EUROPEAN HOSPITAL

THE EUROPEAN FORUM FOR THOSE IN THE BUSINESS OF MAKING HEALTHCARE WORK

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Italy's healthcare reform

Italian healthcare is still hitting the headlines. Although Prime Minister Mario Monti announced plans for healthcare reform at the end of 2011 – effectively cutting healthcare spend by €2.5 billion, as well as increasing the retirement age – the on-going exposure of hospitals and emergency care failures is drawing huge attention and has even prompted investigations by state prosecutors. *Brigitte Dinkloh* reports

After two senators inspected Rome's Umberto I policlinic and discovered an Alzheimer's patient tied to a stretcher, Health Minister Renato Balduzzi has been sending inspectors to hospitals and the State Prosecutor opened investigations against the emergency units at San Camillo, Tor Vergata and Umberto I. At the beginning of March those investigations were expanded to cover the rescue services, parts of the local health authorities (Asl) and more hospital departments in the capital region.

The Italian healthcare system needs reform. This much is agreed among citizens venting their anger on internet forums about long waiting periods, over-filled hospitals, deficient hygiene, unfriendly staff – and politicians.

Therefore, one of the first reforms to which Prime Minister Mario Monti has committed heavily indebted Italy is also a healthcare reform in the emergency package '*Salva Italia*'.

The law, adopted in December— by both chambers of the Italian legislature — *inter alia* calls for closure of unprofitable hospitals, the introduction of a €10 per diem charge for each day of hospitalisation, limiting free access to regional healthcare centres, and the complete transfer of prescriptions costs to the patients. In 2012, the state intends to cut a total of €2.5 billion from the national healthcare fund that bears some 40% of the costs of the national healthcare budget. The healthcare reform is thus part of the emergency programme submitted to the European Commission by the Italian government.

However, most of the anger in Italy has been caused by the increase in the retirement age. As of 1 January 2012, this was raised for women to 62 years and men to 66. By 2018 it will be increased to 66 for women and 70 for men.

The rule by which Italian workers previously were allowed, under certain circumstances, to retire regardless of age after working 40 years, increased at the beginning of the year to at least 41 years for women and at least 42 years and one month for men. In subsequent years this minimum working life will be increased by one month per year. Whoever begins to collect retirement benefit before the retirement age will have benefits cut by 2% annually. At the same time the benefits increase by 2% annually for each additional year worked after retirement age has been reached.

Although life expectancy in Italy continues to increase, the Italian medical associations are very critical of the rise in the retirement age because, in contrast to other European countries, Italy still has no partial retirement rule. The increase in the retirement age means that even elderly physicians will have to serve and perform surgery, whereby e.g. the association of head physicians (Anaao Assomed) views this as a risk to patient safety.

The new retirement rule also does nothing to relieve youth unemployment, currently 31% in Italy. Unlike in industrial enterprises, hospital productivity cannot be raised when neither the number of permanent staff nor the number of beds can be increased.

In addition, the inflation adjustor for pensions exceeding €936 has been eliminated for 2012 and 2012. A minor consolation in future ought to be the supplementary pension payment from the national pension fund for employees of the regional health authorities (Fondo Perseo). However, this is likely to provide only minimal compensation for the cuts in the state pension.

Spain's deep crisis continues

Cuts in pharmaceuticals spending, doctors' jobs threats, A&E closures, non-payments to medical suppliers – can a new government save their country and its NHS by massive stringency and tax hikes? Our correspondent *Dr Eduardo de la Sota Guimón* reports

The Spanish National Health System (NHS) must ensure equal access to healthcare services for all citizens. The service is publicly funded and structured into two healthcare levels: primary and specialist. The NHS is decentralised, providing Autonomous Communities (ACs) with funds from general taxation to provide the same basic services, to which they may chose to add (non-NHS funded) techniques, technologies or procedures.

Public health expenditure in Spain (including long-term care) accounts for about 72% of Spain's total health expenditure. Healthcare accounts for 8.4% of the GDP – about the same figure as the Spain's global Budget Deficit for 2011 i.e. 8.5% of GDP. Public and private healthcare expenditure in Spain account for 6.0% and 2.4% of GDP, respectively.

The huge deficit in the country's Public Healthcare System, coupled with the current Spanish public deficit crisis has pushed the Ministry of Health to adopt spending cuts – and further cuts are expected. As said, Spain's healthcare system is decentralised and the Ministry of Health has very little room for margin other than cutting back on pharmaceuticals, so the adopted measures focused mainly on these – in agreement with the Autonomous Regions through the Inter-territorial Council on Healthcare.

Cuts already made:

Drug prices – With the massive use of generics, revision of certain drug discounts applied between pharmacists, pharmaceuticals and distributors, changes to the way drug prices are set and revised and with more than one revision per year now permitted. Certain ACs (e.g. Castilla La Mancha) stopped

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EH 2/12

New law raises concerns for Germany's out-patients


Josef Düllings


Johann-Magnus von Stackelberg


Thomas Kruse

Under a new health delivery Act only seriously ill in-patients will receive out-patient treatment at the same hospital. The rest will have to go to a new 'medical specialist service'. The new system can only cause problems say medical workers. Report: *Susanne Werner*

Germany's VStG (Healthcare Delivery Structure Act) will revise the delivery of out-patient specialist medical care at the interface between out- and in-patient sectors.

The new law stipulates that only seriously ill in-patients can continue out-patient care at the same hospital – a reform criticised by the country's hospital staff. 'The new provisions ought not to so limit the clinics that, after hospitalisation, patients may no longer take advantage of the hospital physician with whom they are familiar and have placed their trust,' warned Dr Josef Düllings, President of the VKD (Association of Hospital Directors in Germany). With the VDGH (Association of the Diagnostics), in March the VKD hosted a management seminar in Berlin entitled *The Future of Patient Care Delivery – Legal Challenges and Hospital Best Practice*), focusing on the revised §116b Social Security Code (SGB) V, which stipulates that previously supplied out-patient treatments at hospitals will be transformed into the 'out-patient medical specialist service' (ASV).

Applications for ASV work

Clinics and contract physicians wanting ASV work must apply to their respective state agency and, if no refusal is issued within two months, their work may commence.

Expertise must be demonstrated beyond that of a general specialist physician's qualifications. In addition, high standards of facility organisation, technology, architecture and hygiene must be met.

The hospital physicians and medical specialists in private practice are to be reimbursed by health insurers for this new service at the same rate, i.e. as an individual service at fixed prices without budget controls. The view is 'Whoever can, will be allowed'.

The rather non-bureaucratic access to the ASV aggravates health insurers. At the Berlin meeting Johann-Magnus von Stackelberg, chair of the GKV (umbrella association of the state health insurers' associations) demanded '…a coherent public policy solution that prevents unnecessary general increase in services'. Currently the legal provisions are so unclear that many interpretations are conceivable.

Indeed, there is still much needed clarification. The *G-BA* (Joint Federal Commission) has to issue appropriate directives for specific implementation by the end of 2012. The law provides that, in the first instance seriously-ill patients or whose illness has been particularly difficult, as well as those with rare illnesses and those needing highly specialised services, are to be taken up by the new delivery service and provided with hospital out-patient treatment.

Presumably the majority will be cancer patients. While the illness is comparatively easy to define, dealing with other requirements is more difficult: Is there such a thing as a mild form of cancer? If so, how can it be defined? Is it possible to estimate the scope of treatment for the various illnesses in advance?

Potential healthcare delivery gaps

German hospital directors expect that ultimately their institutions will be disadvantaged. While the hospitals will have to maintain many services, patient access to them will be restricted significantly and also will raise questions regarding remuneration.

Above all, representatives of highly specialised facilities, such as the Comprehensive Cancer Centre, view the legislation sceptically. Others fear that the new law will threaten the overall provision of medical care. Thomas Kruse, department head at the Kiel Municipal Hospital warned: 'In future, hospital out-patient services will have to limit themselves to a certain spectrum of illnesses. This can lead to gaps in healthcare delivery, especially in rural areas'

His feelings are also mixed over the cooperation between hospitals and contract physicians mandated by the law. In his experience such cooperation is difficult to establish because the relationship involves an unequal burden: 'Clinics have to consider the interests of the private specialist practitioners because they can channel the stream of patients by changing their referral practice and also hinder the hospitals' market entry.'

Dr Düllings sees the new provision as 'tightening the thumbscrews' on the hospitals. Ultimately, he believes, the out-patient sector is not even prepared for the specialist medical care delivery. 'Patients already experience long waiting periods for out-patient physician appointments. For that reason alone, the options for pre- and post-hospitalisation urgently need expansion.'

Spain's deep crisis continues

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paying pharmacists a few months ago, putting the situation in permanent conflict since 2011.

Co-payment – Already approved in Catalonia (the most advanced NHS region) consists of a €1 payment for each prescription (called 'moderator ticket'), to save the region €100 million annually. This co-payment will probably soon extend to other regions, although almost nobody 'dares' mention it. As published RTRS, medical suppliers have not been paid for about two years, and Catalonia doctors have been told to accept pay and bonus cuts for 1,500 medical residents or lose their jobs. In recent months, the Catalonia government also shut down some clinics and emergency units.

Last September, the residents staged marches through Catalan's capital, Barcelona, draped banners around hospitals and doctors' unions threatened to strike. However, many senior doctors are afraid to fuss and possibly lose jobs when one in five Spaniards are unemployed. 'All of this due to years of mismanagement by politicians! The money has run out,' said one doctor, who remains anonymous.

As in many developed countries, Spain has a growing aged population on state pensions, while smaller families fail to add funding. Unlike other countries with public healthcare, complaints about long waits to see doctors were rare, but some Catalonia patients must now wait and doctors warn of a decline in quality care.

Delayed payment, central buying, rationalised services

The time of delay varies from 45 days in Euskadi and Navarra (richest regions), up to 750 days in Andalucía and Castilla La Mancha. A centralised purchasing of products and services to providers is difficult to achieve, especially in a decentralised system, but will be implemented for sure. Ambulatory and surgery waiting lists are increasing rapidly, and certain services (ambulatory) are not provided over weekends. Emergency services are overloaded in many places.

Increase in financing

In parallel, the Ministry is expected to agree to a increasing public financing of the NHS by 1% from the current 5.7% to 6.7%, probably through fiscal revenue from tobacco and alcohol taxes, although it remains to be seen whether the Ministry of Economic Affairs will or can accept further spending hikes. In March 2012, the 'healthcare cent' was established by the Castilla León Region, north of Madrid; this is 5.6 cents in a euro per litre of petrol. Roche, the multinational pharmaceutical firm, says this region is more than 900 days behind in bill payments, raising fears in the area that Roche could start withholding drugs for some hospitals, as it did in very financially troubled Greece.

What can the new government do?

In November 2011, the conservative Popular Party, led by **Mariano Rajoy**, won a parliamentary majority in the elections. As recently pointed out in the New York Times, new Prime Minister Rajoy benefits from having a freshly elected, single-party majority behind him, which his current counterparts in Greece and Italy have lacked.

Spain is facing the risk of another recession and the magnitude of the euro debt crisis has made even supporters of the Popular Party question whether a centre-right government can deliver the swift turnaround that financial markets are demanding. On December 30, PM Rajoy announced an austerity package consisting of $7.8 billion in tax hikes and $11.5 billion in spending cuts, in an effort to close a budget deficit expected to reach 8.5% of the GDP in 2012 – 2.5 percentage points above the government's target. On March 15 the new PM decided to reach a 5.3% of GDP deficit by the

The 27th Annual EAU Congress

Urologists from 80 countries met in Paris to hone up on new urology techniques. *Jane MacDougall* reports

Around for almost 20 years, minimally invasive technologies such as laparoscopy and robot-assisted surgery are popular subjects – and aired again during the 27th EAU Congress held in February at the Palais des Congrès, Paris. Some experts, including Professor Clement-Claude Abbou, (Creteil, France) believe that robots have been developed without recourse to EBM (evidence-based medicine) and, to prevent surgeons becoming "the slave of any current or new robot" they need to be validated by medical professional groups in the same way as new drugs. During an EAU session, he also warned against creating unnecessarily high expectations in patients when describing results from robot-assisted surgery.

Nevertheless the da Vinci Si Surgical System booth attracted the crowds. Urologists keen to practise their operating technique used the *Skills Simulator* the 'immersive virtual environment created for the system. Designed to integrate with an existing Da Vinci console, this portable component covers a variety of exercises that enable evaluation of surgical performance over a range of skill categories needed for the correct utilisation of the Surgical System. These are relevant to surgeons of all disciplines.

Such a system allows residents to gain valuable practice time and experienced surgeons to warm-up and be completely familiar with the robot's console before performing an operation. As Dr Axel Bex (Amsterdam, NL) said during his presentation on combination therapy for high risk and metastatic renal cell carcinoma 'outcomes depend very much on the skills of the individual surgeon'.

Novelty in imaging is offered by the Lithoskop multifunctional lithotripter from Siemens, marketed with the promise 'discover the future of urology today'. Developed for virtually all urological applications, any urological operation can be carried out on this single system without patient repositioning, thereby combining optimising workflow with patient comfort. Ideal for treating kidney and upper ureteral stones, the system also provides excellent X-ray and endoscopy capacity and features state-of-the-art ultrasound with comprehensive 2-D and 3-D imaging capabilities. High imaging quality also decreases imaging time, thus minimising radiation exposure.

Imaging on a much smaller scale is provided by the CUBEscan hand-held Bladder Scanner a 3-D ultrasound device from Korea. The BioCon-700 measures urine volume in a patient's bladder, determines the bladder's outline and calculates bladder volume. A pre-scan function shows a live ultrasound image of a horizontal planar cross-section of the bladder helping to locate it and improve accuracy. Designed to diagnose urinary retention and evaluate many common urological conditions the device helps prevent unnecessary catheterisation and reduce urinary tract infections.

Carers may also use it to monitor and treat incontinence.

For prostate cancer the new Advanced Medical Diagnostics Prostate HistoScanning is an ultrasound-based tissue characterisation technique shown to detect clinically significant prostate cancer in several clinical trials. The application uses tissue characterisation algorithms to visualise and position the extent of differentiated tissue suspected to be malignant. Used in routine clinical screening, the system allows a complete examination of the prostate, giving high quality 3-D images that allow the localisation and volume of suspect tissue to be determined. Clinically validated by comparison with histology in patients undergoing radical prostatectomy, sensitivity and specificity have been shown to be greater than those of MRI. HistoScanning can help physicians with treatment selection, planning and in the follow-up of patients best served by active surveillance. New applications for breast, ovary and thyroid cancer are in development.

Details: www.intuitivesurgical.com; www.medical.siemens.com, www.mcubetach.co.kr; www.histoscanning.com

end of 2012, and 3% by the end of 2013. Clearly, the shortcut measures aim to be constant and aggressive.

In January 2012, in an attempt to solve the problem of regional debt, Spain's central government moved to shore up the finances of its 17 regional governments - some having trouble paying their bills - while taking steps to tighten control over their spending. Budget Minister Cristóbal Montoro said that the government would create a credit line and advance about $10 billion to the regions, money they were not scheduled to receive until later in the year.

The regions needed the cash to pay suppliers, many of them small businesses that had not been paid in months, even years. Education and healthcare have been particularly problematic because those costs have been growing. At the same time, some main sources of financing – taxes on real estate sales and building permit fees – have dried up with the collapse of the housing boom. For that reason, some regions may actually want the central government to take back some responsibilities, as was suggested in July by officials from the regions of Murcia, Valencia and Aragón. Nevertheless, the Basque Country (Euskadi) has claimed more autonomy. Decentralisation is beneficial for some systems and not so for others...

KIMES 2012

Notching up the superlatives

Korea's largest healthcare festival and the biggest in the fair's history confirmed the event's importance this February when the 28th Korean International Medical & Hospital Equipment Show (KIMES) proved to be an amazing show of medical technology.

This year's event had to be scheduled a month earlier than usual, due to the Nuclear Security Summit drawing representatives from 50 leading countries to Seoul in March. Nonetheless, 1,436 international and domestic medical manufacturers were at KIMES 2012, taking the exhibitor record higher than ever. Breakdown: 458 Korean firms and 978 foreign, including the USA: 121, Japan: 75, China and Germany: 77, Taiwan: 36, Italy: 18 and England: 14 companies.

About 30,000 advanced medical devices, hospital equipment and healthcare products were exhibited for around 60,000 visitors, including 2,000 foreign buyers from 70 countries.

Hosting the show, the Korea Medical Devices Industrial Cooperative Association and Korea Medical Devices Industry Association expected to make KRW1.4 trillion from domestic consultations and $470 million from export consultations.

During KIMES more than 60 medical equipment seminars were conducted, as well as a conference on hospital/clinic management and financial technology for medical personnel.

Korea's Alpinion Medical Systems

Pragmatic and happy to take a long deep breath all the way to the top

ILJIN, the shareholder of Alpinion Medical Systems, which began as a Korean die-casting and electrical business 44 years ago, is today an international high-tech company. Whilst still to the fore in the power transmission and distribution business, with products such as transformers, cables and switchgear, the company also produces raw materials such as synthetic industrial diamonds and copper foil for use in electronic equipment and batteries. 'If you open up a cell phone, you see a lot of foil. It's a basic material for electronics. We also make LED. Our product portfolio is highly diversified,' explained Jungsuk Huh, President and CEO of ILJIN Holdings. During an interview with *Daniela Zimmermann* (*EH*, which included Y C Hwan, CFO of Alpinion Medical Systems', one of ILJIN's 14 subsidiaries, the discussion turned to the firm's medical equipment manufacturing

Established in 2007, Alpinion produces ultrasound imaging systems for diagnosis and therapy, as well as advanced piezoelectric and single crystal transducers. The company's E-CUBE ultrasound series, for example, includes the E-CUBE 9, which debuted at MEDICA 2011. This handsome equipment, which won the Red Dot design award in that same year, features superior image quality with its own advanced transducer technologies, including the world's first 4-D single crystal transducer. Alpinion is also the only company in Korea to develop and commercialise HIFU (High Intensity Focused Ultrasound) systems, considered to be the 'future of ultrasound technology'.


Jungsuk Huh

'We decided to enter the medical device industry because there will be many opportunities in healthcare in the future,' Jungsuk Huh explained. 'For most of our businesses you need to take a long breath, which means you have to wait. When you start from the development stage, it takes a long time until a product is commercialised and accepted by customers. Our basic materials business has the same characteristic – it takes a very long breath. With a medical device, I know that we have to put in a lot of time until it is mature as a product and accepted by doctors.

'We have good electronics engineers. We can utilise these resources to develop an imaging device. That can be a synergy and may be our reason to enter and succeed in this business.

'I know I need a lot of patience. Twenty years ago, we invested in a biomaterials business in Boston, Massachusetts. We are still growing the company. It began from the development stage – by a very prominent doctor from Harvard Dental School. We met when he only had the idea of developing the biomaterial concept, which is used for the musculoskeletal (MSK) area.

