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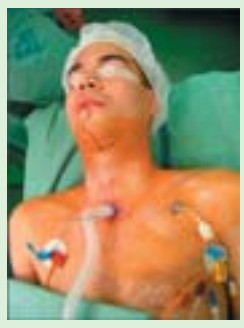


VOL 16 ISSUE 2/07 APRIL/MAY 2007

Contrast media

In 1993, the world market for contrast media was already estimated to be worth $ 3 billion. In 2001, an astonishing 12.2 million contrast medium-supported CT studies were carried out in Europe alone. Currently, the overall sales of contrast media are estimated to rise to $915 million in Europe in 2008.

In its brief history, two major developments occurred:

A switch from hyper- to low-osmolar iodinated agents (late 80s), after costs on the latter dropped

The widespread introduction of MRI contrast agents (90s), which largely accounts for the reduced market share of iodinated contrast media sales, from 91.7% in 1992 (world; non-ionic agents) to 60.7% est. (Europe) in 2008.

While many more compounds have been approved since – for use in the various imaging modalities – with the exception of the advent of ultrasound agents in Europe (1991) these are largely for use in specialist or research applications, e.g. intra-vascular (blood-pool) or tissue-specific (targeted) imaging.

See reports on contrast agents, plus adverse events in Radiology – Lab/Pharma pages 12–16

EU directive threatens use of MRI

New powerful alliance seeks to delay and amend legislation

EH correspondent **Christian Pruszinsky** reports from Austria

Hannes Swoboda

Gabriel P Krestin

Ingele Meulenbergs

Nicholas Gourtsoyiannis

Formed during the European Congress of Radiology (ECR), held in Vienna in March, the *Alliance for MRI* combines political forces, scientific objectives and the interests of patients. It currently includes 20 members of the European Parliament and representatives from the Health and Consumer Protection Directorate of the European Commission from England, Germany, Italy, Finland, Austria, The Netherlands, Belgium and Luxembourg, along with representatives from the European Society of Radiology, European Union of Medical Specialists (Radiology Section), European Brain Council and the Luxembourg Medical Council. Within the Alliance, the interests of patients are represented by the European Federation of Neurological Associations (EFNA) with the European Parkinson's Disease Association and European MS Platform, European Heart Network, Alzheimer Europe, Austrian Lung Association, Austrian Epilepsy Association and the Belgium Tumour Group.

A new, powerful alliance, comprised of leading politicians and healthcare groups (see box), aims to pressure EU Authorities to revise the controversial directive 2004/40/EC (EMF)*. All the organisations involved in the new Alliance for MRI fear that the planned implementation of the directive, which is to be incorporated into national legislation by April 2008, will prevent the use of MRI for interventional procedures and, in essence, will mean the end of diagnosis of, treatment for, and clinical research into cardiac disease, cancer and neurological diseases with MRI technology.

G P Krestin, Professor of Radiology at the Erasmus MC, University Medical Centre, Rotterdam, points out that for over a quarter of a century MRI has been used for examinations of over 500 million patients – without any proof that it constituted a danger to either health workers or patients, and where the upper limits set out in the directive have, in some cases, been exceeded more than a 100 times.

Medical Progress and Research must not be hindered

There can be no doubt that the authors of the directive, which aims to preserve the safety and health particularly of healthcare workers by protecting them from the dangers of physical agents (electromagnetic fields), cannot possibly have intended to make the use of MRI practically impossible, thereby preventing around eight million MRI examinations annually within the EU, 400,000 of which are carried out on children and 80,000 on patients under anaesthetic.

In a very moving statement Ingele Meulenbergs, who had suffered a brain tumour and is now a representative of the EFNA, explained that the use of MRI for her meant the difference between life and death. 'I would like other people, with or without disabilities, who are not as yet diagnosed or treated, to have the same chance that I have had.'

continued on page 2

Cops hunt 'cash for ops' surgeons

By **Keith Halson**

France – The country's health ministry is facing growing calls for a full public inquiry after allegations that surgeons have been demanding huge cash payments from patients keen to jump hospital waiting lists, and for charging exorbitant fees for 'private' operations.

In some cases, the sums demanded have been up to 15 times higher than the tariff scale agreed by the Sécu, France's social security system. Surgeons in the Paris area are alleged to have been running private practices so lucrative that they have pocketed up to €500,000 a year, yet work only two half-days a week. One Parisian woman revealed that a surgeon asked for a cash payment from her 79-year-old husband when he was lying on the operating table.

The scandal surfaced when a retired factory worker from Chalon-sur-Saone, in the central Bourgogne region, blew the whistle on the 'under-the-table' payments after revealing that a heart surgeon had demanded €5,000 to operate on him. So far, although it has begun an inquiry into the alleged incident, this surgeon's professional association has stood by him. However, sources close to the Chalon area health authority (CPAM) revealed that it is considering legal action.

Now police across France are investigating other hospitals and clinics, after numerous patients have come forward with complaints about similar attempts at extortion and fraud by medical professionals. Some have alleged that they were asked to hand over two envelopes stuffed with cash – one for the surgeon and the other for the anaesthetist – in exchange for operations they were told could be carried out 'without delay'.

A 46-year-old woman patient at a hospital in Metz-Thionville, in the north-east of the country, claimed that the chief heart surgeon demanded a cheque for €3,000 after operating on her damaged heart valves.

She was also upset by the 'poor standard of care' she received. She said the surgeon failed to visit her until six days after her operation, that she was never clinically examined nor asked about her health.

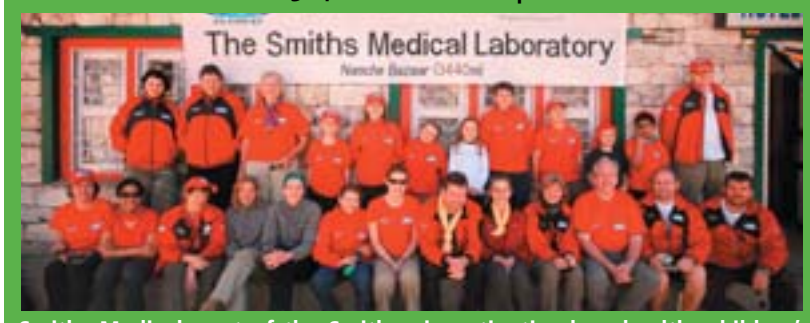
The woman, who wished to remain anonymous, has since complained to the regional health authority and also to the head of the hospital's administration, who promised to hold an internal inquiry.

'However,' she said, 'from the first, there has been no sign of life whatsoever. From the second, I am still waiting for a reply and an explanation after 10 weeks. This is not simply about the money – I just don't want this to happen to anyone else.'

contents

Lab on the tip of the world

The Smiths Medical High Altitude Laboratory is open for business – 3,400 metres up Mount Everest



Smiths Medical, part of the Smiths Group, has organised and is maintaining one of four main laboratories for Caudwell Xtreme Everest – the biggest human biology study ever performed at high altitude.

As they climb progressively higher, to reach Everest base camp at 5,300 metres (17,225 ft), over 200 volunteers are to be studied by some 60 doctors and scientists. More detailed research will be performed on a group of experienced mountaineer scientists who aim to climb to Everest's summit at 8,850 m (29,035 ft) to take the first arterial blood oxygen measurement at the top.

Caudwell Xtreme Everest is being conducted by a team from University College London (UCL) and is supported by The Caudwell Charity.

The lab is also the base for the Smiths Medical Young Everest Study (SMYES), which will investigate how nine British children cope with low oxygen levels in Everest's foothills. Doctors and scientists from Great Ormond Street Hospital (GOSH) and The Institute of Child Health, at UCL, are running SMYES. They hope to find links between the human body at its limits during critical illness and changes that occur at high altitude. In common with intensive care patients, high altitude mountaineers have a low level of oxygen in their blood. The team hopes to improve the chances of survival for very sick children by investigating how healthy children's bodies cope and adapt at altitude. It also aims to improve the quality of life for those with chronic/long term lung diseases and to develop new methods of detecting and treating children with disturbed sleep patterns.

Professor Monty Mythen, the Smiths Medical Chair of Anaesthesia and Critical Care at University College London, opened the lab. 'What we learn from these people as they push themselves to the limit of human performance, will help us to understand what is happening to patients fighting for their lives on intensive care units. At sea level, you can't tell who will cope and who won't. On Everest, if we can understand more about what makes someone a rapid adapter, we might be able to find the switches and adapters to help others to cope.' The professor is in the middle of spending three months running the lab. It will close at the end of May.

The lab is equipped with advanced medical testing equipment including heart and lung function monitors and cardio pulmonary exercise testing equipment. Smiths Medical, which donated medical equipment to the expedition, pioneered the development of single use devices to help people breathe. Over the past decade, the firm has contributed around £4 million towards medical research at UCL.

Details:
www.smiths-medical.com/youngeverest

Expanding medical horizons

Christian Pruszinsky reports from the ECR 2007

This was the motto of the ECR 2007 in Vienna, where a group of high-ranking experts discussed diseases of the 21st century; research competition between the US and Europe; the conditions needed to progress leading medical R&D – moderated by Congress President **Professor Christian J Herold**.

