rate in a hospital by an average 31% for all types of medication errors.'

In the course of her research, she has encountered another two current phenomena that could endanger patient safety in future. Technical defects of equipment have increased significantly due to the state of investment in hospitals, Prof. Spies pointed out. Therefore, it is very important that anaesthetists regularly check equipment. Additionally, there is a lot of fluctuation among younger staff, whilst at the same time the workload for doctors and nurses is continuously increasing. 'In the future, it will become even more important that the entire team is continuously trained in all processes and workflows,' she advised. 'Whether or not quality and safety are right depends significantly on how well-rehearsed the team in the operating theatre works together.'

Intensive care reports: Pages 9-11

Ranking healthcare systems worldwide

Does France provide the world's best health service? How is a good healthcare system defined? Who decides that one healthcare system is better than another? What do we expect from a healthcare system? The answers depend on your perspective, says EH Paris Correspondent *Jane MacDougall*

The World Health Organisation (WHO) last ranked worldwide healthcare systems based on 1997 data in its World Health Report Health Systems: Improving Performance published in 2000. Over a decade ago and still this report is being debated and discussed the world over as politicians and policy makers try to create sustainable and effective healthcare systems for their countries.

The WHO's assessment was based on five indicators. On these criteria, France was ranked best 'overall healthcare' in the world. Is this really a true reflection of healthcare in the world and France in particular? What does France have in each of these categories that make its healthcare so good?

Population health was the first criterion measured, because health is, after all, the defining objective for any health system. To assess the overall health of a population, WHO chose to use disability-adjusted life expectancy (DALE), which is directly comparable to life expectancy estimated from mortality alone and can be readily compared across populations.

At the time of the WHO study France's life expectancy was 3rd highest in the world. Today, at 81 years, it is the 10th highest by 2011 estimates in the CIA World Factbook.

The second criterion measured was health inequality. Within the population a health system ideally should protect the ill and infirm from financial risk. Since Lionel Jospin's government introduced 'universal health coverage' in 2000, health cover has been extended to everyone legally resident in France, regardless of employment or income.

An important element of the French insurance system is solidarity: the more ill a person becomes, the less they pay. This means that for people with serious or chronic illnesses (e.g. cancer, AIDS, diabetes or severe mental illness etc.), the insurance system reimburses them 100 % of expenses and there are no co-payment charges. However, although access to GPs is equally accessible for both rich and poor in France, a recent report has shown that there is an uneven distribution of care at specialist level with higher-income groups having greater access to this level of care (Thomson and Mossialos. Primary Care and Prescription Drugs: Coverage, Cost-Sharing, and Financial Protection in Six European Countries. Commonwealth Fund Pub. 1384 Vol. 82). However, in every country except the UK, higher-income groups use specialists at higher rates, which may reflect both higher cost-sharing for specialist visits and an uneven distribution of specialists in other European countries.

Overall level of responsiveness was the third factor examined. Responsiveness is a measure of the 'human face' of the healthcare provided, whether or not it meets the populations' expectations of how they should be treated, in terms of attitude of healthcare providers, quality of services, choice of provider and waiting times.

A survey of nearly two thousand key informants in selected countries was used to assess the level of responsiveness in 200 countries while, in others, indirect methods were used. In terms of level

EHFG 2011

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Personalised medicine: the 'virtual twin'
Despite big cost increases, in the last three decades advances in treatment for the most common diseases – cancer, cardiac disease, Type-2 Diabetes, obesity and rheumatoid arthritis – have been alarmingly modest.

Experts pointed out that the EU flagship project IT Future of Medicine could redress this. For a project cost of €1 billion over the next decade, a saving in healthcare expenditure of up to €100 billion a year is projected. Concerted advances in cloud computing, cell and molecular research, genome decoding and analysis tools for large volumes of data could help scientists to create a 'virtual twin' of each patient. This could simulate an individual body's reaction to environmental conditions, lifestyle or medication, and enable the detection of any pathogenic changes even before symptoms occur.


Günther Leiner


John Dalli

Similarly, such systems could suggest personalised treatment options, inclusive of information on what effects and risks are to be expected in an individual case.

Prof. Angela Brand of the Institute for Public Health Genomics (IPHG) at the Faculty for Health, Medicine and Life Sciences (FHML) at the University of Maastricht and Director of the European Centre for Public Health Genomics (ECPHG) said: 'We know that a certain percentage of people will respond to a certain drug, but not whether an individual will be among those likely to respond or not. Therefore, the chance of a cure and a lot of money is wasted on failed attempts.'

Because, in principle, each disease should be regarded as a so-called rare disease, the objective of research must be to develop treatments with high degrees of effectiveness for small, precisely defined patient groups, based on genomic information, rather than developing medication for many applications with a relatively low degree of effectiveness, added pharmacologist Andreas Penk.

2020 Europe – 230,000 doctors short
A shortage of doctors has been widespread for some time. In the Czech Republic thousands of doctors threatened to emigrate a few months ago due to low income. Slovakian hospitals are threatened by a mass exodus of doctors; some say 4,000 doctors in 51 hospitals intend to leave this small country for economic reasons. How international this problem is, or could become, was highlighted.

According to the EU Commission, if nothing is done, European healthcare systems could be short of a million skilled employees by 2020. It estimates a shortage of around 600,000 nurses in 10 years time and a shortage of 230,000 doctors. In Germany, for instance, patients in rural areas will increasingly have to accept treatment by mobile medics – present in certain areas only on certain days. 52,000 doctors will have to be replaced by 2020.

Doctors' migration has turned into a business. Specialist companies place doctors from Eastern Europe wherever there is a shortage of trained medical staff.

The number of foreign doctors in West Germany between 2001 and 2009 increased by 53%; in East Germany by more than 300%. Austria also suffers shortages, particularly in rural areas.

A large number of doctors also will retire in the next few years. The need for trained nurses will also increase sharply. Austrian Minister of Social Affairs **Rudolf Hundstorfer** predicts the need for a further 17,000 nurses by 2020 – just to cope with demographic changes. However, according to a study, only 24% of those surveyed could see themselves working in this field.

Great Britain: Almost 50% of doctors are from abroad
The shortage of doctors will particularly impact on poorer countries, warned the World Bank's health politics expert **Armin Fidler**, because wealthier states are likely to drain staff from them. Although some countries are working to improve employment conditions in their healthcare systems, staff is increasingly recruited from abroad – from hospital workers to home carers.

47% of doctors working in Great Britain have come from abroad; in Poland it is just 1%, according to the European Observatory on Health Systems and Policies. Over 10% of Romanian medics are already emigrating to Western Europe. 'A Romanian general practitioner in France earns ten times as much as in Romania,' Armin Fidler underline.

The discrepancy between industrialised countries and sub-Saharan Africa is even more alarming. Only 3% of the qualified, worldwide medical staff actually works there, which is made even worse by the increased demand in the north and west. However, migration does have positive aspects. Hundreds of thousands of Filipinos nurses work all over the world – their money sent home is an important economic factor.

The 'rescue umbrella'
The only way to counteract shortage is to improve income massively. According to a Euro Observer study, between 2005 and 2008 Lithuania increased doctor and nurse salaries by 20% annually, thereby preventing a mass exodus. Poland also managed to attract some emigrant doctors back to return by offering better salaries. However, in Romania, a 25% drop in salaries increased emigration.

Günther Leiner would like to install a permanent safety net against threatened medical staff shortages. He stipulates that, in the future, funds should be set aside from the financial transaction tax currently under discussion – but this is still a long way off.

Finally, EU Health Commissioner **John Dalli** emphasised the importance of innovations to facilitate more services with fewer means. He also pointed to the success of the 'Partnership for Healthy Ageing' campaign across Europe. In terms of financing such innovations, he referred to the very recent EC decision on new Cohesion Funds, accessible to all European regions to fund intelligent innovations that could increase healthcare efficiency.

of responsiveness the USA was ranked highest with France only 16th, behind many other European countries including, Germany, Denmark and Switzerland. It ranked much higher though for the distribution of responsiveness – the fourth factor considered. This was determined by asking the interviewees for the survey whether they could identify groups that were frequently excluded from healthcare. Four groups were often mentioned; poor people, women, old people and indigenous groups or racial minorities.

The final factor taken into account was fairness of financial contribution.

The health system in France is largely financed by the government. In 2005, France spent 11.2% of GDP on healthcare; this is more than most European countries. However, per capita at approximately €2,439, it is roughly similar to spending in Germany, the Netherlands, Denmark and Sweden.

Due to criticisms of its methodology and the difficulty of producing such a report, WHO has not entered into another comparison of world healthcare systems.

So did France really have a better overall health system and does it still, ten years on?

On a personal note, as a user of the system for the past 20 years all I can say is that it has never let me or my family down but does make it the best?

USA: The new Ann & Robert H Lurie Children's Hospital of Chicago

In 2012, Chicago's Children's Memorial Hospital will be in transition, with a change of name as well as location, when its top class technology, physicians, scientists, staff and patients transfer to a new state-of-the-art complex three miles away. Here, Thomas J Sullivan, President of the Children's Memorial Foundation, and Dr Martina Klein, Director of Social Marketing, Fundraising and Communications for the organisation, present the background of this impressive project which, they also describe as incorporating 'the unique capacity to adapt to the inevitable changes that will occur in the decades to come'

Martina Klein and Thomas Sullivan

Chicago's leading provider of paediatric specialty care, with more than 146,000 individual children treated in 2010, is undertaking an extremely ambitious initiative, the construction of a totally new hospital facility in downtown Chicago. The 127-year-old distinguished Children's Memorial Hospital will relocate some three+ miles and become the new Ann & Robert H Lurie Children's Hospital of Chicago.

Opening in June next year, the 23 storey, 1.25 million sq. ft. Lurie Children's will be in the heart of Northwestern University's academic medical centre, barely two blocks from Chicago's 'magnificent mile', and will house not only its extensive clinical services, but also medical education programme and aspects of its varied research endeavours.

Named in honour of Chicago philanthropist Ann Lurie, who made a transformational gift of $100 million to make the new hospital a reality, and her late husband, the $1 billion project was around 80% complete in May this year. It is being funded by a combination of private philanthropy ($425 million) bonded debt ($200 million), sale of the existing campus ($75 million), sale of a proprietary home health business originated by Children's more than 15 years ago ($100 million), federal and state governmental support ($50 million), along with retained earnings and investment returns.

The financial equation to underwrite Lurie Children's requires a minimum of $425 million in brick and mortar philanthropy, the largest priority of a $600 million comprehensive philanthropy campaign (Heroes for Life), one of the most ambitious fund raising initiatives ever undertaken in the Chicago environs. It requires the generosity of many people who care about kids and who have both the inclination and financial means to support this landmark undertaking.

To create world class excellence in paediatric medicine and science takes a bold vision, meticulous planning and extraordinary resources, not to mention inspired leadership from people who appreciate that challenges really are opportunities in disguise.

The planning and execution of Lurie Children's has involved extensive teamwork, with more than 500 physicians, nurses and staff, volunteers, parents and even young patients evaluating virtually every aspect of the project. From the complexity of medical technology to be installed, to the design of the critical care units, to the configuration of patient rooms and their furnishings, to the colours and animal photos on walls numerous opinions and suggestions were sought and considered before decisions were made.

What does the transformation from today's Children's Memorial Hospital to Lurie Children's mean to those it is being designed to serve? For the patients and their families – whether they are few-days-old infants, teenagers or young adults, being treated for cancer, cardiac anomalies, neurological disorders and numerous other maladies – it means access to leading-edge paediatric medicine and science.

The new downtown hospital will be significantly larger than its current 700,000 sq. ft facility located in the Lincoln Park neighbourhood, some three miles north from Chicago's Loop. It will open with 288 private patient rooms, resulting in a 30% increase in in-patient capacity.

Also inherent in the Lurie Children's project is the long-term option, if dictated by growing volumes, to relocate out-patient clinics and faculty offices to an adjacent building, which would ultimately allow for expansion to 343 in-patient beds.

And finally... 9 June 2012

The hospital's transition team is working with state regulators and local officials to ensure that, on this 'opening' day, Lurie Children's will be licensed to operate both the old and new hospitals, until the patients transfer is complete. The project will involve 10 ambulances travelling every hour to transport around 200 youngsters the three-mile distance from old to new – a potentially 16-hour final task before this already renowned hospital begins its promising future.

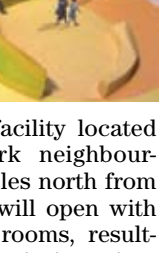
Manufacturers, please!

Improve medical products labels for quicker recognition

For 100% safety, medical products should be better labelled. While legislators, regulatory authorities and certification bodies stipulate that manufacturers should provide clear information, in reality this is not always the case, as explained by orthopaedic surgeon Jan A de Lint MD, of the Amphia Hospital in Breda and Kliniek Zestienhoven in Rotterdam, the Netherlands.

Since the German Association of Medical Technology – Bundesverband Medizintechnologie e.V. (BVMed) – represents 230 medical technology manufacturers and distributors, we asked BVMed's Deputy Managing Director, solicitor Rainer Hill, to response to the criticisms

Jan A de Lint, senior orthopaedic surgeon and lecturer on orthopaedics and anatomy



Rainer Hill

Dr de Lint: In hospitals, medical practices and particularly operating theatres (OT), many sterile packaged goods and appliances are needed and often must be unpacked without delay for immediate use. The article – a scalpel, stitch, implant – is typically recognised at a glance, based on shape and color of packaging and other physical features. However, where package and shape are not unique for their content, the label has to be read to make the right choice. Evidently, an appropriate and prompt recognition of contents is mandatory for safe, quick delivery to the instrument table. One would therefore expect that contents recognition from the label has high priority in the manufacturing process. However, there are many examples of the opposite.

Food, hazardous substances, pesticides, shoes and baby clothing have better standardisation of labeling than medical devices and disposables!

Medical firms are eager to have their brand, logo or company name prominently on the package. Often this comes at the expense of space and readability of the contents description. Type, diameter, size and material are often poorly recognised on the label and only found by cumbersome searching of the label between barcodes, re-ordering numbers and company details.

It is of paramount importance that the contents of a packed item are immediately recognised from the label. In terms of font, size and relationship to other information on the label, the text should be immediately eye-catching and legible at a distance. When appropriate, a sketch or pictogram of the contents is very helpful, in addition to this text, and will enhance the recognition.

Another aspect of labeling is content recognition in a stacked situation. Products are often packaged in an outer box or tray and it should not be necessary that the entire contents of a tray has to be spread on the floor to find a certain type or size.

In short, there is often no focus at all on the practical display of product information on labels.

The ultimate goal should therefore be an international standard in labeling for medical goods. The European hospital community could take the leadership in this.

I would suggest the following requirements:

A recognisable label
- color – contrasting with package color
- size – minimum size, e.g. 5 x 7 cm.
- font – legible at a distance; i.e. minimum font size

Indication of contents
- dimensions
- properties of the product
- quantity of items
- use before: … / sterile until : …

Information for all stakeholders
(user, buyer, purchasing, inventory, retailer)
- user information (OT) has primacy
- lot number
- reference number
- barcodes
- company logo

Label still legible
- in a box, rack or display
- after opening the package

Is such clarity so difficult to achieve?

Rainer Hill: 'First we have to clarify which packaging level we are talking about: Is this the primary wrap that directly protects the product and keeps it sterile, or are we talking about the secondary packaging that has to show the necessary information, or the tertiary, meaning transport packaging.

'The debate about labelling of medical products most frequently concerns the secondary packaging. Larger units, such as those sold to hospitals, for example 1,000 hypodermic needles, do not include instructions for use – IFU – for every single needle. It's the hospital that has to ensure that the safety-relevant information provided with the entire unit is always accessible when needed by the staff. Thus, this is an issue that concerns not only the manufacturer but also the hospital.'

The legal framework

'In the EU, labelling of medical products is unambiguously regulated. The information to be provided by the manufacturer encompasses labelling as well as instructions for use. Annex I of the Council Directive 93/42/EEC states statutory product requirements which are rather general but which are clarified by harmonised European standards that were commissioned by the European Commission.

'As far as labelling of medical devices is concerned, there are EN 980 on symbols for use in the labelling of medical devices and EN 1041 on information supplied by the manufacturer of medical devices. EN 980 allows the manufacturers to replace multilingual text by unified symbols that are used throughout Europe.

The role of CE marking

'The statutory requirements regarding CE marking, which certifies conformity to EU legislation, of medical devices are inter alia defined in the section 'Essential Requirements' of Annex I of Council Directive 93/42/EEC and encompass labelling.

'In Germany EU legislation is in force via reference in section 7 of the Medical Devices Act, the Medisinproduktegesetz MPG. Additionally, section 11, paragraph 2, sentence 3 MPG requires all safety-relevant information to be provided in German or in the language of the user. That means an exception to the mandatory use of German is possible if a hospital and manufacturer agree on a different language for the product information, for example, English. If such an exception is intended, the parties to the agreement must ensure that the entire staff – from medical director down to junior nurse – is sufficiently versed in English, to avoid misunderstandings and errors in the product's use. If this is not the case, non-German product information can be considered a defect for which the manufacturer is liable.'

Control mechanisms

'Conformity with labelling requirements on the product itself and/or the sales packaging is checked by different bodies, depending on the product risk class. They coming make sure that information and content are in accordance. In the past, certain German regulatory authorities intervened only after a dangerous event had occurred. Preventive control of samples is not a standard operating procedure in all countries. New administrative regulations, coming into effect in early 2012 in Germany, intend to harmonise market control and control by the regulatory authorities.

'To facilitate labelling even further, an EU regulation on electronic labelling of medical devices is expected to be enforced in early 2012.

'This regulation would allow electronic instructions for use to be provided in addition to, or as a replacement of, print IFU – for example via the internet rather than with each single item. However, the e-labelling option is initially limited to certain product groups, such as implants, or large equipment such as CT and MRI systems. For other medical devices e-labelling is far from imminent. Product information that is primarily intended for the industry can be provided as bar codes or data matrix codes.'

***Example 1*:**
No. 5, a standard stem hip prosthesis
Positive: Modest size of company logo; recognition enhanced by a pictogram of the prosthesis.
Negative: The essential information 'No.5' and 'Standard stem' are separated

***Example 2*:**
A knee replacement part
Positive: Legible content, modest size of company name/logo.
Negative: Content legibility is somewhat offset by a 'crowded' appearance of text and reference number

***Example 3*:**
Disposable attachment ophthalmology
Negative: Content is not indicated on the label, oversized barcodes

EH correspondent wins journalism prize

***European Hospital* correspondent Michael Krassnitzer has been awarded a journalism prize by the Austrian Society for Plastic, Aesthetic and Reconstructive Surgery (ÖGPÄRC). Michael received the prize during the Annual Meeting of the Austrian Society for Plastic, Aesthetic and Reconstructive Surgery this September in Innsbruck, Austria. The journalist and author reports on the event, the largest meeting of its kind in the German speaking countries, on *Page 7*.**

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Trail blazing bariatric surgery devices

Sewing machines for over-stitching, pleating, clipping and more

Major advances in Natural Orifice Transluminal Endoscopic Surgery (NOTES) lead to a tremendous interest in new surgical endoscopes. The advantages of minimally invasive surgery via natural body orifices, such as the mouth, are obvious: less post-operative pain, a minor infection rate, minor incisional hernia, shorter hospitalisation and, finally, better cosmetic results. This made NOTES an attractive alternative to laparoscopic or open surgery in many gastro-intestinal fields. In the treatment of morbid obesity today, bariatric surgery is already unimaginable without endoluminal procedures. *Karoline Laarmann* reports


Giovanni Dapri

Due to huge medical demand, endoscope manufacturing has become fiercely competitive. According to a *companiesandmarkets.com* report in August 2011, by 2016 the global endoscopy devices market could be worth more than $33.7 billion, growing at a compound annual growth rate of 6.4% over the reporting period. No wonder new endoluminal techniques and gastroscopes are rising up like mushrooms.

Dr Giovanni Dapri, Assistant Professor at the Department of Gastrointestinal Surgery, European School of Laparoscopic Surgery, Saint-Pierre University Hospital, Brussels, Belgium, is a renowned expert in endoluminal therapy who knows all the trends in weight loss surgery.

Speaking first about endoluminal procedures without any surgical incisions, Dr Dapri differentiates between primary and revision bariatric surgery. Focusing on primary surgery in patients who have previously not undergone surgical treatment, he explains: 'For primary procedures, today we have the opportunity to perform a trans-oral gastroplasty. Mainly in use was the TOGA system (Satiety; Fig.1a) which allowed for a restrictive procedure similar to conventional vertical band gastroplasty.' This consisted of a set of flexible staplers designed to be introduced and operated trans-orally to restrict the stomach's capacity. Thus the TOGA sleeve stapler was placed in the stomach and opened, creating a vacuum that brings the stomach folds in on itself. The tissue was then sucked into the stapler and titanium staples were delivered to create a narrow sleeve.

The endoluminal vertical gastroplasty performed with EndoCinch (Bard; Fig.1b), another type of transoral gastroplasty, was initially invented for the endoscopic treatment of gastrooesophageal reflux disease. Principally, it works equally with TOGA but, instead of staples, it uses a needle and thread. EndoCinch can also be used in revision interventions.

Unlike TOGA and EndoCinch, which create an endoluminal channel in the first stomach tract, a third endoluminal method exists that is not yet available in Europe, though its feasibility and safety have already been proved in clinical studies at the University of Laval, Québec, Canada. 'With the Transoral Endoscopic Restrictive Implant System, in short TERIS (BaroSense; Fig.1c), we'll also soon be able to perform a similar procedure to gastric banding, but completely through the endoscopic procedure,' Dr Dapri explains.

With TERIS, a specialised tool is passed down a protective tube from the mouth to stomach, where it pulls in the stomach wall to produce a fold of tissue that is then used to anchor the implant. A number of these folds are made, coupled to the silicone anchors, and then attached to the implant.

To avoid further surgical interventions, minimally invasive endoscopic techniques have also gained a foothold in revision strategies. In patients who present complications, or show insufficient weight loss or a weight regain after bariatric surgery, a second group of endoluminal procedures exist – some already launched commercially, some still under development. 'Due to a stretched gastric pouch and an additional habituation of the digestive tract after gastric bypass or gastric banding, about 20% of patients experience a renewed weight regain after some years. So, the aim of these revision techniques is to restore the size of the pouch and stoma close to the original post-bypass proportions,' Dr Dapri explains.

One of those devices is StomaphyX (EndoGastric Solutions; Fig.2a). During the procedure, sections of stomach tissue are sucked into a small opening in the device, which creates folds of tissue resembling a pleat. Then multiple fasteners are placed at the base of each suctioned portion to make the pouch smaller.

A second device, the TransPort (USGI; Fig.2b), is already available. During Revised Obesity Surgical Endoscopy (ROSE) procedure it uses sutures with tissue anchors to create multiple folds around the stoma to reduce its diameter. Sutures are then placed with anchors in the stomach pouch to reduce the amount it can hold. There is also a variation of this technique in primary surgery, called POSE (Primary Obesity Surgical Endoscopy) procedure.

Recently introduced to clinical practice is the OverStitch Endoscopic Suturing System (Apollo; Fig.2c). Although there is little data collected about OverStitch as yet, Dr Dapri says, 'At this year's Digestive Disease Week in Chicago, Dr Christopher Thompson and team in Brigham and Women's Hospital, at Harvard Medical School, Boston, presented promising results, with a reduction of the stomach diameter from 26.2 to 7.4 mm with the OverStitch system.'

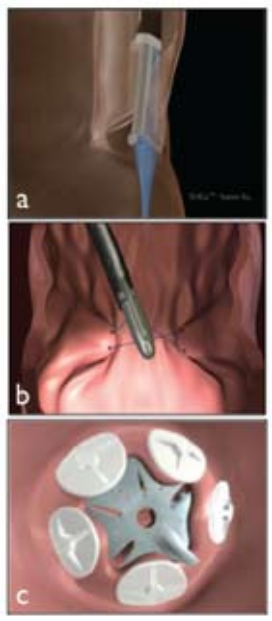
Figure 1

There is also a system that works not with classical suturing but by using clips. With the Over-the-Scope-Clip-System (Ovesco; Fig.2d), the clip is delivered by means of an applicator cap mounted on the tip of a gastroscope. It is self-closing, firmly anchoring the tissue to be compressed for haemorrhage or closure of a wall lesion.

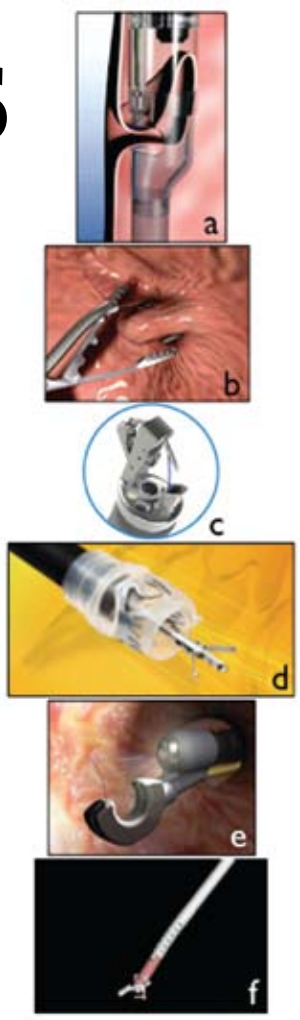
Figure 2

Dr Dapri knows of two other suturing devices in the research phase – the Spiderman (Ethicon; Fig.2e) and the Flexible EndoStitch (Covidien; Fig.2f) – that aim to tighten the stoma at the gastrojejunostomy and decrease the size of the gastric pouches. In the future, he believes both techniques could be deployed for primary suturing procedures, as well as for non-invasive revision interventions.