'Why did we start this very hard medical device business? We first considered it in 2004. Korea is a country with few natural resources, except human ones. At that time, all the smartest students in the country were going to medical school and into engineering – especially electronics. Korea's economy is therefore driven basically by the IT-based business, above all manufacturing. Due to that resource, the medical industry itself, or the healthcare industry generally, could develop very quickly in Korea. In the world healthcare market, which totals about $350 billion, Korea has just one percent of the market share on the manufacturing side. We think Korea can increase its market share.'

Asked whether a further natural progression would be for the firm to take a leading role in the medical industry, Jungsuk Huh responded: 'That's our idea. Basically ILJIN grew into a technology-driven company. We are focused on engineering our technology, so that's a perfect match for this business. We are very good at long-harvesting business - it took 20 years to develop the Boston business, almost 15 to become successful in copper foil and in diamonds it took a long time to develop the product. So I think in the medical device business cash-back will take maybe 15 or 20 years. However, being technology-driven we can endure for a long time. That's a perfect match for ILJIN, and a perfect match for the Koreans. That's why we started Alpinion.

'M&A by big players and continuous shift-up of technology by overall manufacturers are a trend in the ultrasound market,' he added. However, ILJIN's leaders are far from fazed by any of these factors. 'We're enjoying this moment; we are now challenging and knocking on the market door. There might be hard times to face in the near future – this year and next– but I think that we can enjoy that.'

Indeed, ILJIN intends to invest more in healthcare and medical devices. It already includes the Boston enterprise and has invested in a specialist immunosuppressant pharmaceutical company in Canada. For now this is a small investment, he said though adding: 'We believe it will progress in the future. We will participate more if the program goes well – which we expect. We have some plans, but they're still secret.

The group's perspective is certainly forward looking. 'The five-year goal is that we will not be number one in Korea or Asia. If we acquire a lot of companies we can get bigger and have higher revenues easily, but getting the sales or growing bigger is not the point. We want to be the most valuable, most respected company in this business. That is our principle and philosophy. Acquiring or investing more is just one path we'll choose. This principle or philosophy cannot change.'

At this point, the discussion turned to the design and construction of Inchon International Airport, a national gateway for foreign visitors to Korea. 'The ceiling construction of the whole airport buildings is ILJIN's engineering', Jungsuk Huh said proudly. 'So is the airport power cable.'

'We started our business in electricity – power. The core attribute of the power business is reliability. Philips and GE – why have they been in the business for 100 years? They are reliable. ILJIN also has that reliability.'

So, in a way, ILJIN welcomes every visitor to Korea? 'Yes,' the CEO confirmed with a smile.

Samsung aims to join the world's leading medical devices firms by 2020

European Hospital was at KIMES 2012 to gain a deeper understanding of Asian and especially South Korean healthcare. There, our Executive Director _Daniela Zimmermann_ met with Jae-Moon Jo, team leader in medical equipment development and Senior Vice President of Samsung Electronics, to discuss the firm's plans for expansion in healthcare devices markets worldwide

What is Samsung's strategic vision for the firm's medical equipment business over the next decade? It will, said Jae-Moon Jo, build a new growth momentum for Samsung Electronics. The company expects its annual revenue to reach USD $400 billion by 2020 – and expects, in the healthcare sector to achieve US$10 billion revenue in that year. The firm's aim is to become one of the *Big Four* medical equipment companies. 'To achieve this goal, we will secure global competitiveness in X-ray and ultrasound businesses and expand to include other devices such as MRI,' he explained.

Will Samsung develop more medical technology and systems to round up its portfolio?

'In terms of ultrasound, Samsung has focused on OB/GYN and mid-range markets, but we will also roll out premium ultrasound, a POC device, and various applications within this year,' said Jae-Moon Jo. 'In the digital X-ray business, Samsung plans to expand its portfolio with product variants, along with new products launched on KIMES 2012.

'Samsung's in vitro diagnostics (IVD) will move on to immunoassay and a haematology analyser from clinical chemistry. Particularly, Samsung acquired Nexus in November 2011, a US company that has cardiac diagnostic solutions. Nexus will launch new products related to cardiac diagnostics and will enhance the competitiveness of Samsung's IVD business.'

Will Samsung invest in product development or buy other companies to complete its portfolio?

'Samsung Electronics will continue to invest in R&D. However, Samsung always wants to cooperate with companies, organisations, and universities that have competence, new ideas, and technologies,' Jae-Moon Jo pointed out. 'Following the acquisitions of Medison and Nexus, many companies around the world were interested in cooperation with and investment from Samsung, so we reviewed various business opportunities. We are always open to cooperation, if companies want to achieve synergy from Samsung Electronics' key strengths, including technologies accumulated in CE/IT and global platforms of manufactures and distributions.'


Jae-Moon Jo

The market is replete with strong competitors – Siemens, GE, Philips, Toshiba as well as China's newcomers. What is Samsung's strategy to compete?

'It's very simple. We'll focus on the unmet needs of our customers. To do so, Samsung will obtain differentiated products and technologies that allow doctors to diagnose quickly and accurately. We're also interested in patient safety, so reducing the X-ray dose will be our priority. We believe that Samsung has core competence in this area because the medical equipment sector is going through digitisation and convergence among several technologies. Additionally, Samsung is ready to explore various business opportunities to increase innovation. Samsung will take a more strategic approach in future cooperation and investment. Finally, we will leverage the solid business infrastructure of Samsung Electronics around the world.'

Entering Europe

'Although European economies experience low growth rate these days, the medical equipment market in Europe is the second largest in the world, so Europe is very important for our business. Therefore we'll enter the European market this year. Also, emerging markets, such as China and Latin America, are attractive for Samsung because the average growth rate of the medical device market is between 7% and 10% and because Samsung can contribute to the improvement of their healthcare system.

Do publishers play an important role in spreading Samsung's strategies?

'We believe publishers such as *European Hospital* play a vital role in heralding technological advancements in medicine, and it motivates health medical equipment firms to push the bar higher in technological innovation.

MALTA'S SAINT JAMES HOSPITAL GROUP

Embarking on any business enterprise is never a small feat, but when that business is healthcare the task becomes gargantuan – and even greater if opening a healthcare facility in a country where the economies of scale create immediate difficulties. There's also the problem of the main competitor being the free-of-charge public sector. Planning and forecasting budgets is thus tough, since private healthcare receives neither government tax rebates nor any other possible incentives. Against that backdrop, EH Correspondent *Moira Mizzi* reports on a brave entrepreneurial achievement

Today, general practitioner **Dr Joseph Muscat**, known as 'Josie' by patients and staff, can look fondly on his two hospitals, several hospital and community out-patient clinics, as well as a clinic Hungary and another in Libya. Known as *The Saint James Hospital Group*, this family run enterprise has been locally at the forefront in hospital and community care, providing the latest technology for every medical sector.

Brian Bondin has worked with the Group for 13 years, for the past three as General Manager of the main hospital in Sliema. Among all his daily challenges, he confesses that the most daunting is internal politics between staff members, especially those directly involved with patient care. The aim of the staff and Dr Joseph Muscat the Group's chairman is to place each patient in a holistic perspective whilst operating a multidisciplinary approach.

However, drawing together every professional, including top management, to adhere to hospital protocols, standards and guidelines is no day in the park – particularly since the staff includes full timers, part-timers and self employed workers, the majority of the latter being medical specialists.

Resistance to change, usually stemming from fear of the unknown, is humungous and among the limiting factors that work against progress. Evidence based practice, nowadays widely used abroad, is far from local implementation, perhaps mainly because the local Health Care Service does not have the necessary solid and comprehensive restructuring programme.

Setting up such a structure is among this young, enterprising general manager's top priorities; he believes only then can the hospital function with a degree of responsibility, reliability and accountability, qualities of tantamount importance in a sector catering for highly vulnerable people. However, although all the required guidelines and protocols have been drafted for some time, unfortunately implementation is proving difficult.

For the group to function well another two important factors need consideration, Brian Bondin believes. First, the group needs to cater for the needs of patients and medics using the hospital facilities and see them *both* as clients; a specialist using the Group's facilities needs to feel safe and confident that the apparatus he uses and the supporting staff are up to a professional standards; the patient believe this is the best service he can pay for and his rights will be safeguarded throughout. Secondly, more cohesiveness among the management hierarchy is warranted, thus avoiding communication breakdown and 'layering' in the Group's structure. He strongly believes in a lean management structure to avoid the high level of bureaucracy that ravages the public healthcare sector.

Staff shortage is another constant hurdle. Despite working conditions at the Group's facilities being better than in the public sector, many medics still find it difficult to leave Malta's public health service – because most public service employees fear leaving the service because it offers better security.

Months of bureaucracy

Any attempts at employing staff from EU and non-EU countries are met with months of bureaucracy resulting in unmet deadlines and stricken projects. The recent legislation obliging employers to allow both vacation and sick leave to casual workers did not help to alleviate this, not to mention the marked increase in the financial burden created.

Despite this slippery and difficult grounding, Saint James Hospital Group can pride itself with innovative improvements in management systems and cost reduction strategies. The Medical Advisory Committee, which monitors the performance of medical staff and assists management to take certain business decisions, is one such measure. The recently revamped Purchasing Department uses a tendering system to ensure the best price for the best product is clinched involving all parties before any specific medical equipment is purchased, thus curbing on wastage.

The Biomedical Engineering Department, a brain child of the new management, is an in-house department that maintains all medical equipment, conducts all preventive maintenance, incorporates schemes aimed at training staff to make the best use of equipment and supports entities such as the University of Malta in offering sponsorships for its interns to train on medical equipment. Mentoring facilities from the hospital are also offered to the Faculty of Nursing and the European Society of Physiotherapists.

An in-house barcoding system of all entities within the group, including the patients, is also being set up to induce further accountability, traceability and cost-effectiveness within the enterprise.

One new challenge for the Group is to make the best use of IT. The group is now looking into setting up a more functional information system of electronic records and to integrate IT more into its equipment.

Brian Bondin asserts that the future of private healthcare hinges on a serious national discussion (forum) between all parties involved to focus on the following top priorities:

An in-depth study followed by a national strategy, incorporating all the key players including those of the private sector.

Health systems should be uprooted and job roles and designations properly outlined. Nordic countries may be a good starting point for answers to our problems.

The government should investigate the possibility of a subsidised health insurance that would surely minimise the burden on the National Health Service. (In Malta only a small percentage of the population is privately insured). One possible incentive could be that Private companies that offer employees private health insurance be given advantageous tax rebates and credits.


Brian Bondin

A proper Public Private Partnership has to be set up, especially in a country such as Malta that cannot afford to waste money on duplicating efforts and services. Governments will need to explore further the possibilities to subcontract their services to the Private sector, especially when recent studies and analysis prove that Private Healthcare is run more cost effectively than any government facility.

Private Healthcare should become more focused on specialisation rather than generalisation thus continuously attracting patients who yearn for highly professional and personalised care. For the next decade, offering a top-notch service will be the challenge for all private healthcare facilities; this will include facing new technology that will make health less labour intensive and more technically involved.

Governments should be the 'Change' agents of the future, the catalysts against bureaucracy, paving the way for technical advances and to legislate in favour of the patients' well being.

One day all of us will need one type of healthcare service or another. Therefore, all today's health administrators and healthcare professionals should ensure that the possible service needed in a couple of years' time will be what they are hopefully striving to improve and not allow it to deteriorate or worse – disintegrate.

Large hospital acquisitions in Germany

Fresenius subsidiary Helios on its way to become market leader

According to a study* of company mergers, with the privatisation of hospitals, Germany is in an exceptional position in Europe. No other EU country sold so many and such large hospitals so quickly as this country has done. The concept of selling entire university hospitals is unknown elsewhere in Europe. Accordingly, the market share of private enterprises has increased. Over recent years the wave of privatisation lost a little steam and the concentration process shifted. Instead of buying up communal hospitals the large providers are now expanding through the takeover of smaller private companies

The hospital group Helios, a Fresenius subsidiary, clinched the latest hospital buy-up this March, taking over 94.7% of shares in Damp Holding AG based in Hamburg, Schleswig-Holstein and Mecklenburg-Vorpommern. Thus the largest German Hospital Group (2011 turnover: €2.7 billion) swallowed up the facilities of the Damp group (2010 turnover: €427 million)

Size before class?

The hospital world in Northern Germany is therefore undergoing a fundamental change. Whilst the Damp group previously maintained a comparative balance between small, medium and large hospital operators the trend is now towards concentration. In Mecklenburg-Vorpommern the large German providers Helios and Sana are now represented in all parts of this Federal German state.

Along with the maximum care hospital in the capital Schwerin, the Helios group is also operates the hospital in Stralsund and rehabilitation clinics in Leezen and Ahrenshoop.

Due to the distance of the former Damp Hospital in Wismar to the Helios Clinic in Schwerin, the hospital in Wismar was separated out from the facilities of the Damp group and sold to Sana. Sana is now running the Wismar and Bergen hospitals in on the island of Rügen. Hence medical care along the coastline of Mecklenburg-Vorpommern is firmly in the hands of the two large concerns and two existing university hospitals. It remains to be seen how Helios and Sana will generate synergy effects.

Meanwhile, in Schleswig-Holstein, whilst the Helios group previously had no presence there it has now gained three acute care hospitals (in Damp, Schleswig and Kiel) and three rehabilitation clinics, as well as numerous centres for out-patient medical care and out-patient rehabilitation care, along with touristic establishments (a hotel, holiday park, congress centre and yacht harbour) in Damp.

The Paracelsus group has pulled out of Henstedt-Ulzburg because the hospital was too far from other facilities owned by the group for any possible synergy effects.

The boards at the hospital groups Westküste (Heide and Brunsbüttel) and the Hospital Nordfriesland (Husum, Tönning, Niebüll and Föhr-Amrum) are currently looking into possible mergers. The reasons for this surprising convergence, according to representatives of both, are the 'dramatically declining general conditions'.

Among the problems, compared to the other German states, are low base case values, problems recruiting junior doctors – the expense is higher for this along the coast and – as well as the preservation of locations that are below the critical size, but which are relevant to overall care structures.

Employees' protest

Whilst a possible fusion of the communal hospital groups in Schleswig-Holstein should have little impact on staff, the 8,000 Damp group employees have been warning of strikes since the beginning of 2012.

At the core of the dispute between verd.i and the employer is the Damp group's collective agreement, which only expired at the end of 2011 and which the trade union wants to renegotiate. The board of the Damp group refused this, in view of the impending takeover by Helios. Oliver Dilcher, tariff negotiator at verd.i: 'This is (…) not about a transition, as the Helios collective agreement only covers the field of acute care. Rehabilitation clinics, therapy centres and services are not covered by the Helios tariff agreement. Our objective is to carry on with the Damp tariff! This is superior to the one provided by Helios. And again, we do not want a transition – we have a collective agreement that covers everything!"

Employees fear that, once under Helios management, there will be wage losses of up to 15%. Verd.i is currently asking for a salary increase of 7.5% and a one-off payment of €200.

Employees most recently expressed their views during a large demonstration in front of the company's HQ in Hamburg.

The acquisition of the Damp Group seems to be just an appetizer for the "main course" goals newly appointed Fresenius chairman Ulf Schneider put on the menu. Fresenius offers the shareholders of Rhön clinics €22.50 per share. If more than 90% of the shareholders accept the deal, a new giant with more than 120 hospitals and about €80,000 employees will appear on the German and European market. The above-mentioned study concludes: 'Whoever sells their hospital today won't really know who owns it tomorrow.'

Along the German Baltic Coast and elsewhere in the country this statement comes true for many employees and patients.

**Study by the Public Services Union verd.i on company mergers in the hospital market from 2007 (Niko Stumpfögger: Hospital Fusions and Competition Law).*

Energy contracting for a greener hospital

Modernisation and a financing model facilitate savings of up to 50% in primary energy consumption

Every year, European hospitals face energy costs in the €billions. In Germany, for instance, the sum is €1.7 billion. According to Ulrich Brickmann, Head of Marketing for Energy Efficiency at Siemens AG, Division Building Technologies, 'If hospitals could save 20% of this amount the annual, national energy bills could be cut by 300-400 million.' That estimate is conservative. 'With consistent implementation of all energy efficiency measures we could save up to 50% of primary energy. Taking into account that 70-80% of German hospitals have modernisation needs in this area there really is an enormous potential for savings, which has not yet been given enough consideration.'

Helped by Siemens, the Aller-Weser-Clinic in Achim, near Bremen, has achieved fantastic savings. Following the implementation of the Energy Saving Contracting scheme, energy costs were halved and the volume of electricity purchased from the network was cut by almost 75%.

Analysis just before the modernisation showed a quite typical situation. The heating, ventilation and air conditioning systems were much the same as when first installed as well as oversized and designed in a redundant way. The ventilation and air conditioning systems in many areas no longer met occupational safety, hygiene and energy requirements. Heat recovery was minimal, with low efficiency, heat distribution was the same as when the systems were first installed; the cooling fluids used contained a cooling agent that soon will be illegal and the process of heating drinking water was out-dated, to name but a few disadvantages.

'An important starting point for energy improvements of the conventional, oversized heat distribution network was the recalculation of the heating load, relating to the current utilisation concept, as well as an inspection of the hydraulics,' Ullrich Brickmann explained.

The Siemens engineers calculated that the main flow and return flow pipes, which were based on the original heating requirement, could be downside from a diameter of 250mm to 60-80mm. 'Although 90/70°C systems were the norm when the buildings were first constructed, in day to day running it transpired that there were significantly lower temperature differences and therefore high volumes of circulating water, i.e. the hot water was being unnecessarily circulated around the building,' he said.


Ullrich Brickmann


Lothar Ragaller

In the context of the Energy Saving Contracting project the rebuilding of the main distributor was therefore an important measure for a permanent reduction of the heating requirement and pump power. Hence all standard single stage circulation pumps were exchanged for adjustable, high efficiency pumps, exactly sized control valves were fitted and the overflow from flow to return flow was scaled back.

Overall, the hydraulic restructuring of the main distribution resulted in half the volume of water being circulated and the pumping power could be significantly reduced. Demand regulation of the initially 'fully heat-supplied' internal areas of the hospital, which nowadays only require heating in exceptional cases, also contributed to this reduction. With this and further measures, it energy costs were cut from just under half a million euros in 2007 to only €280,000 annually.

CO_2 emissions fell by 55% (-1,444 tons). With this result the Aller-Weser-Clinic is on the way to achieving certification from *Friends of the Earth Germany* as an energy-saving hospital.

Helped by the Siemens AG energy saving partnership, Hospital GmbH, in the Weilheim-Schongau district in Bavaria, also modernised its systems at a cost of around €3 million. 'We replaced the oil-fired steam generators (e.g. those for kitchens and sterilisation areas) with electric boilers that only operate on demand. Our oil-fired steam generators previously remained switched on for 365 days a year. This also necessitated a large amount of maintenance,' explained Lothar Ragaller, Head of the Department of Technology and Buildings. The hospitals in Weilheim and Schöngau now emit 1,600 fewer tons of CO_2 annually and, since 2008, have saved around €250,000 a year in energy costs.