Everyone agreed that increased life expectancy in developed countries will change healthcare demands radically, due to the shift from acute illnesses to chronic disease. Today, 75% of the USA's healthcare expenditure is on chronic disease treatments, with an upward trend, said **Dr Elias Zerhouni**, Director of the National Institute of Health (NIH) – annual research budget: 29 billion dollars. He assumes that, in the future, medical and scientific institutions will not 'only' have to find solutions for known health problems, but also confront new, often unforeseeable threats, e.g. infectious diseases caused by resistant micro-organisms, pandemics aggravated by worldwide travel, or even biological warfare. The overriding objective must be to take a big step from curative medicine to preventive and personalised medicine, he said, then spoke of a current NIH research initiative, the *Pharmacogenetics Research Network*, which uses the latest data from genome research, examines interactions between active agents and molecules and studies biological processes through which active agents are removed from the body. Other NIH research projects focus on, for example, *Alzheimer's disease; integrated sensors and lab-on-chip for lab tests; imaging osteoarthritis; autism; technologies for nerve regeneration; imaging for cancer research and care; influenza drug screening, and AIDS structural biology*.

Decisive factors in medical research are the development and implementation of innovative findings from genome research, the development of suitable biomarkers, embryonic stem cell research, pharmacogenetics, cell biology, nanobiotechnology, robotics technology as well as new imaging procedures. Global competition for the best scientists in the medical disciplines is correspondingly hot. Countries increasingly compete to attract the most talented and imaginative students in medical research to their own universities.

Professor Liselotte Hojgaard, Chair of the Committee for the European Medical Research Council (EMRC) and Head of the Department of Clinical Physiology and Nuclear Medicine, PET and Cyclotron Unit at Copenhagen University Hospital, explained that Europe has a lot of catching up to do in this area: '*The relative share of public research money allocated to medicine and the life sciences is 55% and only about 30% in Europe. In the US they spend 2.6% of GDP on research, in the EU only 1.93 – and US GDP is 30% higher than European GDP.*' Add to that the diversity of all the systems: Whereas the US has a large, standardised budget for funding, a common strategy and objective, co-ordinated approach and just a few, highly specialised, private universities, in Europe 90% of funding for R&D comes from national research institutions and 7–8% from the EU budget.

The EC Framework Programme 7, which anticipates spending in the region of 50 billion Euros on R&D from 2007 to 2013, represents an important step forward. €12 billion of this will go towards the new European Research Council (ERC) – the first cross-national agency to promote forward-thinking research work. The Barcelona objective to increase the proportion of the GDP spent on research in EU member states to 3% by 2010 should increase the budget further. However, the fact that each country has its own specific objectives, strategies, priorities and traditions, and there is still disagreement over how research funds should be spent, remains problematic.

Interdisciplinary co-operation and cross-national projects, including universities and research institutions, are becoming benchmarks for the efficiency of European research policies: '*The European Institute for Biomedical Imaging Research (EIBIR) has a mission to create an environment and infrastructure that strengthens biomedical imaging research in Europe. This initiative is warmly welcomed and supported by EMRC*,' said Professor Hojgaard. The European Strategic Forum of Research Infrastructure (ESFRI) is developing proposals on large research infrastructures in biobanks, translational research and clinical trial centres and at the moment on the roadmap for European Research.

Global market place of ideas

Attracting the best talent produces the best research results, if those scientists receive the best working conditions and training, and the highest level of creative freedom – essential to nurture innovative ideas.

William R Brody, President of John Hopkins University, Baltimore (annual budget 1.5 billion dollars) sees advantages for the USA in the ever-rising global competition to attract talented scientists. The allocation of research subsidies is based on peer-review-systems. So universities that can recruit the most talent can count on significant research funding. Little political pressure, a flat, organisational structure and a calculable, basic financial configuration ensure good working conditions for universities and research teams which, unlike in Europe, are not dominated hierarchically. This appeal ensures that US universities fare very well in global recruitment of talent. In the technical disciplines and computer sciences almost 50% of PhD students are from abroad, every third university lecturer at these universities also comes from abroad.


William R Brody


Elias Zerhouni

However, Brody sees great challenges in the competition for the most talented medical researchers in the US:

- Decreasing funding endangers important investments – for a few years, subsidies for fundamental research have not been adjusted to account for inflation
- Stricter immigration laws, implemented following 9/11, have complicated foreign student recruitment
- Other countries' efforts to attract new, international academic talent has led to noticeable headhunting
- Research-oriented universities are under significant financial pressure due to the cap on state funding.

He sees a fundamental change in scientific culture because of the development of interdisciplinary structures: '*…to work on, for example, degenerative neurological diseases, may require biologists, neurologists, geneticists, radiologists, computer scientists and biomedical engineers to work together.*' Data-sharing is a key word for the future.

EU directive threatens use of MRI continued from page 1

ESR took no part in the decision-making process

Professor Nicholas Gourtsoyiannis, President of the European Society of Radiology, said the intention of the directive 2004/40/EC (EMF)* for the protection of workers against electromagnetic radiation (mobile telephones, power supply lines) was by all means commendable, but he regretted that the limits set out in the directive are based on hypothetical and incomplete, or out-dated, information**. He also remarked that the ESR, as the responsible European association, was not consulted once during the decision-making process for this directive by the EU authorities. This could have prevented many of the problems in the run-up to the current situation, he said, appealing to the European Commission as follows: The Alliance for MRI requests that, as a matter of urgency, the EC:

Informs Member States, notably Ministries of Health, as well as implementing ministries and agencies, of the unintended consequences of the Directive

Informs Member States of the Commission's expert study, currently being undertaken into the impact of the Directive on MRI, and requests a delay in implementing the legislation until the results of the study are known (expected in Oct. 2007).

Proposes an amendment to the legislation, introducing an EU-wide derogation for MRI.

Politicians aim for damage limitation

MEP H Swoboda, Vice-Chairman of the European Parliament Socialist Group and founder member of the Alliance for MRI, gave his wholehearted support for the objectives of the Alliance and acknowledged his sympathy for efforts of some countries to exclude MRI during the implementation of the directive and its inclusion in national legislation (as is currently the case in Finland and Austria), but he pointed out the difficulty of such one-sided steps (distortion of competition, possible breach of European law).

However, as it cannot possibly be the intention of the European legislators to prevent millions of patients from benefiting from the indisputable medical progress achieved through MRI technology, Swoboda confirmed the need for swift and concerted action to solve this problem on a European level, and to avoid unintentional consequences for Europe's healthcare systems. This must be based on new scientific examinations and findings, he said: 'We in the European Parliament will call on the European Commission to bring any new scientific results to the attention of the Council and the Parliament as soon as they are available. I hope that, by bringing people's attention to this problem today, we can ensure that patient care in Europe does not suffer. I encourage all concerned parties to support the work of the Alliance for MRI to obtain an EU-wide derogation for MRI from the scope of the directive as soon as possible.'

With these combined forces from the worlds of politics, science and patient interests it should be possible to implement the necessary and justified preventative measures for the health and protection of workers from electromagnetic fields, within the timeframe given, without this at the same time resulting in a setback for the diagnosis and treatment of, and research into many diseases, such as would be the case if the inconceivable renunciation of the use of MRI technology was to happen.

** EU Physical Agents 2004/40/EC (EMF) Directive to reduce adverse health effects on workers linked to short-time exposure to electro-magnetic fields*

*** Guidelines of ICNIRP 1988 (International Commission on Non-Ionising Radiation)*

The Netherlands roundup ...

By EH correspondent **Michiel Bloemendaal**

For many years, in almost all Dutch hospitals, assistant-doctors have worked alone during evening, night and weekend shifts, when the responsible physicians are not available. They man accident and emergency units, must learn for themselves on general wards and often face life and death questions.

According to a study from Groningen University, one in five assistant doctors have a burnout, while 40% of them suffer fatigue. The chances of a qualified specialist seeing a hospital patient are very small. Often the specialist is not in the hospital after 'office hours', or is on vacation, or at a congress, and therefore hard to reach. Many young hospital doctors see themselves as 'production slaves'. They are also afraid to criticise specialists, for fear of losing their jobs.

The *Dutch Order of Medical Specialists* is 'choked' by these findings.

Blunders by assistant-doctors

Every year, doctors in training to specialise in medical fields make 1,000 mistakes – some with very serious consequences for patients. The study found that fatal mistakes in diagnosis were made in determining certain types of cancer. Also deadly mistakes were made in determining the right kind of medication. The result of a bad relationship between an assistant doctor and a qualified gynaecologist was the death of a baby.

According to the University of Groningen many of these mistakes could have been prevented: they are often the direct consequence of long working hours, high pressures and the too great responsibility of assistant doctors. In addition, assistant doctors not always well-taught by specialists.

Wireless on the Web in bed

Increasingly, Dutch hospitals are offering patients wireless internet access. At the IJsselland Hospital, in Capelle, for example, patients in bed can use their laptops to surf the net or send e-mails. It was simple for a hospital to facilitate this, because a number of systems were already available for the staff to work wirelessly. A simple adaptation gave patients the same option. However, patients are not allowed to use a GSM-telephone, because they interfere with medical equipment.