Although Dr Dapri is convinced that endoscopic procedures will shape the future of bariatric surgery, especially for the revision procedures, he thinks more mid- and long-term studies are needed in primary interventions because technical refinements are nowhere near complete. 'In a further step, I expect the development of robot-assisted gastroscopes and more flexible graspers to move even more precisely through the gastrointestinal system.'

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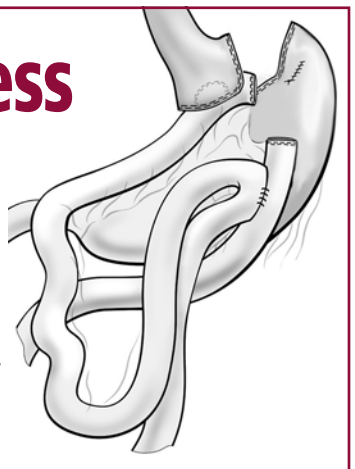
The 16th IFSO World Congress

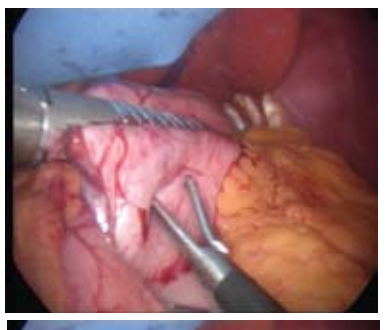
September saw the international crème de la crème of bariatric surgery descend on Hamburg for the 16th World Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO 2011). Among their discussions: new minimally invasive procedures, the importance of aftercare and the lack of recognition of the importance of surgical treatment of the severely obese in some countries. *Michael Krassnitzer* reports



According to **Dr Karl Miller**, President of the Austrian Society of Obesity Surgery, and Head of the First Surgical Division at Hallein Hospital, Salzburg, 'Surgical intervention is the most effective form of long-term treatment for obesity. Conservative treatment has only a modest success when it comes to weight reduction and its maintenance.' Surgical treatment procedures, he adds, successfully avoid life-threatening complications a well as severe degenerative problems associated with morbid obesity.

The results of the Swedish Obese Subjects Study presented by **Professor Lars Sjöström** (Univ. of Gothenburg, Sweden) yet again confirm the capabilities of obesity surgery. Compared to conservatively treated obese patients, the overall mortality of surgical patients was 29% lower after ten years. In that period, the surgical patients lost an average 19.2 kg, whilst conservatively treated group gained an average 1.3 kg. Prof. Sjöström also pointed towards the considerable metabolic effects of surgical intervention: In more than 70% of insulin-dependent diabetics a diabetes remission occurred shortly after surgery.

The EndoBarrier is a new, minimally invasive procedure. A tube-like liner is inserted via endoscopy and positioned in the upper duodenum with a type of wire mesh stent. By guiding food past the lining of the duodenum, over a length of around 60 cm, the device creates a barrier between the food and intestinal wall. The organ is simultaneously stimulated to produce hormones that optimise metabolism: 'This can achieve a weight reduction of around 20%. The intervention is highly successful for Type II diabetics,' said Dr Miller, who was the first surgeon outside the US to have used another, minimally invasive procedure, the S.P.I.D.E.R. system, which facilitates stomach reduction through a single access point of 18mm in size.



Aftercare

IFSO Congress participants consistently agreed that adjustable gastric bands, gastric bypass, stomach reduction and all other procedures are not enough for long term success just on their own. Aftercare by an interdisciplinary team and the correct administration of dietary supplements are a vital part of treatment, Dr Miller emphasised. 'Only team work between surgeons, internists, dieticians and psychologists will bring significantly more success than surgery alone.'

Another hot issue is that medical insurers in Germany do not cover the costs of obesity surgery. In Austria, for example, some 6,000 bariatric procedures are performed annually, and the insurers adhere to international guidelines for this procedure, whereas in Germany, with a ten-fold larger population, the number reaches 2,000 annually. The German experts are demanding that all medical insurers should reimburse the costs of surgical procedures, including pre- and aftercare.

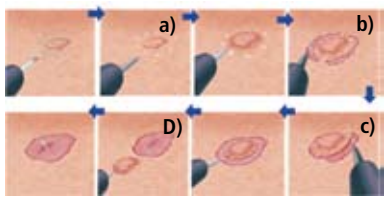
Visceral medicine in 2011

Excising the entire cancer tumour from the stomach prevents relapses. This procedure can now be performed endoscopically. *Holger Zorn* reports from the Visceral Medicine 2011 Congress in Leipzig

Although in decline, stomach cancer is still one of the most common cancers. 50,000 men and 32,000 women developed stomach cancer across the EU (EU-27) in 2008. The mortality rate in the advanced stage is more than 70%. The cause is almost always an infection with the stomach bacterium helicobacter pylori.

The earlier a tumour is detected in the stomach wall the better the chances of a cure. Endoscopic submucosal dissection (ESD) makes it possible to operate on even large stomach tumours in one go during the early stage of the disease, which lowers the risk of a relapse. A completely removed tumour also delivers more precise information on other risks.

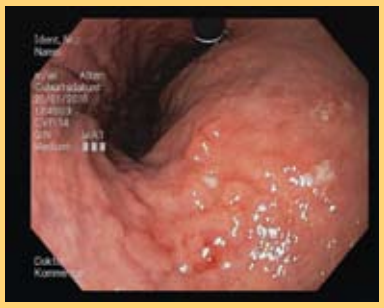
An ESD is carried out like a gastroscopy, with the help of a flexible endoscope guided through the patient's mouth. The doctor flushes the mucosa around the tumour with saline solution through the endoscope, which thus becomes distinguished from the lower layers of tissue. A wide area is then cut around the specimen and the surgeon severs the submucosa (tissue under gastric mucosa). 'When the resection of a tumour is not possible 'en bloc' with other endoscopic procedures, ESD is the method of choice,' explained **Dr Siegbert Faiss**, who heads the Gastroenterology and Hepatology Department at the Asklepios Klinik in Hamburg Barmbeck.

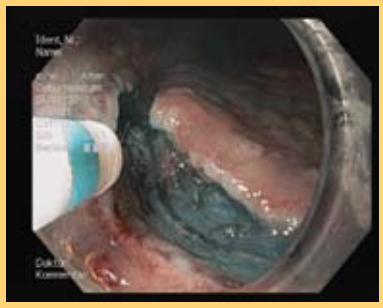


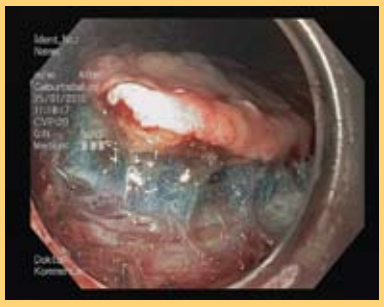
Schematic display of endoscopic submucosal dissection:
a) Marking the specimen, b) cutting around specimen, c) submucosal dissection of specimen, d) removal of specimen resected en bloc

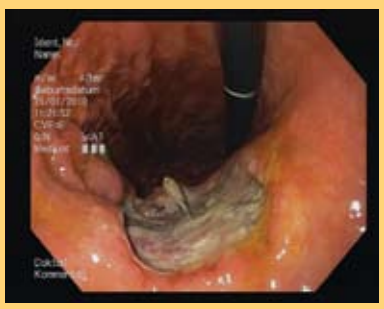
Whilst the procedure is already established in Japan, in Europe early stage stomach cancers are mostly removed using a wire sling. Although this is easier and quicker, larger tumours can only be resected piece by piece. This makes later microscope assessment and a precise risk assessment more difficult. In addition, cancer cells potentially remaining in the body put the patient at risk of tumour recurrence.

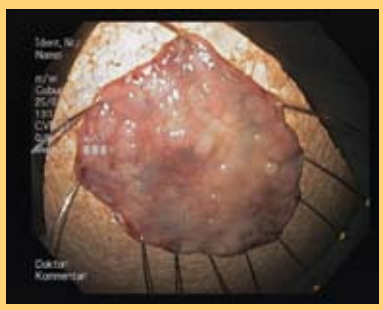
Early stage stomach cancer. Endoscopic submucosal dissection (en-bloc-R0-resection)

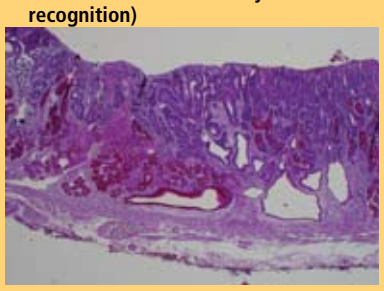

2. Early stage stomach cancer


3. Cutting around the previously marked specimen


4. Submucosal dissection (submucosa has been marked with blue dye for better recognition)


5. Complete resection


6: Specimen removed is 6 x 4 cm in size


7: Histological en-bloc-specimen with curatively resected early gastric carcinoma (T1m; G1, L0, V0)

Quoting a study carried out on more than 90 patients in Augsburg Hospital (Endoscopy. 2010 Dec; 42 (12):1037-44), **Professor Helmut Messmann**, gastroenterologist and director of the 3rd Medical Clinic at the hospital, said 'Those patients whom we treated with ESD had a significantly lower rate of relapses.' However, the procedure is technologically very challenging, requires a lot of practice and should therefore only be carried out by experienced experts.

A new definition for plastic surgery

Gathering in Austria, plastic surgeons proclaim the need for clarification and standards. *Michael Krassnitzer* reports


FISCHILL PR/APA FOTOSERVICE/PICHLER

Gerhard Pierer

'Plastic surgery used to be an exotic subject, but it has now moved into the centre of medicine,' declared Professor Gerhard Pierer, Director of the University Clinic for Plastic, Reconstructive and Aesthetic Surgery at Innsbruck Medical University. Reason enough for a new definition of this medical field to aired during the largest German-speaking congress of plastic surgeons, jointly held this October by the Austrian Society for Plastic, Aesthetic and Reconstructive Surgery (ÖGPÄRC), the German Society for Plastic Reconstructive and Aesthetic Surgeons e.V. (DGPRÄC) and the Association of German Aesthetic Plastic Surgeons (VDÄPC).

As Dr Pierer explained, plastic surgery is now comprehensively integrated into the treatment of soft tissue tumours and the treatment of accident victims. Today, the plastic surgeon is involved with a patient from the initial diagnosis to treatment planning, integration with surgical implementation and finally rehabilitation, he pointed out, adding: 'Therefore, he frequently assumes the role of coordinator.'

The plastic surgeon as case manager in the interdisciplinary treatment of patients is the self-image being promoted by members of the three specialist professional associations. 'As a representative of a discipline that is traditionally not limited to certain body areas, the plastic surgeon has a solid overview of the situation and a patient's needs. This enables him to decide when and which type of treatment should be administered,' explained Dr Elisabeth Zanon, a plastic surgeon in private practice and Member of the Board at ÖGPÄRC.

The increasingly complex challenges of treatment not only require coordination but also new kinds of cooperation. In Innsbruck, for example, the Centre for Breast Health at the University Clinic for Plastic, Reconstructive and Aesthetic Surgery already holds interdisciplinary panel meetings prior to commencing each treatment procedure. All the involved medical specialists (in oncology, surgery, orthopaedics, radiotherapy, pathology, plastic surgery etc.) discuss and coordinate the course of treatment for each individual case.

Speaking on quality assurance, Dr Helmut Hoflehner, Univ.-Doz. and Assistant Head of the Schwarzl-Klinik in Graz, Austria and President of the ÖGPÄRC, pointed out: 'Often a doctor's qualification is not clear to the patient. Many call themselves 'beauty surgeons' because this title is not protected – and it's also used by doctors who have had no surgical training.' Patients treated in private practice are often also treated with minimal resources due to costs.

Therefore, to regulate the entire process of patient contact from the first appointment to the last check-up, ÖGPÄRC has initiated the establishment of European standards for aesthetic surgery.

Meanwhile, 22 countries worldwide, as well as important European and international plastic surgery organisations, are presently working on the new standards. 'The project is to be completed in 2013,' Dr Hoflehner said. By then, at least in Austria, it should no longer be possible for a gynaecologist, for example, to carry out liposuction.

This is also the hope of Professor Peter M Vogt, Director of the Clinic and Polyclinic for Plastic, Hand and Reconstructive Surgery at Hanover Medical School and President of the DGPRÄC. 'Unfortunately, in Germany it's currently not possible because the Federal Constitutional Court has valued very highly the principle and right to practice freely.'

Recently, a specialist in oral and maxillofacial surgery, who had also performed breast enlargements, abdominal plastic surgery and upper arm lifts in his practice, successfully fought a conviction passed by the Court of Professional Conduct.

A new publication exposes the effects on past members of the German Society of Surgery. Report: *Bettina Döbereiner*

Surgeons under National Socialism

Hans-Ulrich Steinau, Hartwig Bauer and Michael Sachs


Rebecca Schwoch


Heinz-Peter Schmiedebach


Hans-Ulrich Steinau

This August, sixty-six years after the end of WWII, the German Society of Surgery has published the first critical biographies of those who served as its Presidents during the National Socialism period. *The German Society of Surgery 1933-1945*. The presidents' speeches was commissioned by the Society itself and composed by an independent commission of historians. Uncompromisingly revealing facts often eliminated in the past, the collection demonstrates the Society's entanglement in the politics and ideologies of National Socialism.

As early as 1933, in the run-up to the annual assembly of the German Society of Surgery, all Jewish and politically dissenting speakers were told to withdraw their lectures. Those who did not follow the instructions in advance were addressed by the then President Professor Wilhelm Röpke in his opening speech: 'I ask all speakers whose appearance could, due to the present-day national trend, provoke agitation and discord, to rescind, because the calm, orderly course of our conference and the dignity of the German Society of Surgery is more important than anything else.' His message met with resounding applause. Later, the President wrote a note stating that the number of speeches had thus been 'shrunk' to the 'reasonable level' of 52 lectures, so the congress programme could be 'done properly'.

Professor Hans-Ulrich Steinau, the Society's President from 2006 to 2007, personally initiated the book. 'We believe, that our own historical identity with our forefathers and also paragons must not be limited to the daily use of the Lexer Chisel and that, facing forced sterilisation and the cruel examinations of prisoners, we need to look for answers about the genesis of unscrupulous scientific curiosity, anticipatory obedience, careerism and the perversion of ethical grounds,' he explained, during the book launch in Berlin this August.

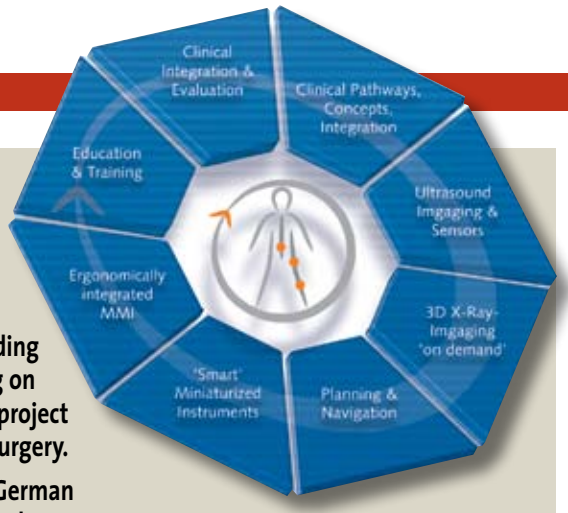
Persecution did not stop with that speakers ban. From 1933 onward, Jewish physicians in the public sector were swiftly dismissed. Even for resident panel doctors (Kassenärzte) life became difficult. From 1938 onward they were prohibited from calling themselves doctors or physicians. Based on the Society's register of members, medical historian Rebecca Schwoch, who, along with Professor Heinz-Peter Schmiedebach and Professor Michael Sachs, is a member of the independent commission of historians, has identified up to 217 members who suffered discrimination, dismissal, persecution, murder, or were forced to escape or driven into suicide. With data still lacking, the Society will continue to research the individual fates of those 217 members.

Even some highly respected forefathers of surgery were affected by the 'Erbgesundheitspolitik' (Politics of National Socialism aimed at eliminating 'hereditarily defective people'). For example, in Munich's surgical university hospital, headed by Professor Erich Lexer, inventor of the Lexer Chisel and the 1936 President of the German Society of Surgery, 1,050 so-called 'hereditarily defective people' were forcibly sterilised between 1934 and 1937.

Today, Prof. Schmiedebach warned, 'We won't have National Socialism any more, but we will face a scarcity of resources and the problem of their allocation. In this scenario prejudices could rapidly become virulent and respectively play a role in the distribution of resources.' Therefore, he emphasised, it is still important to sensitise medical students to the subject and ensure they can quickly detect politically, culturally, economically or even scientifically induced prejudices.

Hopefully, the publication will contribute to that is objective.

OrthoMIT



More than 30 clinicians, researchers and industry partners (including Siemens, Aesculap and SurgiTAIX, an RWTH spin-off) are working on OrthoMIT, Germany's largest collaborative orthopaedic research project that aims to develop future strategies for knees, hip and spinal surgery.

The project, which has received more than €13 million from the German Federal Ministry of Education and Research (BMBF), is expected to have a platform available by early 2013 to evaluate and demonstrate the evolving system.

Subprojects within the complex of minimally invasive orthopaedic therapy (OrthoMIT) are studying product and quality management, training, ultrasound, mechatronics, navigation and the integrated workstation as a network. *Anja Behringer* reports

Klaus Radermacher, Professor of Medical Technology at RWTH Aachen University and head of the OrthoMIT project, explains: 'The smartOR is a continuing project, which results from the large success of the orthopaedic subproject *TP 13 – the Integrated Workstation*, and also looks at the very complex aspect of risk management for modular, integrated operating systems for other surgical disciplines.

'An important aspect for the future operating theatre is the development of useable contributions for international standardisation in the risk management of IT networks in medicine. Research institutes, hospitals and industry partners will utilise the smartOR demonstration environment as an experimental development platform for the validation of developed concepts, for training and for successful future marketing.'

The optimisation of clinical workflow, as well as surgical strategies and protocols, is central in order to reduce the costs of a surgical intervention. The use of new procedures and technologies leads to shorter operating and rehabilitation times and therefore to shorter hospital stays. Patients and medical staff are exposed to lower radiation doses and complications are rarer. The surgical team's workload and the imprecision of surgical execution are to be reduced. This also includes aspects of postoperative care and rehabilitation, in as far as they are caused by the specific therapeutic strategy, or concern measures of quality assurance.

Through analysis and modelling of specific clinical workflows in different surgical disciplines a dynamic adaptation of the system to changing environments and user profiles is possible. User friendliness and acceptance for the human-machine interfaces will also be increased.

Surgical instruments are equipped with novel, miniaturised sensors that not only facilitate the precise localisation and navigation of the instrument but also the immediate evaluation of bone quality or any occurring working forces or joint forces. Intelligent mechatronic assistance systems support surgeons in fatigue-proof holding and the precise guidance of instruments and sensors.

Also planned are novel miniaturised robotic systems that alleviate problems encountered with previous systems and enable highly precise, efficient bone processing - and also, therefore, new minimally invasive procedures such as joint preservation and joint replacement. As the quality of therapy is characterised by the quality of available tools and procedures and the training and skill of the surgeon in using the technology, the project also envisages the integrated development of the most modern, computer-assisted training systems for surgeons.

All measures are united by the overall objective of reducing costs through the integration of modern technological procedures and tools into the surgical workflow, and into the entire treatment process, from diagnosis to rehabilitation.

Based on the WHO-supported, global, multidisciplinary initiative the '*Bone and Joint Decade*', the project focuses on surgery for the hip, knee and spine, all equally affected by osteoarthritis, osteoporosis and trauma.

From an economic viewpoint, the objective of OrthoMIT is to create a new generation of modular, computer-integrated surgical workstations and tools that support the surgical therapy process from pre-operative preparation via intra-operative surgical work to postoperative care and rehabilitation. A vital prerequisite for this is that the networked medical systems work with open standards across manufacturers, under assurance of effective risk management. This is something that the industry must work on jointly.

The role of German industry for orthopaedic surgical products on the world market is also to be strengthened. The worldwide market for orthopaedic products in 2002 was US$12-13 billion, with a growth rate of 9-10% a year.

OrthoMIT industrial objectives

- new minimally invasive surgical strategies
- new techniques for interventional ultrasound based imaging and registration, especially of MRI data and multiplanar and volumetric interventional X-ray imaging with a new electronic flat panel detector
- miniaturised sensor-integrated instruments
- enhanced knowledge based planning and navigation systems
- synergistic manipulator systems and active mini robots
- an integrated ergonomic surgical workstation
- integrated modules for case based education and training

Mobile surgery firm steers towards Italy

Having secured significant contracts with hospitals in Sweden and the Netherlands, the UK-based mobile surgical services firm Vanguard Healthcare aims for further expansion in Europe. *Mark Nicholls* reports


CEO Ian Gillespie


On the way: a Vanguard truck and stationary mobile ward system in service (below)

Vanguard Healthcare provides mobile operating theatres, wards, mobile clinics, endoscopy suites and mobile day surgery units for periods ranging from a single day to a number of years, though a typical contract length is five months.


Combined operating theatre and ward

Over the past few years the company's services have been deployed extensively by the UK's National Health Service and private health providers and it is now beginning to support a number of European hospitals in various ways, from adding extra capacity to offering alternative theatre accommodation during periods of refurbishment.

Ian Gillespie, Vanguard's CEO, explained that the company is a flexible solution provider and: 'The jewel in our crown is the mobile operating theatres. If someone wants an operating theatre quickly, we can deliver it overnight, set it up and be ready for procedures in the morning. We can also provide whatever operating theatre equipment is needed, from tables to anaesthetic machinery and, while not providing the consultants or the anaesthetists, we can provide all other support staff required.'

The various high-tech units can be linked together, e.g. a mobile operating theatre to a mobile ward, whilst others, say eye surgery or cataract units, can be truly mobile and moved to different locations to provide a local service.

During hospital refurbishment, a unit can be supplied for a short period of time, ensuring continuity of care and no disruption for patients or patient pathways. 'When there is a typical refurbishment contract,' he explained, 'the mobile operating theatre would be linked to the hospital with a corridor. Patients would not know they were being treated in a mobile operating theatre. We also have had a good response to them from surgeons.'

Earlier this year, Vanguard clinched contracts to meet specific operational needs for major hospitals in Sweden and the Netherlands. Vanguard deployed its mobile laminar-flow operating room facilities at the private Medinova Kliniek Klein Rosendael in Rozendaal, near Arnhem. Thus the hospital maintained surgical capacity whilst undergoing major refurbishment and upgrade of existing facilities.

This contract followed the deployment of facilities at Stockholm's Södersjukhuset, where the hospital used the British firm's mobile services to boost ward capacity in its emergency department over a three-month period.

'Vanguard,' its CEO said, 'has now made significant steps towards instigating a change in the way mobile healthcare solutions are approached across Europe – specifically in terms of boosting capacity or providing continuity of services during reconfiguration of existing facilities for whatever reason."

Founded in 1999, Vanguard has grown rapidly and across its 40-strong fleet of operating suites, endoscopy units and day clinics has seen more than 140,000 procedures completed in its units.

Facing stringent healthcare budgets, and much else, mobile services can be the answer to solve specific and vital surgical needs in Europe. 'We hope that mobile healthcare solutions will become quickly recognised as the standard operating procedure,' Ian Gillespie added. Vanguard's growth strategy in Europe has been based on fostering partnerships with local agents who, according to the CEO, 'provide the necessary on-the-ground intelligence and knowledge of the intricacies of each healthcare economy in each target country'.

Combat Trauma Innovation 2012

Medical advances learned from treating military casualties severely injured on the battlefield are helping to enhance medicine for British civilians. *Mark Nicholls* reports on a conference to hasten advances into the public arena


Prof. Keith Porter

The rise in military casualties, with British troops operating in war zones in Iraq and Afghanistan over the past decade, has facilitated significant developments in civilian medicine within the United Kingdom's National Health Service (NHS). Those advances are set to be outlined at the *Combat Trauma Innovation 2012* conference in London (17-19 January), where international guest speakers from military and civilian hospitals share best practice on how medical developments learned from battle wounds can benefit civilian health services.

An example of the partnership between military and civilian medicine in this country is in Birmingham, where the Selly Oak Hospital – now the Queen Elizabeth Hospital – has made great advances in treating British military personnel injured in Iraq and Afghanistan.

Keynote conference speaker Sir Keith Porter, Professor of Clinical Traumatology at the University of Birmingham and Consultant Trauma Surgeon at the city's Queen Elisabeth Hospital, will particularly focus on transferring skills and technology between military and civilian healthcare in a session focused on how increasing cooperation has helped enhance patient survivability and examine the lessons learned between medical facilities at Bastion (the key UK base in the Helmand province, Afghanistan) and Birmingham.