Describing their joint work as very constructive and innovative, Lothar Ragaller particularly praised the transfer of know-how from Siemens to his department: 'Actions were always carried out in close consultation with the head of Building Services and the Operations Engineer. Due to subsequent monitoring, both sides were always kept up-to-date with the savings.'

The motivation for a continuous improvement of building energy efficiency is more prominent with the Energy Saving Contracting modernisation and financing concept than with modernisations carried out by an organisation on its own, or with heat contracting offers. 'Energy Saving Contracting has the big advantage that it can guarantee the hospital annual energy savings according to the individual modernisation plan, along with the high quality of measures implemented. The security that this gives hospitals for their budgets eases the implementation,' Ullrich Brickmann pointed out.

Within the energy saving partnership Siemens can advance the means for modernisation, which the hospital can pay back over 8-12 years from energy costs saved.

Siemens' offer applies to modernisations and hospital new builds. The Siemens division Building Technologies reports modernising around 30 hospitals in Germany under the Energy Saving Contracting scheme, including university hospitals in Muenster, Heidelberg, Mainz and Halle (Saale).

Teleradiology use in Europe

A new survey brings fresh insight into radiologists' thoughts on teleradiology in Europe. Conducted by radiologist Dr Erik Ranschaert from the Jeroen Bosch Hospital, Den Bosch, The Netherlands, the findings were presented in March to a Special Focus Session at the European Congress of Radiology in Vienna. *Mark Nichol*s reports


Erik Ranschaert

The Radiology on the road: Working when you are away from home ECR 21012 session examined challenges and opportunities posed by teleradiology, the use of hand held devices, portable reporting and legal issues. A question posed by Dr Erik Ranschaert -- *Teleradiology in 2012: growing or shrinking in importance?* – presented findings from his European Teleradiology Survey, which looked at the issues, challenges, driving factors and future of teleradiology in Europe and beyond.

The aim of the online survey – with 32 multiple choice and three open questions - was to map current use of teleradiology in Europe, he said, and to examine the potential and appetite for further implementation of teleradiology services in Europe.

Among the 368 participants from 35 different countries, the largest responses came from Belgium, Austria, UK and The Netherlands. The data revealed that teleradiology is used by 65% of respondents either in institutions or at home, for second opinion requests and to transfer images to a company or academic centres for research purposes.

When quizzed about the advantages of teleradiology, the most important aspects from respondents was the chance to collaborate, ability to sub specialise and as a way to improve efficiency.

Outsourcing was used by 35% of respondents (49% of those as part of their regular workflow and 42% for second or expert opinions) and of the work outsourced, 52% went to a commercial provider within their own country, 32% to a tertiary centre and 13% to a provider in the EU with the remainder going elsewhere.

Dr Ranschaert said outsourcing also solved temporary capacity problems, though some people were concerned the quality of reports would be reduced.

Asked what could improve teleradiology, 81% said clear national and EU legislation covering teleradiology was needed, while 78% felt there should be an obligatory quality assurance system in place. But, he added: '80% had a positive or strongly positive opinion about teleradiology and 46% think its importance will grow, while 20% maintain the need for better standards and better financial and legal controls.'

Key reasons to develop future teleradiology, according to respondents, are the shortage of radiologists, the need for specialist advice and need for on-call reading. Increasing healthcare costs and decreasing budgets also see teleradiology perceived as a 'relatively cost effective solution'.

While demand and PACS availability was a driving factor for teleradiology, there is variation in PACS across Europe. Nordic countries have 100% availability, with the UK close behind, while France and Greece only have PACS coverage of 25%, which makes teleradiology difficult, he said.

In the EU, most teleradiology is in-house or within an institution and amounts only to 2% of all procedures – with the UK and Germany the biggest users - compared to 20% in the US.

Dr Ranschaert concluded: 'Teleradiology is likely to be an integral part of healthcare delivery across Europe and its impact will definitely increase but there are still key issues to be solved about cross border use, security, quality assurance and financial flexibility and with language there needs to be more semantic interoperability between countries.

'There is still a need for a quality framework and, from a legal point of view, there should be uniform European legislation with regard to teleradiology.'

The survey was conducted with the support of the European Society of Radiology and full results will be published in the near future.

During the session, Professor Osman Ratib from the Department of Medical Imaging and Information Sciences, University of Geneva, Switzerland, examined the use of PDAs (Personal Digital Assistants) and other hand held devices in radiology.

The medical field quickly adopted new handheld technologies and, he predicts, there will be higher resolution images available in small format and a greater use of portable devices in a clinical environment, such as surgeons taking their iPads into the operating theatre as part of standard theatre equipment.

Consultant radiologist Dr Richard FitzGerald, from the Royal Wolverhampton Hospitals NHS Trust, said there remained issues over the regulation of teleradiologists and, he added: 'We should not just be concerned with cross border regulation in Europe but also take in the global perspective. My advice to radiologists is not to let standards slip when using mobile devices and check your indemnity cover if doing teleradiology, particularly if reporting in another country.'

A dynamic HIMSS 12 in Las Vegas

To date, the US administration has subsidised care organisations to the tune of over US$3 billion to implement IT -- particularly electronic health records. Nor is that the end. Healthcare IT shows no sign of the general decline in US economy. Therefore, it's no surprise that HIMSS12 (www.himss.org) in Las Vegas broke all records, with 37,000 attendees including a large proportion of hospital representatives and numerous Europeans. In excess of 300 sessions and 1,100 exhibitors turned the gamblers' paradise in the Nevada desert into a Mecca of know-how transfer and business initiatives – at least during show hours, writes EH correspondent *Finn Snyder*


Interoperability is the key enabler for an unencumbered flow of information: IHE Showcase at HIMSS12

Hospital IT topics aired at HIMSS12 included some US-specific items, such as the introduction of ICD-10, *Meaningful Use*, software for ACOs, and technology for patient engagement. Whereas the ICD-10 classification is already implemented in various countries, other topics from this selection are also of European interest: Meaningful Use, the US guideline that provides criteria for the current multi-stage IT subsidising strategy, may well lend itself to determining investment projects on our continent. 'Accountable Care Organisations' are pioneering patient or case management, which is also making headway in Europe. Additionally, 'consumer orientation', engaging patients interactively in the care chain, may also have a future on our side of the Atlantic.

Interoperability

Improvements to quality of and access to medical care, increased efficiency and reduced cost are primary goals of the current healthcare IT campaign in the USA. Dr Farzad Mostashari predicted that the majority of patient cases will be documented solely by electronic health records (EHRs) in 2013. As National Coordinator for Health IT he considers Phase 1 of the US support initiative and the Meaningful Use criteria catalogue a success story.

Figures made public by Kathleen Sbelius, US Department of Health and Human Services Secretary, testify to that almost 2,000 hospitals and more than 41,000 physicians received in excess of $3 billion in incentive payments for ensuring meaningful use of health IT, in particular certified EHRs. Phase 2 of Meaningful Use will be about engaging the patient, exchanging information, and supporting clinical decision-making. Dr Mostashari is also looking into integrating IT in imaging into the initiative.

Health Information Exchange (HIE) provides the backbone for cross-sector exchange of clinical information; interoperability is the key enabler for the unencumbered data flow required to meet the challenges. In this context, standards similar to those used in the National Heath Information Network (NHIN) Exchange are currently being implemented in Europe's epSOS project. In this vein, interoperability player Health Level Seven International (HL7) announced that it will now make available several standardisation documents to the market -- free.

The numerous hot technology issues discussed in the sessions and shown in the exhibition echo Europe's medium and long-term top trends – mobility based on smartphones and tablets, tools for analysing clinical and business data, converging communication, nurse alarm systems, and auto-ID. While embracement of new technologies, over time, has been rather similar in the U.S. compared to countries such as the UK and Germany, U.S. funding initiatives may now lead a widening of the gap.

** HIMSS13 will be held in New Orleans from 3-7 March 2013*

CT use increases for CAD diagnosis

Mark Nicholls reports from Vienna

Computed tomography (CT) has become central to the diagnosis and characterisation of coronary artery disease (CAD) and, in the future, could even supplant invasive coronary angiography as the technology increases sensitivity.

In the UK, for lower-risk patients with chest pain the first line of testing is already a calcium score – a CT examination to check for the build-up of calcium in plaque within coronary arteries.

Cardiac imaging: from diagnosis to prognosis, was the theme of a Special Focus Session at ECR 2012 in March, chaired by Michael Rees, Professor of Cardiovascular Studies at the School of Medical Science, Bangor University Wales. 'Cardiac imaging,' he pointed out, 'has come a long way, particularly in the last 15 years, with huge strides having been made. In the UK, new guidelines for patient care mean that, with patient history, we can now stratify patients according to risk – low, medium or high – and usually on the basis of their symptoms, and the treadmill test is now being replaced by calcium screening for low-risk patients as the first line of investigation.'

Rozemarijn Vliegenthart

Additionally in the UK, recent publication of National Institute for Health and Clinical Excellence (NICE) guidelines on treating patients with chest pain shows the prominent role played by imaging modalities. 'This is very interesting because, for the first time, it incorporates imaging tests into the patient diagnostic pathway,' said Prof. Rees. The calcium score represented a big change in the way patients are investigated, he added.

If the calcium score is high, the patient will go on to have either a coronary CT angiogram (CCTA) or an invasive coronary angiogram. Low score patients may have CCTA or other tests, or be treated with medication.

The future looks very good in terms of imaging, 'not only with directing therapy but with monitoring therapy as it happens,' he said.

Dr Rozemarijn Vliegenthart (Radiology Department, Groningen University Medical Centre , the Netherlands) said that, in asymptomatic individuals, risk factors are not sufficient to predict who is at high risk of coronary events. 'There will be a shift to biomarkers and other measures of atherosclerosis in the heart, but coronary calcium screening by CT is the only non-invasive method of atherosclerosis in the heart itself,' she said.

The predictive power of calcium screening for asymptomatic patients was found to be 'far superior' to other risk factor scores and that the predictability increased when calcium score was added to risk factors, which often saw the patients placed in a better category for risk, Dr Vliegenthart explained, though adding that further analysis is needed to see if calcium scoring is cost effective and for which groups.

In symptomatic patients, she reported that calcium scoring and ischemia testing has shown to be effective predictors of future events but that there was less agreement on the value of calcium testing in symptomatic patients, but it does improve prognosis assessment compared to ischemia testing alone.

The absence of coronary calcium also makes the risk of coronary events in future years very unlikely, both in asymptomatic individuals and in symptomatic patients.

Professor Filippo Cademartiri (Head of Cardiovascular Imaging at Giovanni XXIII Hospital of Monastier di Treviso, Italy) said CCTA has the potential to predict cardiovascular events better than conventional methods and that it can provide incremental prognostic information. CTCA, he said, may become a valid tool for assigning patients to different treatment strategies.

Significant advances have also been made in MRI with stress MRI scans and late contrast enhanced scans becoming more common as a test for medium-risk patients.

Dr Jan Bogaert (University Hospital Leuven) outlined the role of MRI predictors in CAD and said that MRI has an increasingly important diagnostic and prognostic role to play.

Feuding cardiologists

A €35,000 DRG reimbursement for TAVI has put Germany in the lead for this procedure – and prompted sharp competition and disputes between cardiologists and cardio-surgeons, *Holger Zorn* reports

Since the first successful TAVI procedure a decade ago, when French cardiologist Alain Cribier guided a catheter-mounted artificial heart valve via the femoral vein, right atrium and atrial septum to the aortic valve position and opened the balloon to release a new valve, a dramatic increase in TAVI procedures occurred in Germany. The reason is not mystifying: the DRG reimburses a whopping €35,000 for the intervention. In 2007, 157 were recorded; in 2011 the figure had reached 5,083. If this trend continues, health insurers will pay more than €200 million for TAVIs in 2012.

The battle for patients is surging as hospitals hurry to provide hybrid ORs and thus gain a windfall.

This has triggered a family feud among medical associations, partially being fought via the media (unusual in Germany). In 2009, the DGTHG (German Society for Thorax, Cardiac and Vascular Surgery) and DGK (German Cardiac Society) recommended: 'The intervention should be performed jointly by cardiologists and cardio-surgeons [...] in a cardiac catheter lab or in a hybrid operating theatre, since the management of complications immediately requires the professional know-how of both disciplines'. [Source: Kardiologe 2009;3:199–206]

Forty-one university hospital-based heart surgeons and cardiologists begged to differ, suggesting they themselves should be the sole providers of TAVIs: 'Transcatheter aortic valve implementations ought to be performed exclusively at healthcare centres that have dedicated and long established departments or clinics for interventional cardiology and for cardiac surgery [...] External facilities that do not have an experienced cardiac surgery team are not suited to offer this intervention'. *[Source: Cardio News 2011;14(03):20–21]*

This, however, prompted the ALKK (Working Group of Managing Hospital-based Cardiologists) to respond: 'Patients who have no realistic cardio-surgical option, or who strictly refuse cardiac surgery based, for example, on a living will, ought to have access to treatment by an experienced team of cardiologists in an excellently equipped catheter lab in line with current definitions and precautions'. *[Source: Kardiologe 2011;5:366–71]*.

TAVI opens access to an entirely new group of patients since about 4% of over 75-year-olds have severe aortic valve stenosis. With three-year survival rates of about 33% the prognosis without intervention or surgery is extremely poor. Additionally, although surgical open-heart repair or valve replacement is the gold standard, every second patient is considered inoperable and thus does not receive surgical treatment.

The so-called PARTNER trial, the first randomised clinical comparison of the Edwards Sapien transcatheter heart valve implantation with medical and surgical management indicated that among TAVI patients the one-year rate of mortality was 20% lower than among patients who had received only pharmaceutical treatment.

The study also showed that the outcomes of both transfemoral and transapical interventions were better than the surgical outcomes: 30 days after the intervention 3.4% of the patients and 30 days after surgery 6.5% of patients had died. One year after the intervention, mortality rates were almost at the same level (24.2 and 26.8%).

However, a prospective survey of the 2009 German TAVI registry, with 697 patients from 22 centres, concluded differently: 30 days after the replacement valve implantation, 10.2 % of patients had died; 39.3% required a pacer after the intervention; 84.4% had received a Medtronic CoreValve, only 15.6% an Edwards Sapien device. [Source: Eur Heart J 2011;32:198–204].

The demand to restrict performance of the intervention is frequently justified by the allegedly higher rate of complications. However, results from the PARTNER trial show a complex picture: whilst the interventions lead to stroke and vascular complications more frequently, surgery causes haemorrhages and atrial fibrillation more often. In their recent analysis of the German TAVI registry the ALKK recorded only 11 cases out of 1,177 (1%) where a transcatheter intervention had to be abandoned in favour of open-heart surgery. Interestingly, this switch from intervention to open-heart surgery was required in more transapical accesses – which are closer to the surgical procedure – than in the less invasive femoral accesses.

New valves, due to be launched, may well reduce complications even further – perhaps one reason why cardiac surgeons like to demonstrate friendly relations to cardiologists – they even invited one to preside over their Freiburg-based congress in February. However, behind the scenes, at a strictly confidential meeting, the managing cardiac surgeons had already announced an investigation into a very first serious incident recorded at a hospital without an established and institutionalised cardiac surgery department – hoping to stop, or at least decelerate, the spread of so-called interventionism.

Brand	SAPIEN	CoreValve	JenaValve	Acurate TA	Portico
Manufacturer	Edwards	Medtronic	JenaValve	Symetis	St. Jude Medical
CE approval since	Sep 07	May 07	Sep 11	Sep 11	2012 expected
Implantations	n/a	> 10,000	< 1,000	n/a	< 500
Femoral/apical	yes/yes	yes/no	no/yes	no/yes	yes/exp
Leaflet material	bovine	porcine	porcine	n/a	bovine
Sizes [mm]	23/26/29	26/29/31	23/25/27	n/a	23
Highlight	Sales has been reached $93.2 million in fourth quarter 2011	the only TAVI therapy available for subclavian access	anatomically correct positioning without rapid pacing	controlled self-positioning of the valve after delivery	valve may completely resheated for repositioning

Tab: Katheter-based aortic valves, commercially available in Europe or expected to be launched this year. Other products / companies with first-in-men trials (e.g. AorTx, Direct Flow, HLT, Sadra or Ventor) are not included. Own compilation.

The steep increase in TAVIs and high reimbursement has prompted hospitals and industry to greater participation

The PARTNER Trial

Cohort A and B Results

Aortic stenosis is characterised by the hardening and narrowing of the aortic valve that pumps blood into the body's main artery. It affects nearly 5% of those over 75 in Europe, with an estimated 16,000 Britons suffering from severe aortic stenosis. For those with severe disease, without surgical intervention, the prognosis is extremely poor and the three-year survival rates are less than 30%.

In Europe, transcatheter aortic valve implantation (TAVI) is now an established, evidence-based, alternative to open aortic valve replacement in patients with aortic stenosis who are unsuitable for conventional cardiac surgery. Over 1,500 procedures have now been performed in the UK with outcomes that match or exceed international norms.

The PARTNER trial

The Placement of AoRTic traNscathetER valves (PARTNER) trial evaluated the Edwards Sapien valve in patients with aortic stenosis who are considered either high-risk or inoperable for conventional open-heart valve surgery.

Within the trial, Cohort B included 358 patients with severe, symptomatic aortic stenosis deemed inoperable for traditional open-heart surgery. Patients were evenly randomised to receive either the Edwards Sapien valve or standard therapy.
Cohort A involved 699 patients with severe, symptomatic aortic stenosis deemed at high risk for traditional open-heart surgery. Patients were evenly randomised to receive either the Edwards Sapien valve with transfemoral or transapical delivery or traditional open heart surgery.

Cohort B

These data were previously released in September 2010 and published in the New England Journal of Medicine and found that rate of death from any cause at one year was 20% lower with TAVI than with standard therapy. The study's authors concluded that balloon-expandable TAVI should be the new standard of care for patients with aortic stenosis who are not suitable candidates for surgery.

	30-day			1-year		
Outcome	TAVI (n=348)	AVR (n=351)	p-value	TAVI (n=348)	AVR (n=351)	p-value
All cause mortality - %	3.4	6.5	0.07	24.2	26.8	0.44
Major vascular complications - %	11.0	3.2	<0.001	11.3	3.5	<0.001
Neurological events - %	5.5	2.4	0.04	8.3	4.3	0.04
Major Strokes - %	3.8	2.1	0.20	5.1	2.4	0.07
Major bleeding - %	9.3	19.5	<0.001	14.7	25.7	<0.001
New atrial fibrillation - %	8.6	16.0	<0.001	12.1	17.1	0.07

In November 2010, a quality of life analysis of the PARTNER Cohort B data revealed that patients experienced both cardiovascular and physical health benefits thanks to TAVI. The study's authors concluded that the physical improvements were roughly comparable to a 10-year reduction in age. On a scale from 0 to 100, where a 20-point improvement is considered substantial, the Edwards transcatheter valve patients had a 25-point improvement in quality of life scores compared to the control group at one year.