Seeking security

The majority of Dutch hospitals want to employ more security guards and install more video cameras, according to a survey of a large group of hospital managers. The managers said that, because of the cost of this, they would ask the government for funding. Presently, hospitals pay about €50 million annually on their security, but they believe this is not enough to keep them safe.

An eye on private clinics

Following the death of a 20-year-old woman treated with liposuction, from 2008 the *Dutch Inspection on Healthcare (IGZ)* wants all private clinics to supply it with medical quality and performance data. The goal is to improve the checks on the private hospitals. Patients will be able to use the data to choose a clinic or hospital. Those that do not perform well are to be investigated.

Christian J Herold

Wolfgang Schuetz

Liselotte Hojgaard

To promote this increasing interdisciplinary co-operation John Hopkins University has established a number of new centres, e.g. the Institute for Nanobiotechnology; Institute for Computational Medicine, and the Brain Science Institute, where neuroscientists and other brain researchers can work with geneticists, technicians and experts for imaging procedures.

Professor Wolfgang Schuetz, Vice Chancellor of the Medical University of Vienna (MUW) and Prof Christian Herold spoke of changes to academic research in Austria. The trend towards a peer-review system to rate projects leads to higher quality standards, performance-oriented research funding through an increase in income from third-party funds (+50% over three years), the advancement of internationalisation through new partnerships, e.g. with Yale School of Medicine and Stanford University, but particularly the development of not exclusively clinic-oriented fundamental research in strategically important and trend-setting research areas, are all distinct markers of change. Not without pride did Herold report about the *Centre of Excellence* for High-Field MR at the Medical University of Vienna. Set up as a co-operation between the Clinic of Radiodiagnostics and the Centre for Biomedical Technology and Physics, already it is ranked among leading international centres of this kind.

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I can only present an opinion ☐ Yes ☐ No
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relatively modern ☐ Yes ☐ No
state-of-the-art ☐ Yes ☐ No

Do you use/buy second-hand equipment? ☐ Yes ☐ No
If so, what do you use of this kind?

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Is your department linked to an external computer network? ☐ Yes ☐ No
Is your department involved with telemedicine in the community? ☐ Yes ☐ No
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Do you attend congresses or similar meetings for your speciality? ☐ Yes ☐ No

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EH 2/07

RADIOLOGY

What's on at the 88th

Like any other congress, the 88th German Radiology Congress will present the latest research, workshops and refresher courses. Neuroradiology and throat and head radiology will lead key subjects, because, **Professor Ulrich Moedder**, this year's Congress President, told us, '…they emphasise the necessary dialogue between individual clinical disciplines and radiological diagnostics and therapy in an ideal way.'

Risk management and quality assurance in hospitals and surgeries will also be discussed. However, there are major transformations ahead, he revealed: 'Our courses have been completely changed – and, for the first time, they've been designed around a three-year programme. During that period, the basics of radiology will be taught systematically. For doctors in training for a radiology qualification we offer a special training course called *The basics of image analysis*.'

In addition, on International Day at the congress, renowned radiologists from Europe and the USA will introduce current standards used in mamma-diagnostics and prostate-diagnostics. 'So, the set-up of this year's radiology congress has changed quite a lot,' the professor pointed out.

Asked which research area he considers the most promising, Prof Moedder cited molecular imaging, which marks cells, or individual molecules, that are typical for a disease process and so hints at changes long before they can be detected via conventional imaging procedures. The congress will also discuss reports about the first positive effects of stem cell implants prior to the removal of liver tissue, he added. 'In future these should make it possible to surgically remove liver tumours and metastases more effectively in a larger number of patients. Further developments in interventional, minimally invasive procedures in neuroradiology and general radiology are also very important.'

140 exhibitors will display products during the congress. Asked which innovations will draw the crowds, the professor referred to MRI. 'The current focus is on improved and faster image processing. New iron oxide contrast media for MRI examinations will shortly be introduced to the market. It is hoped that they will detect metastases in the lymph nodes more precisely and will identify centres of inflammation in organs at a very early stage.

'Functional MRI has been an important topic in recent years. The introduction of 3-Tesla equipment opened up and posed numerous new research opportunities and questions that, prior to this, had been unthinkable for technical reasons. Now 7-Tesla MRIs are available, significantly increasing these research opportunities. They provide ever new, fascinating details on the functioning of the human brain. All in all, new MRI technologies are used for considerable research.

'The use of dual-source computed tomography in cardiac diagnostics is having quite a broad, positive effect on healthcare system. It facilitates a detailed examination of the heart without using catheters, in many cases making invasive cardiac diagnostic procedures obsolete. From this, we can expect a significant improvement in patient care.

'In computed tomography the focus is on new machines with larger numbers of detectors that should increase spatial resolution even further, whilst lowering radiation exposure.

'Rapid progress in stent and

Want to invest into healthcare? Then you must invest in radiology

Dr A Tamosiunas, Associate Professor at the Radiology Centre in the Medical Faculty at Vilnius University, Lithuania, and Director of the Radiology Centre at Vilnius University Hospital, discusses the present situation and future development of the radiology services in Lithuania with EH correspondent *Andrius Vagoras*

To invest in healthcare you must invest in radiology – that's as clear to Dr A Tamosiunas as is the huge amount of funding this requires. Over the next four years, he points out, about 62 million euros should be spent on radiology equipment alone. That's the Government's official estimation – endorsed, several months ago, by the Health Ministry within the investment programme *Optimisation of Radiology Services in Lithuania 2006–2010*.

However, the funding does not correspond with the real demand for radiology (at least five times higher). According to Dr Tamosiunas, who contributed to the programme: 'This is a very minimal amount, which is absolutely necessary to avoid expanding the existing gap between state-of-the-art radiology in Lithuania and other European countries. Besides, it must be assumed that the investment programme covers only equipment, and that is just one issue. The same applies to issues of radiological examination costing by the State Patient Fund. Presently they do not meet the real cost.'

The programme's analysis of the current state of radiology in Lithuania clearly shows that it is very complicated.

Most existing conventional X-ray machines do not have optical amplifiers and only 13 of the 378 machines are partially digitised. The majority are over 20 years old and should be changed as soon as possible. *Per se*, an X-ray procedure is considered to be a consultation with a radiologist, and is not reimbursed separately by the SPF. Formally, it is equivalent to a consultation with other specialists – who need no equipment.

Additionally, 23 of the country's 35 computer tomography (CT) scanners are single slice – and only four are 16-slice. 'There is an urgent need to acquire at least two 64-slice CT scanners. This would allow cardiac and peripheral blood vessels examinations to be switched from the costly invasive angiography procedure to a non-invasive procedure. We also need multi-slice (at least 16 slice) CT scanners in hospitals that provide emergency services, and very close to the hospital emergency units. This is absolutely necessary for urgent and definite diagnoses in emergencies and for patient allocation to the right department,' Dr Tamosiunas explained. The existing cost of a CT examination (about 50 euros) is definitely inadequate, even to cover the costs of a very simple (one or two slices) CT investigation and this valuation is not differentiated. It means, that the more often a sophisticated CT scanner is used, the more financial loss is 'gained' by the institution. Unfortunately, even this inadequate valuation is not endless. The SPF can only reimburse a definitive number of CT investigations. Usually we reach this 'limit' by the middle of a calendar year, and all other CT investigations performed after that limit diminish the existing valuation. At the end of 2006, for example, it turned out that the official valuation of CT examination was lowered by 40%, due to the performance of over-the-limit CT examinations.

The overall accessibility of magnetic resonance imaging (MRI) scanners in Lithuania is very unsatisfactory. MR angiography and multi-phase MRI widely performed in most European Union countries are almost never performed in Lithuania. Four in eight MRI units are in private hospitals and have low accessibility due to the very high cost per examination. MRI costing issues are identical to CT costing. It is also not differentiated, very inadequate and limited to the calendar year.

Obviously, the biggest technology gap in Lithuanian radiology is in nuclear medicine. Four in five gamma cameras are over 20 years old and only one rotational SPECT gamma camera (in Kaunas Medical University Hospital) fits current European standards; Vilnius, the capital city, needs at least five.

According to the Dr Tamosiunas, if costing issues are not solved very soon, managing other problems will become very complicated. Current valuation is two or three times less than the actual cost. It leaves no opportunities to set funds aside, increase salaries, and organise training. 'Setting adequate funding for radiology examinations in Lithuania could be viewed as an investment – which also would be very well timed because it would enable an overall improvement in healthcare and conserve future funds,' Dr Tamosiunas pointed out. Access to specialised healthcare is still good, he added, but the right choice of treatment is not always optimal due to misdiagnoses. The benefits from constant and well-differentiated investment in radiology are well known: earlier diagnoses, earlier treatments and much else for patients and services.

Things are not getting worse – 'That's the greatest news,' said Dr Tamosiunas, smiling. Attention and support from government organisations is constantly increasing and, though very gradual, the perception of radiology's

German Radiology Congress?