Sir Keith said: 'The escalating military workload to Queen Elizabeth Hospital in the course of the last decade has been a major influence in developing robust, functional and happy relationships between the military and civilian sectors. The work demand has driven arrangements for additional military personnel including clinicians (trauma & orthopaedics, plastic surgery and anaesthetics) as well as nursing and allied health professionals.

'In addition, we have agreed policies to meet surge requirements including additional operating lists at nights, weekends and in the daytime, and also creation of beds and, of particular relevance, intensive care beds.'

At the conference he will explain how the efficiency of the whole care chain, from pre-hospital care (by medics in the combat zone), through the medical facilities at Camp Bastion and on to Birmingham, is reflected in 'the significant number of unexpected survivors seen in this patient cohort.' Sir Keith: 'Therefore, benefits to our NHS patients are enormous and we ensure that we deliver the same level of care to these patients as well as our military patients.'

Areas of improvement include resuscitation, surgical priorities, damage control principles, micro and mycological issues as well as continuity of care, including an early rehabilitation prescription.

Sir Keith will also explain how the National Institute for Health Research (NIHR) Centre for Surgical Reconstruction and Microbiology for translational research will take that work to a higher level for both military personnel and civilian casualties. 'This will ensure that the important messages learnt within the military experience become practice within the civilian services.'

Supported by the UK's leading healthcare agencies, including the Department of Health, Ministry of Defence - Defence Medical Services, Royal Centre for Defence Medicine, NIHR, University Hospitals Birmingham, and the London Ambulance Service, and with top international trauma experts from military and civilian services as speakers, the conference expects delegates from many countries.

Speakers also include Dame Sally C Davies, Chief Medical Officer for England and Chief Scientific Advisor; Vice Admiral Philip I Raffaelli, Surgeon General, UK MOD; Lieutenant General Charles B Green, Surgeon General, United Sates Air Force, and Dr Fionna Moore, Medical Director of the London Ambulance Service and Clinical Director for Trauma, London.

Acknowledging the priority of emergency care in the armed forces, the event director Richard Mathews pointed out that the substantial emphasis on innovation and development in technology, practices and procedures in the past decade have led to a substantial increase in patient survivability, and it is now time to 'discover exactly how these lessons and developments can be adapted into the civilian emergency healthcare sector'.

**18 January. Time: 9.55 am. Professor Keith Porter: Transferring Skills and Technology between Military and Civilian Healthcare*

Combat Trauma Innovation 2012

17th January – Mass Casualty Focus Day – providing an insight into the UK's preparations for mass casualties during a large public event, e.g. the London 2012 Olympic Games.

18th – Pre-Hospital Day – exploring how civil and military organisations are preparing for, and responding to emergency situations

19th – Clinical Day – focused on dealing with trauma patients clinically.

The 'sepsis team'


Jean-Louis Vincent

'We are all aware of the importance of early diagnosis and rapid appropriate treatment of patients with severe sepsis. Yet, many patients still do not receive satisfactory early management and the application of recent guidelines for sepsis management is still inadequate,' writes Jean-Louis Vincent MD PhD, from the Intensive Care Department, Erasme Hospital, Université Libre de Bruxelles, Belgium. 'One of the reasons for this deficiency is the complexity of patients with severe sepsis in whom appropriate management involves multiple components, from laboratory tests and cultures to hemodynamic monitoring to therapeutic interventions, all of which need to be performed as soon as possible after diagnosis to maximise chances of survival.

How should we approach our patients with severe sepsis or septic shock? How can we simultaneously and effectively perform all the necessary tests and treatments? Take blood and cultures, attach monitoring devices, insert intravenous/central/arterial lines, start antibiotics, arrange imaging and X-rays, ask for a surgical opinion or arrange for an operating room to be available, administer fluids, give vasopressors …? No matter how efficient we are as individual doctors, a single doctor or nurse simply cannot adequately manage a patient with severe sepsis within acceptable time delays.

Here, we can learn much from other fields of medicine. For example, severe trauma patients are now never (or very rarely) managed by single physicians, but rather by a team including, as a minimum several doctors and nurses, but which may also include anaesthesiologists, paramedics, radiographers, specialist surgeons, etc. Similarly, in-hospital patients who experience cardiorespiratory arrest will not be managed by one individual, but by a Crash or Code Team of personnel specially trained in resuscitation techniques and able to travel rapidly to the patient in need. Each member of the team has a specific role so that all aspects of management are covered. Importantly too, all necessary equipment is immediately available in a single mobile unit, the 'Crash Cart'.

In the same way, patients with severe sepsis should be managed by a 'Sepsis Team' comprising several physicians and nurses, and also possibly an infectious diseases specialist, radiographer, phlebotomist, etc.

The Sepsis Team should be available 24/7 and responsible for stabilisation and early treatment of *all* patients with severe sepsis. Critically, one member of the team must be allocated as leader, to direct and drive ongoing management and ensure that all aspects of care are covered in the most efficient and effective way. Without a good Team Captain, the process risks becoming disorganised and chaotic with no clear instructions as to who should be doing what, when.

In our hospital, rather than a mobile sepsis team, we have a dedicated 'shock lab', which treats all patients in the hospital or emergency department who develop shock, including septic shock. This unit is staffed by a team of nurses and doctors trained in shock management and equipped with all the necessary monitoring devices, a respirator on 'stand-by' mode, and intravenous solutions and drugs ready to use.

Several studies have now demonstrated that sepsis teams can improve outcomes for patients with severe sepsis and we must encourage their development. By ensuring rapid initiation of all necessary treatments, specialised sepsis teams or units can effectively increase the chances of survival for patients with severe sepsis.

ORGANISATION AND TECHNOLOGY AS FACTORS OF SUCCESS IN A&E


Wilfried von Eiff

Point of care technologies (POCT) have an important, quality enhancing, risk-reducing and cost-impacting role within the extremely time-critical medical decision structures of a central Accident and Emergency department, says Professor Wilfried von Eiff, Centre for Hospital Management, University of Muenster, Germany

The NOPAC study (Emergency Admission and Point of Care Technologies) carried out by the Centre for Hospital Management at the University of Münster, examines to what extent the prompt and plannable availability of selected laboratory parameters (D-Dimer; TSH; NT-probBNP; Troponin I/T) can reduce pressure on staff, medical equipment, functional diagnostics, intensive care, and so on, so that the cost of a patient's care process can be reduced.

The NOPAC study has found that the laboratory-diagnostic turnaround time is a significant driver of the overall emergency care process for medical quality, patient outcome and overall cost of care of an emergency patient.

Needs-driven and economic care of emergency patients is linked to a small number of key success factors as follows:

1. Process integration and networking

The central A&E department is the hub between the emergency medics who initially provide treatment and further treatment provided on the ward. This means that service providers within the emergency care chain should be coordinated with one another to ensure that the patient receives appropriate, high level medical care without delay at each point in time.

Therefore, an important success factor for the A&E department is professional, intensive and prompt communication with the emergency doctors in pre-clinical care. The more qualified the ambulance team is to deal with stroke, heart attack, or trauma patients, the earlier and more precisely the relevant data can be transmitted to the A&E department before a patient's arrival in hospital.

Experiences from the AMI network of the Kerckhoff-Klinik in Bad Nauheim, Germany, show that the period between the first medical contact after a myocardial infarction and the opening of the vessel in the catheter laboratory is (contact-to-balloon-time) under three hours and the door-to-balloon-time under 90 minutes if emergency doctors take a patient's blood when still in the ambulance, evaluate the 12 channel ECG and report the patient's imminent arrival to the catheter laboratory via the 'red telephone'.

2. Admission to short stay ward and chest pain unit

This type of ward ensures that the following problems are avoided in the treatment process:

- Admission to the wrong type of ward and department due to an unclear diagnosis as a result of time pressure (for instance, 25% of angina pectoris patients with suspected acute coronary syndrome have an extra cardiac diagnosis)
- Unnecessary secondary transport within the hospital
- Time delay in diagnosis and treatment due to non-availability of technology (MRI, CT etc.) or of colleagues providing a second opinion
- Lack of capacity buffers for short-term monitoring, therefore blocking of examination and treatment spaces or premature transfer to a ward

3. POCT Technologies

Looking at the generic process of emergency care (image 1), it becomes clear that the quality (reliability of measurements) and the length (turnaround time) of the part-process laboratory diagnostics are critical success factors for clinical quality, patient satisfaction and the costs of clinical emergency care and aftercare.

Laboratory services based on POCT technologies increase the patient safety, speed up diagnosis and treatment processes and reduce contingency and process costs; this particularly applies if, through the fast availability of laboratory parameters, functional diagnostics can either be bypassed or reduced in a process enhancing manner, or if it can be used case-specifically for an earlier clarification of the diagnosis.

POCT facilitates the fastest possible availability of, particularly, the decision-relevant parameters Troponin I/T, BNP/NT-proBNP, D-Dimer and Lactate, with Troponin I/T and Lactate being the most significant predictors of increased risk of morbidity.

- BNP/NT-proBNP levels are available after 35 minutes and facilitate early clarification of pulmonary or cardiac causes respectively and make it possible to detect heart failure. Classic early functional diagnostics (X-ray) clearly lags behind.
- BNP/NT-proBNP levels are available after 20 minutes via POCT and facilitate early detection of cardiac decompensation as well as CHE differentiation in case of dyspnoea and pulmonary embolism respectively.
- This POCT risk evaluation (BNP/NT-proBNP) replaces the more time-consuming echocardiography (ideal case: 10 minutes; reality: 2-3 hours) and supports the decision for early discharge into out-patient care.
- TSH is a further time-sensitive factor, as the TSH levels decide at which point which imaging procedure can be used. TSH levels are normally only available after 60-90 minutes via central laboratory diagnostics. Therefore it would be desirable that the TSH level is qualified and available within 20 minutes via POCT technology.
- Creatinine levels for clarification of kidney function and determination of contrast media tolerance can be available via POCT after 2 minutes.

If the D-Dimer levels are available after 20 minutes for a patient with leg pain (suspected thrombosis) an immediate decision can be taken, together with a WELLS score examination, whether the patient can be discharged or whether they should be classed as high risk; in this case a Doppler examination is carried out, which means that functional diagnostics can be bypassed. The resulting gain in time of about 1-2 hours increases patient satisfaction and avoids a crowding effect of patients who have to be monitored in A&E.

With the care of acute coronary syndrome (non-STEMI) patients, the availability of Troponin I levels after 18-20 minutes (Troponin T levels after 12 minutes) is of significant clinical and economic relevance. On the one hand, the risk of undetected heart attacks (EVA syndrome) reduces through the use of highly sensitive troponins; on the other, the total length of stay in the A&E department per ACS patient reduces from 05/05:30 hrs (central laboratory) to 04/04:30 hours (POCT diagnostics).

Results of this POC solution:

- Significantly shorter length of stay of ACS patients (reduction of 40-60 minutes)
- Avoids blocking of examination and treatment beds
- Avoidance of premature transfer to the 'wrong' ward (such as intensive care ward for instance with daily costs of €1,000 - €1,200) because of lack of capacity in A&E
- Quality, targeted follow-on treatment
- Avoidance of crowding effects

The NAPOC study also shows that POCT technologies in A&E also facilitate a controlled and plannable diagnostic process from the A&E doctors' viewpoint: The variances in turnaround time (from taking blood to availability of results) for Troponin T are between 40-160 minutes with the central laboratory solution and between 13-34 minutes in the case of a POCT-supported organisation (technical setting: AQT90 Flex).

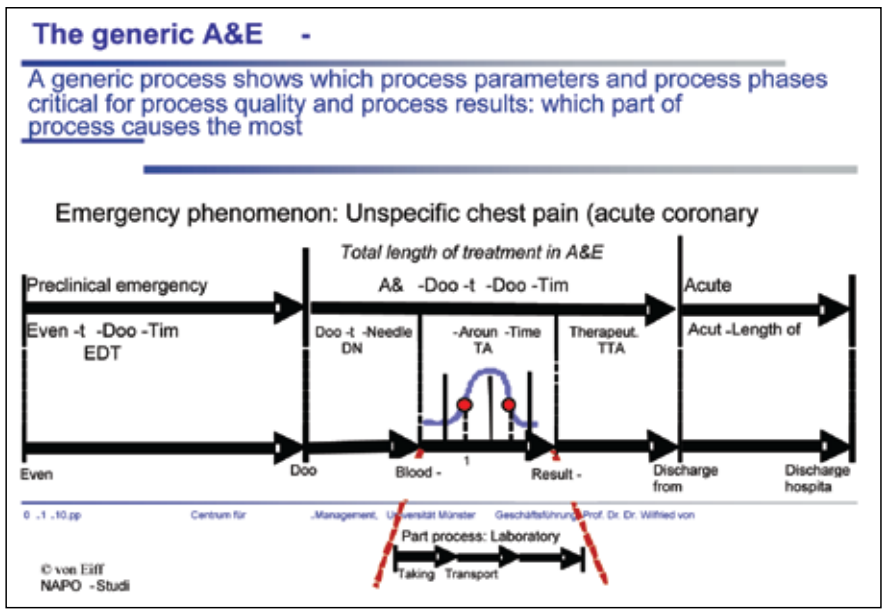
Highly sensitive POCT diagnostics also supports in areas where not all patients in need of treatment can be identified with other diagnostic procedures: The rate of heart attacks not detected by the 12 channel ECG is between 10-20%.

The NAPOC study also makes clear that consistent use of POCT in emergency medicine alone is not sufficient for the utilisation of all rationalisation potentials. If the work of Renaud et al. is analysed as to the confounding factors, it becomes obvious that POCT advantages can be (over-) compensated by other structural or organisational disadvantages. The POCT solution is faster by an average of 71 minutes compared to the central laboratory solution: The fact that the length of stay in A&E is almost identical for both technology settings can possibly be traced back to the fact that both a short stay ward and a chest pain unit were integrated in the central laboratory setting at the same time.

Finally, we can assume that the demand for capacity in A&E could be reduced by 25 – 28% through POCT in combination with other structure and process optimising measures.

The question as to the economic advisability of an investment in POCT technology (in the present setting around €28,000 for an AQT90 Flex) is not limited to a pure cost comparison per sample sent to the central laboratory. The key issue is that this investment decision is also assured by inclusion of the criteria 'quality and promptness of diagnosis', 'process follow-on costs' and 'risks for the patient' (see risk-weighted process cost analysis – RPA – in image 2).

1.Turnaround time and variance of availability of critical laboratory parameters determine the clinical and economic success of the A&E department



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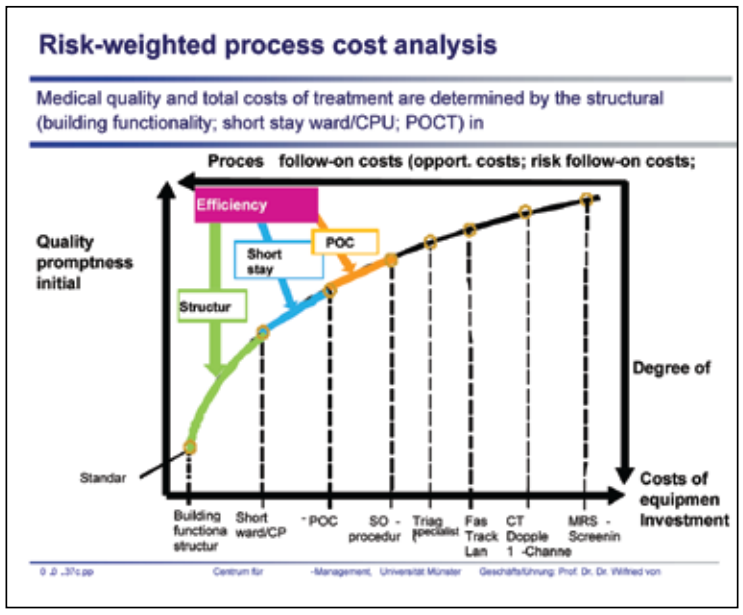
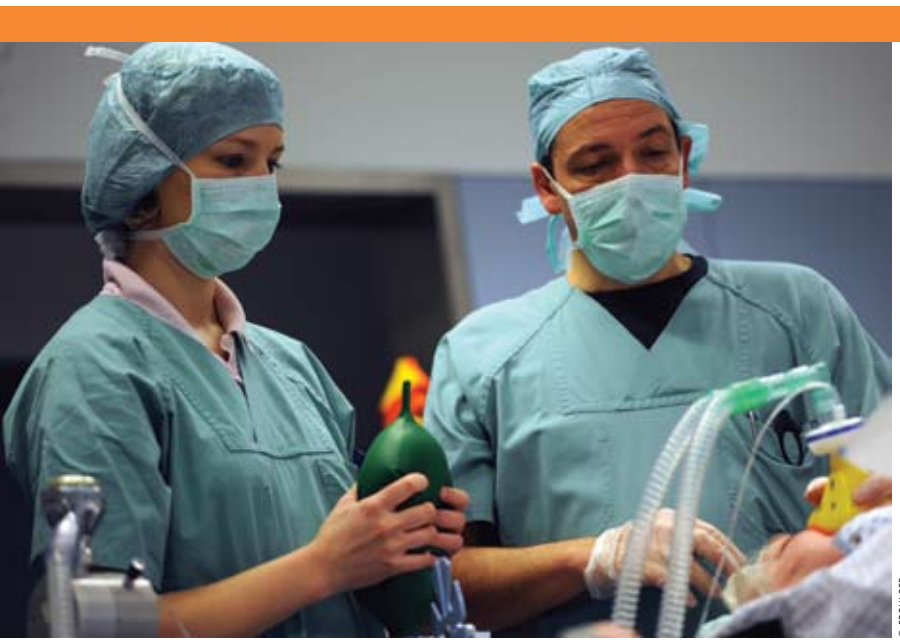


Summary

Quality and efficiency of emergency care directly depends on prompt diagnostic laboratory medicine: the importance and proportion of laboratory medicine within the overall diagnostic process and its results is up to 70%. To reduce the turnaround time (from samples requesting to the availability of sample results in the location where treatment decisions are made) time-and treatment critical parameters can be better determined with POCT equipment. The effects:

- a shorter wait for the patient
- earliest possible start of treatment
- therapeutic prognosis improves
- pressure on monitoring capacity in A&E is reduced; and
- qualified discharge diagnosis and qualified treatment decisions respectively reduce pressure on intensive care medicine and intermediate care.
- For the A&E department, a POCT is a self-determined process for the ascertainment of diagnosis-relevant and time-critical laboratory parameters (such as Troponin I/T; CK-MB; D-Dimer). Patient risks, patient satisfaction, medical results and process costs are all positively impacted by POCT in the A&E department.
- Further critical factors of success in clinical emergency care are:
- process integration and networking of preclinical, clinical and post-acute emergency care, and the
- setting up of short stay wards and chest pain units.



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A better sleep in the operating theatre

Xenon anaesthesia not only preserves the heart and circulation but also prevents post-operative delirium. The high cost of the gas is made up for by a shorter length of stay, reports EH correspondent *Holger Zorn*

Another operation - the third in three years – this time, to replace the artificial hip of the 87-year-old patient. The old lady is scared, not so much of the pain – with which she believes she can cope – but the anaesthetic: She has twice spent several days in a state of confusion and delirium after anaesthesia and had been tied to the bed to avoid a fall and breakage of anything. During that time she did not know where she was, but later realised. Embarrassed, she never wants to repeat those events.

Matthias Reyle-Hahn, Consultant at the Evangelisches Waldkrankenhaus Spandau, often hears such stories. For ten years he has been offering a particularly gentle anaesthesia with the noble gas Xenon. US frogmen discovered its narcotic effect when they tested noble gases as oxygen additives. Xenon was licensed as a narcotic substance in Germany in 2005; Air Liquide produces and markets it under the trade name LENOXe. Its effect is analgesic as well as hypnotic and it has a rapid onset and offset due to its low blood-gas-partition coefficient. The patient's blood pressure remains stable, the heart's pumping function is not impaired and the patient quickly wakes from the anaesthetic.

Many high risk patients make their way to this hospital on the outskirts of Berlin, including those severe heart disease, multiple allergies, or a hereditary predisposition for overheating of the body (malignant hyperthermia), in which the muscles react too strongly to conventional anaesthetics. In around 90% of patients that has a fatal outcome. Other typical patients are older people who have already experienced confusion after anaesthetic administration. 'In ten years, we've not seen a single case of severe delirium after a Xenon anaesthetic,' says Dr Reyle-Hahn. However, it cannot be completely ruled out despite this experience: 'It is possible that very light forms may be overlooked.' This should now be researched in university hospitals on a larger number of patients.

Some time ago the Charité Berlin began a trial of this narcotic gas in the urology and gynaecology departments. 'The stable circulation under Xenon can deceive doctors about the patient's real condition,' says Professor Claudia Spies, director of the Clinic for Anaesthesiology, with a focus on surgical intensive care medicine. 'Therefore we started the trials in a very clear area; from next year we will also be using Xenon in general surgery.'

The planned study is to explain why Xenon can prevent a severe delirium after surgery in older patients. Animal experiments point towards the fact that Xenon protects the brain cells (source: Ann Neurol. 2011 Jul; 70 (1) :133-50). That this effect also works in humans was shown last year by Marianne Thoresen, James Tooley and John Dingley at St. Michael's Hospital in Bristol. They saved a newborn baby from severe brain damage by administering a combination of mild therapeutic hypothermia and a Xenon anaesthetic. 'These preserving characteristics of Xenon are also of interest for anaesthesia in older patients,' Prof. Spies believes.

However, the gas is rare and only occurs in traces of the earth's atmosphere. Its manufacture is complex and energy-intensive. A two-hour anaesthetic requires around 16 litres of Xenon. Depending on the length of the operation this costs between €150 and €300 – and therefore ten times as much as a conventional anaesthetic with Isoflurane or Sevoflurane. Moreover, there are now only two manufacturers worldwide who offer anaesthesia workstations that can be used with Xenon. Nonetheless, Dr Reyle-Hahn sees an economic potential for the user: 'It is the best anaesthetic we can currently offer,' he says, 'and it does pay off.' Even after 12-16 hour operations patients wake up within minutes and are responsive. As fewer complications occur during surgery the length of hospital stay is also shortened.

Matthias Reyle-Hahn: After Xenon anaesthetic, he has not seen a single case of severe delirium

Congenital heart disease

New research carried out in the UK has revealed that young children with congenital heart disease are at risk of having harmful toxins in their blood, particularly following surgery. *Mark Nicholls* reports


Nazima Pathan

A team from Imperial College London has found that babies and toddlers with high levels of toxins from gut bacteria in their blood were likely to take longer to recover from surgery and spend more time in intensive care.

They also acknowledged that more needs to be done to protect children who have heart surgery from bacterial toxins, with options including the use of drugs that neutralise them or treatments that protect the gut.

Now they are embarking on a new focus of research to help identify, ahead of surgery, which patients are most at risk and to focus treatments on helping reduce that risk.

Paediatric consultant **Dr Nazima Pathan**, from the National Heart and Lung Institute at Imperial College London, is the lead author of the study which has been published in the American Journal of Respiratory and Critical Care Medicine. 'The gut usually acts as a barrier that protects the body from toxins,' she explained. 'However, our study suggests that, in some babies with congenital heart disease, the gut isn't able to do this job properly. These babies are often small and undernourished, and the heart defect can mean that the blood supply to the gut is abnormal. On top of this, they have to cope with the trauma of surgery and our study suggests that all these factors can affect the protective barrier function of the gut.'

Bacterial fragments called endotoxins, which cross into the blood from the gut, stimulate the body's immune system and can affect the function of vital organs. The researchers measured the levels of endotoxins in 40 children aged between two months and 46 months who required surgery for congenital heart disease and had been admitted to the paediatric intensive care unit at Royal Brompton Hospital, where Dr Pathan is also a paediatric consultant.

The results showed that, even before surgery, over a fifth of children had higher than normal levels of endotoxins – and levels rose after surgery. Overall, 27.5% of the children had raised endotoxin levels after surgery.

The highest endotoxin levels were measured in small children and those whose heart defects resulted in compromised blood supply to the gut.

What also emerged was that children with high endotoxin levels showed more signs of organ dysfunction and tended to spend longer in intensive care.

While the children may have been exposed to bacterial toxins during surgery, the levels of toxins in the blood continued to rise in the days after surgery, suggesting that bacteria in the gut were the main source.

Dr Pathan added: 'We were surprised at how common endotoxaemia was in these children and how strongly endotoxin levels correlated with poor clinical outcomes. 'Not many children die from surgery, but the problem is that the longer they stay in intensive care, the greater impact on their longer-term neuro-development,' she pointed out. 'Most children recover well from surgery for congenital heart disease, but we want to reduce the chances of further complications so that young children don't have to spend as long in intensive care.'

The next research stage involves working with Imperial colleagues to define how vulnerable children can be protected from harmful toxins.