Cohort A

The results of a pivotal clinical study of high-risk surgical patients with severe aortic stenosis treated in Cohort A of the trial were announced at the 2011 American College of Cardiology's (ACC) 60th Annual Scientific Session & Expo in New Orleans, USA. The data demonstrated that the study achieved its primary endpoint at one year, concluding that survival of patients treated with the Edwards Sapien transcatheter aortic valve was equivalent to those treated with surgical aortic valve replacement.
In this cohort, the study found that TAVI was non-inferior to surgical aortic valve replacement (AVR) for all-cause mortality at one year, 24.2% v. 26.8 % respectively. In addition, mortality at 30 days was lower than expected in both arms of the trial, with TAVI at 3.4% and AVR at 6.5%. The observed mortality in these AVR patients was lower than the predicted risk of operative mortality of 11.8%.

Overall, the trial data has shown that TAVI gives patients substantially better quality of life whilst achieving a survival rate at one year equivalent to that of conventional surgery and significantly better than for patients who receive standard care.

Edwards Sapien valve

The Symetis Acurate TA Aortic Bioprosthesis and delivery system

NEW

A new transcatheter aortic valve implantation (TAVI) system for transapical treatment of severe aortic stenosis – Acurate TA and delivery system –is a second- generation TAVI device to treat elderly patients. Launched by the Swiss firm Symetis SA, the system gained CE approval last September is on sale in Europe.

The Acurate TA Aortic Bioprosthesis is composed of a non-coronary leaflet surgical-quality porcine tissue valve sutured into a self-expanding nitinol stent that is covered with a PET skirt on both the interior and exterior of the device. The bioprosthesis is self-aligning and can be re-sheathed until final deployment.

Available as small, medium and large, the Acurate TA delivery system is a single operator catheter designed for easy implant positioning within the native annulus followed by a swift, two-step deployment. Compared with other TAVI systems, the manufacturer points out, the implantation procedure accompanied by tactile feedback facilitating release in the correct annular position, translates into a shorter learning curve compared to other TAVI systems currently on the market or still in clinical trials.

In addition, '... the robust clinical dataset of 90 implanted patients allows for comparison of the Acurate TA to published statistics from first generation TAVI devices suggesting comparable or improved initial outcomes,' Symetis adds.

Clinical Experience

Between November 2009 and July 2011, Symetis sponsored two clinical studies of the new TAVI system in Germany: TA FIM (n=40) and TA Pilot (n=50).

Both studies were single-arm, prospective, multicentre trials that enrolled high-risk patients with severe aortic stenosis (AS).

The combined cohort consists of 90 patients with severe, symptomatic AS who were enrolled at six investigation centres. The midterm outcomes (six months) are available for the combined patient cohort.

The long-term follow-up data at one year is available only for the 40 TA FIM patients.

Agfa HealthCare's Cardiovascular Information System

The Impax CV12A, a new version of Agfa HealthCare's Cardiovascular Information System (CVIS), was introduced this March during the American College of Cardiology's (ACC's) 61st Annual Scientific Session & Expo in Chicago, USA. Agfa HealthCare has listed among its assets that it is designed and delivered in an innovative modular approach, enabling users to adopt and benefit from new features when released the first CVIS platform to offer industry-wide standardisation that enables interoperability, with its support for SNOMED CT*, LOINC** and RxNorm Reporting

Improved access to technology

The particular modular design of the platform lies among its core advantages, the firm points out. As the first of its products to use this structure, Impax CV12 enables users to take advantage of new product developments as and when they are released. Beginning with version 12.0 and continuing through future product releases, the system '... establishes a framework in order to provide users with the robust functionality that they need,' the company points out. 'With the very first release, users can benefit from a new patient management module that includes enhanced search capability, an improved graphical user interface (GUI), and a patient work list designed for improved cardiologist workflow.'

According to Charles Wickens, the firm's Global General Manager for Cardiovascular IT, 'By adopting best practices from other areas of healthcare, Agfa HealthCare is successfully delivering a redesigned version of our IMPAX Cardiovascular product that will bring improved access to technology and feature developments, while also enabling users to achieve a new level of regulatory standardization. Impax CV12 is the first step in a long-term product vision that, because of our innovative design approach, will enable us to continue meeting the needs of cardiologists and their healthcare organizations both in the short term and for years to come.'

The manufacturer also adds that the system has been developed to support SNOMED-CT* and, subsequently, other standard terminologies, to help facilitate regulatory reporting compliance by customers.

Central to the Impax system is a robust infrastructure that, along with support for Oracle 11g and Microsoft Windows Server 2008r2 software, makes the product easily upgradable and able to be rolled out remotely, the firm adds. 'This streamlines the process for upgrades and serviceability, saving facilities time and resources. The product can also be virtualised to reduce the hardware footprint so organisations can achieve a lower total cost of ownership. Finally, facilities can depend on the security of the system, which meets the rigorous Department of Defence (DoD) security requirements.'

The new system also supports the company's Imaging Clinical Information System (ICIS) platform to bring images into the Electronic Patients' Record (EPR). 'Whether a facility elects to have integrated cardiovascular DICOM archiving and viewing at the departmental level, or on the enterprise level, Impax Cardiovascular can meet the need. A vendor-neutral CVIS, Impax CV12 will feed into the vendor-neutral ICIS repository, eliminating the need to manage images and data at the departmental level, while also allowing for improved delivery of care by providing access to the comprehensive longitudinal patient imaging record. With the ICIS services platform, images and associated data are available to clinicians, at virtually any location, in a meaningful and clinically useful way.'

** SNOMED CT – Systematised Nomenclature of Medicine – a registered trademark of the International Health Terminology Standards Development Organization.*

*** LOINC – Logical Observation Identifier Names and Codes – a registered US trademark of Regenstrief Institute, Inc.*

SNOMED-CT, LOINC and RxNorm Reporting support features are expected to be released this year. They are not available in the USA and Canada.

Working at the heart of Arizona Heart

Three high-tech operating theatres gain sophisticated Ziehm C-arms

Among the area's top cardiac and vascular disease specialist hospitals, Arizona Heart has invested in several technological advancements over the past year, including Ziehm Imaging's digital flat panel C-arms for its three advanced technology suites. The *Vision RFD* hybrid edition delivers distortion-free, high-resolution images for interventions and represents a cost-efficient alternative solution to fixed installed systems, Ziehm Imaging reports, adding that Arizona Heart also installed 12 of its ceiling-mounted monitors.

Procedures on the cardiovascular system include percutaneous or catheter-based interventions on complex aortic problems. Dr Grayson H Wheatley III MD performs an increasing number of hybrid procedures that combine the advantages of traditional open surgery with image-guided catheter-based interventions. 'The Ziehm C-arm is often used for long and complex cases, which can take hours to complete. This system offers an image quality that is comparable with many fixed imaging systems, and it has never shut down due to inadequate heat management,' he pointed out. 'A reliable imaging solution is critical -- the last thing we want to worry about when treating the patient is the C-arm shutting down because of overheating.'

The Ziehm Vision RFD is exactly tailored for hybrid OR use, the manufacturer points out. 'With up to 25 images per second, its powerful monoblock generator also produces high-quality X-rays of moving objects, such as beating hearts. The C-arm features a user-friendly Touchscreen interface that's mounted on the sterile OR table, an injector interface that synchronises contrast media with the imaging process, and an interface for external displays.'

Lead technologist Scott Cox RT is part of the team performing 120-150 endovascular and hybrid procedures monthly. 'One of the best things about Ziehm C-arms is that it's very easy to switch between live angio, subtracted road-mapping and the archived images using the touchscreen interface mounted on the C-arm.'

Ziehm Imaging's service also includes medical staff training and continuous support during installation. Commenting on this, Shanna Woyak, COO at Arizona Heart, said: 'They are accessible and visible and have played a viable role in our physician and staff education on the C-arms.' The firm, she added, went 'above and beyond to accommodate our needs'.

EuroPRevent2012

CVD prevention experts will meet in Dublin from 3-5 May for the leading international forum for preventive cardiology, *Finn Snyder* reports

Ian Graham

Cardiovascular disease (CVD) is Europe's major cause of death. 'It's essential that everyone is brought up to speed with the latest research,' urged Professor Volker Adams, co-chairperson of the Congress Programme Committee for EuroPRevent (details: www.escardio.org) organised by the European Association for Cardiovascular Prevention & Rehabilitation (EACPR), a registered branch of the European Society of Cardiology (ESC). Over 1,200 cardiologists, family physicians, nurses, allied health professionals e.g. dieticians, sports scientists, psychologists, health planners and policy-makers are expected to attend.

EuroPRevent will be dedicated to communicating strategies for the prevention of many deaths due to CVD. Measures include smoking cessation, weight loss, improved diets and increased exercise. During the event, the new *European Guidelines on Cardiovascular Disease Prevention* in Clinical Practice will be announced and the latest studies on lifestyle interventions presented, together with cutting-edge research on sports medicine, cardiac rehabilitation, population science, health policy, and basic and translational science.

In three days 46 symposia will be held in four parallel sessions, with highlights including telemedicine, new facts on the obesity challenge, the latest data on fish intake in primary prevention, the impact of arterial stiffness for cardiovascular prevention, and the role of heart rate in prognosis. An interactive master class on hypertension underlines the importance of hypertension, which affects one in four adults in Europe. In excess of 500 abstracts have been selected for presentation.

The symposium 'New guidelines for preventing atherosclerotic cardiovascular disease: East meets West' will explore common ground between Japanese and European guidelines. This session, said EACPR President Professor Pantaleo Giannuzzi, is of major significance since it marks the start of the association's new global approach to prevention. 'We believe that the educational programmes developed by EACPR have the potential to be of value to countries all over the world.'

New technologies

'Telemedicine is developing but has a long way to go', explained Professor Ian Graham, from Trinity College, Dublin, who co-chairs the Congress Programme Committee and Local Organiser.

A session (symposium 1) will focus on telemedicine in cardiac rehabilitation and prevention. Telemedicine '…may be the way forward in helping people to maintain lifestyle advice, for example by providing interactive help and encouragement on exercise and smoking cessation,' he said.

Everyone uses Google; smartphone apps and interactive programmes are developing … in this vein, ESC offers an online interactive tool to predict and manage the risk of heart attack and stroke in Europe. 'HeartScore' (www.heartscore.org) aims at supporting clinicians in optimising individual cardiovascular risk reduction. Technology companies are moving into risk estimation. A device to detect early arterial disease to augment risk estimation based on conventional risk factors will be exhibited during the Dublin event.

'New technology will inform future guidelines – initially in diagnostics and risk estimation, and increasingly in interactive education and risk management,' Prof. Graham predicts.

The ESC's new interactive web-based Guideline Learning Tool, to be launched at EuroPRevent, will cover the broad content of the guidelines, case histories, and questions and is intended for cardiologists, GPs, nurses, dieticians and medical students, will cover the broad content of the guidelines, case histories, and questions.

Breathing space

If the hopes of inventors are to be believed, in around 20 years' time there will be 'real' artificial lungs -- for now the endpoint of a history that began 84 years ago with the invention of the iron lung. Until then, non-invasive and invasive mechanical respiration will continue to dominate the hospital, complemented by extracorporeal procedures for blood oxygenation and decarbonisation, writes *Holger Zorn*

In the autumn of 1928 the starter's gun fell for the first clinical lung replacement procedure: a hollow tube made from metal into which the patient was positioned, closed airtight at the neck and abdomen. Rhythmic changes of air pressure in the tube led to chest expansion and constriction and air entered the lungs in the normal way via the mouth. Although it was not possible to treat diseased lung tissue with the help of the 'iron lung', it was possible to treat paralysed respiratory muscles – and plenty of patients needed this treatment.

Just into the century a known virus began to change – poliomyelitis. Known previously as a disease that occurred only sporadically, it now swept across continents like a pandemic. With the help of the iron lung it was possible to support the breathing in children who suffered acute symptoms of paralysis until their respiratory muscles recovered.

However, some patients never recovered; they depended on this technology for the rest of their lives. The iron lung therefore demonstrated the consequences of maximum intensive therapy and is still synonymous with being a cold, steely prison. Exactly 60 years ago around 30 patients a day were being admitted to the Copenhagen Municipal Hospital with respiratory paralysis during a new outbreak of the disease. In view of this pressure, anaesthetist Björn Ibsen developed an alternative treatment whereby patients were intubated and ventilated over long periods of time with bags. Two years later, Ibsen also founded the world's first intensive care ward in the same hospital.

Invasive ventilation

These days, modern ventilators with special tube systems facilitate lung ventilation for premature babies without damaging the yet immature tissue – lungs of babies where the volume corresponds with the size of a plum.

Computerisation in medical technology, together with an increasingly better understanding of lung physiology, has resulted in continuous innovations. Ventilation modes designed to monitor the volume were combined with pressure-controlled modes. There are now special ventilation procedures for all the different diseases of the lung (see table).

Current machines are capable of specialist manoeuvres that open closed areas of the lung. With this so-called open lung technology the ventilator temporarily increases pressure in the lungs to a level for only a short time, which, if maintained for a long time, would cause great damage. Closed areas in the lungs then open and can be ventilated. The machine fastidiously ensures that there is never a neutral or even negative pressure at the end of the following ventilation cycle. The positive end-expiratory pressure protects these areas from renewed collapse.

These days, the computer also takes over large parts of the process involved in weaning patients off the equipment. It recognises any attempt the patient makes to breathe on his own and even supports this. The weak respiratory muscles begin with the intake of breath, but if this intake is too flat the ventilator completes the process – always with a guarantee that, if the patient is completely exhausted, the machine will take over again completely.

Non-invasive ventilation

Another approach is the use of airtight facemasks. Using the most up-to-date algorithms they ensure that patients who are awake are supported in all their breathing. Small leaks are detected and compensated for. Such non-invasive types of ventilation can, for instance, support patients with coronary disease who suffer from fluid on the lungs. The risks of a long weaning process from ventilation or of an anaesthetic, which would be an additional strain on the patient's cardiovascular system, are thus avoided.

Extracorporeal 'ventilation'

If the lung tissue itself is incapable of working at all then even the most modern ventilator cannot help, says Michael Rühl of the University Hospital Greifswald. 'We use special membranes here, which imitate lung function. As with the pulmonary alveoli, the gasses here permeate from one side of the membrane to the other. Blood low in oxygen is directed out of the body through tubes and flows past this multi-layered membrane, which, despite its small dimensions, has the surface area of a football pitch. It is then oxygenated and the carbon dioxide is removed before it flows back into the body.'

Clotting has always been a problem with this process; however, surfaces now facilitate oxygenator use over several days. Lung injuries or viral diseases are the most typical indications for this treatment in adults, along with infections amongst intensive care patients.

The German ECMO Centres always have a few more patients during the annual flu season, but this treatment is very invasive, expensive and not free of side effects: 'An ECMO,' says Michael Rühl, 'is only connected if there is the chance of a cure, or if lung transplantation can be carried out.'

Many new procedures are being trialled, and not all make it to the clinical application stage. The so-called 'liquid ventilation', originated in deep sea diving, was meant to treat respiratory failure from around the turn of the millennium. This procedure involves perfluorocarbons (fluids which, strongly enriched with oxygen, are to achieve better lung oxygenation) being nebulised in the breathing gas. Although some studies have shown the effectiveness of the method, it is not superior to modern ventilators. In fact, none of the procedures are an adequate substitute for a real lung.

Artificial lung

At least the issue of material required for a possible artificial lung has now been resolved. Robert A Potkay of the Advanced Platform Technology Centre, Louis Stokes Cleveland VA Medical Centre, has developed a silicone rubber that contains extremely fine canals (see image), similarly to those in the lungs.

The possible diffusion distance is very small whilst the surface-volume ratio is high. This means that the lung could be supplied with simple air rather than oxygen, and this with a size that would not hamper an implantation (source: Lab Chip; DOI 10.1039/c1lc20020h).

The development of this tissue is the first step because, whilst the heart could pump blood into the new lung, the chest muscles would have to be able to expand the tissue via negative pressure in order to replace the original – an enormous challenge for the support apparatus.

Therefore, the replacement of one of the most complex human organ systems has not yet been achieved.

Mechanical ventilation

Controlled		Assisted/Synchronized	Spontaneous
Meaningful only if the foreign regulation of breathing prevents additional complications		Only with a patient's own breathing stimulus who determines respiratory rate and rhythm. The duration of inspiration depends on respirator's flow and patient's effort to exhale	The patient dictates rate and rhythm of respiration and breathes out fully independent, eventually with positive ground pressure (PEEP)
Volume	**Pressure**		
e.g. Volume Controlled Ventilation	e.g. Pressure Controlled Ventilation	e.g. Intermittent Positive Pressure Ventilation / Simultaneous Intermittent Mandatory Ventilation autoflow®	e.g. Bilevel Positive Airway Pressure; Continuous Positive Airway Pressure; Pressure Support Ventilation; or Airway Pressure Release Ventilation

The Hitachi Aloka ProSound F75

NEW

Three radiologists, who focused on different clinical applications using different diagnostic techniques, have reached the same conclusion: the next-generation of ultrasound brings new capabilities for detection, differentiation and advanced diagnosis of disease, *John Brosky* reports

Visualisation of nerves compressed by tendons for carpal tunnel syndrome is especially impressive with the new resolution levels, as well as subtle tendon abnormalities in the finger, he reported.

The advanced visualisation reinforces his role as a radiologist with surgeons. 'If a decision were to be made without this visualisation, typically the surgeon would cut the tendon,' he said. Instead he was able to show the patient's symptoms were caused by a stump neuroma of only one millimetre, thanks to the high resolution of the B-mode.

In another example, Dr Geertsma showed how 'any ultrasound system can show this ganglion cyst'. However, by using Hitachi e-Flow signals to display haemodynamics, combined with the high resolution of the ultrasound platform, the patient's real condition was revealed to be nerve compression leading to a diagnosis of tarsal tunnel syndrome.

Frederik Giesel MD, from the University of Heidelberg, demonstrated how the ultra-high resolution of the Hitachi Aloka ultrasound technology is especially relevant for contrast-enhanced studies of patients with neuroendocrine liver metastases undergoing radio-peptide therapy.

The portability of high-end capabilities on this next-generation ultrasound also lends itself to assessment of selective intensive radiotherapy (SIRT), he said. These ultrasound assessments, validated as concordant with CT scans following therapy, create an advantage for early indications of the effectiveness of therapy. 'They are robust and repeatable, and are particularly valuable in both the out-patient setting and at the patient's bedside,' he said.

Professor Thomas Fischer (Charité Hospital, Berlin) presented applications for prostate cancer showing convincingly how the enhanced resolution of the B-mode alone enables radiologists to detect, distinguish and closely examine tumours.

His special focus for colleagues in Vienna was a demonstration of the ability to fuse MRI images with real-time ultrasound. Once image volumes from MRI are loaded to the Hitachi HI Vision Preirus ultrasound scanner, images generated in real time from a trans-rectal ultrasound transducer can be viewed using an array of advanced techniques including elastography, broadband Doppler and contrast harmonic imaging.