Ulrich Moedder

SOURCE: UNIVERSITY CLINIC DUSSELDORF

catheter technology have improved treatment options in interventional radiology and represent significant advantages for patients.'

Refresher courses and workshops

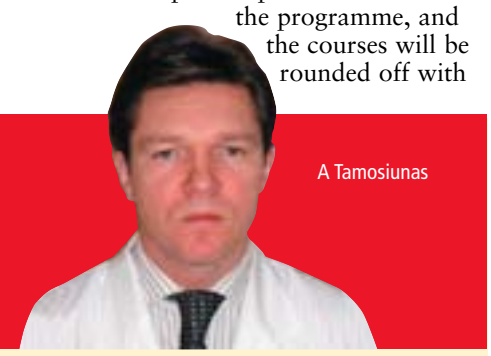
The very diversified topics and contents have been designed to fit a three-year period. Courses include paediatric radiology or neuroradiology, with others focused on procedures such as ultrasound scans, the professor explained. Training also will be provided in some of the increasingly important interventional procedures, e.g. carotid artery dilation.

Other highlights will include a highly interactive basic radiology course for doctors, and hands-on workshops in which new procedures, such as image-controlled therapies, can be practised on dummies. 'The use of stents to treat constrictions of cerebral vessels, of the renal arteries and pelvic and leg arteries is attracting particular interest. Vertebroplasty – an interesting therapy option for osteoporosis patients – is also in the programme, and the courses will be rounded off with a chance to practise CT virtual coloscopy,' the professor added.

Given the current glut of junior radiologists in Germany, we asked what the congress might do to stabilise this situation. 'Attracting young doctors to radiology is an important and continuous process. It depends on the ability to communicate the outstanding perspectives of this medical discipline and on the ability to offer solid and structured training. Young doctors who decide to specialise in radiology must be given the chance to learn all aspects of in- and out-patient radiology during training. The German Radiology Congress acts as a role model, but the implementation should happen during daily routine in a hospital.'

Today radiology is an integral part of many therapies – particularly MIS. We asked what other areas are similarly developing and what the future holds for the interventional radiologist? 'Procedures to open and close vessels are already integral parts of optimum patient care, such as dilation of cerebral vessels to prevent strokes, treatment of cerebral bleeds and treatment of smoker's leg,' Prof Moedder pointed out. 'There are also many different possibilities for interventional radiology to treat back pain. Interventional radiologists can also administer local therapy for defined tumours, such as liver metastases, as well as to treat infections or abscesses in the lung or abdomen.

'In the future, when we're able to make diseases visible on a cellular level, we will be able to treat them earlier. So radiology will make an important diagnostic and therapeutic contribution towards patient care in various areas.'


A Tamosiunas

exclusiveness is evolving: only radiology can identify diseases when other medical specialities can find no typical or other symptoms.

The role of the radiologist is gaining prestige. For many years, top medical graduates rarely chose to work in this field; last year 60 graduates from the Vilnius Medical Faculty applied for the one place in radiology training. This four-year curriculum has been prepared according European standards, and should be recognised in other EU countries. Two Lithuanian medical faculties can train 8–9 radiologists annually, which Dr Tamosiunas considers insufficient. Almost 25% of Lithuania's 400 (approx.) radiologists will retire in a few years. In addition, only about a hundred radiologists have the full range of skills needed in modern radiology. Many practicing radiologists need to attend courses, for which funding is not available. Thus the only real way to solve the dearth of radiologists would be to increase future traineeships by 10–15.

For now, Dr Tamosiunas' main concern is the introduction of a SPECT scanner to the Radiology Centre. As this is a first for Vilnius University Hospital, there are additional needs: a qualified physician, sufficient SPF funding, new accommodation, etc. This year the doctor expects that the Ministry of Health's working group in charge of radiological examination costing will make the right decisions about the indications for those examinations and their costs. Consequently, work with the SPECT and other equipment would not only provide physicians with examination results, but also maintain the new equipment and new jobs. Otherwise, it will become just an additional staff workload and, in due course, present new problems.

Slovak's private radiology institute

First came state-of-the-art equipment, then patients. Now, says **Peter Bořuta**, patience is also needed, before perhaps the chance to carry out research becomes a reality

Peter Bořuta MD PhD is Professor of Radiology and Head of Radiology at Slovak Medical University, in Bratislava, and Director of the Diagnostic Imaging Institute in Trnava.

When, a few years ago he was approached to establish a state-of-the-art radiology institute in a polyclinic next to Trnava's university hospital, he and his partner travelled to Germany to observe private radiology clinics there. Two years ago they installed MRI equipment at Trnava. 'After that we introduced mammography, then ultrasound, CT and conventional X-ray with computerised radiology. So now Trnava can provide complete imaging diagnostics. In addition, we train radiologists, radiographers, and nurses to work in radiology.'

Funding for the new institute came from a Slovakian bank. 'We were the fifth to want an MRI unit – the first was in Banska, which had been effective, so the bank was interested. However, it was a hard battle because the bank knew nothing about me or my partner. We supplied our details – my partner is strong on money and I'm a little better on X-ray. They tried a contract with us; we proved we were not so bad, then the bank gave us better conditions, so then came the rest of our equipment.'

In Czechoslovakia the Trnava Institute is the first to have a 64-slice CT scanner. It also has 22 trained personnel, eight of whom are radiologists – because the open MRI system is slower than high magnetic machines, so three physicians are needed for the magnet and the institute also runs two shifts, Dr Boruta explained. 'We are up and running, but completely new in this region, so as yet we have few patients.'

After his first job (six years) focusing on cardio-radiology in a children's hospital, Dr Bořuta became the first radiologist to use Brataslava's CT scanner. 'I worked with that old axial scanner for a long time, so I'm certified to combine CT and cardiology.'

Asked how changes in eastern Europe impacted on his work, Dr Bořuta reflected it has not been easy to change one political system for another. 'After our border opened many radiologists went to Czech or western countries – most to England, where pay is ten times higher compared with the USA. I must pay my radiologists more than in the US. We work so hard that they can have better pay and they have more interest because I don't just give them money, but also the chance to work with the most sophisticated equipment and to do complex diagnoses. So when an insurer has a problem about where to send a patient, we explain that, for angiography, MRI is better than conventional angiography. Also, I'm lucky because radiologists have to come to me for training, so I give the okay if they are excellent and work hard. So I ask whether they want hard work, with excellent equipment and better pay and most say yes. If they work in England they get more pay, but must spend more – and not everyone wants to be in England.'

However, foreign work and training has its benefits. Trnava personnel have trained in hospitals in other countries, among them one in Copenhagen, where they worked on Toshiba's 64-slice. Also, years ago, Dr Bořuta trained in Freiberg and Heidelberg. Continuing contact with those colleagues resulted in the formation of a *German-Slovak Academic Radiology Association*. 'We established it during further training in Heidelberg, to exchange new information about our work, new teachings and modalities and what we are using in oncology – for example, the 64 slice scanner.' In addition the association agreed that the Institute's physicians and medical students can receive training in Heidelberg.

Research

When the first CT scanner was installed in the bio-medical research institute in Bratislava, because the institute was next to the hospital, close cooperation resulted and Dr Bořuta participated in research. 'In our CT department we particularly worked closely with neurosurgeons on stereotactic techniques. From 1983–86 the main problem was artifacts in the fixed ring. We worked with the

Paediatric radiology
Small patients, big needs

Children are not small adults. As well as special technical requirements, their treatment needs particular handling by the radiology team.

In Europe, qualifications to become a paediatric radiologist are not too consistent. According to the report Radiological Training Programmes in Europe, produced by the European Association of Radiology (EAR), countries such as Norway, Poland, Portugal, Italy and Greece do not require radiologists to train for paediatric radiology. However, Germany, Ireland and Romania require three-year paediatric radiology training, whilst some other countries require five years of training.

Due to special indications and particularities of child anatomy, paediatric radiology calls for considerable experience as well as a trained, diagnostic eye. The internet also offers individual training offers and opportunities for experts to exchange ideas, reading lists and research material to help with case studies. For example, the website www.pedrad.info, accredited by the American Roentgen Ray Society (ARRS) and the Radiological Society of North America (RSNA) offers comprehensive training and links, as well as a list of paediatric radiologists working in hospitals and clinics in Europe and the US.

Apart from specialist medical knowledge, dealing with young patients calls for empathy and a way of explaining things that is appropriate for children. Quite often the children's fear of examinations that involve large equipment, such as CT or MRI, is bigger than the pain they might be experiencing. Children's books, such as comics about a little heroine MAXX (e.g. 'That's me – MAXX') published by Schering, explain the function of CT and MRI examinations in funny stories, so children can find out what happens in the big tube, 'who' takes the pictures and 'why' lying still is so important. Parents also need to receive full information, so that they can adequately prepare a child for examination, as well as have reassurance themselves, particularly concerns about radiation exposure that might be unfounded.