As most congenital heart procedures are elective, she said, doctors can try to reduce the toxins risk by planning and use of relevant drugs, though in a way that does not negatively affect the bacteria levels and helps preserve the elements of bacteria in the gut that are beneficial to the children.

Congenital heart disease is among the most common birth defects, affecting about one in every 145 births. While some abnormalities are minor and require no treatment, many babies and young children must undergo surgery to correct the defect.

Royal Brompton and Harefield NHS Foundation Trust is a national and international specialist heart and lung centre. Based in Chelsea in London and Harefield in Middlesex the Trust is renowned for paediatric cardiac surgery and groundbreaking research with a number of leading institutions. However, while it is the UK's largest centre for the treatment of adult congenital heart disease, its children's heart surgery unit is now under threat of closure due to a major National Health Service reorganisation of paediatric heart surgery centres.

Dr Pathan's study was funded by Heart Research UK (£84,500) and the Higher Education Funding Council for England (HEFCE).

ESC ROUNDUP Fixing heart conditions

Devices to treat chronic cardiac disease are winning credibility with new evidence from large-scale patient registries, *John Brosky* reports

With a record 32,946 participants, the annual congress of the European Society of Cardiology this year became the largest cardiology meeting in the world.

Traditionally oriented to pharmaceutical therapies, this year medical devices gained ground against drugs with successful outcomes for treating chronic conditions, such as arrhythmias, blocked arteries or deteriorating valves.

At past ESC meetings such studies were typically from manufacturers with highly selective patient populations and narrowly focused on device performance. ESC 2011 marked a turning point with the emergence of doctor-driven studies based on real world patient registries with a single goal, to know whether patients get better or die.' This is the year for registries,' proclaimed the new ESC president, **Michel Komajda MD**, proud of the success of the society's effort to introduce wider clinical evidence for devices.

Better outcomes with new generation stents

Placing a metal sleeve inside an artery to keep it open became a widespread practice in Europe until experience showed the body, reacting against this unnatural device, would close up the artery again.

Manufacturers responded by coating the tiny tubes with a drug to prevent this restenosis. Sales of drug-eluting stents (DES) then soared until 2006, when the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) showed they simply did not work.

SCAAR was back at ESC this year, this time to show that, with third generation DES, manufacturers have finally got it right.

Results of 94,384 stent implantations in Sweden, from November 2006 to October 2010, showed the new DES are associated with a 38% lower risk of clinically meaningful restenosis and a 50% lower risk of stent thrombosis compared to old generation DES. Significantly, after 15 months, patients with the new DES no longer have adverse effects.

A Japanese study based on ESC-developed methods reminded cardiologists that, for complex cases where several arteries are clogged, open heart surgery is still the better treatment. The CREDO-Kyoto registry of 2,981 patients with triple vessel disease showed bypass surgery had a 'protective effect' against future cardiac events while the risk for all-cause death was significantly higher for stents.

A study from western Denmark showed a coordinated strategy to rush patients directly to a cath lab for stenting saves lives and improves long-term outcomes.

A registry analysis for 9,514 patients demonstrates field triage by emergency medical teams saves one hour over hospital processing, resulting in lower mortality and lowering the risk of repeat adverse events.

ICD home monitoring does not reduce mortality

Patients at risk of sudden cardiac death as a result of rhythm disturbances routinely receive an implantable cardiac defibrillator (ICD).

In Western Europe the average rate of implantation is 140 ICDs per one million people, far below the shocking utilisation in the USA, where 600 ICDs are implanted per million people.

Because a cardiologists' office is quickly overwhelmed by the required follow-up visits every three months, remote monitoring features were introduced to ICDs.

Studies show home monitoring devices are safe and help reduce the office workload. But does automatic reporting from the device reduce adverse events and lower costs for a healthcare system? The short answer is no.

Two French studies presented at ESC are among the first to challenge the cost-benefit of ICD home monitoring.

France has one of the lowest implantation rates among developed countries with just 88 ICDs per million people. Before encouraging wider use of these devices, the French Ministry of Health asked for proof that remote monitoring is worth the added expense.

The EVATEL study, paid for by the ministry, revealed that remote monitoring does not affect the rate of major cardiovascular events, showing no difference in survival and hospitalisation at one year between a monitored group and a control group.

The ECOST trial, sponsored by Biotronik followed 433 French patients for 27 months and reported a clear benefit for home monitoring with a 72% reduction in the risk of hospitalisations related to inappropriate shocks.

Unfortunately, the financial impact from the two studies was not reported, because the French ministry is still studying the results.

The difference in findings was explained by the fact that ECOST looked at one device with a smaller patient group, whereas EVATEL is the first trial to include all manufacturers across a large population of 1,500 patients.

Heart valves: Still viable after four years

ESC was the battle ground for studies on transcatheter aortic valve implantations for many years. Because these devices are now in front of the USA's Food & Drug Administration, the focus has moved to the other side of the Atlantic.

Yet, European cardiologists hold an important edge with long term results among 30,000 patients who have received these devices.

The open question is: How long do the valves last?

The strongest real-world analysis is the FRANCE II registry, with 2,419 consecutive patients from 33 centres in France, which includes the only two devices approved for implantation – CoreValve from Medtronic and the Sapien valve from Edwards Lifesciences.

Procedural success was reported as excellent and the valves are performing well.

The German Heart Centre in Munich reported on 393 consecutive patients receiving a CoreValve between 2007 and 2011. The device shows sustained improvement of haemodynamic values up to three years after implantation.

A small study of 50 CoreValve patients from seven centres in Europe and Canada is unique for having the longest follow-up period. Receiving a valve in 2005 and 2006, more than half of patients have since died, but not as a result of device failure and the valve continues to perform well for the survivors.

A review of 177 patients implanted with the Edwards valve in Rouen, France, starting in 2006, also showed solid device performance.

Electronic 'nose' smells heart failure

Vasileios Kechagias PhD, from the University Hospital Jena, believes a new device can sniff out the potential for heart failure.

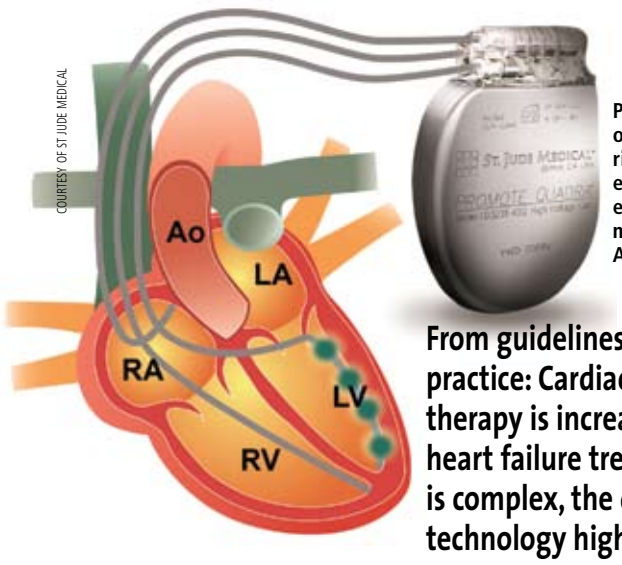
Emphasising that the results are from a pilot study and the device is far from finished, Dr Kechagias said the study succeeded in demonstrating among 126 patients that the 'electronic nose' detected heart failure with 89% sensitivity and 88% specificity.

The device consists of metal oxide based gas sensors, each with a different sensitivity to various odorant molecular types.

The first version of the nose is a bulky cube that is strapped to the forearm, and the detection session takes 30 mi nutes. It also needs to be connected to a high-end gasometer and molecular analysis system at the University for Applied Sciences in Jena. Nonetheless, the potential is intriguing with the possibility of one day seeing a miniaturised version for a skin patch that remotely transmits the readings.

'Sometimes it takes something crazy to shake up our ideas,' said ESC session chairman Frank Ruschitzka MD, from the Zurich University Hospital.

Cardiac resynchronisation therapy



COURTESY OF ST JUDE MEDICAL

Placing of CRT electrodes – one in right atrium (RA), one in right Ventricle (RV). The third electrode gives off its pulse energy to the left ventricle (LV) muscles via four poles (Ao = Aorta, LA – Left Atrium)

From guidelines to daily clinical practice: Cardiac resynchronisation therapy is increasingly important in heart failure treatment. The therapy is complex, the demands to medical technology high. *Holger Zorn* reports

More than 3.6 million new cases of heart failure (HF) occur in Europe every year. Almost 40% of those patients die within a year of their first hospital admission; only 25% of men and 38% of women are still alive five years after their diagnosis. Around 20-25% of patients suffer from ventricular dyssynchrony (*Source: Pacing Plin Electrophysiol. 2003 Jan; 26 (1 Pt 2): 155-7*) and could benefit from cardiac resynchronisation therapy (CRT).

In 1994, Serge Cazeau, cardiologist at Val d'Or Surgical Centre in St. Cloud, France, implanted the first four-chamber pacing device into a 54-year-old patient with severe congestive heart failure (*Pacing Clin Electrophysiol. 1994 Nov;17 (11 Pt 2) : 1974-91*). In 2005, CRT was included in the ESC guidelines. Meanwhile, every year in Europe over 30,000 devices are implanted.

The cause of mechanical dyssynchrony is a cardiac conduction abnormality, a left bundle block (LBBB) with delayed ventricular conduction, which leads to uncoordinated regional contraction/relaxation. Medication can only treat this indirectly.

Cardiac resynchronisation therapy bypasses the blockade in the cardiac conduction system through the transvenous insertion of a third electrode (in addition to the normal pacemaker electrodes, which are inserted into the right atrium and the right ventricle). It is then positioned above the left ventricle via the coronary sinus in a coronary vein. Continuous stimulation of both ventricles forces them back into the right rhythm and the heart is resynchronised (see image).

14 randomised studies, involving 4,220 patients, proved that CRT can improve cardiac function and capacity in patients with severe HF. The hospitalisation rate decreased by 37%, mortality by 22% (*JAMA2007;297(22) :2502-2514*).

Newer studies led to an extension of its recommendation to mild HF patients and those with indication for a pacemaker: For instance, the MADIT-CRT study showed, for 1,820 patients from 110 centres in 14 countries, that in NYHA Class I and II patients with LBBB, early CRT intervention reduces the relative risk of all-cause mortality or first HF event by 57% when compared to ICD therapy (*NEJM 2009;361 (14) :1329-38*). Study leader Arthur Moss (University of Rochester) said: 'CRT-D therapy offers the same advantages for ischaemic as well as non-ischaemic patients. The data of the MADIT-CRT study are convincing and contribute towards closing the gap in our understanding of heart failure class I and II.'

Around 5-10% of transvenously implanted CRT systems do not succeed. Special implantation aids are therefore as much the objective of continuous development as new electrodes. Left ventricular electrodes are now mostly not actively positioned with screws but via traction through the electrode shape and its surface friction against the vascular wall in the target vessel.

Frank Amberger, Senior Product Manager at St. Jude Medical GmbH, explains: 'Because of this passive fixation the electrode can't just be implanted in any given position; its position depends on the course of the veins in the heart.' If transvenous access is not possible, epimyocardial electrodes offer an alternative. 'These electrodes,' he says, 'are screwed in or surgically sewn into the wall of the left ventricle via mini-thoracotomy after opening of the pericardium.' Non-surgical access, e.g. via subxiphoid puncture of the pericardium, are under development (*Card Electrophysiol Clin 2010;2(1) :135-46*).

However, an implanted CRT device does not always improve HF; only 35% and 22% respectively of patients are classed as responders and super-responders, defined by a reduction of left-ventricular end-systolic volume (LVESV) by 15-29% or 30% respectively and more than six months after the intervention. 21% of patients are non-responders, with an LVESV reduction of less than 14%, and 22% are negative responders, with LVESV actually increasing (*JACC 2009;53:483-490*) – for Dr Amberger enough potential for optimisation of CRT, be it through better patient selections, identification of the optimum location for stimulation, or through improved stimulation-algorithms.

Analysts also recognise this potential: In a 2008, a Frost & Sullivan study determined the market volume of CRT for seven key Western European regions – Germany, France, Italy, Spain, the UK, Benelux and Scandinavia. Based on a figure of €832.5 million for 2008, F&S forecasts €1.943 billion for 2015, with a compound annual growth rate of 9.5%.

The 1.2-Tesla workhorse

Hitachi's open MR system *OASIS*

Radiologist Michael J Kasotakis: 'We use Hitachi's Oasis 1.2 MRI as an extremely reliable workhorse. Feedback from staff and patients on this open system is absolutely positive'

St. Joseph Mercy Hospital, a 537-bed teaching hospital in Ann Arbor, Michigan, is part of Saint Joseph Mercy Health System, which leverages the resources of seven hospitals, five out-patient health centres and further care provider organisations across five counties in southeast Michigan. In August 2008, the large hospital, with a high volume of patients, became one of the first sites to operate the *Hitachi Oasis MRI 1.2 Tesla* in North America, since then, 13,000 studies have been carried out.

In October, during the Lunch Symposium '*Exploitation of State-of-the-Art Technologies in Modern MRI Imaging*, held at the 28th Annual Meeting of the European Society for Magnetic Resonance in Medicine and Biology (ESMRMB), neurologist **Dr Michael J Kasotakis** described the hospital's extensive experience with the system.

European Hospital asked why the hospital had chosen to use this particular 1.2 Tesla MRI. 'Back in 2008, we had several 1.5 devices and one 3.0 Tesla MRI in operation,' he explained. 'We were lacking equipment for open imaging, to accommodate, in particular, bariatric and claustrophobic patients whom we were starting to lose to the periphery. Only a few vendors had open-bore MRIs at the time; Hitachi had just come out in the market, and their facility was in Cleveland – just a two hour drive from our site. We scrutinised the machine and, from the beginning, were very much impressed with its functioning, easy handling, features, and footprint. It was perfect timing, and a perfect choice.

'A quarter of patients in Michigan are obese; we've scanned 600 lb patients! However, we decided not to triage MRI patients, and are not limiting use of the Oasis to specific groups. Our aim was to use the machine as a workhorse for all applicable patient cases. We keep it busy, running it real hard – seven days a week, 16 hours a day. Our volume is huge. More than half of our cases are spine work; neuro and musculoskeletal rank next in a number of cases, plus abdomen and further cases.

'With regard to all our criteria, the Oasis has been performing to our full satisfaction. We have seen very little downtime; and support from the vendor's team has been very intensive, ensuring smooth operation.'

Image quality

'We get very imaging good results on neuro, musculoskeletal, angiography, and all other pertinent patient cases,' Dr Kasotakis confirmed. 'There's very little motion in the patient's static; MR angiography is exquisite, and post-processing algorithms provide excellent images even for the challenging obese patients. In my presentation at ESMRB, I showed that results compare very well with those of a 1.5 Tesla; you simply cannot tell the difference.'

Cooperation with the vendor's R&D department

'We work with them as a beta site and have witnessed many of our suggestions being integrated as standard features, such as rails facilitating the positioning of obese patients on to the table. IV lines are another aspect – setting up an attachment next to the patient table can help accommodate the patient's hand and greatly facilitate IV access.

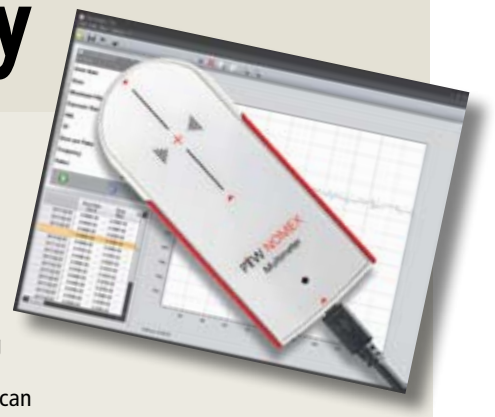
Really positive patients' feedback

'I'll illustrate patient reactions with one example: Shortly after we had gone live with the Oasis, a patient came in who had been scheduled to be on a closed MRI. There had been no issue of him being claustrophobic, but when he got sight of the conventional MRI, he said "I can't do this". We walked him across the hall and showed him the open system, asking him, "Well, how about this?" The openness of the machine calmed him down, and we carried out the exam successfully with no anaesthesia or sedation.

'Today, we get referrals from over 50 miles away – even from the University of Michigan Hospital, where they have no open MRI available. In total, this means that we have improved significantly the positioning of our hospital in market.'

Details: www.hitachimedical.com

A miniaturised X-ray measuring system for dosimetry



The Nomex multimeter, a miniaturised non-invasive measuring system for absolute dosimetry and quality control in X-ray diagnostic radiology, will be demonstrated in several upcoming European medical trade shows*, including Medica in Dusseldorf.

Produced by PTW, the device can be used for radiography, fluoroscopy, dental, dental panoramic, CT and mammography applications. An HVL reading is also available for mammography.

The multimeter measures dose, dose rate, irradiation time, dose per pulse, pulses, tube voltage (kVp), total filtration (TF) and the half value layer (HVL) in one single shot. Additionally, the dose rate and voltage waveform with full 2 kHz can be stored.

With USB connection for a notebook or PC running the Nomex software, no additional accessories, e.g. power supply or display, are needed for its operation. Because the multimeter is independent of orientation, uncomplicated measurement positioning and adjustment are guaranteed, the manufacturer points out.

When radiation is detected, measurements begin automatically. The dose and kV ranges are set fully automatically, thus avoiding multiple exposures.

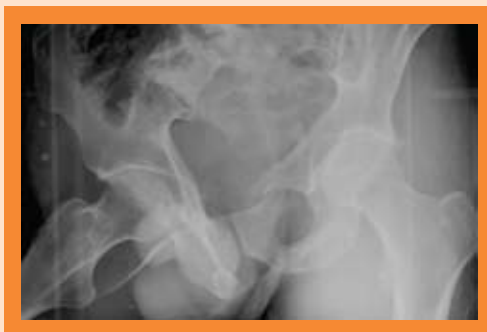
The software can be operated intuitively and allows most convenient and clear data handling, PTW adds. Statistics functions are provided as well as data export in different formats.

** JFR (Hall Passy, booth 124C); MEDICA (Hall 10, booth D56); RSNA (Hall A, booth 3805)*

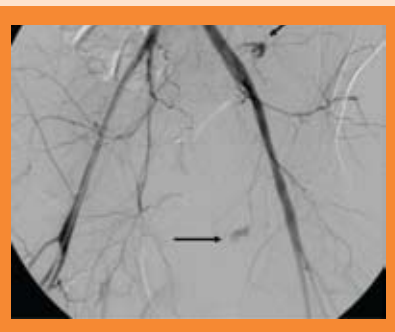
Details: www.ptw.de

Interventional radiology in the trauma unit

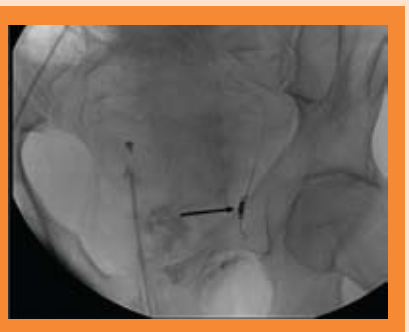
Traumatic injuries result in 800,00 deaths per year in Europe, making this one of the leading causes of mortality and the primary cause of death in patients aged 45 years old or younger. Depending on the type and severity of injury, usually trauma patients are treated by a team of experts from different disciplines. A vital – and often life saving – part in trauma patient care is played by a subspecialty, interventional radiology (IR), says Professor Poul Erik Andersen (above), from the Department of Radiology, Cardiovascular Section, Odense University Hospital, Denmark, which is constructing an entirely new emergency unit to provide integrated expert care



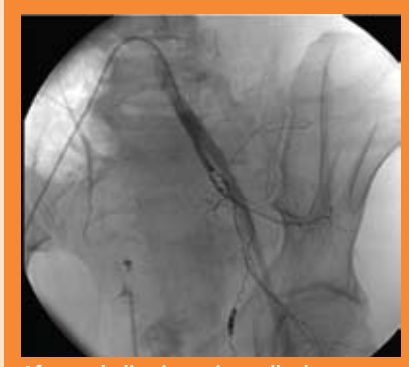
Severe pelvic trauma with multiple fractures and heavy bleeding



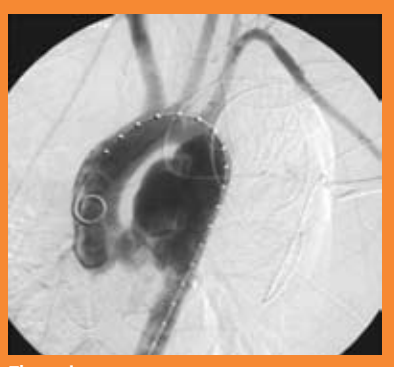
Bleeding visible by angiography with contrast extravasation (arrows)



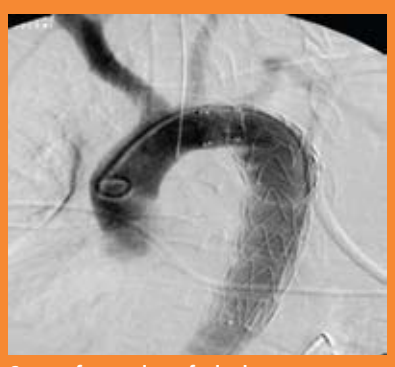
Super-selective, catheter with tip in the bleeding artery and after deployment of an embolisation coil (arrow)



After embolisation using coils there is no further bleeding



Thoracic aorta rupture



Same after endograft deployment to cover the rupture

Odense University Hospital is constructing an entirely new joint emergency unit with direct access to diagnostic (CT) and intervention rooms. Actually, at Odense there are already three intervention rooms with angiographic equipment and one 'hybrid' room equipped so that both surgical and interventional radiological procedures can be performed on the same table – but these are part of the separate radiology department. When patients hover between life and death, Prof. Andersen is convinced that trauma patients should be transported directly from Accident and Emergency (A&E) to a fully-equipped integrated/combined CT and angiography intervention unit, to enable adequate imaging and immediate trauma management in one step. It is very time consuming to move a multi-traumatised patient with tubes, drains, lines etc. from one table to another. In the future, he believes, such integrated approaches will be, at the least, specialist trauma level one centres.

Denmark has four trauma centres, in Odense, Copenhagen, Aarhus and Aalborg, from which only Odense and Copenhagen have a dedicated interventional radiological team on call day and night. The Odense A&E receives 5-10 multi-trauma cases per day.

In the trauma setting, death could be mostly due to destruction of vital tissue, blood loss, and complications from injury and treatment. Hence, haemostatic or haemodynamic stabilisation remains a cornerstone of management. Haemostasis can be achieved through three different strategies: Non-surgically, relying only on the body's own haemostatic mechanisms; surgically, by ligation or coagulation of the bleeding vessel, or interventionally by transcatheter embolisation and vascular repair.

During the last two decades, improved imaging techniques and advances in interventional radiology have led to the better selection of patients amenable to that third management approach. 'IR allows for very fast, super-selective and efficient minimally invasive treatment in emergency medicine, with very few complications,' Prof. Andersen emphasises. 'The procedures are performed with an endovascular catheter that is positioned from the artery in the groin to the target vessels, where we stop bleedings by embolisation using various embolisation materials. In cases such as acute aortic traumas, IR reduces mortality rates to 5% or less in comparison to a surgical technique, where about 50-75 % of patients die of their injuries. That's why the acceptance of IR in this field is very high among surgeons.'

The top three killer injuries relevant to IR are solid organ, pelvic and aortic injuries.

Traumatic aortic rupture is the leading cause of death within the first 15 minutes. It means that the aorta is torn or ruptured, for example as a result of blunt and penetrating injuries. 'As the largest artery in the body, the aorta is a high blood pressure circulation system, so the condition may lead to profuse blood loss and therefore can quickly result in shock and death', he explains.

'Most of the patients die on the accident scene. But, if they make it to the hospital, they have a very poor prognosis. Endovascular intervention has become the treatment of choice in those critical cases. To prevent or stop uncontrolled bleeding, the interventional radiologist chooses a stent-graft, which is inserted into the aorta to cover the rupture hole.'

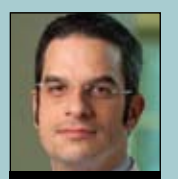
Another indication for IR in a trauma unit is arterial pelvic bleeds. 'These are very difficult to handle by surgery, because they bleed very heavily during surgery and it's very difficult to find the bleeding artery. More effective is a transarterial embolisation to control the haemorrhage. However, there are anatomical limitations to IR procedures, depending on the kind and localisation of bleeding. If the bleeding comes from the veins, we cannot intervene and it won't be necessary because, as these vessels are low pressure vessels, venous bleeds are self limited.'

In solid organs such as the liver, kidneys and spleen, IR plays an important role in that embolisation can be performed super-selectively and thus preserves the non-injured organ area. By surgery, removal of the whole kidney or spleen, or resection of a large part of the liver is often necessary during the operation.

Over the years, IR has completely altered trauma patient management and is a daily help in significantly decreasing morbidity and mortality rates.