'We have two high-end modalities available with MRI, and now with ultrasound, that we can bring together to perform targeted biopsies,' Prof. Fischer said.

While prostate cancer was the immediate subject for his demonstration, the relevance of the multimodality fusion and high-resolution ultrasound suggest interdisciplinary applications for nephrology, gynaecology, gastroenterology and surgery, he said.

Beyond the new capabilities for ultrasound, Fischer emphasised that 'the fusion of human brains on the medical team is as important as the images on new equipment'.

The next generation of ultrasound provides a great compliment to established modalities to enhance surgical planning, and presents a path forward for radiologists, he said.

Dr Giesel agreed, adding that standardisation of protocols and practices will now become crucial. 'The experience of an ultrasound operator remains an issue in ultrasound examinations,' he said. 'By addressing standardisation, we will be able to reach equivalence.'

In his concluding comments, the chairman of the symposium, Carlo Faletti from Turin, underlined the challenge the new power of ultrasound represents. 'We are here not only to demonstrate capabilities, but to deliver a message,' he said. 'We need to define the role of the radiologist in ultrasound examinations not only with high-quality scanners, but as high-quality operators.'

FLY-THRU EXAMINATION

The ability to 'fly-thru' organs with 3-D reconstruction is the leading edge for new ultrasound features on board Toshiba's new Aplio 500, *John Brosky* reports

Radiologists have simply never seen such views of the human body. Using advanced processing for 3-D volume data acquired by ultrasound, clinicians can now 'fly through' the inside of ducts and vessels to explore lesions and masses.

In less than a minute of processing time, radiologists can enter a breast duct or internal organ with an endoscope-like view and then move to regions of interest for a greater understanding of the morphology.

The impact on planning for interventional procedures was clear, but other clinical applications of this unique adaptation of 3-D/4-D images on Toshiba's Aplio 500 ultrasound system have yet to be explored.

An example is an early publication, *Advanced Transvaginal 3-D/4-D Imaging of the Uterine Cavity Paves the Way for Ultrasound Hysteroscopy*, by Bill Smith, Head of Ultrasound for Clinical Diagnostic Services in London.

'The fly-thru capability has stirred a lot of interest and everyone has ideas about how to use what is an entirely new way of looking at the body,' said Christoph Simm, Senior Manager of Ultrasound for Toshiba Medical Systems Europe.

More immediately, clinicians are ready to apply a second new capability on board the Aplio 500, Smart Fusion, which merges and then synchronises both CT and ultrasound images side-by-side on a single screen. The ability to locate hard-to-find lesions provides key advantages for ultrasound-guided biopsy without additional CT scans.

Jean-Michel Correas has the edge on fellow radiologists in assessing the clinical impact of the advanced ultrasound capabilities on the Toshiba Aplio platform. An interventional radiologist at the Necker University Hospital in Paris, he had an early opportunity to apply what he called 'major advantages' to his patient treatment. 'These are all real-life cases,' he said presenting his findings during a symposium at the ECR.

Visualisation is the critical issue for complex interventions, he said, reporting that the Aplio 500 delivered 'better diagnosis, treatment planning and follow up assessment.'

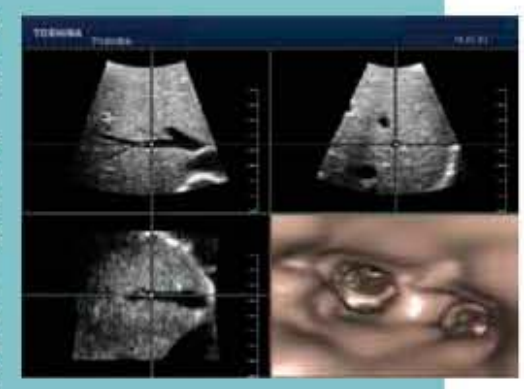
Critically, the high spatial resolution and contrast proved superior for tracking needles and electrodes during treatment, enabling precise placement of tips, as well as the detection of isoechoic lesions that were not visible during treatment planning.

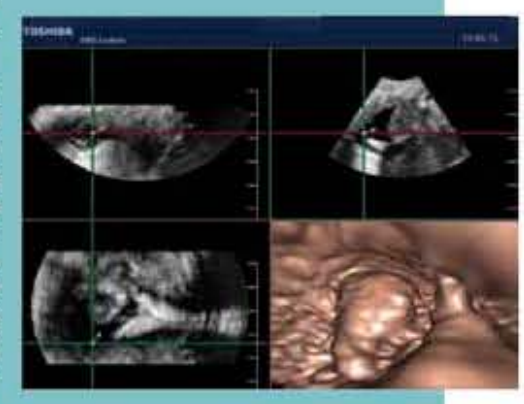
Ultrasound is not the unique tool for interventional radiology and the advantages of CT are essential for mapping the anatomy. However, the enhanced capabilities of ultrasound make it indispensible for guiding treatment with its array of techniques for visualisation that include Doppler for vessel identification, contrast enhancement for vascular activity of tumours, and imaging fusion for real-time guidance.

'Perfusion is the key to diagnosis, and now we have perfusion with ultrasound,' Thomas Fischer MD, from Charité Hospital in Berlin, told symposium participants.

Though using the same contrast agent as with other ultrasound exams, the enhanced performance of the next-generation Aplio platform shows 'very well, very visibly' the vascularisation changes as a result of tumour therapy or a case of bleeding from a puncture. 'These are only visible thanks to the new technology,' he said.

Dr Fischer applied the same agent used for any contrast-enhanced ultrasound examination, Christoph Simm pointed out, but there is a greater sensitivity on the new Aplio 500 platform and new algorithms for processing the ultrasound signal that generate a sharper resolution for aiding diagnosis.





Other advanced image processing features on the Aplio 500 include Tissue Specific Optimisation, Precision Imaging, Differential Tissue Harmonics, and Advanced Dynamic Flow.

The system also offers a full range of features for Toshiba's Productivity Suite with workflow automation tools and ergonomics that include a 19-inch LCD screen with a handle for easy repositioning, adjustable console for convenient patient access, and lighter weight and smaller footprint.

As Christoph Simm said, workflow may seem boring after fly-thru visualisation, but along with image quality, it remains the critical feature for clinicians working in a busy ultrasound department.

Carestream's X-Factor

Speeding the shift to DR and mobility

Carestream Health brought fresh innovations to ECR 2012, among them the *DRX-Revolution* that shares the same DRX-1/DRX-1C wireless detectors as others in the firm's DRX family. In our recent *European Hospital* discussion, Ulf Andersson, Director of marketing and development at Carestream Health in Europe, explained why he considers this mobile X-ray device and the firm's DRX series to be so significant


Ulf Andersson

The Carestream DRX Revolution sets a new standard for all mobile imaging. It fits very well into A&E, ICU or any other department that requires a mobile device.

'To drive, you put your hands on the handle and press a small bar in. The system recognises that it's motorised – but doesn't drive away. There are two circular wheels and tracks with larger circular wheels at the front, which make the machine extremely easy to move and manoeuvre. When invited to try it at ECR, visitors were sceptical but when they touched the machine and started to move it their looks said more than a thousand words about how easy it is to run,' Ulf Andersson explains

The system has a main 19-inch monitor and 8-inch tube head monitor, on which to access PACS images. 'So, it's really a mobile X-ray room. There's one other feature that's absolutely brilliant – the grid alignment. In an old bedside image, when the grid isn't aligned it just looks awful. We put the DRX cassette into the grid, or the collimator feels where the grid is, and this device automatically recognises it.' With the chest, for example, he says the cassette is in the grid behind the patient and when the collimator is placed on the patient's front it automatically 'feels' where the cassette is and aligns the grid. 'You actually get fantastic image quality,' he confirms.

The image quality for portable exams is enhanced due to its powerful 32kW generator, DRX detector and Carestream software that enables easy tube/grid alignment. Yes, the mobile DRX-Revolution is looking good – and with availability set for June customers in many countries will shortly start to experience the benefits

In terms of functionality, Ulf Andersson is also positive: 'Users will get something that no other competitor can provide at this point in time. Could rivals catch up with Carestream in this area? 'We have the detector technology; it's now well proven and well established. We have over three thousand detectors installed worldwide. No one is near to that. We have experience in detector technology and our system is the result of massive input at the concept stage from customers in many countries who told us what they wanted in such a system. This is the result of that collaboration.'

The tube head is easy to position; a collapsible column allows unobstructed views when on the move and the dual-drive system and ability to make tight, 360 degree turns in small spaces means quicker arrival for image capture.

The system also has a long tube head reach, enabling easier X-ray exams despite crowding of other bedside medical equipment. There's also generous storage space for gloves, sanitisers, markers, paperwork and other items.

Outlining the assets of the device, Ulf Andersson explains that there are real differentiators with the DRX-Revolution 'Firstly, everything is based on the DRX detector, which can be used in multiple X-ray systems at a facility. For example, a detector can be used in a mobile unit for early morning rounds and then moved to a general radiology room. DRX detectors can also move from day use in general radiology to mobile systems that serve the emergency department at night. We refer to the versatility of the DRX detector as the *X-Factor*.'

'We also have a new detector that's actually lighter and more robust and gives a fast preview of the images – in only four seconds,' he adds before focusing on the firm's retrofit devices. 'You can actually take the DRX Retrofit kit and put it into the cassette slot of any mobile device. It's basically a computer and a screen – and that computer communicates with the DRX. It's very simple and quickly provides DR on any kind of mobile device.

'You can retrofit DRX detectors into other vendors' mobiles, such as the Siemens Mobilett or GE AMX units, to extend the life of existing equipment and take it to new levels of productivity. Many of these systems have been there for years and are very good machines, so why throw them away? A retrofit with the DRX detector is a great way to take advantage of existing equipment without too much expense.'

DRX detectors present a new way of detector usage, he concludes. 'Everyone else says: *This is the fixed room and this is a mobile one.* Our re-use of the detector is unique as it can be used both in a large room or moved over to the mobile, raising standards for mobile imaging in the process. The X-Factor is bringing a totally new approach to DR.'

Meet the Carestream DRX family

- DRX-1 and DRX-1C systems
- DRX-Mobile Retrofit Kit
- DRX Transportable / Universal Mobile
- DRX Transportable / Field Portable
- DRX-Evolution modular DR suite
- DRX-Ascend System
- DRX-Revolution

DELIVERING SOPHISTICATED TECHNOLOGY TO PRIMARY CARE

Compact, lightweight and easy-to-use, the new F37 from Hitachi-Aloka punches well above its weight with features one expects to find only on high-end ultrasound platforms.

Introduced for the first time at the European Congress of Radiology, the high-resolution imaging technology was the subject of a special symposium to demonstrate how advanced examinations can be routinely performed in primary care.

Functions inherited from higher-class models include Adaptive Image Processing (AIP) where speckle noises are reduced while maintaining the clear boundary of a tissue as depicted by the reception signals. This capability is most useful when it is difficult to see tissue differences.

Up to now, ultrasound diagnosis of solid organs has been based on the examination of the difference of speckle patterns while in other imaging modalities, such as CT and MRI, the same tissue is shown by brightness and heterogeneous tissues are represented by a different level of brightness.

With the new F37 ultrasound system, the radiographer need not scrutinise the speckle patterns by narrowing the eyes to detect differences, but can easily differentiate tissues by looking at the difference in brightness.

Following last year's acquisition of Aloka Co Ltd by Hitachi Medical Corporation, their powerful combination in Hitachi Aloka Medical Ltd has united next generation technologies in high-end ultrasound for use by family physicians and small practices

Unlike speckle removal techniques, Hitachi-Aloka's AIP does not spoil the resolution or the amount of information contained in the original images.

Also on board the F37 (further raising the standards for everyday ultrasound) is Spatial Compound Imaging (SCI) to support optimum acquisition of images for the exam target, and the Image Optimiser, which enables concentrated examinations by simplifying image adjustments.

An unexpected capability on the F37 is Hitachi-Aloka's eFLOW, a high-definition blood flow imaging mode with drastically improved spatial and temporal resolution. This mode makes it possible to display blood flow information with higher sensitivity and resolution than with conventional methods, enabling detailed observation of fine blood vessels, such as those inside a tumour that have proven difficult to display separately in conventional methods. For example, eFLOW has a resolving power that can separately display the hepatic artery running alongside the portal vein.

Directional display, which is useful for identifying blood vessels, overcomes the problem of trade-off between high detectability of low velocity flows and aliasing. The directional eFLOW (D-eFLOW) offers blood flow information with high resolution by optimising the transmission/reception sequence and the settings of colour coding and others according to the purpose of the examination.

The diagnostic value of the F37 is increased with Broadband harmonics that uses the large amplitude transmission, typically represented by compound impulse waveform transmission. The technique of removing the fundamental wave components by phase modulation is used to assure a high and wide frequency distribution and generates images with straightforward sounds, compared with phase-modulated harmonics.

The straightforward design and surprising simplicity of the F37 is the most striking quality of this newest addition to the Hitachi-Aloka line. The layout of the operation panel was designed so that even first-time users can naturally operate the system. The freely customisable operation panel offers a simpler, comfortable exam environment, leading to higher efficiency.

Ergonomics

Examinations can be performed in a natural posture, reducing strain on the examiner. A large-capacity HDD was also adopted to keep a record of everyday examination information.

The clear focus on enhancing performance in primary care for clinics and institutions is expected to bring high-end exams into new regions of Europe and encourage more advanced exams with greater comfort and confidence among new users of diagnostic ultrasound.

The vicissitudes of breast screening

Michael Krasnitzer reports on a controversy without end

The benefit of breast cancer screening for women over aged 50 is beyond doubt. However, what does a systematic search yield for breast cancer in women aged between 40 and 49? This question, which remains controversial, was raised again at ECR 2012.

For Professor Andy Evans (Centre for Oncology & Molecular Medicine, University of Dundee, Scotland) the answer is positive: 'Yes, there is good evidence that women in their 40s should have breast cancer screening.' However, radiologist Matthew G Wallis MB ChB FRCR, at (Cambridge Breast Unit and the NIHR Cambridge Biomedical Research Centre, UK) believes this question cannot be answered conclusively: 'It's a question of the balance between the benefit and the damage.'

Screening advocate Prof. Evans bases his view on a series of studies that confirm the reduction of breast cancer-related mortality in women aged 40–49. However, he admits that these examinations have certain weaknesses. He is largely involved in the 'Age Trail', a current British study. The first study results, published in *The Lancet*, point towards a significant reduction in mortality but, as acknowledged in that specialist publication, are not statistically significant. Two Swedish studies, carried out in Malmö and Gothenburg, used examination procedures specifically geared towards this age group, which don't correspond with the conventional breast cancer screening methods.

Although the critic Matthew Wallis shares the opinion that breast cancer screening lowers mortality, he points towards the problem of the many false positive screening results. 'In around three in 1,000 women examined a carcinoma is detected – but in around 150 patients something is detected that necessitates further examinations,' he emphasises. This leads to enormous costs and affects the quality of life for the affected patients. Moreover, Wallis also points towards the fact that tumours detected at an early stage are all lumped together, no matter whether they are fast growing aggressive tumours or slow growing and less aggressive ones.

The controversial age group of 'women aged 40–49' might just have been inappropriately chosen. 'Maybe breast cancer screenings should start for patients aged from 45,' suggests radiologist Dr Sophia Zackrisson (Skåne University Hospital in Malmö, Sweden). 'We tend to look at ten-year groups, but there is no reason why we have to include 40-year-old women; it could be 45,' Prof. Evans concedes.

A move away from thinking in ten-year steps might be the solution to the controversy. Some countries have already drawn this conclusion. As announced only recently, starting from 2013, all women aged between 45 and 69 in Austria are to be regularly invited for a mammography by personal letter.

Many radiologists are also convinced that better examination procedures are the answer to the problem. MRI facilitates a significantly better view into the breast than conventional mammography, stresses Dr Laura Martincich (Istituto per la Ricerca e la Cura del Cancro, Candiolo (Italy). 'The use of MRI in breast cancer screening could significantly reduce the number of false positive results.'

Indeed, contrast-enhanced MRI is increasingly being used in clinical practice. 'In a high-risk population, the sensitivity of MRI is over 90%, whereas that of mammography plus ultrasound is 60-65% at best,' explains head of radiology Prof. Francesco Sardanelli (IRCCS Policlinico San Donato, Milan, Italy). In terms of 'high-risk population' the professor is referring to those women who are at higher risk due to a familial history of mutations of certain genes (e.g. BRCA1). 'Women in these risk groups should have annual examinations with MRI,' he has stressed.

ECR 2012
Vienna news and views

Mark Nicholls' roundup from this year's European Congress of Radiology in Vienna

IMAGING PREGNANT WOMEN


Daniela Prayer

Figures suggest that imaging of pregnant women increased by 121% between 1997 and 2008, even though radiologists face several critical challenges when imaging these patients. Choosing the best modality, ensuring the dose is not too high to damage the foetus yet ensuring a correct diagnosis is obtained and acknowledging that two – not just one – patients are being treated, are all major considerations.

The *Imaging During Pregnancy* session, chaired by Professor Monika Bekiesinska-Figatowska (Institute of Mother and Child, Warsaw, Poland), also aired the challenges in cases of polytrauma and of diagnosing pulmonary embolism.

Ultrasound and MRI foetal risks

Dr Magdalena Wozniak (Medical University of Lublin, Poland): 'Adverse effects of ultrasound depend on the intensity of the beam, duration and frequency,' she pointed out. 'There are thermal and non-thermal effects as the human embryo and foetus may be vulnerable to elevated temperatures.'

There is a greater risk of inducing thermal effects in the second and third trimester while non-thermal effects are more significant in early gestation, Dr Wozniak explained. Steps to keep the foetus safe during ultrasound examinations include keeping the thermal index below one, using the lowest output for the shortest possible time and limiting the exposure time.

MRI is, she added, a 'well-proven, well-established' modality for imaging the foetus. 'Foetal MRI is recognised as a safe modality and no abnormality effects from foetal MRI have been demonstrated. MRI contrast agents should not be given routinely but can be given if essential to get the diagnosis.'

To keep the foetus safe during MRI, it is important to keep the SAR (Specific Absorption Rate) under 2 w/kg WBA, limit examination time, keep temperature rise to a minimum and always to perform foetal MRI under the supervision of a radiologist, she warned.


Magdalena Wozniak

In looking at the risks of radiation and contrast media to the mother and foetus, Professor Daniela Prayer, head of the division of Neuroradiology and Musculoskeletal Radiology, Medical University of Vienna, said that, when scanning, the dose should not exceed 100mGy and that termination of pregnancy in foetal doses of less than 100 mGy was not justified.

As pregnancy proceeds, she pointed out that the risk of malformation from an examination reduces.

In early pregnancy cases, Professor Prayer said that ultrasound and MRI should be the preferred modality for examination and contrast media can be applied.