Technically there have been rapid developments in recent years that offer many diagnostic and therapeutic chances for children. For example, the LightSpeed Volume Computer Tomograph (VCT), made by GE Healthcare, facilitates the non-invasive diagnosis of cardiac defects in babies and children, e.g. congenital. Due to the detailed 3-D depiction of the heart and coronaries, plus fast image acquisition in less than five heartbeats, this method provides a real alternative to catheter examination.

The Panorama 1.0 T MRI scanner, from Philips, offers a particularly child-friendly solution for MR examinations, because the completely open system counteracts claustrophobia in patients and, even more important, children can remain in close contact with their parents during a procedure, which not only can reduce fear, but also helps to ensure the stillness needed for successful image acquisition. Moreover, to capture orthopaedic

The Philips 1.0T MR allows parents to stay very close to their children

The Mobilett XP, manufactured by Siemens Medical Systems, aims to keep minds cheerfully occupied during examinations

This Janosch MRI scanner from Toshiba Medical Systems brightens subdued hospital decor at the Wilhemsstift Hospital, Hamburg

Slovakian Academic Institute and had ideas about special stereotactic amperages from Stockholm and Germany, but it was too expensive and our technicians didn't have special stereotactic equipment. A Philips representative came to Bratislava and was immediately interested, so Philips began to cooperate with us. However, due to a cross-border communications problem, we had to end this. Two years before the Eastern Block changed, the two mathematicians on the programme went to Freiberg to see Vilmar Fisher, who was making stereotactic equipment, about collaboration. They worked in Freiberg for five years. They now work in our oncology institute, where they don't use a gamma knife, but the accelerator with stereotactic equipment to treat arrhythmias and tumours. We did the research.'

Dr Bořuta's desire to encourage and participate in more research is evident. 'It is part of our philosophy that medical care also needs university research. We have the qualified personnel, equipment and a large number of patients. We can do research. But I must find funds.' This presents a big stumbling block. Sponsors are easier to find in the West, he suggests, though he believes, for eastern European countries, improvements are on the way.

He wants the institute's research to not only focus on cardiovascular imaging, but also on lung imaging, using the 64-slice CT scanner as well as X-ray and MRI. The Slovak Academic Institute is also interested in MRI for lungs, and the combination also interests large groups from Western countries, he said. Other European countries, wanting to coordinate research to improve care in new European countries, might bring hope in terms of funds. Among meetings to that effect, one discussion has led to 'quite a lot of money' now going to eastern countries, he pointed out. However, he said, with regret, that the partners' workload has been too heavy to submit any requests, and although EU representatives had visited, and a lot of paperwork had been submitted, funding did not result. 'You read that in other countries they have a problem finding funds. It all takes time – five to ten years, maybe less,' he reasoned.

Research in Eastern countries, he pointed out, is currently at a basic level, due to lack of funding. For now, he added, raising money to buy necessary equipment has been and must be the partners' basic work. 'We started with the CT scanner in July. Up to December I had a hell of a problem to get the money for the work I did.' And lenders, he stressed, must be paid every month.

Could private patients present a good source of income? In Slovakia, less than one percent of patients are private, he replied, so the insurers pay for 99.9% of patients at his private radiology institute. But, he added, with some puzzlement, the institute has received one female cardiac patient, from Vienna. 'In Austria, insurers don't pay for CT examinations, which is a general problem in Europe,' he explained. In conclusion, he said with a smile: 'In Trnava I must sum up every day whether we have worked well. One bad case and you lose your credentials. So you take no chances, you give quality, and must be patient, because there are also good and bad doctors out there. I only provide a service. I'd be stupid if I told a doctor *You are stupid. Why did you send me this patient?* No, I will thank him for sending that patient to me.'

positioning, the radiologist can move a patient within the machine.

More comfort, less fear, is also the aim of the Vantage's new gradient system. This 1.5 tesla MRI scanner, from Toshiba Medical Systems, powered by Atlas, reduces that typical noise level produced by an MRI machine by 20–30 dB. A further advantage is that almost all kinds of examinations can be carried out feet first.

Equipment decorated with child-friendly motifs offers emotional rather than technical support in paediatric radiology. Some time ago, for its use at the Children's Hospital Wilhelmsstift, Hamburg, Toshiba decorated an MRI scanner with the popular Janosch Design. The hospital's mobile X-ray system Mobilett XP, made by Siemens, features a smiley giraffe. Masquerading as the giraffe's neck, the machine's large C-arm can be positioned for imaging in any projection.

Siemens' syngoBlade, a complete imaging, matrix-based MRI software, ensures clear MR images even of agitated, fidgety little patients. Suitable for neurological and orthopaedic examinations, syngoBlade measures and corrects low-resolution images of each movement by continuous image-taking, to produce sharp images even of 'busy' little patients.

There are many ways of making radiology more suitable for children; however, nothing can replace a comforting word from the doctor and a small reward for bravery.

DETAILS

Equipment

www.bayerscheringpharma.de
www.ge-healthcare.com
www.siemens.com/medical
www.toshibamedicalsystems.com
www.philips.com/medical

Comics

MAXX in Space – Magnetic Resonance Imaging of Children, and *That's me, MAXX – Computed Tomography of Children*, can be ordered in English and German at:
info@diagnostics-schering.de

‘We are really talking about a paradigm shift from treating symptoms to preventing disease’


Jean-Luc Vanderheyden

It will identify millions with ‘silent heart disease’

‘If you want to find a needle in a haystack, X-ray is a good tool. Now imagine how much easer that would be if the needle could glow.’ Thus, **Dr Jean-Luc Vanderheyden** underlined the potential of molecular imaging, during an interview: *Meike Lerner*, European Hospital. ‘If factors that cause cardiovascular diseases could be made to ‘glow’, he explained, ‘then anomalies could be detected before an event occurs.

Currently we are working on the ability to detect patients who would be asymptomatic,’ Dr Vanderheyden explained. ‘There are a couple of cardiology programmes; one, for example, involves a tracer – a molecule – to image the adrenergic receptor – to which norepinephrin binds. Making an imbalance in these receptors visible would enable us to identify the risk of congestive heart failure. The clinical studies are very promising and we are confident that, in the near future, we will be able to identify those millions of people with a silent heart disease who might be at risk of a congestive heart failure.

On the other hand, we are working on progressing imaging technologies, in particular the special contrast agents that correspond with the tracers. With VCT (very rapid CT) we can image the heart in five heartbeats and ten seconds with an extremely low dose of radiation (70% reduction compared with the normal dose). The combination of special contrast agents and advanced technology makes it possible to look particularly at stenosis in a cardiac blood vessel, and therefore identify an at risk patient.’

Do some imaging technologies look more promising than others for molecular imaging in cardiology?

‘In this field we are not concentrating on any particular modality. It is more important to understand the disease, and then look for the imaging modality that will provide the best answers. In oncology we work a lot with PET. GE also has a pilot project for prostate cancer with MRI. In cardiology most of the work has been with SPECT and SPECT tracer, which show perfusion and the patients at risk of heart attacks. But these technologies alone can only show risk in patients already identified due to an event or chest pain. Only if we add this special molecule as a tracer can we see anomalies in advance. To come to the point: talking about molecular imaging really means the combination of a tracer – a molecule, and sophisticated equipment that can detect the signal of the molecule. Of course, software solutions must be developed that allow greater ease of visualisation and help doctors in their diagnoses. Our objective is to use all possible modalities to identify at risk patients. It is less critical which modality is used, from VCT, ultrasound or in-vitro diagnostics.’

Such sophisticated technologies and advanced software always need well-trained doctors to handle those technologies and make sound diagnoses.

‘Yes, education is vital. That’s why we observe all and everything during clinical trials, and then record this information connected with the procedure in a manual – for example, patient preparation.

It’s not just doctors who need to rethink, with molecular imaging patients will also play a greater role and have greater responsibility. Last, but not least, healthcare systems must shift from treatment to prevention and recognise that it will be more important to deal with patients when they do not have heart attack or congestive heart failure symptoms, rather than waiting for symptoms to arrive, then sending them to an emergency room to decide the best treatment.

When we talk about molecular imaging in cardiology we are really talking about a paradigm shift from treating symptoms to preventing disease. Looking at the state of play today, I think we can expect a lot from this field. Already, sophisticated techniques have improved to a lot – two or three years ago we couldn’t see the things we see today. So, there is continuous progress and if we look further into the future we should be able to document metabolic changes that would be negative for ischaemia, including perhaps the effects of hibernation – and certainly we should be able to demonstrate that alteration of the sympathetic nerve function, or the adrenergic ones that result in coronary diseases.

And maybe – in about five years of using molecular imaging – we’ll be able to look at plaque characterisation, including the identification of the vulnerability of that plaque or additional receptor characterisation that can lead to drug therapy. And the last would be biomarkers, to perhaps identify some of the recorded disturbance instability that could be associated with atrial or ventricular arrhythmia.

So, quite a lot of things will be in the works that wouldn’t have been possible without the combination mentioned, as well as the sophisticated technologies and suitable target agents.’