Assessing potential benefits in PET/MRI examination

In recent years, combined examination methods have increased, whereby two examination methods are used in a parallel examination, rather than performed separately. Frederik Giesel MD, Associate Professor of Radiology at the Nuclear Medicine Department, University of Heidelberg, and Philip Herold (Dipl. Econ.), Project Manager at RICT Heidelberg, report on the benefits


Frederik Giesel


Philip Herold

Three major benefits from combined examination methods are expected: First, better exam results for diagnosis and thus increased quality in treatment; next, increased patient convenience by shortening examination time and decreasing the likelihood of poor treatment, and then, cost savings in time, human resources and material, after an initial investment. Such has been the findings in various studies.

This article proposes a comparison not only of combined examination against separate examinations but also an evaluation of the possible benefit of different combinations of examination methods.

For illustrative purposes, PET/MR is evaluated against separate examinations and PET/CT as an alternative combined examination method. The impact is analysed in the TMA staging taxonomy, i.e. lung cancer.

Better exam results

With respect to lung cancer, combined examinations basically deliver output of the same quality in terms of not overseeing lesions as stand-alone methods, such as CT/MRT, bone scan, or mediastinoscopy. Thus the results of all methods shall be treated as equally useful for follow-up examinations.

However, PET/CT has to be complemented by MRT anyway. This is, for example, the case for thorax examinations (T). Because CT cannot provide data of the same quality as MRT for morphological questions, MRT is likely to be done in addition. The best examination result is achieved by including MRT in the combination, for better data quality.

Another example is the examination of remote metastasis in the head (M). As there is a high concentration of glucose in the brain anyway, (FDG-)PET can hardly yield any results suitable for evaluation. CT results are sometimes problematic because of the bone density surrounding the area of interest. Here again, the inclusion of MRT can complement such shortcomings in terms of wider scope of the examination.

Patient convenience

Patients can also benefit from the combination of examinations by experiencing a more comfortable course of treatments, because they only have to attend one appointment, including transportation, paperwork etc. Especially for more severe cases, the number of examinations may significantly drive the overall recovery process.

Increased standardisation and routine help the staff to reduce process time and handle cases more effectively. For example, the time-intensive step of deciding on the appropriate method and eventually revising this decision can be left out. Further economies of scale may occur in the diagnosis routine, as physicians become more specialised and the output (report) naturally more standardised. This in turn also benefits the treating physician.

Cost saving

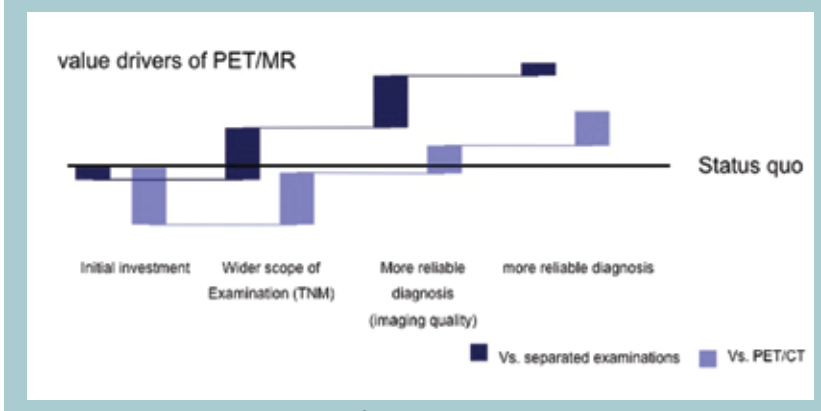
When it comes to investment decisions cost savings are examined in great detail. These are the one-off cost of investment, on-going cost per examination and equipment maintenance.

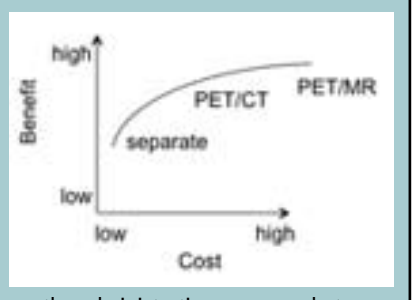
In the initial investment no synergies can be realised when switching from separate stand-alone scanners to equipment allowing for combined examinations. The opposite is the case as additional investments have to be made for integration.

However, on an on-going basis, economies of scale may be incurred in the diagnosis-routine because less staff time (human resources) is needed per examination.

Maintenance and related cost may decrease, as specialisation effects increase. This can be sourcing-related in terms of a help desk, for example. This could also be material related, for example, in terms of tracers.

For lung cancer, the German health insurance system covers PET/CT. However, in most cases additional MR examinations are conducted upon prescription by the physician in charge (M lesions above). As a result, all three methods, PET, CT and MR are employed whereas the marginal contribution of CT is rather small. This is only achieved after a lengthy and thus costly administration process between treating clinic and health-insurance. This process and the related cost could be avoided by integrating PET and MR to a standardised routine.





Conclusion

In summary, it can be observed that the combination of established examination methods is beneficial. Such integration increases patient convenience and decreases cost per examination. Most importantly, diagnostic quality can be enhanced as combined methods complement each other and provide the physician with better data.

Among the combined examination methods it turns out that PET/MR is superior to PET/CT for two reasons. First, MR and PET complement each other in a way allowing for a wider scope of examinations (M lesions above). Second, MR imaging was found to be more relevant than CT (T lesions above). These two reasons are to be traded off against the additional cost upon investment.

Alpinion Medical Systems

Aiming to soar in the league tables


Thomas Roth

The goals are ambitious: Although in the market merely four years, the start-up firm Alpinion Medical Systems states its intention to become one of the prime providers in the ultrasound mid-range price segment. In an interview with Daniela Zimmermann of *European Hospital*, Thomas Roth, Alpinion's Managing Director, explains his corporate strategy and conviction of success

Alpinion is a rather young player in the ultrasound arena. What makes your products special?

Thomas Roth: 'Alpinion is indeed a young enterprise. It was founded in 2007 by two engineers who had both been working with leading ultrasound companies for many years. They are now deeply involved in the development of ultrasound systems that focus on a fundamental issue – providing excellent image quality. To achieve this goal, Alpinion uses the very special single crystal technology.

'We didn't invent it. Single crystal is being used by other companies; but we did optimise the production process and had our process patented. We use top quality materials and apply innovative procedures. For example, we create crystals that, to date, were only used in high-end products. They allow us to apply single crystal technology in our ultrasound system, which is in the mid-range price segment but offers image quality comparable to a high-end or premium system. We plan to launch a bread and butter product line, meaning the equipment will be affordable, offer outstanding image and processing quality and good ergonomics.'

In which countries do you expect to be successful?

'In Europe the major customers are in Germany. So we established a subsidiary in southern Germany to support out corporate HQ in South Korea. We want to be present on the European market. Our sales team has been active since earlier this year and has managed to acquire about 80 trade partners in only nine months.'

What feedback have you been receiving from customers?

'We launched our prototype E-Cube 9 in 2010, at the joint meeting of the Austrian, German and Swiss Societies for Ultrasound in Medicine and also at MEDICA. Feedback was very positive. Our ultrasound system has a great design and offers excellent image quality. Our customers were amazed. That's our philosophy – to create an ultrasound system with superb image quality.'

Who are your customers – hospitals or office-based physicians?

'With our ultrasound system E-Cube 9 we focus on physicians' practices. However, we're in the process of developing further products, which will be ready for the market in the first quarter of 2012. One system will be technically less sophisticated than the E-Cube 9 system, one will be superior to the E-Cube 9. In addition we'll launch a high-end laptop ultrasound system. With these machines we will enter the hospital market.'

The high-end system – what additional features will it offer?

'The system will provide even better image quality. It will offer features that today are standard in the hospital segment, but so far have not been crucial in the practice segment. I will not divulge more at this point.'

Is the new system also geared towards hospital radiology departments?

'We'll tailor this system to different clinical disciplines. Starting out with cardiology is a strategic decision. From day one, we want to show that we have the know-how to develop an interdisciplinary product and we do not need to limit ourselves to a certain medical area or a certain technology. For example, there's an Asian company that initially focused on gynaecology. Now it's difficult for this company to conquer the cardiology or internal medicine segment. That's something we want to avoid by offering cardiovascular products from the very beginning.'

You underline your products' image quality – does any hard data support your claim?

'Image quality is a subjective matter and consequently there are no studies. But we get feedback from the users who know the products in the different price segments. They, the users, are the ones who test the Alpinion system and compare it to reference systems or to the high-end systems available in their hospitals. We don't claim to offer the best image quality in the entire ultrasound market but, compared to systems in the same class, our image quality is one to two classes better.'

What are your goals for the next five years?

'It's our strategic goal to become a global multi-modality provider of medical technology. Let me put it this way: We do not want to challenge the big players in the Premier League, but we want to be first or second in the Second Division. Therefore, Alpinion doesn't only work on diagnostic ultrasound systems. Currently, we are performing the clinical evaluation of interventional ultrasound systems. This is a very interesting and important area, particularly in highly industrialised countries like Germany.

'In oncology, high-intensity focused ultrasound – HIFU – is increasingly considered to be a viable alternative to radiation therapy. This will be the second pillar of our business – the third pillar being the transducers that we manufacture ourselves.

'We also intend to launch further product families in the next five years, either through acquisitions or our own developments, to cover the entire field of diagnostic imaging. We are looking into digital X-ray, MRI, CT and the entire homecare area. That's a major challenge. We will not be able to develop the entire portfolio ourselves but will look around for suitable partners.

Automatic image fusion

Dirk-André Clevert MD, Associate Professor of Radiology at the Department of Clinical Radiology, University of Munich, Germany, describes a new diagnostic approach in abdominal ultrasound

The prevalence of liver lesions is around five percent of the whole population. At the time of diagnosis tumour patients show hepatic metastases in 25-50% of cases and the liver is the main region for metastases in oncological diseases. Therefore, to evaluate the prognosis and establish a therapeutic procedure a reliable detection of hepatic metastases is a prerequisite.

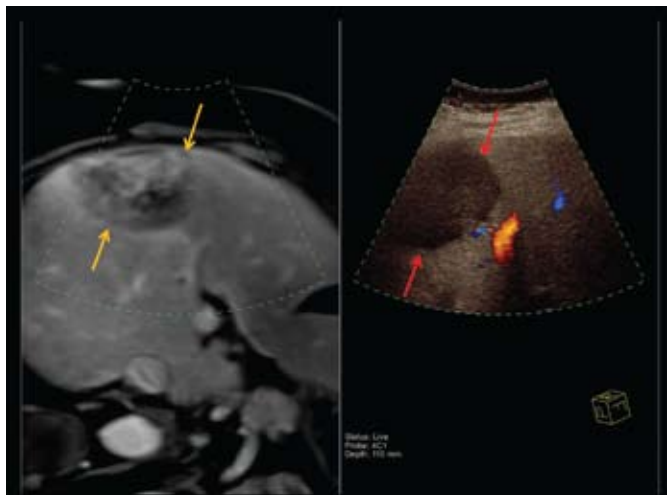
Establishing the number and location of lesions is essential in order to evaluate the prospects of resection, or to plan interventional therapy. Prior to this, the focal hepatic lesion must be accurately characterised. To this end, a second opinion in cases of unclear liver lesions and in cancer follow-up examinations after chemotherapy is extremely helpful and will improve prognoses.

Liver examination using the image fusion technique requires hardware components in the form of a magnetic field generator and an abdominal imaging transducer. Having dedicated positioning software to enable detection and tracking of the transducer is also a necessity. The positioning system calculates the exact position of the respective transducer.

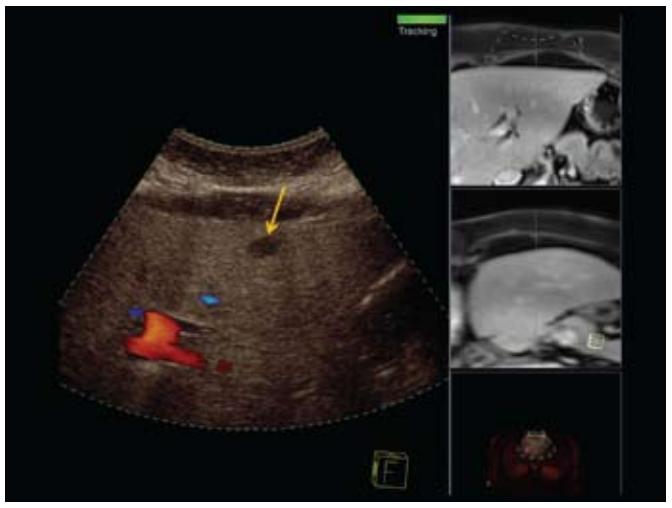
DICOM data of all cross-sectional CT or MRI examinations can be used to upload the images into the ultrasound system for automatic registration. All ultrasound techniques, such as B-mode, duplex-US, power Doppler or contrast-enhanced ultrasound, can be integrated into the image fusion examination. Using the Siemens Acuson S2000 ultrasound system (Siemens Medical Solutions USA, Inc) to use either a conventional magnetic field generator, placed at the patient's side, or a magnetic field generator integrated into a flat plate placed under the patient, and enables enhanced performance with an innovative automatic registration mode, meaning no manual points or plane registration is necessary. This auto-registration provides extremely fast automatic registration of the data, helping to minimise the exam time and improve the registration quality.

After successful automatic registration and image fusion, the registered CT or MRI images will be simultaneously shown on the ultrasound monitor with the respective ultrasound sectional plane. Additionally, two simultaneous CT or MRI planes could be used to improve visualisation of the lesion.

Image fusion combines the advantages of comprehensive anatomical information due to 3-D CT dataset or MRI dataset and



1. A 54-year-old female with known breast cancer and one single liver metastasis in the right liver lobe. Contrast-enhanced MRI depicted the known metastasis (yellow arrow). This was confirmed using image fusion with ultrasound (red arrow)



2. The same patient as 1: In addition, the image fusion technique depicted a new small liver lesion in ultrasound (yellow arrow), which was not visible on the latest MRI examination using two simultaneous MRI planes

Neurosurgical guidance progresses toward navigation

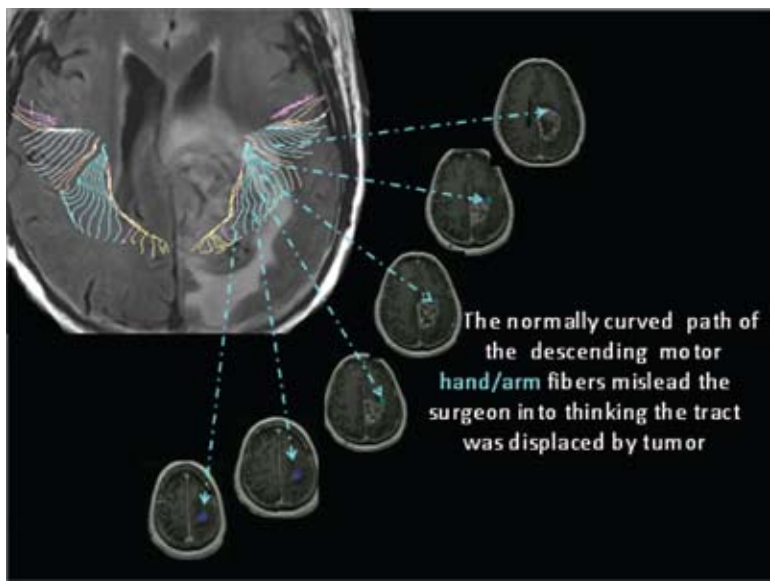
Unique software embeds an extensively annotated normal template into a patient's axial images, Vinodh A Kumar MD reports from the Division of Diagnostic Imaging and Physics, University of Texas MD Anderson Cancer Centre, Houston, Texas

After a decade of mapping the head and neck, as well as chest, abdomen and pelvis for radiotherapy contouring, Anatom-*e* is now providing extensive functional brain mapping for use in diagnostic radiology, radiosurgery, and neurosurgery.

In its first year of pre-operative planning, Anatom-e has provided clinically useful information in over 50 glioma cases resected at MD Anderson Hospital in Houston, Texas.

This unique software embeds an extensively annotated normal template into the patient's axial images. This requires only a few minutes of a technician's time and the results can be viewed in a volume rendered curvilinear reconstruction. This novel presentation of the data is often critical for visualising the nuances involved in tumour localisation and planning of the surgical approach.

Portable Anatom-e display of a volume rendered reconstruction of a patient's brain in the operating room



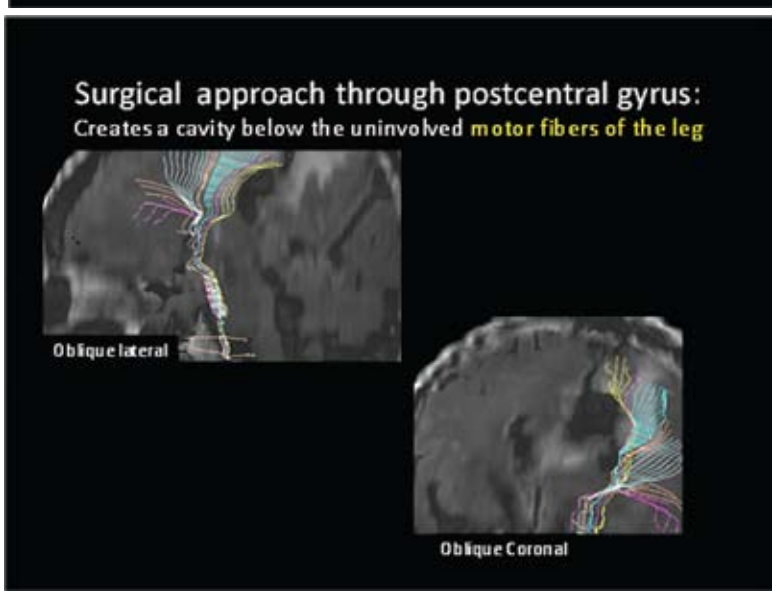


Figure 2a,b . Superior view of a left cingulate tumour with a superimposed 3-D Anatom-e reconstruction of the colour coded motor tracts (leg fibres are yellow and hand/arm fibres are cyan). Individual axial DTI images are inserted along the normal curvilinear pathway of the motor leg fibres. Without the normal pathway for comparison, the fibres appeared displaced by the tumour. Post operative reconstructions show complete removal of the tumour via a small incision in the superior parietal lobule (behind the motor cortex of the leg). The operative approach was carefully planned to avoid the adjacent motor leg fibres successfully

In the example case, a large glioma in the left cingulate region appeared to displace the motor fibres but an identical path is seen on the normal side. The post operative cavity shows the tumour has been completely cored out from within, using an approach that avoided the overlying motor

Neurorad

Europe's largest gathering of neuroradiologists

neurorad 2011 recently drew over 1,000 German neuroradiologists to Cologne, Germany, making this annual congress the biggest of its kind in Europe, as Professor Olav Jansen, President of the German Society of Neuroradiology, pointed out in his opening speech.

Today, neuroradiology is highly active in diverse diagnostic and therapeutic areas, from brain infections, such as those caused by EHEC and HIV pathogens, to spinal assessments following accidents and the care of stroke patients.

Professor Jens Fiehler, from the Clinic and Polyclinic for Neuroradiological Diagnostics and Intervention, University Medical Centre Hamburg-Eppendorf, reported on events in his hospital during the enterohaemorrhagic Escherichia Coli (EHEC) epidemic in early summer this year. Many patients in Northern Germany developed haemolytic-uremic syndrome (HUS) following an EHEC infection, and HUS can lead to kidney failure.

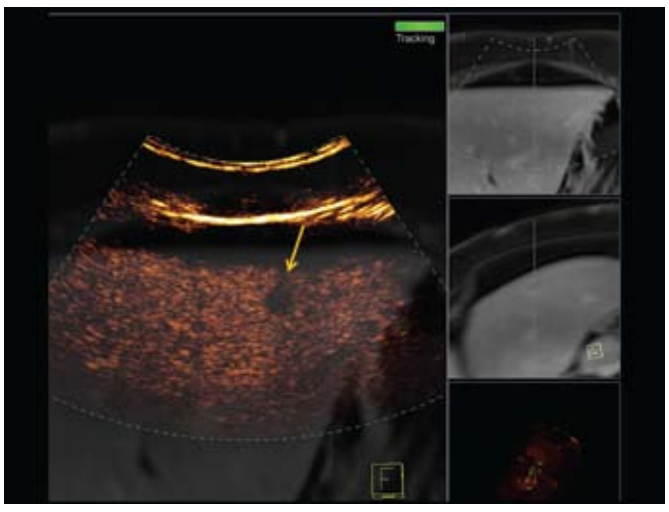
The UKE neuroradiologists were quickly consulted because a large number of patients with HUS developed neurological deficits,

accurate real time dynamic information of contrast-enhanced ultrasound.

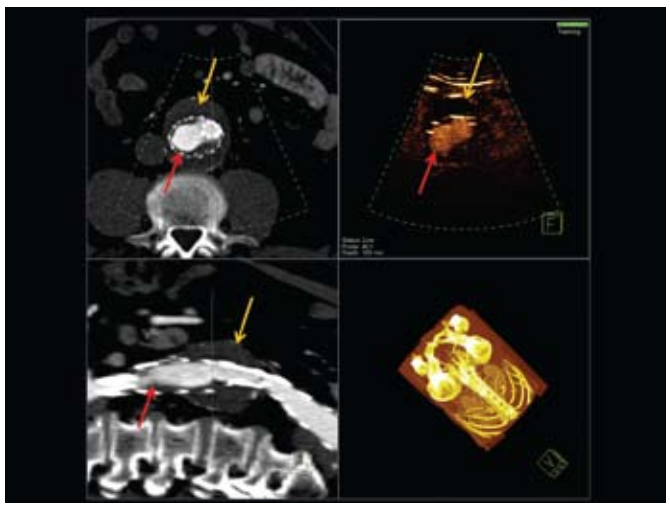
Simultaneous observation of the respective CT or MRI images, in the corresponding axial and sagittal planes, improves spatial orientation of the US investigator and helps to accurately describe the exact site of potential lesions or monitor the lesion in the follow-up of the liver. This may be especially relevant prior to therapeutic interventions such as open surgery or radiofrequency ablation.

Image fusion enables direct comparison between CT, MRI and US data and therefore simplifies the follow-up of patients. This is important because enlargement, or the appearance of new liver lesions, is an indirect sign to change the therapeutic strategy.

Regarding vascular diseases or unclear kidney lesions there are a couple of studies showing the advantages of image fusion using CEUS and MS-CT.



The same patient as 1 and 2. The addition of contrast-enhanced ultrasound with image fusion overlay technique provided additional information, depicting the small liver lesion (yellow arrow) with a wash out in the late phase of the contrast-enhanced ultrasound examination indicative of a new, additional liver metastasis with a maximum diameter of 8 mm



A 68-year-old male with abdominal aneurysm (yellow arrows), treated with an endovascular aortic repair (red arrows). Contrast-enhanced ultrasound depicted the perfused stent graft (red arrows) and excluded an endoleak. This was confirmed using image fusion with two simultaneous CT planes ultrasound

leg fibres. Planning this approach utilised a software feature that can instantly produce extensive anatomic and clinical deficit data for any region of interest. This makes it possible to perform virtual pre-operative surgical procedures.

A prototype navigation system is currently being tested during awake-craniotomies in preparation for submission to the FDA.

The Anatom-e software will be displayed in the scientific exhibition at the RSNA in Chicago

2011

Jens Fiehler

such as speech and memory problems. Some even fell into a coma. Many of these patients were young women – some pregnant, Prof. Fiehler said. This disease pattern was unknown in adults at that time, necessitating imaging of the patients' brains to be able to decide on further treatment.

The EHEC pathogen was a hitherto unknown form of bacteria of the serotype O104:H4. 'To this day it is not clear whether the toxin, the antibodies against it or intermediate products caused these reactions,' Prof. Fiehler said. He also mentioned that the doctors involved feared for their own lives as the course of the infection was not known.

The treatment largely consisted of haemodialysis and autoimmune medication, so far only used in children. Changes observed in the brain, particularly symmetrical changes in the mid-brain and the brain stem, reversed in most cases. 'No symptoms or effects have so far been observed in the babies born to affected patients,' he added.

However, in the case of patients with particularly severe symptoms, the neuroradiological changes had a different pattern, with changes also affecting the cortex. 4.1% of patients in these groups died.

Report: Axel Viola

Diagnosing brain tumours

Stick to the standards!

As a referral neuroradiologist for paediatric tumour studies, Professor Monika Warmuth-Metz, Consultant at the Neuroradiology Department at University Hospital Würzburg, daily evaluates MRI images of different origin and colour. Her resume states: 'All too often the standard protocols set out in the guidelines are not adhered to, which makes evaluation and follow-up significantly more difficult.' Thus, in her lecture '*Brain tumours – how to examine and differentiate them*' during this year´s Ruhr Radiology Congress (Oct. 13-15, Bochum, Germany), she focused on the standard protocols for the examination of brain tumours. So, what does constitute a good standard examination?

Monika Warmuth-Metz: Based on the consensus guidelines of the European reference radiologists on paediatric brain tumour studies and the AWMF guidelines, the imaging of brain tumours comprises a T2 image, a proton density-weighted or FLAIR image and T1 images before and after contrast medium application. The guidelines also state that a T2 image on its own, without proton and FLAIR image, is not considered sufficient, and that the axial plane is the standard. Furthermore, the guidelines stipulate that the examination must be comparable. Although the diagnosis in adults is normally histologically backed up, imaging still plays a vital role.