Polytrauma in pregnancy

Radiologist Professor Andras Palko (University of Szeged, Hungary): 'When polytrauma in pregnancy occurs you need to provide for two patients – the mother and foetus – which is a very complicated situation and requires a multidisciplinary approach. However, we have to remember there is no foetal survival without maternal survival, so the mother's condition takes priority. The exception is in the advanced stages of the third trimester where poor maternal prognosis may mean saving the foetus by caesarean section.'

Professor Palko pointed out that, when polytrauma occurs in pregnancy, rapid radiological examination is essential and CT has the advantage of covering body segments in a short time, though early ultrasound evaluation can rapidly triage unstable patients. 'Ultrasound is the first method off choice but, in polytrauma cases, CT is an indispensable tool.'

Pulmonary embolism

Dr Anna Larici (Dept. of Radiology, Catholic University, Rome) pointed out that that pulmonary embolism in pregnancy is a leading cause of maternal mortality in the developed world – often due to delayed diagnosis. Imaging, she explained, can play a critical role in addressing this.

HYBRID IMAGING: VIRTUAL FDG-PET/CT BRONCHOSCOPY


Till Heusner

Virtual FDG-PET/CT bronchoscopy has been found to be a technically feasible tool for the detection of lymph node metastases in non-small cell lung cancer patients with good diagnostic accuracy, according to researchers at the Department of Diagnostic and Interventional Radiology, University Hospital Dusseldorf and Essen. The team has been clinically evaluating a newly developed software application from Siemens Molecular Imaging and using a Siemens scanner equipped with a 2x64 slices CT scanner and high-definition PET for their research.

Senior radiologist and team leader Dr Till Heusner, said: 'This new tool enables physicians to virtually fly-thru the bronchus system from PET/CT scans and to see "hot spots" resulting from bronchial carcinomas or lymph node metastases underneath the morphological surface. Without the functional PET information, meaning by CT morphology only, these malignancies would not be detectable on a virtual fly.'

A factor in pursuing this line of research by the Dusseldorf radiology team, which collaborated with the University of Essen radiology and nuclear medicine departments, was the need to offer clinicians the most axially displayed radiologic information possible. 'This may help them to more realistically plan interventions such as bronchoscopy-guided biopsies,' Dr Heusner explained.

FDG-PET/CT is an imaging modality in which a PET scanner and CT are installed 'in line' with FDG – a radioactively labelled glucose molecule – injected intravenously prior to the investigation. This accumulates in the vast majority of tumour cells and shows radiologists where tumour deposits are located in the body.

The researchers found that the software application was almost ready for clinical use. 'It runs in a robust way and reaches a high diagnostic accuracy when it comes to the detection of FDG avid parabronchial or paratracheal lymph node metastases in non-small cell lung cancer patients. Even relatively small bronchi in the periphery of the lung can be reached by the virtual fly-through,' said Dr Heusner, whose sub-specialities are hybrid imaging and interventional – vascular and oncologic – radiology, and who heads the university hospital's oncological hybrid imaging working group.

Hybrid imaging is growing in importance all the time regarding primary staging, follow-up and early therapeutic control in a range of malignancies, he pointed out, adding that the next step from the FDG-PET/CT work is to look at MR/PET and the improved soft-tissue contrast it can offer. 'One of the big advantages of hybrid imaging is the possibility to detect very early lymph node metastases. This mainly is the merit of PET – it is able to show us little amounts of tumour deposits when morphological findings suggesting malignancy are still missing. Since PET alone often cannot precisely locate lymph node metastases, the combination of PET/CT as well as MR-PET now can precisely tell us where the lymph node is localised.'

The technique allows radiologists to become much more confident in diagnoses and helps triage patients to the 'most adapted, personalised therapeutic strategy to their disease stage' and may enhance survival chances.

A range of other papers was presented during the session 'Hybrid imaging: PET-CT and MR-PET'.

Dr Paoletta Mirk (radiology department, Catholic University of the Sacred Heart, Rome) outlined her team's work on the 'additional value of dual-phase 18F-FDG PET-CT in recurrent gynaecological malignancies.' They compared this with standard PET-CT and found it had higher sensitivity and higher accuracy.

Dr Kazuhiro Kitajima (Department of Radiology, Kobe University), and team, compared low-dose non-enhanced CT with full-dose contrast-enhanced CT in integrated FDG-PET/CT studies to diagnose ovarian cancer. They discovered that PET contrast enhanced CT is an accurate modality to assess ovarian cancer recurrence.

A team from Padua, Italy, found that PET-CT was more accurate than CT in the detection of bone marrow metastases, while German researchers at the University of Tubingen showed that contrast-enhanced CT improved malignant lesion classification.

MULTI-DISCIPLINARY EFFORTS FOR RECTAL CANCER PATIENTS


Gina Brown

Speaking at the *ESR meets Radiation Oncologists* session, Dr Gina Brown (Royal Marsden NHS Foundation Trust, London) emphasised that radiologists' input is critical in treatment and surgical decisions and that radiologists, oncologists and surgeons should work more closely in the planning and delivery of treatment and surgery for the overall benefit and long-term well-being of rectal cancer patients.

The theme of the session, chaired by ECR President Professor Lorenzo Bonomo and ESTRO (European Society for Radiotherapy and Oncology) President Professor Vincenzo Valentini, was imaging and tailored radiation therapy in rectal cancer.

Dr Brown discussed the staging of patient treatment and said that, with early tumours, MRI was an effective modality because radiologists can see the rectal wall intact, identify polyps, and from this make suggestions to the surgeon that the first treatment might, for example, be local excision.

She also added that patients should have a choice of treatment - dependent on the stage of their cancer and their personal preferences – which can range from primary surgery, local excision, chemotherapy, or regular monitoring of the mesorectum.

Patient selection was critical, with the radiologist playing a defining role but, she added, it was about close co-operation with oncologists, pre-op discussions, MR and surgical surveillance and a good working relationship between radiologist and surgeon. 'You have to get to know your surgeon and work as a multi-disciplinary team to ensure your contribution as a radiologist is as good as it can be.'

Measuring the depth of tumour spread – particularly if it is more than 5mm - is critical and enables the MDT to start to stratify the patient's treatment more effectively. Radiologists can identify high-risk patients, she said, by whether the tumour has spread more than 5mm, or whether there has been extra venous invasion, and also assess the risk of pelvic recurrence.

Staging classifications, she pointed out, have been devised for low risk rectal cancers and there is a clear paradigm for treatment, but the key is to re-stage after treatment and aim to have sphincter-saving surgery where possible.

Dr Brown concluded: 'Radiologists are a crucial part of the MDT in a treatment-orientated strategy. We should not be afraid to suggest treatment options and to audit the quality of the treatment decisions and the quality of the surgery if we are to improve outcomes for our patients.'

Professor of Oncologic and Abdominal Imaging Regina Beets-Tan, (University Medical Centre, Maastricht) discussed the future of imaging in rectal cancer and said there is still no clear evidence as to what the best modality will be. 'The debate now is whether we can go further for organ saving treatment without compromising outcomes and that is what we as radiologists will have to see as our next challenge. To do that, we will need imaging tools that are so precise that we will be able to help clinicians with that selection procedure.'

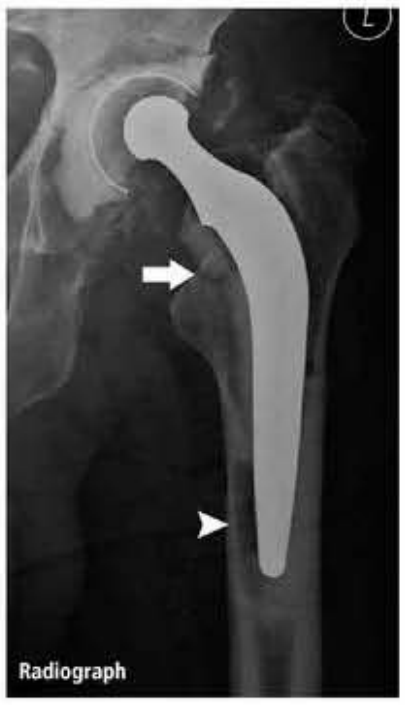
Dr Guido Lammering (Department of Radiation Oncology, University Medical Centre, Maastricht) said that radiologists are expected to have a role in predicting patient responses to treatment because oncologists and surgeons will want to tailor treatment.

IMAGING HIP JOINT REPLACEMENTS

Ultrasound and radiography are helping to identify causes of failures and patient pain from hip joint replacements. However, CT and MRI are also important in some circumstances, according to experts speaking at the state of the art symposium *Imaging Hip Joint Replacement*.

Consultant musculoskeletal radiologist Dr Steven James (Royal Orthopaedic Hospital, Birmingham) outlined the role that radiography and ultrasound play for such patients. 'There is a great deal of information that we can provide regarding specific abnormalities that can be identified by ultrasound, which is a very powerful tool for this patient group.'

Surgeons across Europe use many different prostheses, he explained. In the United Kingdom the tapered, polished, femoral stem is the most common implant - and the femoral head can be ceramic or metal.


Radiograph

While one mode of major failure is dislocation, there are other more subtle problems that need to be identified. To do this, radiologists need to look at serial radiographs for periprosthetic radioluceny.

The fixation of hip replacements can either be cemented or non-cemented and there can be different abnormalities within each – at the prosthesis cement interface, bone cement interface, or at the prosthesis bone interface.

Other issues can include bone sclerosis, component malposition, acetabular component migration, or the femoral stem can subside. These can be identified through radiography examination, he said.

When looking for abnormalities using ultrasound, Dr James stressed that it is important for the radiologist to understand the surgical approach used by the orthopaedic surgeon – whether it was posterior, lateral, or anterior. 'That will give us an idea of which complication we might find. The most common one we may find is the presence of hip joint effusion, which may be an indication of loosening or infection. We can differentiate between fluid and synovium with ultrasound. It's important for the surgeon to know about the presence of a joint effusion because it may be an indication for subsequent joint aspiration.

'The great advantage of ultrasound is that you can ask the patient where the pain is and can identify the pathology accordingly.'

Iliopsoas bursitis, iliopsoas impingement and iliopsoas tendinosis can be identified by ultrasound and he added that image guided injection also can be a helpful diagnostic tool. US can also highlight gluteal tendinopathy and various miscellaneous conditions, while for vascular complications he advised the use of colour Doppler.

Ultrasound is also useful to identify Adverse Local Tissue Reaction (ALTR). Different implants are associated with different types of this complication and they can be symptomatic or asymptomatic.

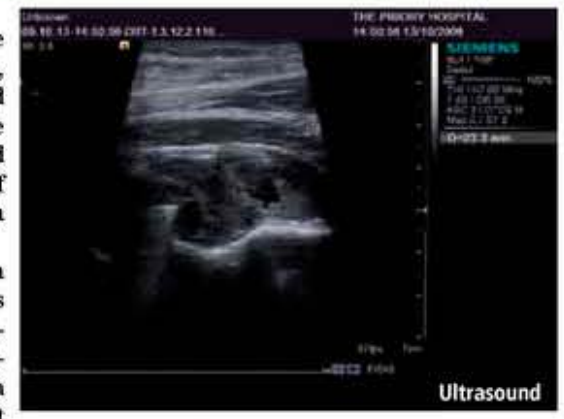
The session heard that it was important for the radiologist to know which type of implant had been used because some problems are specific for certain implants.

Professor Alain Blum (Centre Hospitalier Universitaire, Nancy, France) acknowledged that radiography is the mainstay tool for identifying hip replacement failure but CT scans are important in showing the shape and density of components and can be used to investigate implant failure and help to analyse the status of the bone.

The advantages of using CT, he said, are speed and ease of reading, giving information on the prostheses, cement, bone and soft tissue; it also can be done with low dose, as well as performed in synergy with arthrography.

Metal artefact reduction is important in CT scanning of hip joint failure, Dr Blum stressed.

Dr Stephen Eustace (University College, Dublin) acknowledged that MRI cannot replace radiography, ultrasound or CT in the context of hip joint failure but is a safe modality to use.


Ultrasound

Where it can be a useful tool, he said, is for examining soft tissue and there are situations where it can identify problems that CT or ultrasound may not detect. It is also particularly useful for patients with chronic problems and severe post-operative pain as it can identify deep soft tissue infection.

'MRI is useful and safe in a small number of patients and, when used, may identify the cause of pain and avoid the need for hip replacement revisions.'

3-T MRI IS NOW MORE ACCESSIBLE


Axel McKenna-Kuttner

A new competitively priced scanner promises to make 3-tesla MRI more accessible to a wider range of institutions, according to Siemens Healthcare.

The advantages of the Magnetom Spectra, which combines high quality imaging with affordability, were highlighted in the *Creating the Future of MRI* Satellite Symposium organised by Siemens.

Associate radiologist Dr Axel McKenna-Kuttner (Joint Radiology and Nuclear Medicine Practice, Frankfurt, and head of radiology in its Bad Nauheim practice) who has been involved in the evaluation of the 3T Magnetom Spectra at the centre, detailed the performance of the new scanner, which employs TIM (Total Imaging Matrix) 4G technology - the latest Siemens coil generation. This array structure delivers high spatial and temporal resolution and has good signal-to-noise ratio.

Dr McKenna-Kuttner highlighted the imaging advantages experienced while evaluating the machine when used in areas such as the head, thorax, cardiac, abdomen, wrist, hip and small structures such as fingers.

With the head it was possible to see small structures in detail with a high image resolution, he said, giving comparisons between 1.5-T and the 3-T system.

For the abdomen, he said the Magnetom Spectra imaging was flexible, with excellent spatial resolution and no limitations when scanning heavier patients.

He added that the system worked well in musculoskeletal imaging offering 'superb detail' and scanning time that was no longer than 1.5-T.


The Magnetom Spectra MRI

The system was able to improve workflow, he said, pointing to a reduction of 50% in lumbar spine scan time when using Dixon sequence. 'That's important, because about 20% of our daily workflow is with lumbar spine imaging.'

Dr McKenna-Kuttner concluded: '3-T imaging delivers superior image quality in musculoskeletal imaging and neuro-imaging. The critical regions, such as cardiac or abdominal imaging, have no limitation and 3-T scanning can be executed economically.

'The Magnetom Spectra is an MRI scanner that will enable many radiologists to utilise 3-T for the first time… so we now have the means of delivering better patient care even under tight budget conditions.'

Siemens points out that the Magnetom Spectra is equipped with the firm's MRI workflow solution DOT (Day Optimising Throughput), the benefits of which were discussed by Dr Christoph Bremer (St Franzikus Hospital radiology department, Munster) when used in connection with his department's Magnetom Aera 1.5-T scanner installed in August 2010. With some technicians in his department having limited MRI experience, he said DOT helped simplify examinations.

In a study, his team compared non-DOT workflow (which has nine stages) to DOT workflow (with five stages). Focusing on MR angiography, they studied 10 DOT and 11 non-DOT activities, looking at image quality, SNR measurement, the number of technician clicks, and examination and acquisition time.

In the workflow analysis the examination time for non-DOT was 19 minutes, acquisition time 13 minutes with 110 mouse clicks. With DOT the exam time was 17 minutes, with 11 minutes acquisition time and 74 clicks.

'The complexity of MR examinations has definitely been reduced by DOT, while the image quality is increasing,' Dr Bremer concluded. 'It speeds up workflow and specifically supports technicians with moderate MR experience. However,' he added, 'DOT does not replace technicians' expertise within your team.'

Professor Claus Claussen, Director of the Department of Diagnostic and Interventional Radiology at the University of Tubingen and the session chairperson, also examined the benefits of hybrid imaging, looking at MR-PET and PET-CT.

Hypofractionation

Making prostate cancer therapy more effective, more comfortable for patients and less expensive for society?

Dose escalation, up to 80 Gy and above, may be necessary to successfully treat localised prostate cancer with radiotherapy (RT). 'This is a challenge for radiation oncologists in their search for an optimal treatment of a movable, centrally-located, almost spherical target surrounded by dose-limiting critical organs such as the rectum, bladder and femoral necks', says Professor Raymond Miralbell head physician of the oncology radiation department at Geneva's university hospital.

In Geneva the professor is about to launch the even more ambitious study: *Stereotactic body radiotherapy (SBRT) for cT1c - cT3a prostate cancer with a low risk of nodal metastases (≤ 20%): a Novalis Circle Phase I-II prospective randomised Trial.*

In this, 76 patients will receive 7.25 Gy in five days, one every two days. 76 patients in the other group will have the same dose, but only once every week over 28 days. 'The goal is to observe whether the toxicity is low enough and equivalent in the one group in nine days or, in the other, in 28 days in four weeks. From the literature we know that the treatment should not be excessively protracted, to avoid tumour cell proliferation during the treatment interval, which might increase the load of tumour cells to be killed by radiation,' he explains. '


Raymond Miralbell

The future for curative radiotherapy for prostate cancer may be a mix of more and less: more total dose and more dose per fraction delivered in less number of fractions (hypofractionation), to a lesser treatment volume boost to the dominant tumour-bearing region inside the prostate.

In the last two decades hypofractionated high-dose rate brachytherapy has been successfully employed in delivering a focused boost after standard fractionated external beam RT to the prostate pelvic nodes. External stereotactic body RT (SBRT) can be used as a contemporary dose escalation approach comparable to HDR-BT, to escalate the dose to the prostate non-invasively and in optimal radiation safety conditions.

Prof. Miralbell's benefits in the use of this therapy include:

Moderate hypofractionation (from 2.5-3.5 Gy) has been a standard treatment procedure in the UK, Canada and Australia for many years

Treatment delivery is fast, with reduced numbers of fractions being better for patients and perhaps less expensive

Advances in image-guided target conformation prevent normal tissue surroundings from large radiation doses and minimise potential toxicity

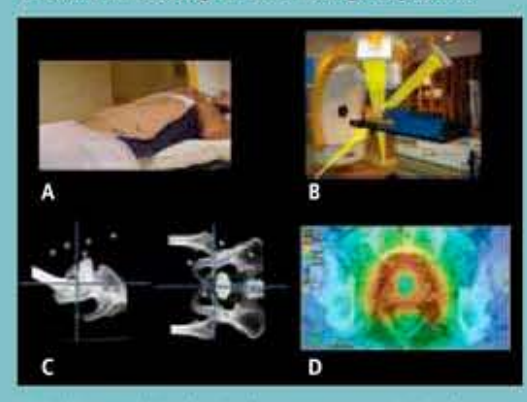
Hypofraction is radiobiologically sound against prostate cancer cells with relatively low radiosensitivity and high repair capacity of sub-lethal damage.

Indeed if, for instance, after delivering a standard dose per fraction of 2 Gy the survival fraction of the tumour cells would be about 75% after twice the dose per fraction, i.e., 4 Gy, the survival fraction might be only 15%, a killing effect of five times more cells by just doubling the dose. 'Hypofractionation is the challenge to deliver very high doses to very small volumes, very well defined and very well guided by the imaging. So we take the benefits of radiobiology and technology', the professor explains.

Just a few preliminary studies have recently shown the potential of hypofractionation in improving the therapeutic outcome.