Jean-Luc Vanderheyden, inventor on 10 patents, author of over 50 publications.
In 1980, received a Pharmacy degree at the Université Libre de Bruxelles. Five years later, he gained a doctorate in analytical chemistry for his work on cardiac imaging agents at the University of Cincinnati. Then, as a researcher at top firms he worked, for example, on a monoclonal antibody fragment used to image lung cancer; a radio-labelled peptide for the diagnosis of somatostatin positive tumours, and a molecular imaging agent for apoptosis.
In 2001, he was Visiting Associate Professor at the Division of Nuclear Medicine University of Massachusetts Medical School and, in 2004, a member of the reading/examination committee of PhD students. He also has chaired sessions on apoptosis and basic oncology-related imaging at the Society of Nuclear Medicine’s annual meetings. He has also both reviewed and been awarded SBIR grants, including, in 2004, an SBIR fast track on In vivo apoptosis imaging with fluorescent probes.
In November 2005, Dr Vanderheyden joined the Technology and Medical Office of General Electric’s Healthcare division, where he leads the Global Molecular Imaging research team.

ONCOLOGY

It will help us to detect undeveloped tumours

In recent years new imaging procedures have delivered many answers and solutions for oncological diagnostics and therapy. However, one question could not be answered: Is a tumour developing? The ability to detect dysplasia – the early stages of cell changes from which tumours develop – would answer this question, and present a huge advance in oncology. Now, thanks to researchers such as **Professor Juergen Borlak** and team – **Professor Michael Galanski**, **Dr Christian von Falck** and **Dr Thomas Rodt** – a significant milestone is in sight. The pace towards it quickened due to molecular imaging, which can capture the formation phase of a malignant tumour. Using hepatocellular carcinoma as an example, Prof Borlak explained the team’s research to Meike Lerner of European Hospital

Meike Lerner: When are these procedures likely to be ready for clinical use?

At the moment the procedure, as well as the different tracers, are already being preclinically trialled. Because of PET diagnostics the results can be fairly easily transferred into clinical practice, as the PET examination needs only very small quantities of each respective tracer to produce diagnostically useable images. This also means that there should be no problems with tolerance. We believe that, for clinical use for certain applications, this method should be ready in about a year’s time.

Your dysplasia research centres on the liver. Could the results be transferred to other organs?

The display of a dysplasia depends on whether an organ is affected in its entirety or only partially.

Prof Borlak: The importance of early detection, particularly for hepatocellular carcinoma, can be seen in patients with PSC (primary schlerosing cholangitis) or cirrhosis of the liver. In these cases the liver shows chronic changes. Conventional methods, such as CT, MRI or ultra sound can localise these changes, but these imaging procedures cannot confirm whether dysplasia is present. This has to be confirmed via biopsy, which is not always practical when a multitude of changes has been detected.

Even if there are no current dysplastic changes we know that with this disease pattern the probability of tumours developing and having to be removed – or even a liver transplant being necessary – is very high. If the point where the tumour developed is known, then surgical intervention can be carried out in time and liver resection should be sufficient. However, this has been the big dilemma so far – knowing that the formation of tumours is highly likely, but still not being able to intervene in time because the immediate preliminary stage of the tumour – dysplasia – cannot be detected with the imaging procedures that have been available to us to date.

Now, however, molecular imaging is giving us the opportunity to detect and examine these early changes with the help of specific tracers that show metabolic processes typical for dysplasia.

We are initially testing this method in animal experiments, in which we examine the biological processes of dysplasia. We have a model that reflects the human disease pattern very well, and to examine dysplasia development in great detail. We have found metabolic and cellular changes that can be selectively found in dysplastic tissue, and now aim to make these specific biomarkers visible with different tracers. This should enable us, for the first time, to capture dysplasia from an imaging perspective and to distinguish it from simple regenerative proliferation. Based on this knowledge, we can then define the decision tree and determine whether we need to intervene surgically, with medication or not at all.

A further, important point is that we can not only show dysplasia, but localise it, which means we can see


Professor Juergen Borlak heads the Department for Molecular Medicine and Medical Biotechnology, in Germany’s Fraunhofer Institute of Toxicology and Experimental Medicine

the tracer. In the liver, for instance, neuro-endocrine tumours can be made visible with somatostatin receptor agonist following Dotatoc-Tracer labelling in the liver, spleen or adrenal gland. Other organs do not have those receptors, which is why this special tracer does not work and display in the PET is not possible. The difficulty here in my view is to find specific biomarkers that can characterise the tumours.

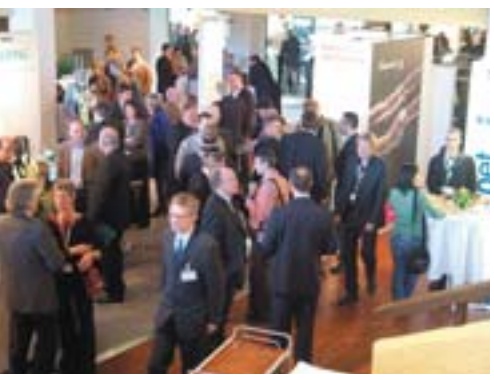
Here the use of antibody-based molecular imaging, where antibodies are marked and therefore made visible, could play an important role. And, there is a further benefit: therapeutic use. If we manage to selectively capture the direct interaction of the antibody on the surface of a tumour we not only have a suitable tracer for diagnostic imaging but also the opportunity to test the therapeutic effectiveness of the antibody. This is where I see the future and opportunities in molecular imaging, for the years to come.

A further step, resulting from possibilities for molecular imaging, is the quantification of tumours. This is where software applications will be used that make it possible to determine the volume of a tumour quantitatively, based on certain algorithms. This is very relevant for our lung cancer model, as it is a diffuse tumour spread. The question here is how to measure tumour growth, because it is not a distinct tumour, but tumours in different locations. The idea is that, based on the volume of the aired lung, and of the tumour, therapeutic success can be determined quantitatively. In return, the aired volume should allow quantification of the area affected by tumours.

Learning what can *and might be done* with MRI

Austria – In recent years scientists have produced multi-channel MRI systems, new coil concepts and new contrast media, all of which have helped to shift radiology towards the centre of patient care.

Covering such innovations and their uses, the International Magnetic Resonance Imaging (MRI) Symposium, founded by Professors Lissner, Doppman and Margulis, inevitably became an important entry in radiologists' diaries. At the 12th symposium – held this year at



Garmisch-Partenkirchen, Austria - **Professor Maximilian Reiser** said: 'We will build bridges with other diagnostic procedures in the usual way, to evaluate their significance for developments in MRI.'

The congress highlighted the fact that, particularly in molecular imaging, there is a high synergetic significance for various procedures, e.g. positron emission tomography, optical imaging, along with new developments in MRI. These and their possibilities for clinical use were discussed.

The success of last year's MRI symposium, with participants from 17 countries, and much positive feedback, led the organizers, **Professor Hedvig Hricak** and Professor Reiser, to mostly maintained that structure.

Meet the experts

Due to high demand, the interactive small group discussions of interesting cases with renowned experts were extended. These focused on ear, nose and throat (ENT).

For the basic MRI course the professors said they had particularly aimed to present practical and understandable information. Also, at the end of the first day of teaching, they had introduced typical

clinical cases, so that everything taught could be tested interactively with the course participants.

This event is certified by the German Academy for Advanced Training in Radiology and the Bavarian Medical Association. Due to the broad spectrum of topics covered attendance is almost enough to qualify for a year of training credits.

The 2009 MRI symposium will be held in Garmisch.

The 3-Tesla MR-guided intra-operative surgical suite

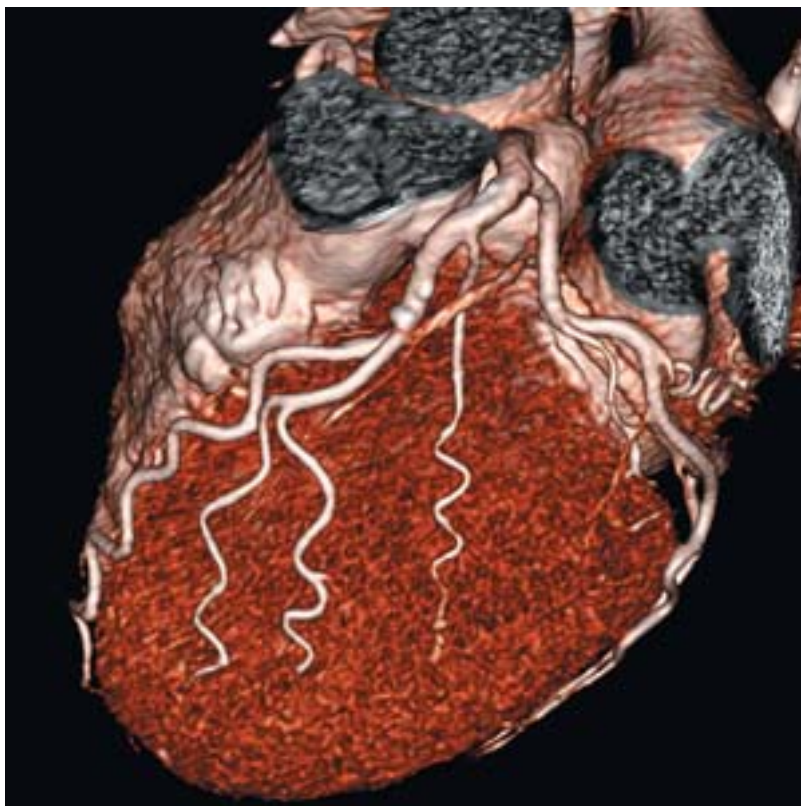
A next generation MR-guided intra-operative surgical suite has been installed at Barrow Neurological Institute at St. Joseph's Hospital and Medical Centre following collaboration with GE Healthcare and Maquet GmbH & Co. KG. This, GE reports, includes one of the world's most comprehensive portfolio of neuro-imaging solutions, using 3-D imaging to navigate and validate treatments, to help increase both accuracy and speed of interventions.