A referral neuroradiologist for over 20 years, Monika Warmuth-Metz was appointed Professor of Neuroradiology at the University of Würzburg in 2006. For the last three years she has worked exclusively on neuroradiology referrals, and mainly for the German Society for Paediatric Oncology and Haematology HIT studies. The professor is also a member of the German Cancer Society's expert commission for brain tumours in adults, and chairs the imaging working group for the SIOP Europe subcommittee

Why are the guidelines so often ignored?

'They are only recommendations, not prescribed protocols. Another reason is that the new sequences, which go hand in hand with technological progress, push the importance of a standardised examination into the background. It is, of course, important and right to use new procedures, but the standard examination should not be forgotten. For example, MPR sequences, i.e. T1 weighted, three-dimensional sets of data, are very popular at the moment. They deliver important information for the operational-navigational and radiation planning systems.

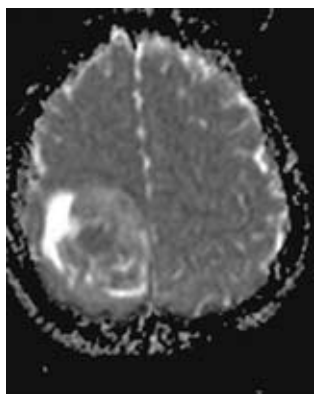


Figure 1: The ADC image of a highly cellular tumour shows a clear, inhomogeneous diffusion disorder because of high cell numbers

'However, over and over again I see that this sequence is frequently used in alternation with a spine echo sequence. Unfortunately in this case, the signal intensities of both sequences are hardly, or not at all comparable. In other cases, we receive excellent examinations where all opportunities of functional imaging have been exhausted, but where the post-operative examination for the determination of the extent of the remaining tumour is missing. Consequently the entire examination or individual sequences have to be repeated to avoid a wrong assessment.'

Which differential diagnosis do you need for brain tumours?

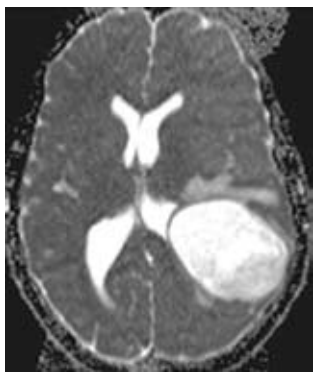
'Basically, we have to differentiate between primary brain tumours and secondary brain tumours. Among the secondary tumours we have, for instance, meningioma and especially metastases, which make up the largest number of lesions.

'These days, due to the longer lifespan of cancer patients, the ratio between primary tumours and metastases is 50:50. With each mass in the brain– at least in adults – you have to think about metastases. With primary tumours in adults, the highly malignant, higher grade glioma tend to prevail. However, there are also non-tumourous changes that can perfectly imitate these images. This includes a brain abscess, which can easily be confused with cystic glioblastoma or cystic, highly malignant glioma.

'Differentiation is carried out using diffusion weighting, i.e. the ADC image that shows a clear and homogeneous diffusion impairment in the case of abscesses. However, diffusion and ADC images respectively are also suitable for the determination of malignancy in glioma as indeed is the case of the more cells there are the higher the grade of malignancy.

'Proton spectroscopy offers further options. It can be used to detect free lipids, which normally are not present in the brain and point towards necrosis. If a glioma is present that has free lipids, this image only really fits a necrotising, primary tumour, i.e. a glioblastoma.

Figure 2a: In a low-cell tumour, diffusion is not affected and the ADC image is therefore light



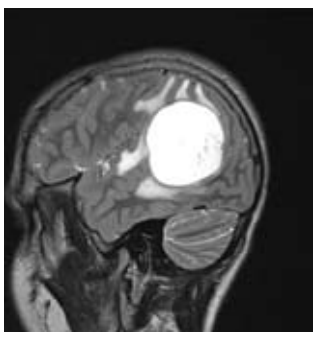


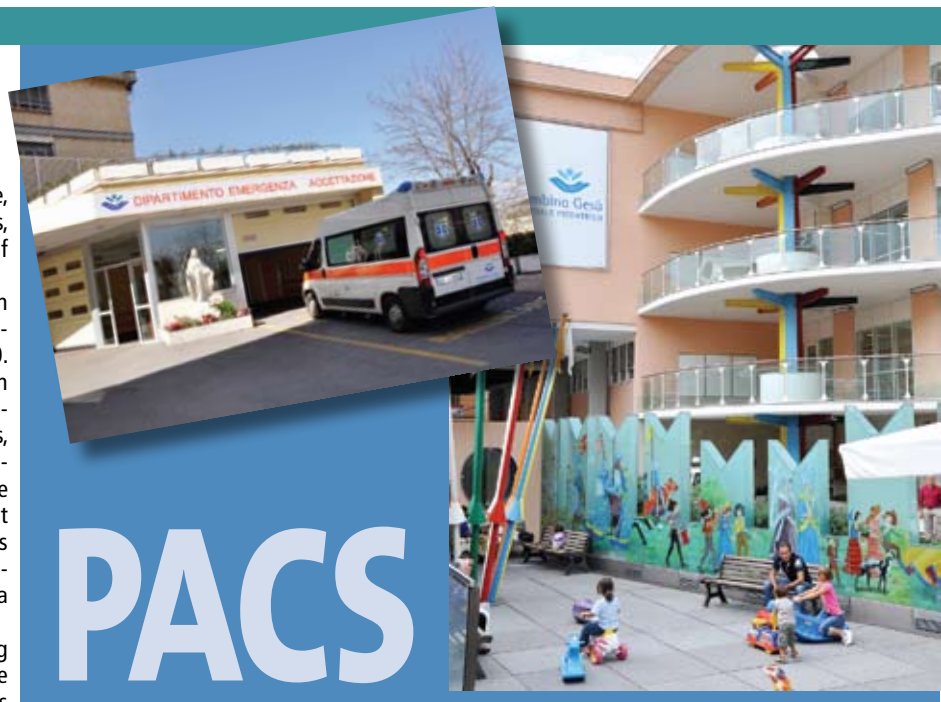
Figure 2b: A very high T2 signal also fits with a low-grade glioma rather than a highly cellular tumour

'Another, important differentiation is that of lymphoma, which are not primary brain tumours but haematological systemic diseases. However, they can present as images identical to those of higher grade, primary brain tumours. Differentiation is important here because primary lymphoma should, for instance, not be treated with corticosteroids prior to biopsy, as this makes the histological confirmation much more difficult.

Which aspects of the highly complex area of brain tumours and their diagnosis are important for radiologists in private practice?

'From my point of view, it's less important to go into the subtleties of differential diagnosis. As radiologists in private practice carry out follow-up examinations it's much more important to determine if and how these are being carried out in a comparable manner because the complete response evaluation and therapy planning are based on the results of a follow-up examination. Therefore, the message is: If something is being measured, then on a comparable basis, please. And the second message in this context is: Please don't carry out follow-up examinations without full knowledge of the previous examinations and their sequences respectively. If this advice is being adhered to, we'll actually have gained a lot.'

Report: Meike Lerner



PACS improves care in Italy's largest children's hospital

Located in Vatican City in the heart of Rome, the Ospedale Pediatrico Bambino Gesù not only profits from a literally blessed base but also from an advanced IT-infrastructure in the radiology department. For over a year and a half, the largest children's hospital in Italy has worked with the Carestream PACS, connecting the institution with two cooperating sites, one in Palidoro, one in St. Marinella. During our European Hospital interview, Dr Paolo Tomà, Director of the Imaging Department, spoke of his institution's needs and how these have been met through a PACS implementation

Covering the entire medical spectrum, Bambino Gesù hospital is dedicated to children from all over Italy and even Europe. With strong expertise in paediatric cardiology and surgery including organ transplantation and neurosurgery, the need for excellent imaging options is huge. Dr Tomà's department is equipped with a latest generation multi-slice CT and two MR-scanners; another MRI is installed in Palidoro centre.

130,000 examinations are performed annually in all three hospitals; around 90,000 in Rome.

Dr PauloTomà: 'A key component of our work is of course to keep radiation and intervention as low as possible. Besides ultrasound, MRI is the most important modality in clinical practice, especially in thoracic/cardiac imaging we cannot avoid CT examinations. In combination with X-Ray images – all three sites are completely filmless – we therefore create a huge amount of data that needs to be handled fast and seamlessly.'

With the old PACS there were huge limitations in data access, meaning that radiologists had problems in obtaining the right pictures at the right place in the right time. 'Two years ago we decided to invest in a new PACS to solve those limitations and guarantee a fast access. We opted for Carestream - which I already had good experience with in my previous job.' He explained. 'What I appreciate most about the system is the excellent post-processing possibilities. The ease of use results in a much quicker image access and quicker diagnostic outcome, which is crucial especially in emergency situations.

Today, all three sites are connected to the Carestream PACS with one central archive in Bambino Gesù hospital. Images acquired in Palidoro or St. Marinella can be seen in real time at the workstations. Another advantage, Dr. Tomà pointed out, is the comparability of old and new images and images from different modalities: 'The PACS automatically recognises the anatomic part and allows quick, precise comparison of images that have been captured at different times or with different modalities.'

In all, 25 workstations are connected to the central system and have access to all patient data stored on the servers. Two separate servers are connected through a high performance fibre channel; images stored on the first server are real time and mirrored on the second server for business continuity. Both PACS servers are connected through a semantic cluster to have high redundancy.

A third server, installed for long term archiving, is connected to a high capacity tape library. It is based on a 30 Terabyte archive that hosts all examinations since 2003, all images are online for ten years.

Dr. Tomà: 'The integration of the system was quite seamless, only the matching with our HIS (Hospital Information Services) was kind of tricky – but this is normal because the HIS is mainly designed for administrative applications. In general, we're very happy with this solution because it fits perfectly into our infrastructure and fulfils the needs of the decentralised communication between the hospitals.'

Radiologists need specific knowledge to assess children and adolescents

Comprehensive additional training is necessary in Germany, to specialise in paediatric radiology, and only seven among the country's 35 university hospitals provide paediatric radiology professorships. Thus, there are only about 80 specialists in this field and very few work in private practice. Aiming to revalue paediatric radiology, the Ruhr Radiology Congress (RRC) is for the first time dedicating separate events to this subject. Professor Gundula Staatz, who heads the Paediatric Radiology Department at the Clinic and Polyclinic for Diagnostic and Interventional Radiology,at the University Clinic Mainz, was among those responsible for the selection of topics. 'We will provide information on questions that all radiologists may encounter in their practice and which they must able to answer even if there is no paediatric radiologist at hand.'

In 2000, Gundula Staatz (right) was awarded the Society for Paediatric Radiology Science Prize for her work in this field. She is also on the Board of the German Radiological Society and editor of the Paediatric Radiology section of the RÖFO, the country's long established specialist radiology journal

Within the forthcoming Ruhr Radiology Congress programme related to paediatric radiology are three, somewhat sensitive, diagnostic topics: Bone and thoracic diagnostics and child abuse. The sessions intend to highlight current knowledge and familiarise participants with the underlying diseases.

In bone diagnostics, for example, Prof. Gundula Staatz explains the need to know the musculoskeletal system and growth stages of children and adolescents and be able to classify them. 'Radiologists need to assess which changes during childhood and adolescence are normal and at what stage you are looking at something pathological. That's not always easy, because bones can look quite patchy due to haematopoietic marrow.' Frequently there are also benign changes to the bones, such as non-ossifying fibroma. 'These normally heal by adulthood and should not be considered as malignant bone tumours.' Images from infants and young children need a highly trained eye. 'When it comes to joint diagnostics, it is important that the radiologist knows where the centres of ossification are in children and adolescents, and how the joint cartilage develops.'

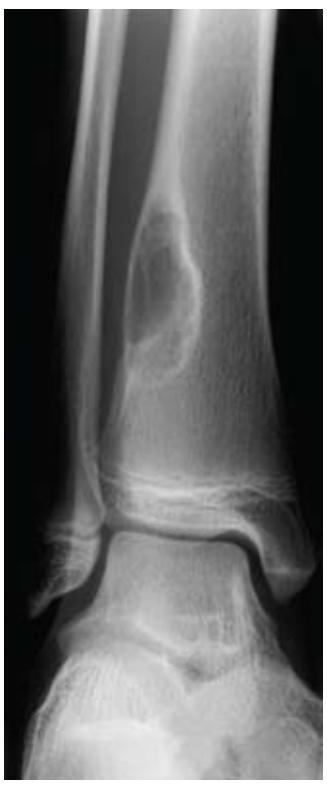


Fig 1: Non-ossifying fibroma in the distal tibia of the right lower thigh

Thoracic diagnostics

The focus of the RRC sessions is on thoracic diagnosis of infants and young children. Questions frequently facing radiologists, she says, include, 'How do I distinguish between bronchitis and bronchopneumonia? What do I need to look out for in children who show pneumonic changes, i.e. pneumonia, and how do I recognise complications?' Again, such examinations are all about recognising the specific features of childhood and deciding if and when further examinations with other imaging modalities are needed.

Other thoracic diagnostics subjects will include lung malformations, infectious diseases, tumours in childhood and the diagnosis of foreign body aspiration.

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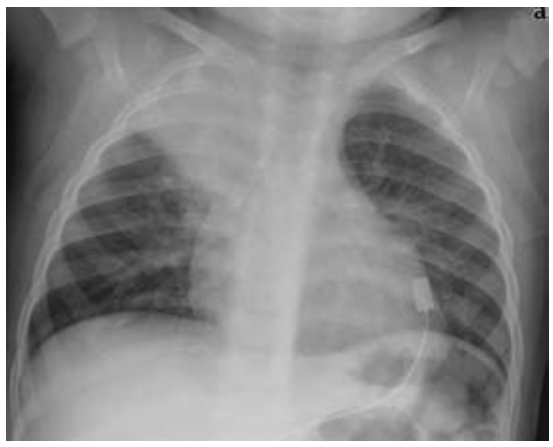


Fig. 2: Right upper lobe pneumonia in a 1.5-year-old child

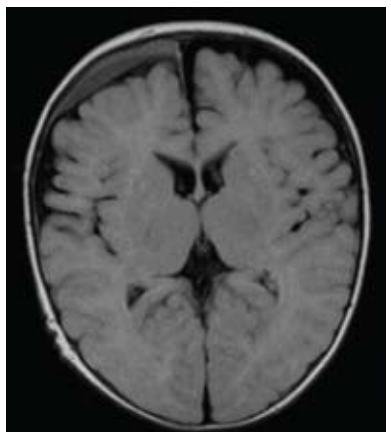


Fig. 3: MRI image of the CNS (FLAIR) in a case of shaken baby syndrome: Detection of a subdural hygroma in the right frontal area, with different signal intensity

Continued from page 19

Child abuse

This is one of the most difficult areas in which paediatric radiologists contribute their expertise: 'Professor Mentzel, from Jena, will introduce a current national study on this subject. It is about the important of second opinions in cases where there is a suspicion of child abuse,' Prof. Staatz explains.

In recent years, the rate of reported abuse has increased drastically. According to statistics of the Federal Criminal Police Office, she points out, in 1993 there were 800 cases among children under age six years; in 2008 there were almost 2,000. Experts also suspect a high number of unreported cases. Therefore, radiologists – particularly paediatric radiologists – need to know the specific indications of child abuse.

Among these, Prof. Staatz points to fractures of different ages, the presence of certain types of bone fragments or also injuries to several ribs, which can be interpreted as potential evidence in the same way as skull fractures above the brim line. 'Children can suffer injuries below the brim line if they fall whilst playing, but everything above the brim line points towards the presence of an external force.'

Shaken baby syndrome

Here is another important subject: The shaking of a baby leads to potentially life-threatening injuries, such as subdural bleeding and parenchymal brain injuries. Prof. Staatz: 'In these cases the objective is to determine how old the haematoma are and whether the description of what is supposed to have happened is plausible. In cases of very strong suspicion, other imaging procedures, such as MRI, should be used in addition to cranial ultrasound.'

The procedure in a case of child abuse is generally multidisciplinary, she points out. Mostly it is paediatricians who initially become suspicious and request further radiological examinations. 'As radiologists we then have to make our contribution to the decision as to whether or not the image fits with the description of how an accident is supposed to have occurred.' If the suspicion is substantiated, forensic medicine usually becomes involved. 'Examinations can also be legally requested via the child welfare office if the parents don't give their permission. In these cases the children are also admitted to hospital by way of protection.'

Contrast-enhanced ultrasound

The benefits for children

For the paediatric radiologist an ultrasound system is as essential as a wrench for the mechanic, for three reasons, says Professor Michel Claudon, Head of the Department of Radiology at the Children's Hospital of Brabois, University of Nancy, France: 'High image quality due to the low weight of children, which allows medium frequency, the absence of radiation and the possibility of performing an examination without sedation or anaesthesia due to real time imaging.' For *European Hospital* he outlined how children might benefit from the latest ultrasound advances, including contrast enhanced US

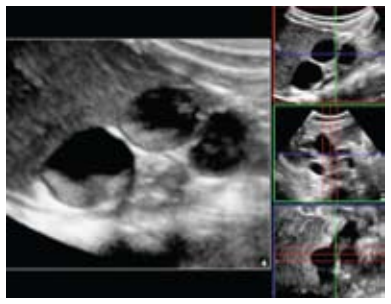


Figure 1: 3-D acquisition of a kidney in a newborn : cysts are clearly isolated, corresponding to a dysplastic kidney and not an hydronephrosis

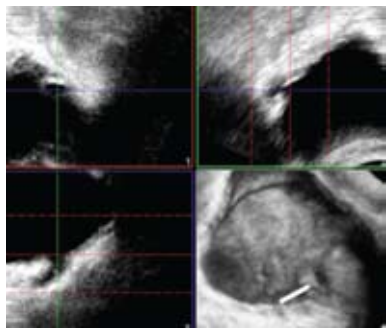


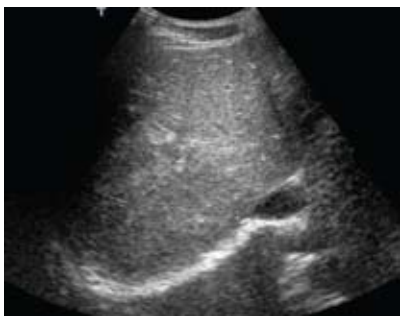
Figure 2: Ultrasound cystoscopy in a 2 year old boy with a duplex left kidney and a refluxing ureter: 2-D images show the lower ureter in different views but the 3-D cystoscopic approach much better demonstrates the pattern of the opened ureter

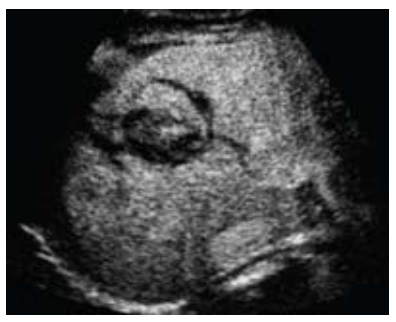
Are developments in ultrasound, such as 3-D, contrast agents or elastography, part of your daily work with small patients?

Professor Claudon: 'Elastography is not used that much in children. Firstly, we already have easy access to most of the organs. Secondly, tissue in children is often too soft to be characterised based on palpation. And finally, the most important purpose of elastography in adults, namely the characterisation of stiffness of the tissue to detect cancer, is more or less superfluous in children because tumours in young patients are often quite big and therefore easy to differentiate from the surrounding tissue.

'However, contrast-enhanced ultrasound is very useful in paediatrics. There are two major indications: The detection and follow-up staging of reflux between bladder and the upper urinary tract, which is quite common in children. Secondly, there are classical indications, such as spleen or liver trauma and the characterisation of focal liver lesions. In those cases contrast agents would be very helpful, but there is a dilemma: Sonovue, the only ultrasound contrast agent available today in Europe, is not approved for children. This means that physicians are forced to use it off-label, with the consent of the parents.'

Figure 3 A and B: Contrast-enhanced Ultrasound examination in a 15-year-old boy with a history of abdominal trauma: baseline image does not show major abnormalities, but after the IV administration of 2ml of Sonovue ® (Bracco), the fracture of the liver is clearly depicted





Are there efforts to find a solution and 'legalise' its use for children?

'Of course; several organisations are working on a solution. At the meeting of the International Society of Paediatric Radiology in London, last May, representatives from the European Society of Paediatric Radiology, the European Society of Uroradiology and the European and World Federations of Ultrasound in Medicine and Biology discussed the possibilities of beginning the approval procedure with the manufacturer of Sonovue (Bracco, Italy).

'There already are various clinical results regarding CEUS. On behalf of the European Society of Paediatric Radiology, Dr M Riccabona, from Austria, conducted a survey that indicated more than 4000 contrast-enhanced examinations were performed on children during recent years throughout Europe.

'These mainly concern reflux, but also intravascular indications. No adverse events were reported. This is good news and we think we should proceed with the approval process, although we know it will take time. The first step – putting the topic on the agenda – has been done and we now have to define how to get the European authorities on our side.'

What about volume imaging in ultrasound?

'Volume scanning has developed from a nice toy to a clinically valuable method. And, with the introduction of purely electronic probes (matrix technology) without mechanical motion it's becoming even better. The scanning time decreased from a few seconds to only fractions of a second. It is much more efficient and at the same time offers improved image quality. 'The issue that's now being debated is how we proceed from there. Do we just add volume acquisition to the 2-D image? This is possible and clinicians would benefit from this new method, for example by calculating the volume of an organ. Or, do we use 3-D as a complementary tool to 2-D examinations? The third alternative could be to acquire volume images and assess them afterwards, as we do with CT scans today.

'Of course this shift will change our workflow because we'll no longer see the result of the examination immediately. Volume scanning would mean examining the patient, reviewing the images and then making a diagnosis. This additional time would slow down the workflow but it would offer additional diagnostic options.

'In view of these developments I'm sure that 3-D will play an important role in ultrasound in general in the future – particularly in paediatric ultrasound.'

Documentation and certification

For years, interventional radiologists have voluntarily collected data for quality assurance purposes. Now specially developed documentation software paves the way to certification


Arno Bücker

The German Society for Interventional Radiology and Minimally Invasive Therapy (DeGIR) has been developing its nation-wide quality assurance programme since 1987. 'We launched this instrument very early and on a voluntary basis. Other medical associations have been forced to do so by law,' explains **Professor Arno Bücker**, Member of the Board at DeGIR and Director of the Clinic for Diagnostic and Interventional Radiology of the University Hospital of Saarland, Germany.

Today, the software that was specially developed for data collection and documentation purposes is a cornerstone of quality management and the certification process used by the interventional radiologists' professional association: Only those physicians who document interventions with this software will be certified.

The 'father' of quality assurance in interventional radiology is nuclear medicine specialist and radiologist **Professor Lothar Heuser**, senior consultant (Director) at the Institute for Diagnostic and Interventional Radiology, Neuro-Radiology and Nuclear Medicine in Knappschaftskrankenhaus, University Hospital Bochum, Germany. Prof. Heuser, who has been involved in the system's creation from day one, is today still the leading developer of the software.

Advances in information and communication technology have brought a major boost to data collection. 'In the first years, way back in the 1980s, we filled in paper forms. In 1994, we launched a standardised software package, but we still worked with diskettes. The real break-through happened in 2005, when we acquired a server where the data have been collected and processed ever since,' he explains.

The software records 31 different interventions in 131 regions of the body. The interventional radiologists collect data on the type and number of interventions, access routes and therapy paths, successful as well as negative outcomes and the materials used. In addition, they archive imaging, findings and lab data. 'There's one drawback, though: The data still have to be entered manually and they cannot be automatically culled from the other information systems in the hospital. This procedure needs staff resources within the facilities that participate in the programme – and prompts criticism as well as scepticism,' Prof. Bücker admits.

To increase the system's user-friendliness in everyday clinical work, a task force is in the process of reviewing the modules and reducing the complexity of data collection. 'We looked at every single module and parameter and really struggled hard to decide whether it should be retained or can be discarded,' Dr Bücker says. Example: the side of the body where the intervention took place. 'At first we thought that this is superfluous information, which can be omitted. Then it became clear that we need these data in order to recognise follow-up interventions.'

Today, Prof. Bücker says, the DeGIR uses the software in the certification procedure. 'Interventional radiologists, educational and professional training institutions, or central facilities such as vascular centres, participate in the quality assurance programme,' he says. 'Since our software is a quality assurance tool it's part of the certification process. The institutions can certainly use certification to illustrate their commitment to quality.'

It was definitely worthwhile to expand the quality assurance programme and to offer certification as an additional incentive. 'The number of users of our software has increased markedly,' he reports.

In 2010, more than 50,000 data sets were registered; about 70,000 are expected in the current year.

To date around 180 radiology departments, institutes or clinics participate in the DeGIR quality assurance programme.

3-D mammography


The Amulet

Utilising eye to brain characteristics

Films with vivid 3-D images draw millions to cinemas – regardless of the plot. This technology, which is based on a stereoscopic effect, is not only entertaining but also medically relevant, as demonstrated by the Amulet three-dimensional digital mammography system produced by Fujifilm. This technology also utilises particular characteristics of the human eye: the left and right perceiving the world from different angles. The two images coming together result in spatial representation – even if what is looked at is not three-dimensional.