However, back in 2001 extreme hypofractionation began with the Novalis machine. Two weekly fractions of a very high radiation dose (i.e. 5-8 Gy) were given at the end of a standard fractionated irradiation programme of 32 times 2 Gy in daily sessions, to test the same hypofractionation concept that high-dose rate brachytherapy could already obtain.

The results were very encouraging, especially considering the patients' advanced local disease status, with an eight-year biochemical disease-free survival (bDFS) and disease-specific survival (DSS) results of 95% and 100%, respectively. Among the cured patients testosterone levels at last follow-up were back to normal in 90% of patients.



a) Patient positioning before treatment: Lying in an immobilisation body cast and fixing five small spherical pins (infrared sensitive) in the skin
b) X-ray imaging (two oblique views, right-left) from the pelvis to check the geometrical reproducibility of the internal structures (bones and fiducial markers) before treatment, thus helping to correct the position of the patient if necessary
c) A lateral and an anteroposterior view of the pelvic structures and skin markers from a 3-D reconstructed digital image obtained from the simulation CT before treatment planning (ballistic step)
d) Dose distribution inside the target (i.e. the prostate) based on the chosen treatment ballistic sparing the urethra (in the centre of the prostate) and the rectum (behind the prostate). Each colour wash represents a percent value of the prescribed dose (e.g. brown for 100%)

days) may show a worse tolerance due to the short treatment time, patients treated along the more protracted second arm (28 days) may risk a lower control probability because of an accelerated repopulation of tumour cells. 'We want to be sure that the effect will be as good as we expect, thus a rate of 90-95% cure.'

Extreme hypofractionated stereotactic-guided IMR to the dominant tumour-bearing region within the prostate is feasible and shows an acceptable toxicity as well as an excellent outcome. Accurate target definition with functional MRI, an efficient immobilisation device, and reliable control of internal organ motion, are all key factors to assure the highest precision in this treatment technique. Additionally, optimal dose homogeneity within the target, an OTT of five weeks or less, and fraction treatment duration of 15 minutes or less, should be attempted to gain the maximum benefit of SBRT for prostate cancer.

Way back in 1950s accidental observations and reports showed that it is possible to reduce the insulin dependency amongst Type 2 diabetics by bypassing the duodenum.

Dr Michael Frenken was the first doctor in Germany to operate on Type 2 diabetics with the primary objective of achieving diabetes remission. By bypassing the duodenum during the digestive process and the passage of food it was possible to reduce the insulin dependency of Type 2 diabetics. His results confirmed earlier

Diabetes

Anja Behringer reports on


Cardiologist and principal investigator Rolf Dörr

With an aging population multimorbidity is increasingly a major challenge for hospital care. Diabetes is one of the medical conditions frequently encountered in multimorbid patients since cardiac and vascular diseases are often accompanied by dysfunctions of the blood sugar metabolism.

In his recent study *Silent Diabetes*, published last November in Diabetologica, Dresden-based cardiologist Rolf Dörr MD explored the relationship between diabetes risk and the severity of coronary artery disease (CAD). Although this relationship affects the available therapy options, many at risk patients are never identified because they are not adequately tested, Dr Dörr points out. Even more alarming, 'different blood sugar measurement methods provide different results'.

In 1,015 patients who had had a coronary angiography but who had not previously been diagnosed with diabetes, Dr Dörr and team measured HbA1c and performed an oral glucose tolerance test (oGTT), also called a blood sugar stress test. Based on the OGTT, (51% of the patients were classified with NGT (normal glucose tolerance), 1% with IFG (impaired fasting glucose), 34% with IGT (impaired glucose tolerance) and 14% were diagnosed with diabetes. According to HbA1c measurements, 58% of the patients were classified as normal, 38% as borderline and 4% were diagnosed with diabetes. These results indicate that HbA1c alone misses a substantial proportion of patients with silent diabetes and that every cardiac catheter patient with suspected or diagnosed CHD should undergo an oGTT.

The German Diabetes Foundation thus recommends oGTT and an HbA1c test to reliably identify cardiac patients at risk because in single tests too many diabetes cases remain undetected.

Dr Dörr underlines that it is important to know whether patients with coronary vasoconstriction have diabetes. He explains, for example, that diabetes mel-

and CAD

a neglected risk factor

An HbA1c test is not sufficient to detect diabetes. Diagnostic safety is provided by oGTT, which measures blood glucose increase/decrease after sugar intake

litus patients should always receive drug-coated stents to widen the arteries, while a bypass is the surgical intervention of choice when several vessels are concerned and CAD is severe.

If diabetes is properly managed then surgery, even a major intervention, is not associated with an increased risk. This, however, is not the case when complications such as CAD, neuropathy and nephropathy are present. In any case, surgery for diabetics needs special preparation and precautions by both patient and surgeon. Since stress hormones are released during surgery, the blood sugar levels increase, which means higher insulin doses are necessary.

If surgery is planned for a diabetic, preparation should begin a few weeks before.

- The surgery should be discussed with a diabetologist because adequate blood glucose levels reduce post-surgery wound healing complications and infections. HbA1c should not exceed 53 mmol/mol (7%).
- The anaesthetist needs information regarding the diabetes therapy, for example whether it is drug-based (if so which medication is administered) or insulin-based. Some oral diabetes medications (sulfonylurea and Metformin) must be discontinued two days before surgery, because under surgical conditions those drugs may cause dangerous lactic acidosis.
- During 12-hour fasting before surgery the insulin dose needs to be adjusted. During surgery an infusion of 5% glucose and minerals is provided separately from the insulin via an infusion pump. During and for some time after the intervention, blood glucose is measured in 30 to 90 minute intervals and the infusion pump is adjusted accordingly. After surgery the regular insulin or medication therapy is restarted with normal meals.

** The Silent Diabetes study was co-initiated by the Forschergruppe Diabetes e.V. at Helmholtz Centre in Munich, Germany, and supported by Roche Diagnostics, a researching company and market leader in in-vitro diagnostics*

observations. However, the type of surgical procedure, the length of the disease and the period of time for which the patient has been dependent on insulin are all significant factors for a complete remission.

Dr Frenken, who is a now a consultant at the Department for General, Visceral and Transplant Surgery at University Hospital Heidelberg, hopes that a prospective, randomised and controlled multicentre study, led by the University, and involving around 400 people, and beginning in mid-2012, will confirm his observations.

Surgery proves successful for Type 2 diabetes remission

Michael Frenken

Obesity is physically debilitating – and costly for healthcare. Losing excess weight has positive effects on the entire metabolism and improves life expectancy. However, for patients who cannot lose their morbid, excess weight through diet, today's surgical interventions can help towards permanent weight loss – and reduction in insulin dependency for diabetics

Since 2005, Dr Frenken has operated on 142 patients with Diabetes mellitus Type 2 at the hospital in Monheim. 90% of these patients were morbidly obese (BMI over 35), 10% had a BMI under 35 and were therefore, according to current legislation, not entitled to weight-reducing surgery because of morbid obesity. 82% of patients who had the surgery were insulin-dependent. This is the largest study series published in Germany so far.

Dr Frenken used three types of weight-reducing surgery for his interventions, i.e. the very popular gastric bypass (for 31 patients), biliopancreatic diversion, also known as the Scopinaro procedure (for 17 patients), and biliopancreatic diversion with duodenal switch (for 94 patients).

The result was a dramatic improvement of the Type 2 diabetes within only a few days after surgery at a point where patients had not yet started losing weight. The reason for this is not yet clear; most probably the improvement of blood glucose levels can be traced to specific hormonal changes that occur after bypassing the duodenum, and which happen very quickly – but are, in principle, also reversible.

What are the predictors of success?

Not all patients who underwent surgery were free of diabetes afterwards. However, based on Dr Frenken's examination results it is now possible to predict relatively well who might benefit from the surgery, i.e. gain a complete remission.

However, even patients who do not achieve a complete remission can benefit considerably from surgery. The most successful procedure has been shown to be biliopancreatic diversion (BPD) in both its versions. Even patients who have been insulin-dependent for 5-10 years achieve a 90% remission. Only 50% of patients undergoing a gastric bypass achieve those results. Patients who have been insulin-dependent for less than five years achieve a remission quota of 80% after gastric bypass surgery and of 95% after BPD.

However, if patients have been insulin-dependent for more than 10 years the insulin producing cells in the pancreas are so burnt out that a complete cure for these patients – or to alleviate the insulin dependency completely – is usually no longer possible. The remission rate after BPD then drops down to 50% and after gastric bypass to considerably lower than 50%.

Another possible argument for biliopancreatic diversion as the procedure of choice to treat Type 2 diabetics patients who have been insulin-dependent for longer is that the recurrence rate after gastric bypass is up to 40% after five years, but after BPD it is only a maximum of 4% in a much more diseased patient population.

The explanation for this may be that after gastric bypass surgery the remaining beta cells are stimulated into increased insulin production because there is still an insulin resistance, even though this is much improved, whilst after BPD there is literally a recovery of the beta cells because this type of surgery facilitates a complete recovery of inulin sensitivity.

The decisive feature of Type 2 diabetes is that patients have an insulin resistance, i.e. although they initially produce sufficient insulin, the peripheral organs, particularly the liver, as well as fat cells and muscles do not recognise the insulin signal properly and the body has to produce more insulin for the glucose to be metabolised appropriately.

In the development of Type 2 diabetes there is the initial insulin resistance, which is compensated for quite a long time by increased insulin production, up to the point where this compensation mechanism no longer works. From a certain point the pancreas can then no longer produce increased amounts of insulin and, from then on, patients slowly develop into manifest Type 2 diabetics. Their blood sugar levels increase and that raised blood glucose level has a toxic effect on the pancreas, with continued destruction of the insulin producing cells functionality in the pancreas.

The soon to begin multicentre study will show evidence, at the highest level, as to whether the expectations generated by Dr Frenken's results in Monheim are justified. 'If, eight years after the start of the study, we can show that through surgery it's possible to lower the mortality rate as well as the rate of diabetic complications in Type 2 diabetics, then this will be a breakthrough for this procedure,' he concludes.

SEEING EYE TO EYE

Heidelberg's doctor/nurse equal partnership concept raises staff/patient satisfaction


Gisela Müller

For the past decade the surgery and anaesthesiology departments at Heidelberg's 340-bed University Hospital have encouraged cooperation between doctors and nurses that has set the standard for other hospitals within its remit. Under the motto *Care at eye level*, the physicians transferred certain responsibility of care to nurses, resulting in a significant improvement in healthcare provision with simultaneous improvements to the working ambience as well as treatment quality.

Gisela Müller, the head of Nursing and Services at the hospital's Surgery Department who manages some 800 nurses and service staff (including physiotherapy, social services and cardiac technology), said the concept positively impacted on negative aspects of clinical life, turning uncoordinated processes, insufficient dialogue between the professions, long waiting times, fluctuations in capacity utilisation of operating theatres and beds into events in history.

Initially, the concept came about when Professor Markus Büchler joined the surgery department about ten years ago. 'Because he regarded nursing care as an equal partner we could make structural and other changes on a completely different level,' she explained. In a university hospital, which traditionally sees a strong fluctuation amongst doctors, nursing is perceived as a continuous, stable entity within the organisation. Nursing and medical directors in Heidelberg work 'at eye level', i.e. they are equal partners.

This partnership extends to all departments within the hospital. 'In the course of professional communication over the years, we found a common language,' Gisela Müller said, adding that she is involved from the start in all communication structures, i.e. participating in hospital management meetings as well as regular doctors' meetings.

A competence shift in wound, pain and patient management

The question that opened up the concept was: Who does what best? 'This showed, for instance, that the changing of dressings should be the responsibility of nurses rather than doctors. The patient now doesn't have to wait until the doctor returns from the operating theatre in the afternoon. Instead, wound management is carried out at regular times. This improves the treatment plan and daily structure for patients,' she explained.

For pain management, certain tasks were transferred to the pain nurse who carries out ward rounds for postsurgical patients. Once daily, an anaesthetist supports them in this task.

For medical colleagues this transfer of tasks means they can concentrate on their key competencies while the nurses provide more assistance with planning and organisation. The establishment of the central patient management concept is directed with the same objective. 'Previously, patient management was often dependent on a consultant, but nowadays an experienced member of nursing staff pulls the strings. They, and their colleagues, are reliable contacts for the patient from the point of admission right through to discharge.' All information converges so that bed capacity and operating theatre management are also controllable.

Through cooperation with hospitals providing the area's primary care – and because of contacts with referring doctors, patient care is controlled by central patient management. Less severe cases are treated in cooperating hospitals whilst more complex cases are treated in the university hospital's surgery department.

Due to all these measures the performance statistics rose significantly. Thus the central patient care concept has been transferred to all other hospitals linked to Heidelberg University Hospital.

The 'eye level' concept is not only an economic success. The working climate, satisfaction among employees, patients and referring doctors, along with treatment quality have all improved, based on the daily appreciation and respect between doctors and nurses.

New network could lower accidents mortality

Surgeons and radiologists unite to ease image transfers

The *TeleCooperation TNW* project, a new development in Germany's medical care for severely injured patients, links with several hundred hospitals to ensure the rapid transfer of image data across the country.

This as yet unique radiology network, developed by the German Society of Trauma Surgery (DGU) and the Information Technology Working Group at the German Radiological Society (DRG), is run by the DGU subsidiary, the Academy of Trauma Surgery (AUC).

The DGU has worked for some years on various related quality assurance projects, including the *Traumaregister DGU* that, up to 2011, collated data on about 50% of severely injured accident victims. Through its trauma networks, DGU drew together over 800 hospitals that regularly care for the severely injured in regional networks. TeleCooperation TNW is now providing a national infrastructure, closing existing communication gaps between hospitals. 'Participating hospitals can exchange X-ray images regionally within their own Trauma Network, as well as cross-regionally for consultations with specialists,' said Professor Tim Pohlemann, DGU's First Vice President. Rural regions, or those difficult to cover, will very much benefit from the new network, added to DRG President Professor Michael Forsting.

The financial and organisational expenditure for hospitals is comparatively small – all that's needed for data transfer is a computer with internet access. Even transferring larger data bundles – say around 1,000 image files – should not take more than 15 minutes. Handling is described as 'easy' and costs – particularly for smaller hospitals – appear to be affordable. The basic teleradiology packet is about €100 a month to run and can be enhanced by further modules.

For an additional sum the system can make X-ray images available on the computers of doctors working from home, to network them in via the portal for a consultation without having to travel to the hospital – thus the hospital clinician always has a specialist at hand, explained AUC Managing Director Professor Johannes Sturm.

Images also can be viewed on a Smartphone or tablet-PC.

In the long term, TeleCooperation TNW sees itself as an open and extendable platform that all medical disciplines working with images can utilise and which is not restricted to accident and emergency care. General practitioners, physiotherapists and rehabilitation clinics can also connect to the service.

Around 30-35,000 people a year are severely injured in accidents and need urgent, appropriate and competent care within minutes

The network system also demonstrates how cooperation between specialist medical associations can work. After all, prompt, correct care in an emergency depends largely on the quality of images and fast access to them. 'Radiologists often see themselves as service providers for other medical disciplines. In many cases they are the link between specialists, the central diagnostic interface, and the drivers behind the chosen treatment,' Prof. Forsting pointed out. Teleradiology networks have already been set up in many German areas, but what was missing was a system to ensure the immediate data transfer adhering to data protection laws.

Further opportunities to extend the network may follow – even worldwide. The DGU subsidiary already helps hospitals in Dubai and China with teleradiology procedures. 'It is perfectly conceivable that we will extend our range of services,' said AUC's Prof. Sturm. However, Prof. Forsting stressed that the transfer from Germany of X-ray images to obtain diagnoses abroad will not occur; the law stipulates that diagnoses must be carried out in Germany.

Report: Susanne Werner

The fmCh Public Database

Swiss surgical patients can check on and correct their treatment data and thereby facilitate reliable hospital benchmarking

In 1995, surgeons in the Biel, Burgdorf and Zurich Limmattal hospitals founded the Working Group for Quality Assurance in Surgery (AQC) to collect and compare treatment data. Today, although initially belittled, this first surgical quality network numbers around 70% of all Swiss hospitals.

Initially used by general surgeons and trauma surgeons in particular, the network now has representatives from all surgical sub-specialities and attending doctors are increasingly inputting patient data and treatment results onto this AQC database, with adherence to data protection laws. Since September 2010, patients have been able to check the accuracy of those entries with the help of the fmCh Public Database and, if necessary, officially object to them.

For this so far unique transparency in medical quality assurance worldwide, the fmCh Public Database was awarded the first Swiss Quality Innovation Award at the 3rd National Quality Symposium 2010.

Published quality data without public control are almost worthless. Through the use of the Public Database data quality and their significance increase and become more reliable as they take into account the most important aspect of treatment: the satisfaction and well-being of the patient. The opportunity for direct feedback also increases the relationship and mutual trust between patients and doctors. 'Being asked to check their own data makes patients feel valued, and the hospital presents itself as a transparent and patient-oriented institution. In return, the doctors responsible for data collection have a strong incentive to input data truthfully and accurately,' Dr Luzi Rageth (from the AQC), explained.

Participation in the fmCh Public Database does not entail a large expense. In participating hospitals patients being discharged are handed a letter that explains how they can access the quality assurance data about themselves. They receive an questionnaire for postal replies, or a password for an electronic response (www.publicdatabase.ch). The patient can then check the accuracy of his/her own data, such as state of health on admission, diagnosis and surgery, as well as case-related or postoperative complications and give any feedback. The hospital can accept the patient's request for corrections or choose to discuss them.

The first results from the fmCh Public Database are encouraging. Individual hospitals have had a response rate of 30%. Overall, almost 1,800 patients have responded, of which 83% confirmed the data entered without any need for correction, whilst 17% requested corrections. In 14% of cases the responsible doctor accepted the corrections request immediately; only in about 1% of cases did doctor and patient views not concur at all. Overall, this shows very high patient satisfaction with the doctors and hospitals. 98% of patients who gave their feedback around 6-8 weeks after discharge would recommend the hospitals participating in the Public Database, rating them a 5 or 6 (corresponds with a German 2 or 1).

So far, based on AQC data, about six hospitals are participating in the interactive version of the Public Database, which is structured so that it can also be used by other quality assurance systems, e.g. Swiss Registers.

The ISO-certified AQC and the Public Database ideally fit into the quality assurance set-up of the hospital. AQC tools are perfectly matched with one another. From data capture to validation and analysis, all tools are connected to the same database to generate the greatest possible use.


Luzi Rageth

With currently more than 750,000 cases, AQC data collation is a self-contained system where the doctor alone decides what happens with the data entered.

AQC data can be entered as follows: Transfer directly from the HIS, via hard copy questionnaire or via adjument.net. From May, there also will be an opportunity to evaluate via the online portal www.aqc.ch

Only a controlled flow of data moves from the AQC database into the fmCh Public Database, with the internal data remaining in the hospital. Dr Rageth hopes that participation in the Public Database will then increase further because only a larger response rate will facilitate a representative publication of the data.