Developed with input from radiologists as well as neurosurgeons, the 3-Tesla MR surgical suite has multiple possible uses. The GE neurosurgical suite provides MR imaging in one room of the surgical suite, and an operating theatre (OT) in another. Surgery is performed on the Maquet MR/X-Ray compatible OR table system and real-time imaging is performed on the GE Signa HDx 3.0T MR scanner. Uniting the two is a state-of-the-art transport system that enables patients to be moved quickly and safety to, and from, MR to OT during surgery, minimally invasive procedures or therapies.

Thus, patients can be evaluated during, not after, surgery to assess its success, and a real-time 3-Tesla MR image can be evaluated without patient transfer to another table.

CAD

CTCA offers better, cheaper diagnosis than cardiac catheterisation



Although cardiac catheterisation is considered the current gold standard for coronary artery disease (CAD) diagnosis, a new cost-effectiveness model* indicates that, in many cases, a CT coronary angiography (CTCA) not only provides a better diagnostic outcome but is also cheaper. *Meike Lerner* discussed the implications of the study and his cost-effectiveness model with **Dr Marc Dewey**, of the Radiology Institute at Charité University of Medicine – Berlin

In 2002, researcher Marc Dewey joined the Radiology Institute at Charité University of Medicine – Berlin. His doctorate was awarded in 2004 for his thesis on MRI and cardiology; the following year this also won the Behnken-Berger Award. Dr Dewey's research on cardiovascular imaging continues - the cost-effectiveness model study is one of over 40 scientific publications he has authored

'Our model is based on clinical studies regarding the sensitivity and specificity of the different diagnostic methods: cardiac catheterisation, coronary angiography and calcium scoring, using CT as well as stress MRI with dobutamine,' Dr Dewey explained. 'This means, we did not perform clinical studies ourselves but analysed published data on the accuracy of these methods.

Consequently, our calculation has to be verified in practice. More so since our model is based on one crucial practical aspect: a thorough medical history taken by a physician. In the end, the effectiveness of a method depends to a large extent on the pre-test probability – the assessment of the probability of a disease according to certain clinical parameters. Indeed, from a cost-effectiveness point of view, not all patients are suited for a CTCA.

'Rather the results of our cost-effectiveness analysis indicate that in patients with a pre-test probability of over 60% a CTCA does not make sense. This holds true not only from an economic point of view but above all from a medical point of view, since, in patients with a high pre-test probability, the likelihood of a treatment increases – and the likelihood that the treatment can be performed with a heart catheter. Moreover, patients with a high pre-test CAD probability cannot be safely ruled out to have disease with non-invasive tests. Almost always, this group shows positive results, consequently those patients have to undergo catheterisation anyway. Unfortunately, current common practice is that, for example, patients with a 70% pre-test probability first undergo a non-invasive test – only to find out what was to be expected: the patient requires catheterisation. That obviously generates additional costs.

When is a CTCA recommended?

'About a third to 50% of symptomatic patients have a pre-test probability of less than 50–60%. This means CAD can be reliably excluded with a CT examination. Due to the high sensitivity of this method, the rate of false diagnoses is below 10%. Therefore, from a cost-effectiveness point of view, patients with a low pre-test probability – less than 60% – should not undergo cardiac catheterisation. This is also clinical practice: an immediate invasive approach is avoided for those patients. Nevertheless: according to a study, two thirds of all cardiac catheterisations in Germany do not lead to immediate therapeutic consequences. This is reason enough to reconsider. Fortunately, in other European countries the figures are not as extreme. Scandinavian countries, the Netherlands and Great Britain have significantly fewer superfluous heart catheterisations. These are countries where the state has quite a say in the healthcare system and where the financial interests of the actors in the healthcare system are not as intense – that is, reimbursement is not based on the type and number of examinations.

'We hope our model can raise awareness of this fact and help focus on non-invasive gentle methods that have medical and economic advantages for patients

MARKETING NEWS

NEW

Digital dashboard software for PACS admin

Eastman Kodak Company is selling its new Carestream Digital Dashboard software that enables system administrators to monitor equipment performance, storage utilisation and user volumes for the company's Carestream PACS and information management solutions. Kodak also reports that the next version of this software will support monitoring of the Carestream Radiology Information System (RIS).

'Without leaving their desks,' says Kodak, 'PACS administrators can use the digital dashboard to verify that devices are operating and communicating on the network. A simple red/yellow/green display gives immediate feedback regarding the status of any monitored device. An integrated, product-specific menu enables the launching of frequently used tools with a single click. The dashboard also makes it easy to track the number of concurrent users for a device, the number of read and unread imaging studies, as well as the status of other tasks.'

At Cedars-Sinai Medical Centre, in Los Angeles, California Imaging Informatics Manager David Brown, said he monitors five PACS and storage archive servers, using the new software. 'If I see a process is in trouble, or a directory is almost full, I can take action before any of our users are impacted. Most PACS administrators don't have time to go into UNIX to conduct individual checks,' he added. 'Dashboard does, automatically. It also provides access to database information, including database table space that is not available anywhere else.'

At another test site for Kodak's new software – St. Vincent Mercy Medical Centre in Toledo, Ohio – PACS Administrator Leslie Beidleman reported that it identified a glitch: 'One of the dashboard indicators identified that some of our studies were not being backed up, and it highlighted areas of malfunction so they could be corrected.'

Further details: www.kodak.com/go/health.

Korean ultrasound firm wins leadership award

Medison, the Korean-based manufacturer of diagnostic ultrasound systems founded in 1985 and pioneer of the first commercial real-time 3-D ultrasound scanner, recently received the 2007 *Frost & Sullivan Competitive Strategy Leadership Award*.

The company's range of ultrasound products includes everything from portable to digital 3-D and 4-D systems. The F&S award was given in recognition of Medison's strategic initiatives to establish itself as a leading enterprise in the European ultrasound market.

Karthik Arun B, head analyst at F&S commented that Medison accomplished high growth in Europe – the world's biggest and most advanced market – by aggressive strategies and customer-oriented management and, she noted: 'It especially showed great accomplishment in the high-end 3-D ultrasound system.' Indeed, in 2006, Medison's market share was almost 40% in the high-end 3-D and 4-D ultrasound segment in Europe.

Medison's CEO **Jae-Bum Choi** said: 'We'll build on this foundation to globalise the company by creating a system of local headquarters.' 85% of Medison's sales are derived from exports. Employing just 430 people in R&D, sales and marketing, the firm also maintains 10 overseas subsidiaries and 100 agencies in 90 countries. It plans to open local headquarters gradually by 2010. Initially, last year, Medison set up European headquarters in the Netherlands.

Other awards – Medison also won the *F&S Product Differentiation & Innovation Award* in 2001 and, in 2004 was rated as *The Highest Growth Rate Enterprise* by the Klein Report, which focuses on ultrasound systems – the firm had recorded 94% in sales growth in the USA.

During the recent *23rd Korean International Medical & Hospital Equipment Show* – KIMES 2007 – a 4-day event that is one of Asia's biggest medical products exhibitions, **Joong-Ho Lee**, Senior Managing Director in the Marketing Division of Medison, told Denise Hennig of European Hospital that ultrasound has a strong future. 'We are developing another new technology for ultrasound and we expect synergies between our existing technology and the new one. We're also testing and examining the efficiency of the 4-D and 3-D ultrasound. One very specific thing – and the differentiating factor of 3-D and 4-D technology – is that we not only want to take good images of a baby's face, ideally we want to combine our technology to improve diagnoses and to

with low to intermediate pre-test probability.'

Despite all the advantages, a CT examination means radiation exposure. Does your model indicate that MRI is a viable option?

'Obviously we don't want to ignore the (albeit minor) risk associated with radiation exposure – but that risk is comparable to that of cardiac catheterisation. However, the situation is quite different as soon as you have double tests: CT and catheter. In terms of cost-effectiveness, the advantage of CT is its accuracy compared with stress echocardiography, stress ECG and MRI coronary angiography. CT sensitivity is above 90%, that of MRI coronary angiography is just above 70%. In our cost-effectiveness model we looked at stress MRI. This type of examination is more accurate – it has an over 80% sensitivity – but it is neither accurate nor cheap enough to be considered more cost-effective than a CT. Moreover, as the name says, stress MRI means exposing the patient during the CAD diagnosis to a certain degree of stress. However, MRI is very useful to analyse myocardial viability – a crucial aspect for the further management of patients with known CAD. For this purpose, MRI is more accurate than other methods, such as myocardial scintigraphy.'