Glasses on, Dirk Stoesser (right) and Cord Neitzke assess a 3-D image

'With the Amulet we produce images on two levels. However, we actually use a trick: after the first image is taken we immediately produce another one with the X-ray tube slanted by four degrees. Thanks to these second images we can produce three-dimensional images of the breast on the monitor,' explains **Dr Dirk Stoesser**, from the Joint Practice for Radiology, Neuroradiology and Nuclear Medicine in Duisburg-Dinslaken, Germany. Since the beginning of 2011, Dr Stoesser and his colleagues have been among the first to trial the prototype of this innovative technology.

'Real' volume images of the breast are based on studies of at least 15 images and a wealth of information that streams together into a 3-D image on the monitor – in so-called 3-D tomosynthesis. 'The biggest disadvantage of this approach is the high radiation dose required for imaging the volume. With the Fuji mammography equipment we generate this 3-D image with a dose of less than one millisievert,' adds practice partner Dr Cord Neitzke.

The first image is taken with a dose rate of 70%, with the second image – which is responsible for the 3-D effect – only generating 30%. 'Added together, the sum of the dose is about 10-15% lower than the national, average dose generated by a 2-D mammography image,' Dr Stoesser explains.

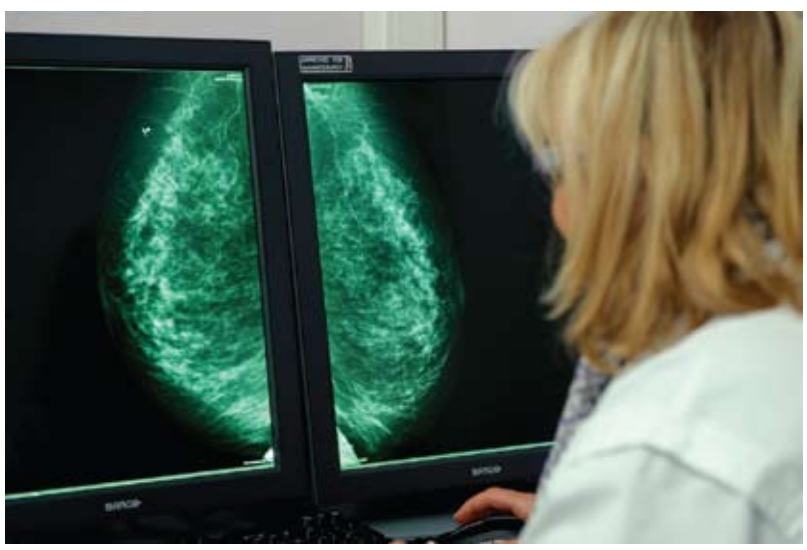
With the current model special glasses, with different polarisation of light for each eye, are needed to view the images. However, in future models, it is expected that 3-D could become visible without glasses. Opportunities for characterisation and quantification are also to be adapted, allowing depth and volume measurements alongside distance measurements.

'So far we have only been able to measure distance, but even this gives us an enormous diagnostic advantage compared to the 2-D view. In the case of dense breast tissue, the 2-D image makes it difficult to distinguish between a primary and a projection phenomenon. Moreover, the 3-D image makes it easier to see the outer limits of a primary growth,' says Dr Neitzke, who views this as confirmation of the added value of this procedure for his practice, because, 'Just as with every other new procedure there's the important question as to whether false-positive, but especially also false-negative results, can be reduced – and whether women will benefit from this. The recall rate must be lowered so that women do not become unnecessarily anxious.'

The assessments of 36 cases of breast cancer carried out by the Duisburg radiologists showed a statistically significant result, which confirms that the 3-D imaging procedure can help to reduce the rate of false-positive results significantly.

Both experts also see this development as a critical point for the mammography screening programme, the benefits of which, based on the latest studies, is now doubted. 'Although imaging procedures are excellent, it is only conventional mammography that's being covered by the programme. The budget does not even allow for an ultrasound scan. What this can lead to is something that we see here in curative mammography every day in the case of women who were screened half a year ago with no diagnosis, but who have now developed breast cancer,' says Dr Stoesser, who would like to see enhanced reimbursement of costs in the context of the screening programme.

Trivialising breast cancer kills women



'As we become more successful in the early detection and treatment of breast cancer, we tend to trivialise it. Yet one in 9 women still get breast cancer. Half of them become depressed, their partners don't know how to react and their families are in disarray. We need to stop trivialising breast cancer. It kills women.' So says Dr Fabienne Liebens, Head of the Saint-Pierre Hospital's Breast Clinic and among the world's leading experts on breast cancer and mammography

Gynaecologist and oncologist Dr Fabienne Liebens coordinates the Multidisciplinary Breast Clinic and Breast Screening Clinic ISALA, part of CHU Saint-Pierre hospital in Brussels. Passionately involved in saving women's lives, she assumes her societal responsibilities as vice-president of the Belgian section of Europa Donna, the independent European Breast Cancer Coalition, currently including 42 member countries.

With some 170 cases per year, the ISALA is one of Belgium's largest breast centres and a key referral clinic. 6,000 women are examined annually and some 13,000 breast examinations performed. Dr. Liebens: 'Our staff numbers 40, of which 80% are women including eight radiologists and seven breast clinicians. We also consult with gynaecologists, surgeons and GPs, and work with an oncology service in our building.'

Empathetic surroundings

The facilities are a striking antithesis of conventional hospital design. 'We didn't want women to feel they were coming to a hospital,' Dr Liebens explained. 'The reception area and waiting room are more like a lounge, which allows you to wait for your consultation in a relaxed way. The interior was designed by a female decorator who knows the clinic as a patient. People see no trace of mammography equipment or technology at the stand-alone clinic. All imaging, interventions and surgical procedures take place back at CHU Saint-Pierre.'

Occupying two active sites, the clinic needs strong quality control. With a keen focus on quality care, Dr Liebens pointed out that the breast nurse is a key to the concept, for she is a patient's personal guide throughout a treatment. For the patient, she facilitates immediate liaison between medical and clinical staff and is present during all medical consultations. 'We have one breast nurse, supported by four assistants who interact with other clinical disciplines,' Dr Liebens explained. 'The governmental plan stipulates one breast nurse for every 150 cases.'

Holistic guidance

'From a study of 1,000 patients leaving the surgical oncology department, 92% are satisfied with our care. Key to this satisfaction is that psychological support is not an option but rather a fully integrated component of all treatment,' she stressed. 'Few, if any patients refuse this – and we found that even six months after the surgical procedure, 65% considered the psychological support and counselling very useful. This proves the importance of our holistic view of the patient.

'The clinic's technology support of digital mammography systems, image enhancement software and associated products is 'well hidden', but it is of course key to our success,' Dr Liebens added. 'We need fast, productive solutions and immediate support in case of problems.

'Agfa HealthCare is committed to the fight against breast cancer. They provide reliable technology but also partner us in patient-focused programmes through support of a wide range of endeavours to increase breast health awareness among women and medical professionals. Agfa was a key supporter of our release of Marie Mandy's book '*Through the eyes of an Amazon*'. This remarkable publication conveyed in words and art the real-life experiences of Marie, a breast cancer survivor, that will give heart to women who must face this disease, its social and emotional ramifications, and treatment up to and including partial or radical mastectomy.'

Encouraging support for prevention research

Dr Liebens is highly concerned about the lack of focus on primary prevention efforts involving breast cancer. The disease incidence in developed countries is increasing, yet there is little institutional and industry focus on primary prevention. 'The knowledge women have on breast cancer prevention is astonishingly low. Surprisingly, the first Belgian research on this issue was done only last year. It showed 85% of women questioned have no knowledge whatsoever of risk factors for breast cancer.'

Video displays in the clinic's lounge provide prevention information and displays in a separate area convey results from prevention studies.

Closing in on DR image quality

Radiologist **Dr Martine Van Beveren** leads the team of seven mammography radiologists who diagnose images using two CR systems. They examine 45 women daily for clinical purposes, proactive screening or medical follow-up, producing some 13,000 studies annually.

'As a mammography radiologist, I'm particularly concerned about breast image quality and dose reduction. To make the patient as comfortable as possible I also prefer fast solutions, which significantly reduce waiting and examination times. Agfa HealthCare's DX-M Digital Mammography system, in combination with CR HM5.0 needle-based mammo detectors, considerably improves the performance of existing CR solutions. Our tests show its quality closes in on full direct radiography (DR) image quality with considerable dose reduction.'

Tomosynthesis proves advantageous in breast imaging

Two years ago Dr Michael Michell (below) and team at King's College Hospital, London, set out to explore the benefits of tomosynthesis over conventional 2-D mammography. Their study has shown advantages in diagnostic accuracy and indicates that tomosynthesis could help to reduce the number of patient recalls for further examination and thus anxiety among women

'We started evaluating tomosynthesis in January 2009 because we became aware of the technology and were fortunate enough to be provided a machine to do some evaluation by Hologic,' explained consultant radiologist Dr Michael Michell, Clinical Director of the King's College Hospital's Breast Screening Programme and National Training Centre. 'Our pilot study covered 750 patients who had routine screening but had been recalled because something abnormal was found on the mammogram. We wanted to study a population that had quite a large number of abnormal findings.'

The hospital's breast screening service covers 220,000 women aged 50-70- years in south-east London, carrying out routine mammography examinations on over 50,000 women per annum. The National Training Centre provides specialist training in all aspects of breast radiology for radiologists, radiographers and other professionals involved in the service.

The team's research has been positive, and has been reported at various meetings in Europe and North America over the past year or so. 'We found that there seemed to be an advantage in diagnostic accuracy to tomosynthesis compared to 2-D imaging, both in the ability of the radiologist to diagnose cancer and in their ability to diagnose either benign or normal findings,' Dr Michell said.

Tomosynthesis is not routinely used at this stage in the UK but is currently being used in his department for the diagnostic workup, along with ultrasound, biopsy and clinical examination. The team is now focusing on how tomosynthesis could be applied in screening practice.

According to Dr Michell, three clear questions need answers: Does tomosynthesis improve the ability of the reader to detect cancer? Does it have the ability to say something is either definitely normal or benign and not cancer? Are there clear cost benefits?

Currently, in the UK and elsewhere in Europe, all screening mammograms are read independently by two separate readers, which is very costly. 'So, if we could achieve the same sensitivity and ability to detect cancers with one reader, clearly that would be a cost saving.'

However, in terms of accuracy there could be clear benefits, particularly in reducing unnecessary anxiety to women. In the UK, following routine breast screening between 90,000 and 100,000 women are recalled each year for further tests and further workup because results are not clear, but the majority do not have cancer. Figures from 2007-08, for example, show that of the 78,900 women screened in England and then recalled for assessment, about 64,000 were found not to have cancer. In terms of their inevitable anxiety, 'If we could reduce that number,' he said, 'it would be a huge advantage.'

Tomosynthesis might provide better information about the tissues and benign lesions, he pointed out, adding that if the number of recalls of those without cancer could be reduced it would not only be good for the women but also healthcare costs. Once the benefits of tomosynthesis have been established, a closer focus on those costs and the overall cost of the technology could be made, for example, whether it takes longer to read tomosynthesis images or the 2-D images, or whether that cost is offset by having fewer readers and less assessment or diagnostic workup clinics.

'It's about balancing the funds you have and ensuring you use them most efficiently – a challenge for any healthcare programme in the world, particularly in Europe at the moment,' he added.

Tomosynthesis is a relatively new technology, and there are differences in the appearance of the 3-D images to the 2-D images. Dr Michell has established a training programme to enable radiologists to work safely and 'use the technique to advantage of patients'. The training package was developed from some of the 750 cases in the London study. 'We have extracted sets of interesting, difficult and subtle cases, which are useful for training,' he explained.

Those experiences have now been shared with radiologists in countries that include France, Switzerland, Italy, Holland, Belgium, Germany, Turkey, Israel and Spain.

CDB-Premium Studies the Effects of Tomosynthesis on Clinical Practice

Tomosynthesis Increases the Detection of Cancer

"The preliminary conclusion for our clinic is that tomosynthesis plays a very important role in detecting and characterizing lesions, especially in nodules and distortions," states Dr. Belfer. "In non-organized screenings tomosynthesis reduces additional views significantly. But, the most important conclusion is that tomosynthesis increases the detection of cancer."

I really believe in the technology and think that tomosynthesis is important for the evolution of mammographic technique," concludes Dr. Belfer. "We still have questions we need to answer about when to do 2D, 3D or combo-mode. I hope tomosynthesis will be the solution."

For the past year, Dr. Aron J. Belfer, a breast radiologist at CDB-Premium in Sao Paulo, Brazil, has been studying the benefits of breast tomosynthesis on outpatient diagnostic imaging in clinical practice. CDB-Premium is a private diagnostic imaging center with five locations throughout Sao Paulo. They perform 700,000 imaging procedures and more than 40,000 mammograms annually. Last year, CDB-Premium installed the Hologic Selenia® Dimensions® tomosynthesis system, becoming the first breast imaging facility in South America to implement the 3D breast imaging technology.

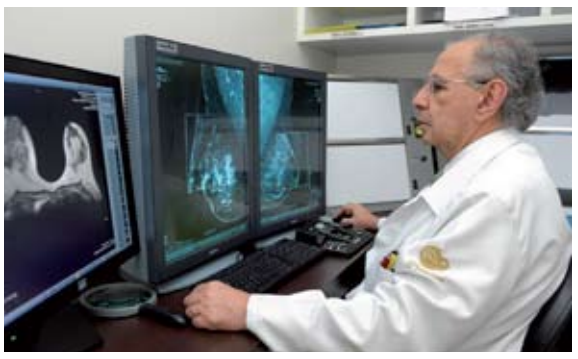
Dr. Belfer firmly believes new technologies will improve the detection of breast cancer. But, he wanted to gain a better understanding of how tomosynthesis would impact the clinic's daily routine. Specifically, what impact would tomosynthesis have on the clinic's ability to detect and characterize lesions? And, would it change the need for additional views?

Dr. Belfer's study was based on 818 patients referred to the clinic for mammograms. Each patient received a combination 2D and 3D exam in the same compression. Two radiologists, and in most cases four radiologists, examined each mammogram, following a very specific workflow. First they analyzed the 2D images and determined if more views were necessary. Then, they evaluated the tomosynthesis images. Based on the combined analysis, Dr. Belfer and his team again evaluated the need for additional views. For the final analysis, the team reviewed the 2D and 3D images together. They evaluated the technology based on lesions visible only on 2D, and lesions visible only with tomosynthesis. Additional evaluation criteria included, extension, characterization, and localization.

Throughout the study, the impact of tomosynthesis on the detection and characterization of lesions was readily apparent. Dr. Belfer describes the case of one patient who was scheduled for a routine mammogram. "Everything appeared normal on the 2D view. But, on one of the slices of the tomosynthesis with optical magnification, we could see clearly one spiculated lesion and possibly a second lesion. When we looked at the craniocaudal (CC) view of the same area, we could see the lesion very, very clearly. We performed a biopsy using ultrasound and found this was a small, invasive ductal carcinoma with two centers."

Increased Detection for BI-RADS 2 and 3

According to Dr. Belfer, the most important reason radiologists can see better on tomosynthesis images is characterization. "We found that you can see BI-RADS 2 and BI-RADS 3 lesions much better with tomosynthesis than with 2D imaging. Of the 465 findings during our study, we saw 26 malignant lesions on 2D imaging, but saw an additional 32 lesions that were visible only on the tomosynthesis images - three of which were malignant. That means that we had an increase of 12% in detection of cancer on lesions seen only on tomosynthesis on this



population. I think this is a very important contribution from tomosynthesis."

"Additionally, in about 40% of the cases, lesions visible on 2D were clarified on the tomosynthesis images, which suggests that we can really reduce additional images – not only spot compression but all the other views that you can image," continues Dr. Belfer.

The study also provided valuable insight into the issue of whether one or two views needed. "Seven percent of the lesions we saw were visible only on craniocaudal (CC) and 7% were seen only on mediolateral oblique (MLO) in the diagnostic setting. Because a significant number of lesions were seen only on one view, we recommend two-view acquisition of tomosynthesis. And a better characterization of normal," continues Dr. Belfer, "is something very, very important, because this has been a big problem in the past."

A Smooth Transition

Over the course of the year, CDB-Premium found tomosynthesis does not change the workflow for the patient or the technologist. "Everything is done in the same compression. The positioning, everything is the same. That's important because teaching new workflows would cost us a lot of time," explains Dr. Belfer.

"The learning curve for radiologists is a little different than we thought," adds the doctor. "Finding the reading protocol that worked for us took some time. But, we solved it and the whole exam from beginning to the end, 2D plus 3D, plus previous exams, everything, now takes about two minutes per study. Of course, now we have 200 images instead of four. But, the clear images give us much more confidence and this results in less stress."

The views and opinions expressed in this article are Dr. Belfer's alone and do not necessarily reflect those of Hologic. The article is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, email: womenshealth@hologic.com

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Breast screening administration

Denmark's web-based portal


Ilse Vejborg

The daily management of around 700 examinations within the national mammography screening programme keeps **Dr Ilse Vejborg** and her team at Rigshospitalet pretty busy. 'We have the largest screening unit in Denmark with 200,000 women aged 50-69 years in the target group invited for an examination every second year,' she explains. 'The exams take place in five units but are centrally managed in one programme with one secretariat sending out the invitations and scheduling the appointments.' Dr Vejborg heads the Mammography Screening Programme in the Capital Region of Denmark. Of the country's five regional health authorities, the Capital Region is one of three that use the Carestream RIS mammography module – the basis for a web-based patient portal that improves the administration of screening appointments

The RIS enables accurate documentation and reporting of all radiological findings. A set of graphics tools captures patient medical and mammography histories, mammography findings, pathology results, follow-up, patient tracking, and includes an automated radiologist report. The detailed capture screen for patient concerns and procedure information includes a drawing tool that allows technologists to convey visual information to the radiologist, which works alongside a single PACS.

The Capital Region has five fixed screening sites, at Bispebjerg, Bomholms, Herlev, Hvidovre and Nordsjaellands Hospitals. Double-blind readings are performed at the two university hospitals, Herlev Hospitel and Rigshospitalet where also recall examinations and surgery take place.

'The evaluations are forwarded electronically via the RIS to the secretariat that is sending out the answering letters as will as invitation, recall and reminder letters' Dr Vejborg adds. Before the web-based patient portal was launched, women had to phone the hospital between 8.00 am and 3.00 pm to re-schedule appointments for screening and recall examinations, creating considerable organisational work for the secretary. Dr Vejborg also adds that many women found it difficult to make appointments by phone when at work. 'The additional administrative burden for the hospital – writing to non-attendees, re-booking and dealing with cancellations – also called for a system that would better suit patients' needs and save valuable hospital resources.'

Another reason to implement the patient portal was that the three Carestream RIS regions were seeking solutions to improve attendance rates. In collaboration with the three regions the company developed the unique portal, which soon became the most visited healthcare website in the region.

The core feature of the portal is a unique password that enables women to enter their personal account and change data. This password is sent together with the invitation, a questionnaire, a leaflet and an explanation how to access the website. Once the women have entered the portal they can navigate through a simple, intuitive process to modify their appointment time, day or location as often as they want for up to three months. At the same time the portal seamlessly communicates with the hospital RIS to facilitate the booking. All actions are summarised and displayed so that the details can be printed. 'For us the comment function is very interesting because we receive feedback from the women, such as why they decide against screening, which is very valuable information', she adds. (Of course, data security is protected; the entire portal works with a secure line.) Today we see an attendance rate around 75 percent. We have not yet seen any significant change in attendance rate after introduction of the web portal.

Currently, Carestream and Rigshospitalet are developing an online patient questionnaire to be filled in by women rather than the radiographers – another step that should further improve service quality, screening administration and workflow efficiency.

Breast screening in the UK

Expert warns that breast screening across the country needs to undergo a dramatic transformation over the next 15 years, *Mark Nicholls* reports


Andy Evans

Radiologist Andy Evans, Professor of Breast Screening at Dundee University in Scotland, believes the emphasis needs to shift from screening all women of a certain age to a targeted screening programme that meets the needs of individuals. That shift, he said, will help to better identify women of high and moderate risk, target resources and be a more cost effective approach at a time when the NHS is under severe financial pressure.

Professor Evans, from the Medical Research Institute at Ninewells Hospital and Medical School in Dundee, said that the approach will help reduce breast cancer mortality among women, lead to less anxiety and unnecessary screenings and ensure women are screened when they need to be. 'In the UK,' he pointed out, 'the amount of money we have to spend on screening is not going to increase vastly, so I think we need to focus our resources on screening the women who are at increased risk. At the moment the only criteria we use for the majority of screening is sex and age.'

The key to a more focussed breast screening approach is to develop a strategy for women from the data emerging from various sources that are considering an array of risk factors. These include volumetric automated breast density assessments, which show that women with very dense breasts are at 4-5 times increased risk compared to women with very fatty breasts; assessing a woman's family history and their reproductive history; data on the texture of breast tissue; the number of low penetrant genes that have an effect on women's breast cancer risk, and evidence suggesting that MRI characteristics can also influence breast cancer risk.

Professor Evans, who is incoming chair of the Royal College of Radiologists' Breast Group, added: 'The real challenge for us is to put all these disparate risk factors together in an algorithm that allows us to stratify a woman's breast cancer risk accurately. From there, we should concentrate on frequent mammography and even MRI of women at high risk. Part of the strategy would also include identifying a group of women who may not need screening at all.'

With ongoing NHS funding pressures, he believes it will become increasingly important to focus resources on the women who are most likely to benefit. He acknowledges that the work to put the various risk factors together still needs to be conducted and wants to see funding for large-scale multi-disciplinary research into risk factors to formulate a screening strategy. Once that work is complete, the challenge will be to stratify women accurately and then institute it in a way that is politically and economically acceptable.

The professor is not comfortable with the current breast screening policy in the UK screening of all women aged 50-70 (currently being extended to 47-73 in England and Wales), plus those with high risk factors. He also remains concerned that the UK has the only breast screening programme in the world with a three-year screening interval rather than every two years. He believes that reducing the interval, rather than extending the age range, would have a greater impact on mortality.

'My vision is that women of a younger age would have a risk assessment performed that would probably involve family history, reproductive history, mammography and a blood test. From that, their risk will be extracted and they will be offered screening that is personalised to their risk. That may involve screening from age 40, or may involve no screening at all.'

However, he acknowledges that changing the screening ranges will not be universally popular.

In the shorter term, he believes it was important to move toward full integration of digital mammography in the UK and, while MRI is currently prohibitively expensive, this may change in the future. Automated whole breast ultrasound may also have a role to play, particularly for women with very dense breasts.

But a more targeted screening programme would have benefits for patients and health systems. 'Women of very low risk can be reassured they are unlikely to develop breast cancer and women of increased risk will have screening tailored to their individual risk,' he said. 'That should lead to a greater mortality benefit in the population as a whole. For hospitals and health systems, this is all about focusing our resources on those patients who are most likely to benefit.'

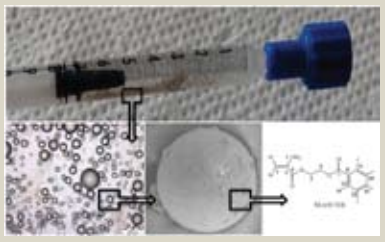
Moving towards personalised therapy

Multimodal visible embolisation particles

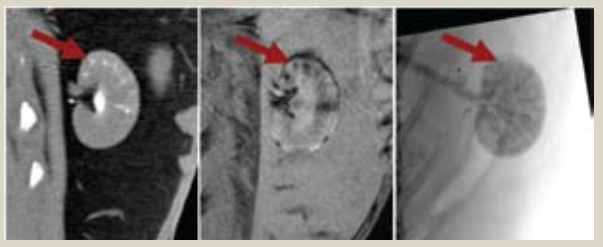
Authors: S H Bartling, J Budjan, M Sadick, H Aviv, S Margel, C Reis, S Diehl, from the Institute of Diagnostic Radiology and Nuclear Medicine, University Medical Centre, Mannheim, Germany; Department of Chemistry, Bar-Ilan university, Ramat-Gan, Israel and the Production and Process Automation Department, Fraunhofer Institute Manufacturing Engineering and Automation

Embolisation – the blocking of vessels - is a key procedure in Interventional Radiology. It plays a steadily growing role in the treatment of various tumour lesions, with hepatic cellular carcinoma and uterine fibroids the main focus.

Different embolisation materials have been developed over time, which vary in size and chemical composition. For TACE (trans-arterial chemo-embolisation) embolisation materials are combined with chemotherapeutics, which are slowly released into the target lesions.



1: Macroscopic picture of particles in a syringe ready for injection. Microscopic and electron microscopic images of the multimodal particles are shown along the chemical structure of the core polymer



2: Multimodal imaging of an animal tumour model (rabbit kidney) after embolisation. The particles can easily be detected in CT (left), MRI (middle) and X-ray fluoroscopy (right)

All currently clinically available embolisation particles share one feature: they are not visible in any imaging modality. Thus direct visibility of the material would provide several advantages, especially combined with 3-D imaging techniques that are increasingly available in modern catheter labs.