For the future, Dr Rageth also plans the utilisation of the opportunities of Web 2.0. for the Public Database, next to the existing evaluation platform and the impending anonymised publication of data. This is to enable patients to communicate directly with one another about hospitals and treatment results in a secure area.

Even if more hospitals could be participating in the initial phase of the fmCh Public Database, Luzi Rageth is convinced that the Public Database will establish itself in Switzerland: 'It gives doctors the security to communicate with patients about the quality of their work. Unlike statistics about complication rates, Public Database shows the interested public vividly where the largest numbers of cases with the best quality are. Instead of drawing attention to failures we deliver the statistics on what is good.'

To date, medics from Germany, France, China, Egypt and even the United Arab Emirates have expressed an interest in the service.

The 129th Congress of the German Society of Surgery

Meeting with EH editor *Brigitte Dinkloh*, Congress Secretary Professor Alexis Ulrich MD (left), Assistant Medical Director at the Clinic for General, Visceral and Transplant Surgery at the University of Heidelberg, outlined the scientific programme, discussed some impressive advances in surgical procedures, and explained why the gathering bears the slogan *Surgery in Partnership*

24-27 April 2012 Berlin Germany

'The 129th Congress is the annual meeting of the German Society of Surgery, which is comprised of ten specialist societies,' Professor Alexis Ulrich explained. 'The congress is also the venue for the annual meeting of the German Society for General and Visceral Surgery. The congress programme is therefore very comprehensive, with more than 1,700 lectures, posters and 19 specialist satellite symposia.

'Each of the four days of the congress has a key focus: On Tuesday it will be on *Research and Studies*, on Wednesday *Surgery in Partnership*, on Thursday *Perioperative and Intensive Medicine* and, on Friday, *Organisation and Management*.'

'The issue is not only the integration of research results into daily clinical life but also state-of-the-art procedures to introduce guideline-compliant and low-risk surgical procedures as well as new operating techniques to the audience.

'A particular highlight will be the live transmission, directly into the largest congress hall, of surgical interventions on the large abdominal blood vessels, pancreas and rectum.

'For the first time, the congress will also host 'grand slam' discussions on controversial topics where the persuasiveness of the opponents can be rated via audience surveys. The German Surgery Congress is an important scientific congress and also an opportunity for training, which is why there will be updates on different treatment strategies for almost all regions of the body.'

Current state-of-the-art procedures

'Starting with rectal surgery, we need to mention total mesorectal excision (TME), a procedure established in Germany since the late 1990s. It is now the gold standard treatment for rectal cancer. However, this new surgical procedure put the entire treatment concept to the test again. Currently there is a question, for example, as to whether and at what tumour stage the conventional, multimodal treatment approach, such as radiation before surgery, is still necessary, given the optimised local radicalness of TME.

'Another branch of research is looking into the individualisation of treatment adapted to the respective tumour stage. The connection between molecular markers and the use of certain antibodies in adjuvant tumour therapy will be another topic. First study results give reason to be hopeful that this so-called individualised tumour treatment will become even more important in the future.

'Minimally invasive surgery will be another important topic at the congress. The controversial issue here is whether even further reductions in the already small number of very small access points for surgery combined with new, significantly smaller but more expensive instruments could result in improvements to the quality of life.

Robots

'Results produced by surgical robots to date will also be of great interest. In any case, experience so far has shown that in regions of the body where, once access has been gained, a lot depends on the tactile sense of the surgeon due to poor visibility, minimally invasive surgery does have its drawbacks. Through the use of robots and intelligent assistance systems – in future with 3-D images – it is hoped that better visibility and therefore better results can be achieved. Advances made in this field will be presented at the congress.

Obesity

'Obesity surgery has become increasingly important over the last few years. It has mainly been carried out – with a low risk of complications – to treat overweight patients. When a gastric bypass – mostly under disconnection of the duodenum - was fitted, a high percentage of insulin-dependent diabetics no longer required insulin immediately after the surgery. This physical mechanism of the clinical cure of diabetics after gastric bypass has not yet been scientifically explained, and many international research groups are currently working on this phenomenon. My colleagues PD D. Beat Müller and Dr Michael Frenken will present a report summarising experiences gained from 140 patients on this topic.

Transplants

'This will also feature at the congress. A lot of importance here is being attributed to the diagnostic evaluation and the avoidance of reperfusion injuries. In the latter case the issue is how to prevent the influx of the toxins, which can develop in the cells after long periods of organ cooling, into the bloodstream.

Pancreas

In pancreatic surgery, where the stomach-preserving Whipple procedure is the gold standard these days, there are still typical complications that should be reduced through improved surgical techniques. In the first instance this concerns the supply of the remaining part of the pancreas, which is prone to the development of fistulas. For instance, one question is whether the seam of the remaining part of the pancreas should be created with the stomach or with the small intestine.'

Radio-chemotherapy

Another topic is the question whether, and for whom, individualised treatment approaches such as radio-chemotherapy lead to better results.

This also concerns patients with locally advanced tumour stages who were previously excluded from surgery. Helped by local radiation it has been possible, as first study results have shown, to achieve tumour reduction in about 25% of cases, which then facilitates radical surgery and therefore improves life expectancy and quality of life.'

A new oral vaccination

'Currently still an experimental approach, the oral vaccination of patients with non-resectable pancreatic cancer involves the use of modified bacteria that carry a certain gene to stimulate the body's immune system into attacking and destroying the blood vessels of the tumour. PD Dr Schmitz-Winnenthal will introduce this study.'

Surgery in Partnership

'Surgery today is inconceivable without its medical partner disciplines. This includes first, obviously, the nurses, but also colleagues from the fields of anaesthesia, oncology, radiotherapy and nuclear medicine. We all know, or should know, that these days the only way to be successful in the sense of curing patients is to work in an interdisciplinary manner.

'However, on the other hand many new developments in medicine sometimes lead to a competitive way of thinking. When stents suddenly open an alternative to a heart bypass or other large vessels, doctors should discuss the pros and cons among themselves to achieve an individualised treatment recommendation. This is the topic that will mainly feature on the Wednesday under the motto *Surgery in Partnership*.'

German surgery today

'In the first 20-30 years after the war we had quite a lot of clinical and scientific catching up to do. The US in particular took the lead in medicine, which, before the outbreak of war, was held by Germany for half a century. German surgery has now caught up to such an extent that there is no longer a clinical supremacy position.

'However, we haven't quite caught up on the same level in science, compared to the US, Scandinavia and the Netherlands, particularly in the case of clinical studies in the sense of evidence-based surgery. Randomised studies have shown that patients benefit when they are not treated with the procedures being most strongly promoted, but in fact those with the best-proven results.

'Being aware of this need to catch up, Professor M Büchler, the current president, encouraged the foundation of the Study Centre of the German Society of Surgery in Heidelberg in 2003. In joint cooperation with the German Research Foundation and the Federal Ministry of Education and Research, the Study Centre supports the planning, implementation and evaluation of multi-centric, randomised controlled studies of all German surgeons, based on the criteria of good clinical practice. This will be demonstrated during the Tuesday focus – *Research and Studies*.'

ORAL VACCINATION AGAINST PANCREATIC TUMOURS

The world's first gene cancer therapy study of an innovative oral vaccine is underway at the Surgical Clinic of Heidelberg University Hospital

For pancreatic cancer patients hope has a name: VXM01. The vaccine contains a bacterium that carries genetic information of the stromal cells and aims to slow down tumour growth and metastases spread.

The scientists use a known strategy: They stimulate the body's immune system by linking the immune defence against the bacterium with the immune defence against the genetic information of the introduced protein.

The project began in December 2012. 'Today, just a few months into the study, the initial results are encouraging,' said Dr Hubertus Schmitz-Winnenthal, principal investigator and head of the section of Endocrine Surgery at University Hospital Heidelberg. 'We are hopeful that the immune defence will react to the vaccine in specific way',

Results in ten days

Developed by Dr Schmitz-Winnenthal with the Swiss-German biotechnology company VAXIMM, the vaccine is being tested in a placebo-controlled dose escalation trial (phase I/II) in up to 45 pancreatic cancer patients. 'Obviously we are closely monitoring the clinical efficacy of the vaccine, nevertheless the study's main objective is the exclusion of adverse effects', the principal investigator explained.

In addition to chemotherapy, either the vaccine or a placebo are administered during a 10-day stay of patients who cannot undergo surgery or where the pancreatic cancer has metastasised. During the trial the dose is slowly increased from patient to patient to determine the most effective dose. At the end of the hospital stay the investigators can evaluate the effects of the vaccine on the immune defence via an immune examination. Biomarkers, MRI and oncological follow-up visualise the therapy results.

Bacterium as a Trojan horse

The bacterium contained in the vaccine acts as a Trojan horse. The modified attenuated carrier bacterium is an approved and well-tolerated vaccine. It transports a gene into the intestinal mucosal cells, which produces a specific protein called VEGFR-2 that is also present in the tumour blood vessels. The intestinal mucosa identifies the protein combined with the bacterium as hostile and thus prompts the immune system to fight cells with VEGFR-2.

Hubertus Schmitz-Winnenthal

The T-cells have a three-pronged strategy: they attack the vessels that supply the tumour with blood and nutrients and are thus a major support system for tumour growth, they attempt to isolate the tumour so that it cannot disseminate, and they attack the tumour cells directly.

Dr Schmitz-Winnenthal: 'Animal studies have shown the vaccine to be effective against several types of tumours. Tumour growth slowed down and metastasisation was reduced. The animals that had been vaccinated had significantly higher chances of survival.'

The first study results on the safety and potential efficacy of the vaccine in human patients are expected in early 2013. Further clinical studies (phase II) will also include patients of other tumour types. If the successes in animals can be repeated in patients, the first oral vaccine to trigger immune responses in the intestines will most likely play an important role in the future treatment regimens of cancer patients.

A cool way to illuminate procedures

The ACEM Medical Company's OT- System, which includes the OT-STARLED 7 and STARLED 5, is based on advanced LED (light emitting diode) technology which, the Italian manufacturer reports, '... guarantees the best work conditions for surgeons and medical teams in the operating rooms.' Indeed, LED technology brings several more advantages than conventional halogen and gas discharge bulbs. There's lower heat generation, excellent colour temperature and an almost never-ending life cycle, for example.

The Starled 7 has 70 LEDs circularly positioned to generate a light spot from 21cm to one metre with a high illumination level and a steady life cycle of 50K hours.

It provides high performance illumination for every type of surgery, the firm points out, adding that the lighting includes ACEM's own intelligent system ACRIS as well as its LIGHT-UP system to enable illumination adjustments according to different applications. The system produces clear, sharp brightness at 160K lux (self-limited) and a steady 95 (CRI) colour rendering over the time. All of which helps to reproduce the exact chromatic scale of the human body's colours.

There's also shadows reduction in the surgical field and total illumination of the surface and at depth and, due to obstacle finding sensors, the Brightness Adaptor allows a constant localisation of the head, hands and shoulders of the surgeon.

Additionally, ACEM has included its I – SENSE control system, which the company reports is '...precise, functional and able to memorise working parameters, which simplifies changes between working modes (standard, automatic, ambient).

The central and lateral handles make manoeuvres easy and a standard video camera can be integrated inside the handle in the centre of the light head or positioned on a separated arm. The video recording systems also can be combined with ACEM monitors.

STARLED 5

In the firm's operating theatre proposal the OT-Starled 7 lamp can be associated with the Starled 5. With 50 LEDs, circularly positioned around the handle, a high illumination level of 135K lux (160K lux optional) is generated for a steady life cycle of 50K hours.

The illumination is not only focused but also – due to a manual focusing via the central handle of the lamp, uniformally ambient and the exact chromatic scale of the colours of the human body are achieved.

The handle can also contain On request, a fixed focus video camera or one with a zoom can be integrated with the handle.

STARLED 3 EVO PLUS

This totally digital lamp is controlled by microprocessors and has a new I-Sense control panel that simplifies regulating and visualising light intensity, ENDO function (light up) as well as light selection – i.e. the use of one, two or all three of its lights.

With a simple manual clockwise or anti-clockwise rotation of the handle the light beams can be focused.

According to use, this equipment is available as trolley, wall and ceiling mounted - single or double configuration.

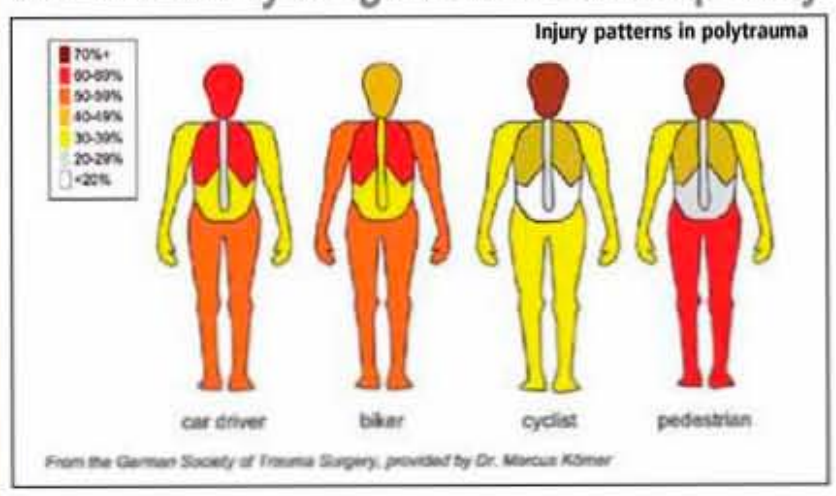
Emergency radiology

The ECR formally recognises ESR as a sub-specialty

The injury was as spectacular as it was gruesome. Struck by a train a male patient was brought to the emergency department in Munich, his right foot hanging on only by muscle and bloody tendons, the bone shattered. Surgeons quickly prepared the patient for an urgent operation to re-attach the foot. Yet, this was not the real danger to the patient's life.

Because the accident victim had a whole body CT scan as a matter of routine at the Ludwig Maximilians University (LMU) hospital the radiologists could show surgeons a more life-threatening spinal injury that needed to be addressed first.

That was the dramatic introduction by Marcus Körner MD, from the Department of Clinical Radiology at LMU, to demonstrate the increasing value of medical imaging for emergency doctors during a State of the Art Symposium entitled *Polytrauma in the Golden Hour*, during the European Congress of Radiology 2012.



From the German Society of Trauma Surgery, provided by Dr. Marcus Körner

This year, the European Society of Radiology (ESR) formally recognised emergency radiology as a sub-specialty, putting its full support behind this critical practice area with a scientific subcommittee to encourage specialised research.

The European Society of Emergency Radiologists was officially founded in October 2011 and is now planning its first congress, to be held this summer in Munich.

The chairman for the ECR Symposium, Ulrich Linsenmaier MD, also from LMU, described an explosive rise is the use of computed tomography (CT) among patients presenting at the emergency department of hospitals.

CT use is doubling every five years due to its ability to rapidly reveal the extent of injury or hidden causes of symptomatic pain. 'Time makes a difference in emergency and establishing the correct diagnosis as soon as possible is critical for the patient,' Dr Linsenmaier said, adding that it also proves to be more cost-effective for a hospital.

Results from a study of 9,689 patients proved conclusively that whole-body CT performed when the patient enters emergency significantly reduced mortality.

Dr Koerner showed how a rapid whole body scan, called a long-range scout view, provides an invaluable first look at the extent of a patient's trauma. A study he presented found the whole body scan replaces conventional radiography by providing a sensitivity of 93% and a specificity of 84% for injuries, as well as a negative predicative value of 97%.

Yet not all medical imaging performed in emergency is necessarily in the right hands, which is the motivation behind the effort to build a sub-specialty among radiologists in trauma.

Along with CT, the use of ultrasound is also rapidly increasing in emergency, but where CT is clearly left in the hands of trained radiologists, emergency physicians and residents do not hesitate to perform ultrasound exams at the patient's side, to the detriment of accurate diagnosis.

The widely used ultrasound exam for focused assessment with sonography for trauma, or FAST, is often regarded as being a simple extension of clinical examination routinely performed by emergency resident physicians in two minutes.

The FAST scan seeks to quickly detect free intra-abdominal fluid or cardiac complications among patients with signs of haemorrhagic shock or suspicion of intra abdominal injury.

Pierre-Alexandre Poletti from Geneva reported studies showing that the FAST scan is better performed by more highly trained radiologists who can provide optimal results for better management of patients with polytrauma.

Free liquids of less than 400 millilitres in the abdomen, such as blood, as a result of blunt trauma, were found among unstable patients with a sensitivity of 98% by radiologists using FAST, compared to 42% by emergency residents.

According to ECR 2012 President Lorenzo Bonomo, recognition of the subspecialty of Emergency Radiology is a first step in a move to re-assert the role of radiologists in this critical area of medical practice.

Eizo's widescreen monitor for the operating theatre

Eizo GmbH, Display Technologies has launched the RadiForce LX600W, a large widescreen LCD color monitor with an LED (light-emitting diode) backlight. Designed for use in operating rooms (interventional radiology, cardiology and surgery), the eight-megapixel monitor features a 3840 x 2160 pixel native resolution, an improved contrast ratio of 4000:1 and higher brightness values of 520 cd/m², and 60-inch screen with an LED backlight. It provides unlimited, flexible image display and is the ideal solution for modern operating rooms. Increasingly, the integration of different imaging systems and multiple surgical disciplines in the same room (hybrid OR) requires variable solutions.

'The RadiForce LX600W utilises the proven safety concept found in the existing model, such as redundant critical components,' the company reports. 'Real-time image display guarantees a safe and stable working environment for the surgeon. Additionally, homogeneous brightness uniformity across the entire screen and five integrated, calibrated look-up tables provide the highest display precision to meet the requirements of a broad array of applications.'

In addition to the basic version there is also a model with protective glass against surface damage, scratches and fluids, and simplifying disinfection.

The monitor also has an improved cooling concept, thus reducing the turbulence from fans in the room.

Wound healing

Modern wound management can shorten treatment and turn in-patient treatment into out-patient care, reducing time and costs. It's all down to today's more sophisticated materials

Bayer MaterialScience contributes much to the medical care with its range of polyurethane raw materials plus thermoplastics and films. For example, Bayblend M850XF, a blend of polycarbonate and acrylonitrile-butadiene-styrene, is very well suited for housings for medical equipment such as surgical instruments, diagnostic devices and drug administration systems. Like most of the firm's thermoplastics it offers very good impact strength and rigidity.

The company's current developments include the Baymedix brand hydrophilic prepolymers used to manufacture polyurethane foams for medical wound dressings. The foams absorb aqueous liquids and retain them better than conventional foams.

They can be combined with Platilon thermoplastic polyurethane films, which are water vapour permeable and allow wounds to breathe. Watertight films keep outside liquids and dirt from the wound.

The films are produced by Epurex Films GmbH & Co. KG – a wholly owned subsidiary of Bayer MaterialScience assigned to Functional Films that also develops non-wovens, foams and adhesives for medical care applications.

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