With direct visible embolisation, material misplacement of embolisation agents could be far better detected than today. Shunting or 'spillage' of particles may be recognised and prevented on the fly. Direct visibility would also allow the clear positioning of embolisation materials within the tumour tissue - tumour regrowth could be correlated to embolised areas. All this might open up new opportunities to refine embolisation therapy and to develop personalised therapy concepts, which are not possible today.

In the past, within basic research, embolisation particles were described that were visible within one imaging modality (X-ray or MRI). We out-performed these developments and synthesised the first embolisation particles, which are visible within more than one imaging modality. They can be visualised in X-ray based fluoroscopy and computed tomography (CT) and detected in radiation free magnetic resonance imaging (MRI).

The interventionalist would therefore be in a comfortable position to change imaging modalities intra-procedurally, without losing the ability to visualise the particles. This could be of immense interest in the case of uterine fibroid embolisation, where radiation dosage is critical. Here, in a multimodal setup, catheter placement could be performed within the angiographic setup, while the most radiation to sensitive organs is caused by the embolisation process, which could then be performed in the MRI site.

Using different imaging modalities is also of interest regarding follow up examinations, which can be done in MRI while the embolisation process itself can take place in conventional X-ray based angiography. This would significantly increase the acceptance of long-term follow-up studies. Follow-up examinations could provide new insight and help to understand and improve embolisation therapy with the long term of new personalised approaches to embolisation therapy.

Embolisation particles consist of a polymerised iodine core with USPIO (Ultrasmall paramagnetic iron oxide particles) on the outside. Both substances are approved and in daily use in clinical practice with a good long-term safety profile. Thus, the design of our particles will hopefully increase acceptance among physicians and patients and might decrease approval hurdles.

They can be created in various sizes (40-200 µm) and could easily be combined with different therapeutics (Image 1). However, research to define exact loading capabilities is currently in progress. Early animal experiments were successful (Image 2).

A standardised and flexible production process will be implemented by Fraunhofer IPA in the Reis group. The particles will be produced in standard quality and defined bandwidths of particle size.

The particle production will be set up in a way that GMP compliance is followed. IP was secured and the transition to clinical practice has begun with commercial partners.

MIR 2011

It was not the sunshine of the Cote d'Azur in September that lured radiologists to picturesque Nice. Far more enticing was the stimulating programme offered by the Annual Scientific Meeting of Management in Radiology (MIR), which, for the first time, also included a Junior Radiologists Course. In discussion with *Daniela Zimmermann* (EH), Professor Peter Mildenberger (above), President of MIR and Associate Professor of Radiology at the Clinic and Policlinic for Diagnostic and Interventional Radiology at the University Hospital Mainz, Germany, outlined the management, hospital and IT challenges faced by radiologists today – and tomorrow

Professor Mildenberger was palpably delighted – attendance numbers were high, presentations excellent, and session discussions exciting throughout the event. 'Reporting standards were a particularly hot issue in Nice,' he pointed out. 'It's increasingly acknowledged that successful diagnostics requires structured reports. Radiologists must precisely understand the clinical issues the referring physicians want answered and in their assessments and recommendations they have to address these issues in order to create clinical value for the referring physicians. Since this is obviously a weakness, we still see in radiology certain questions were widely debated – How should the report be structured? How should the communication process function? What does the referring physician expect from the radiologist? How can the findings be integrated into IT? In the USA, a standardised report template has been developed and, in Europe, the European Society of Radiology (ESR) issued a position paper on the quality of reports.'

The 'Controversies in Ultrasound' session was quite explosive. Asked who should be performing ultrasound examinations, he pointed to the different approaches in different countries. 'It's very clear in southern Europe: the radiologist performs ultrasound exams. In the UK, due to a shortage of radiologists, 80-90% of exams are not performed by radiologists but by radiographers, specifically trained technicians who also do the reporting but can ask radiologists for support. We set up the session as a debate – pro UK and contra Italy. The issue, I'm sure, will continue to be with us at the next MIR, when Professor Dr Lorenzo Derchi, Chairman of the Radiology Department at the University of Genoa Hospital, and one of the ultrasound specialists at ESR, will be the official event organiser.'

On the subject of radiology data management in the future, the professor believes hospitals will still have different information systems: those that primarily manage text-based data, such as RIS, and those managing image data – PACS. 'There is an increasing demand for communication either between internal departments or between different hospitals and doctors' offices. We need new ideas on how to meet this demand safely and efficiently. At the congress, Dr Neelam Dugar, Consultant Radiologist a the Doncaster Royal Infirmary in the UK, clearly said that the Royal College of Radiologists' Imaging Informatics Group will be moving towards IHE XDS. IHE – Integrating the Healthcare Enterprise – is dealing inter alia with the standardisation of IT infrastructures. XDS – Cross-Enterprise Document Sharing – is a core profile with different subsystems. XDS shows how a PACS can be integrated intelligently into the case record, the electronic patient record or personal health record. Many countries have already adopted this IHE structure and thus it makes sense for the UK also to do so.

'Germany, as so often, is doing its own thing. Since the IHE standard is not really accepted there, people are looking for their own solutions. In the absence of generally accepted structures, in 2003 the German Röntgen Society launched and standardised DICOM E-Mail to enable safe, encrypted and authenticated communication with the referring physicians via the internet. Data can be transferred via any e-mail administration programme.

'Our hospital in Mainz is linked to 14 other hospitals and doctor's offices using this protocol. The technology and service provider Visus goes even further and, with Fraunhofer Institut, offers a regional network service that basically works like a telephone directory. In Germany, this approach, which was presented at MIR, may be a useful option for the time being, because the general infrastructure is not developing quickly towards XDS.'

Radiologists in molecular imaging research

'In one of the sessions Professor Luis Marti-Bonmati, Head of the Radiology Department at Hospital Quirón in Valencia, Spain, showed that there is molecular imaging beyond PET. MR is looking for innovative options or opto-acoustic imaging trying to work with tracers. This is a very young research area with lots of potential. Limiting molecular imaging to nuclear medicine and PET does not do justice to this field.'

MIR 2012

Prof. Mildenberger believes that some hot issues in 2011 – such as reporting – will continue to be aired next year. 'Others will be new on the agenda or resurface, such as radiation exposure and examination management, error registries, leadership training and coaching of radiologists.'

MIR 2012 details: www.mir-online.org

All in one: Hybrid imaging with MR/PET

Although like a conventional MR scanner the unassuming exterior is misleading. The casing houses a powerful interior. This is the new Siemens *Biograph* mMR, a hybrid that contains a specially developed PET component fully protected against magnetic field interference. The first clinical installation of the MR/PET was completed in Munich last November. Five others have followed – four in Germany, one in Boston, Mass.

The technical evaluation of the system is taking place at the Department of MR Imaging at the Institute of Medical Physics at Friedrich-Alexander University Erlangen-Nuremburg, supervised by physicist, engineer and head of the department Professor Harald Quick (above). Speaking with *European Hospital*, he outlined the expectations and challenges of the MR/PET technology.

In April 2010, the Siemens MR/PET equipment was installed at the Institute of Medical Physics (IMP) in Erlangen-Nuremburg, giving its team an early start for clinical studies to evaluate the method. 'We began with a group of 50 patients who underwent a standard PET-CT examination, followed by an MR/PET scan,' explained Professor Harald Quick. 'The participants were exposed to neither increased radiation nor increased dose. Since the radio tracer was injected only once, the activity was slightly reduced by the time the participants were ready to undergo the MR/PET scan, but we compensated this fact by simply doubling the PET examination time.

'The device can obtain PET and MR images simultaneously rather than subsequently which significantly reduces examination times. PET data are acquired in the background. We aimed at performing a whole body scan with all sequences, from head to knees, in 30 minutes. Certainly specific localised examinations can be performed more quickly, or they can be added to the whole body protocol.

Evaluation questions

'We looked at very different aspects,' the professor points out. 'Do we see the same as in PET or do we see more, or less? Are the MR and PET data fused correctly?

'We therefore performed many technical experiments prior to the actual study. For example, we tested the method first with phantoms whose structures were known. But the crucial question was obviously whether the method as such works. For me, as a physicist and engineer, it was particularly interesting to see how well PET fares in the "physically hostile" MR environment. Can it provide results that are comparable to PET-CT without deviations or disturbances? Thus far we can tell that the integration of MR and PET components was successful.

The team is now in the process of analysing the data. 'We focused our research on oncological issues. Possibly soft tissue tumours or metastases can be visualised much better in MR/PET than in PET-CT. This would mean that we can reliably detect lesions in organs such as the liver or brain, but also in high contrast bones, which do not show significant soft tissue contrast in PET-CT imaging.

'Moreover MR/PET offers the ability to monitor breathing and heartbeat during the scan. Currently, we are trying to implement motion corrections in PET using MR data. They will allow us to visualise lesions precisely. We could also determine the exact quantity of tracer that accumulates in the lesion, which we cannot do if the lesion moves during the scan – and we cannot do this in PET-CT because we must not expose the patient to longer CT radiation only to detect motion patterns.

Acquisition

'Since every patient has an individual breathing pattern which changes during the examination, we will register this pattern in real-time or with a breathing belt. This information can be recorded at any time, let's say within a time span of three minutes. Later on, we reconstruct the three-dimensional PET data that were thus acquired. Consequently, we do not have a static image but a dynamic one, which allows us to observe the lesion's motion during breathing. That requires enormous computing power. We already have the necessary data and it's now the task of the developers to fine-tune the application.

Will MR/PET replace PET/CT in the long run? 'No, PET-CT is here to stay,' he believes 'Above all in the beginning, factors such as speed, availability and costs will play a major role. Since MR/PET is a time and cost intensive modality, patient selection should be done very carefully and only those patients who benefit most from MT/PET should be scanned. Furthermore, for thorax and lungs we'll continue to need PET-CT to visualise small lung cancer tumours and lesions. Not to forget that PET-CT can be used for patients who currently cannot undergo an MR/PET examination, for example those who have a pacer implant. Nonetheless, MR/PET will surely become a fixture as an additional diagnostic imaging modality in oncology, cardiology and neurology. In research it is already established.'

Details: www.imp.uni-erlangen.de/mri

Cloud computing

Assessing the role of providers today and tomorrow

DEUTSCHE MESSE HANNOVER

Walter F Schäfer explained in EH-2-11 that the term cloud computing designates a novel technological approach whereby the user no longer purchases and maintains physical IT infrastructures and applications but accesses server capacities, software solutions and entire system environments via the internet, deciding which services he needs at that particular time. Here he examines how this on the spot usage impacts on the providers

The consistent application of cloud computing may have a significant impact on the providers' future product portfolios: What hardware will be needed if the server can buy computing power on demand from the internet? Which influences will act upon products and services in the IT infrastructures? What are the strategic impacts on pricing?

The established providers – e.g. HP, IBM, SAP, Siemens or Sun – take cloud computing very seriously and have already designed a wide range of services. Meanwhile other vendors, such as Apple, Amazon, Google and Microsoft, to name but a few, are also chomping at the bit. While the odds-on favourites are jockeying for position in the race for the Cloud Computing Gold Cup, some long shots – lesser known or even upstart companies – hope for an upset victory.

A look at some of the issues surrounding cloud computing provides valuable insights in possible racing strategies.

The service offering

For a few years the number of providers who offer a broad range of IT services via the internet has been increasing. To begin with, the focus was on maintenance and operation of application software. The term 'Software as a service' (SaaS) describes this aspect of cloud computing, which gives the user a high degree of demand-based flexibility.

The logical next step was to offer web-based infrastructure resources, such as computing power, storage space and networks: Infrastructure as a service (IaaS). This concept enables the user to implement and use individual application software.

The third development was 'Platform as a service' (PaaS), encompassing platform solutions, for example, for development purposes. Thus PaaS is an interesting option for companies with their own development team.

SaaS, IaaS and PaaS build upon and complement each other in a logical way and are therefore favoured by cloud computing providers.

The users' response

From the user perspective, cloud computing is still in an early stage, particularly in healthcare. Nevertheless, the technology requires attention since it touches upon questions surrounding medium- and long-term IT investments. Any assessment of the solutions offered by the different providers should take into consideration the following aspects:

• Positioning of the current provider(s)

How do your current providers position themselves with regard to cloud computing? Do they have reference customers for SaaS/IaaS/PaaS? What is their strategy regarding sensitive issues, such as data security, data access or data exchange in cloud computing? Did they modify their pricing structures for cloud computing services?

• Economic considerations

Can the cloud computing services by the different providers be compared with regard to profitability? How can the hospital's need and suitability for cloud computing be assessed? Which economic benefits can be realised in which time-frame?

• Market considerations

What do the competitors of the providers have to offer? What do the market players in the immediate environment think about cloud computing? Are there initial experiences? Are co-operations or joint activities based on these experiences conceivable?

• Internal resources

Are sufficient data available to make financial comparisons between cloud and conventional computing? Which team member can regularly survey the market and collect pertinent data on cloud computing? Should a task force be established?

Recognising the need for

They are cost effective, easy to transport and increasingly popular for complex clinical interventions

Ziehm Imaging's C-arm is a general X-ray unit. 'It's what hospitals really need, because it's a mobile unit that can be moved to the OR, out of the OR, to the trauma room, A & E, or wherever needed - it's r. Ziehm Imaging, he emphasises, has just one focus: the development and production of C-arms. 'It's what sets us apart. Our customers really appreciate the fact that C-arms are our business; we make no compromises; we have to do it right. We don't combine; we don't share resources to do something totally different.'

Today, Ziehm Imaging's C-arms are used in orthopaedics, pain management, interventional radiology, vascular operations and more. *Daniela Zimmermann* met with him to discuss the firm's current products and future prospects

In 2007, Ziehm Imaging began its move into the flat-panel market, because 'It's the higher, better technology,' explains Timo Ihamäki. 'You can store images even with image intensifiers, but they are big, bulky and there's no foreseeable major development anymore. Flat-panel technology is evolving. It offers a better image because there's a higher dynamic range, meaning you can see bone but, in the same image, you can still see the soft tissue – with image intensifiers this may be difficult. It's smaller, so it's easier to position. It makes the procedure simpler. Image intensifiers detect the earth's magnetic field for example, and there's always distortion. A little bit, not much, but it's there.

'Also, if your image is square it's never a perfect square. It's not a huge amount of distortion, but it's there. With flat-panels you don't have to care about those things. Image intensifiers also have a lifetime, you sort of burn through them and then have to switch them – and that's expensive. With flat-panels there's no known process that, just by exposing them with a lot of patients, can destroy them. However, it's still relatively young technology, so there's no long term experience as there is with image intensifiers.'

Ziehm Imaging's competitors in the C-arm market include GE, Siemens, Philips, Shimadzu and Hitachi, depending, he points out, on the country, the application and the procedure. 'We're talking about low end or high end. If we talk about the low end, in Asia you have all the Chinese and Italian manufacturers – and there are many.'

Flat-panel technology offers many advantages, he says, although still more expensive than image intensifiers, but the price gap, he points out, is shrinking.

Whether in private or public hospitals, the main users of the Ziehm Imaging equipment are surgeons and radiologists, which interestingly depends on the healthcare systems in their countries. Timo Ihamäki's sales responsibility lies in Northern Europe – Scandinavia, Benelux countries, UK, Ireland. He explains that, for example in the Netherlands, all the firm's C-arms are sold to radiology departments. 'They own the equipment; they control it. But, in Norway, it's the surgeons. If they want something, they buy it. My dealer there says he doesn't even remember the last time he spoke to a radiologist. The surgeons call the shots. However, in Sweden it's mixed.'

Radiation levels are inevitably a factor. 'You have to follow the Alara principle – as low as reasonably achievable,' he points out. However, whilst in the Netherlands rules are strict, across the border in Belgium it is 'very liberal', he adds. 'Every surgeon has their own C-arm in the hallway, so Belgium is a good market for us – as well as Holland, but very different.'

To date, the company has four mobile C-arm models with flat-panel technology – including the new generation Vision RFD launched this year for hybrid theatres. Philips has one mobile C-arm. Siemens and GE have none. 'I'm sure all the companies are developing something, but we have more models and more experience.'

Since the firm's first unit was launched in 2007, Ziehm Imaging has banked valuable experience. 'You can develop one, make it work in the lab and bring it to the customer, but then how does it behave? Making hundreds work is a different story. We've now shipped about 300 units with flat-panels; 30% of our shipments are with flat-panels, so we're a clear market leader there, because we have the experience and have crossed the critical points. People are now asking for it.'

Presentations and trials for hospitals

Ziehm Imaging dealers can give a presentation of the mobile C-arm, and when a hospital shows interest a C-arm can be delivered, demonstrated and left for staff use for a week or two. 'That makes the C-arm business a little more complicated. You have to handle a lot of logistics. But customers want to work with the real equipment,' Timo Ihamäki explains. 'Then he shows the green light.'

Image guided radiation therapy

Stereotactic system raises treatment levels 20% at a Finnish hospital

Following the acquisition of an Elekta Axesse system, which provides 3-D image guidance technology for conventional and stereotactic radiation therapy techniques, Helsinki University Central Hospital (HUCH) in Finland reports that, after eight months its image guided radiation therapy (IGRT) of lung, brain, pelvis, head and neck tumours has increased by up to 30 patients daily.

The HUCH clinicians had been using a single IGRT system providing 2-D images, which they found to be not ideal for soft tissue imaging. **Mikko Tenhunen PhD**, chief physicist at HUCH explained: 'We wanted a modern treatment system capable of 3-D image guidance and delivery of complex radiation therapy techniques, such as VMAT. We also treat many small tumours, so sophisticated field shaping and patient positioning and immobilisation were critical.'

The team then selected the Elekta Axesse from submitted tenders. 'Especially for lung and pelvic tumours, 3-D cone beam CT beats a pair of orthogonal 2-D images in terms of image quality and ability to generate images using a low dose,' Dr Tenhunen said, adding that the chosen equipment has clearly shown the value of 3-D imaging over 2-D imaging, and increased the number of image guided treatments by around 20%.

In addition to 3-D image guided localisation at the time of treatment, the Axesse provides ultra-conformal beam shaping with Beam Modulator, the HexaPOD patient positioning system featuring six degrees (x, y, z, roll, pitch, yaw) of remote positional correction, non-invasive patient immobilisation and advanced treatment planning with Monaco.

Radiology in Poland

A constantly developing field

Based in the Miroslaw Mossakowski Medical Research Centre, at the Polish Academy of Sciences in Warsaw, Professor Jerzy Walecki (right) serves on the Academy's Scientific Committee. He also heads the Radiology Department at the Medical Centre of Postgraduate Education and is Editor-in-Chief of the *Polish Radiology Journal*. Recently, the professor was appointed as a National Radiology Consultant for the Polish Ministry of Health. In an interview with *Daniela Zimmermann*, Prof. Walecki explained the implications of that role and the state of radiology in Poland today

In his role as a National Radiology Consultant, Professor Jerzy Walecki explained that generally he performs 'advisory, consultative and supervisory tasks' concerning radiology for the Ministry of Health. 'Since I was given the honour of being a National Consultant, I've had to look at the same questions from other points of view. The range of duties is truly wide. I participate in the works of different committees, collective bodies appointed specially to realise a healthcare policy.

'I give my opinion on diagnostic procedures and supervise their agreement with up-to-date knowledge. It's also my duty to express opinions on the staff required to implement radiology tasks. I base my views on the experience of leading radiologists, as well as engineers and medical physicists.

'Radiology education, embracing seminars and courses, has always been of special interest to me. Now, participating in education activities is also my responsibility. I create opinions concerning the realisation of a post diploma as well as specialist training of doctors and representatives of other professions connected with health protection. My opinions relating to the merits of professional training - to which radiologists in Poland are obligated - are taken into consideration in the Ministry of Health.

'Clinical audits are one of the greatest challenges we face in hospitals nowadays. Only audit execution in accordance with the rules can guarantee the same high level to all radiology departments in the country. We should lean towards the optimisation of clinical audits treated as a constant process of outcome improvement in radiologists' activity – always understood as the work done in the interest of a patient.

'The state of radiology in Poland is comparable with that of other European countries. However, the number of radiology employees is not always sufficient. There are also current difficulties resulting from permanently growing expectations related to the field, which develops very quickly. Fortunately, in Poland the regulations concerning obligatory training for radiologists are constantly being improved; knowledge transmitted to doctors is supervised by radiology experts. Without systematic professional training of medical staff, radiology cannot function efficiently.'

In his advisory role, what does he wish to convey to the Health Minister? 'As a National Radiology Consultant I express my opinion on legal regulations

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mobile C-arms

One reason for this, he explains, is that: 'You can do the same things with the flat-panel, but more precisely because there's no distortion. In 3-D imaging, for example, if you use the image intensifier, distortion is always there and will always affect the end result – how much is arguable – but you have to keep it in mind. With the flat-panel that one major source of error is gone.'

Couldn't distortion be corrected by software, as with MRI? 'You could do it but it wouldn't be worth it. You bring some of the magnetic or paramagnetic next to it – that's another story again. It would be too complicated because MRI units are fixed.'

About a third of all C-arms sold by Ziehm Imaging are digital. 'It's growing more and more, especially now with our latest model, the Ziehm Imaging Vision RFD hybrid edition. It's like a hybrid operating theatre with different disciplines working together. Typically, you have a fixed system there, but what does hybrid theatre really mean? There are so many definitions for that buzzword, but basically it's about bringing different people and equipment together. That's what the RFD hybrid edition is targeted towards – it's meant to directly replace or compete with the fixed C-arms that you need in hybrid theatres, because it's powerful and you can do the same applications – and it's less expensive.'

Think about a hybrid room, he suggests. It has to be much larger than a standard operating theatre and thus presents more expense and more physical work for nurses to clean – an investment in itself for a hospital, he adds. 'In a hospital in Germany the nurses said they hated having to clean this room. It's big and the equipment is fixed there. With the mobile C-arm you can do the same thing in a smaller place and, if you don't need it, take it out. If it's wanted somewhere else, take it there and then you have your hybrid room there.'

The mobile C-arm is also automated for interventions. Using the Smart Vascular button, the first image and landmarks are obtained and a signal is transmitted to the injector system to inject the contrast media. A cine-loop is taken and, automatically, the DSA (Digital Subtraction Angiography).'

Recently, when a leading vascular surgeon saw this system, he said "I want that" because, Timo Ihamäki says, it can do the same things as a fixed system, in less space and with less money. 'When word got around that he's getting one, vascular surgeons at two other hospitals wanted it as well. A group of our customers are also really keen. Hospitals that know their fixed system is going to break down don't want to make the same investment, so they buy a mobile C-arm to do the same thing, for less money.

'The "big boys" have the same technology, but they also have the fixed system and maybe don't want to promote mobile C-arms. We don't have that problem; we're free to do it. We're dedicated. We are C-arms; that's what we eat and breathe. We have to do it right.'

That, is what Ziehm Imaging has done since 1972, he points out, adding that when the firm was bought by Instrumentarium in 1998-'99, the buyer had a C-arm called Omega C, which was ditched 'because Ziehm Imaging had a much better product'.

Later, GE bought Instrumentarium and Ziehm Imaging was sold. Today the firm is privately owned and independent and, he adds, 'We're really targeting the advanced applications. The customer who wanted the Ziehm Vision RFD hybrid edition, he only undertakes the difficult procedures in his internationally known hospital. If he says that a mobile C-arm can do the advanced applications, it's a clear sign we're on the right track. This is the way to go.'

relating to radiology. Some of them are still missing, for instance those concerning teleradiology.

'Otherwise, I think about a special programme for young and very young patients. We should provide easy access to MRI for a patient, just as to CT. Doctors should be given a real chance to choose between these two diagnostic imaging modalities in order to diminish X-ray exposure to children. The problem is that we have too few MRIs in paediatric hospitals in our country; we cannot freely choose.

'Generally, I feel responsible for pointing out the problems connected with the radiation protection of a patient. I want to make low-dose protocols really conspicuous. They should be put into practice and conscientiously used in everyday radiology workflow.'

Could his advisory role influence the future of radiology in Poland? 'As a National Consultant I participate in forecasting the needs in radiology and establishing new standards in diagnostic imaging.

'I would like to show concern for the young medical staff – young radiologists in particular. As a National Consultant, I feel responsible for creating really good conditions for the permanent improvement of young radiologists' abilities, as well as the development of their knowledge concerning diagnostic imaging.

'At the same time, I do my best to make young radiologists participate in all kinds of scientific activities and make them present the results of their research in scientific periodicals. As editor-in-chief of the *Polish Journal of Radiology* I want to give radiologists, as well as students, free access to the magazine. Thus the journal is available on the internet without a subscription.

'Of course there are also weak points. We still have too few radiologists in some areas of the country. Concerted efforts should be made to equalise the distribution of radiology staff.

'Nevertheless, I am optimistic about the future. Close interaction and cooperation between young radiologists and experienced radiology specialists – represented by remarkable organisations such as the Polish Medical Society of Radiology (founded in 1925) – ensure the constant development of radiology in Poland.'

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