Would you make specific clinical recommendations based on the results of your model?

'To make certain clinical recommendations based on a cost-effectiveness model is rather difficult. Obviously our data are culled from studies on sensitivity and specificity, but we have not yet applied our models in practice, respectively in studies. As long as we do not have such real-life results, we cannot say whether our model is clinically useful. In real life, there are always a number of components that interact, such as workflow in hospitals, or between them and physicians' offices. In our opinion we clearly need a study on how CT-based diagnosis will influence therapeutic management. This would provide a basis on which general recommendations might be formulated. However, our model does show that, from a cost-effectiveness point of view, CT is superior to other diagnostic procedures for patients with a pre-test probability of up to 60%.

Another crucial question is: Who benefits from cost-effectiveness calculations? Our model looks at CAD diagnosis from the standpoint of society as a whole. To put it simply: We asked how much money can society save in terms of health insurance premiums and related expenses by optimising diagnostic management? The hospitals themselves look at CAD diagnosis from a very different angle: unfortunately, they make more money with invasive procedures because the DRG system offers higher reimbursement rates and thus higher profits for invasive procedures.

With regard to Germany, we also analysed how useful CTCA is from the perspective of office-based radiologists. For them the situation is quite different than for hospitals: current reimbursement rates for CT examinations do not cover their expenses and, even in the long run, they will not be able to reach a break even point. Consequently, office-based radiologists have little interest in implementing our model if it is not accompanied by an increase in reimbursement rates. However, according to our analysis, an increase of the net reimbursement for radiologists of about 75% means the radiologist can reach break even and CTCA still remains the most cost-effective method from society's perspective. We hope this is a convincing argument to increase CT reimbursement rates. For this to happen, however, certain preconditions must be created. As long as this does not happen, our model will remain a theoretical approach. Nevertheless, we consider our cost effectiveness analysis a suitable basis for further optimisation of both diagnostics and management of patients with suspected coronary artery disease.

** Cost effectiveness of coronary angiography and calcium scoring using CT and stress MRI for diagnosis of coronary artery disease. Marc Dewey; Bernd Hamm, Eur Radiol DOI 10.1007/s00330-006-0439-3*

combine diagnosis with therapy if necessary, for example, developing our 3-D and 4-D technology for specialised cardiography.

'Our aim is to develop our ultrasound products, but we'd also like to spend time in the diagnostics area – obstetrics and gynaecology, cardiology and radiology. A good future perspective is Medison leading the ultrasound market in conjunction with different faculties in the medical field – not just showing nice baby faces. We'd like to make human beings live healthier lives.'

www.medison.com

Joong-Ho Lee

Adverse events in contrast media

By **Joerg Larsen MD FRCR**, Consultant Radiologist at the Department of Neuroradiology, University of Goettingen, Germany

Recent reviews of serious adverse events with the use of low-osmolar iodinated (literature review) and gadolinium-based (manufacturer's database) contrast media indicate frequencies of ≤4% and 0.01% of procedures respectively.

This review aims to discuss topical issues in contrast media-usage with reference to serious adverse reactions and their prevention, particularly highlighting the risk of nephrogenic systemic fibrosis with the use of gadodiamide in patients with end-stage renal failure.

Nephrogenic systemic fibrosis

Gadopentate dimeglumine, the first paramagnetic contrast agent on the market, has an excellent safety record. Even the earliest post-market study, which included 15,000 (adult) patients and a group of 655 patients under aged 20, found no more than a 2.4% frequency of headache, nausea or other minor reaction, with only 1.7% minor adverse events in the paediatric arm. At present, eight gadolinium-containing contrast agents are licensed for use in the UK; five compounds carry FDA-approval. While these compounds are generally safe, there is a recognised morbidity associated with their use, anaphylactoid reactions do occur, and some are severe: A 1996 review of the use of gadolinium-based agents in 21,000 patients at a single academic institution revealed severe anaphylactoid reactions in 0.01% of cases, a finding since validated by other authors. In January 2006, a previously unrecognised aetiological connection was suggested between the development of nephrogenic fibrosing dermopathy (nephrogenic systemic fibrosis – NSF), and the administration of gadodiamide during MRI scanning. This notion has received much attention since, starting with an FDA-warning in June 2006 and culminating in multiple editorials in radiological journals and advice from professional bodies in 2007 (European Pharmacovigilance Working Party, Austrian Chamber of Pharmacists, Am Coll Radiol). Irrespective of these warnings, many radiologists are unaware of the issue.

NSF is a scleroderma-like condition that may develop in patients with chronic renal failure, usually end-stage renal failure (ESRF) requiring replacement therapy. There have been a few instances of NSF in patients with apparently moderate renal impairment, based on glomerular filtration rate measurements, but at least some of these cases involved additional acute-on-chronic renal injury when GFR estimation may be inaccurate.

The predominant and disabling manifestation of NSF is cutaneous, through increased deposition of collagen, potentially leading to flexion contractures. Importantly, however, parenchymal organs may also be involved and deaths have been recorded. A proportion of approximately 5% of affected individuals exhibit a rapidly progressive course. NSF might stabilise, but rarely spontaneously remits, and there is no consistently effective therapy, although a rapid correction of renal function might result in reversal of symptoms. The initial report focused on five out of a cohort of nine patients with ESRF, who were subjected to gadodiamide-enhanced MRI. The five developed NSF within weeks of contrast medium administration. Some 200 such cases were recorded in the past year, most relating to the use of gadodiamide and gadoversetamide. However, at least six cases have been associated with gadopentate dimeglumine, but might be attributable to the administration of multiple and/or high doses. The overall risk for NSF development following gadolinium administration in the context of advanced renal disease might be 3-5%.

The development of NSF, i.e. the induction of fibrosis might be related to the presence of extremely toxic free gadolinium ions secondary to a process of transmetallation between the paramagnetic heavy metal bound to a chelating agent and endogenous ions, consistent with different stability between the various commercially available gadolinium-compounds. Delayed excretion of principally renally eliminated gadolinium contrast media in ESRF precipitates the problem, presumably by generating a critical tissue exposure. This hypothesis is supported by the observation that Gadolinium is detectable in biopsies of NSF-affected skin.

Nevertheless, two observations suggest that gadolinium compounds may be 'a necessary but not a sufficient cause of NSF'.

administration

1. Several cases of NSF had a documented earlier exposure to gadodiamide without consequent signs of the disease within the reported interval of 2–75 days.

2. NSF might also occur in patients without a documented exposure to gadolinium compounds.

Contrast-induced nephropathy (CIN)

As with NSF, CIN occurs in the context of chronic renal impairment. Intravascular, particularly suprarenal administration of iodinated contrast media, cause a deterioration in renal function, as indicated by an absolute or proportional rise over baseline, the latter commonly considered when ⩽25%. CIN is thought to occur through a reduction in renal perfusion via a direct effect of the contrast agent through a feedback mechanism dependent upon the osmolality of the medium, i.e. less hyperosmolar agents are less likely to induce the condition.

While the incidence of CIN is low in an unselected patient population, in patients with known renal impairment it was found to range between 12–27%. CIN is principally a self-limiting condition, but there is a high level of associated morbidity and mortality. For example in patients undergoing endovascular coronary interventions, the associated in-hospital mortality of CIN is cited as high as 22%. Today, CIN is the third-leading cause of hospital acquired renal failure.

However, since the condition is inversely related to the glomerular filtration rate, patients at risk might be identified in advance. Appropriate questionnaires, asking for kidney disease history, prior renal surgery, proteinuria, hypertension, gout and, importantly, diabetes, detect 99% of individuals with a raised serum creatinine. Such patient-related risk factors are compounded by procedural risks: the patient's state of hydration, type, concentration and volume of contrast medium used, as well as current use of nephrotoxic drugs, and history of very recent contrast medium administration are all critical.

Appropriate hydration even after the radiological procedure and up to 24 hours is the single most important measure that can be taken to avoid CIN. A urine output in excess of 150 ml/h is advised and, in the case of high dose or intra-arterial contrast media administration, hydration should be achieved intravenously. The use of low – or preferably iso-osmolar contrast agents is also effective. In the search for a protective pharmacological agent, no single drug has consistently been found to be of use. Specifically, there is insufficient evidence for a prophylactic effect of N-acetylcysteine.

Haemodialysis removes iodinated contrast medium but does not prevent CIN and several sessions may be needed. It may take weeks to completely eliminate the agent by peritoneal dialysis. However, while considering its invasive nature, cumbersome set-up and high costs, continuous haemofiltration is effective in preventing CIN.

One should be aware that any deterioration in renal function might not become evident clinically, or through laboratory chemistry, until a week after the intervention. Measuring check serum creatinine at 24 hours will certainly miss a relevant proportion of instances.

Advice regarding the prevention of CIN and its management has previously been provided by the *European Society of Urogenital Radiology* in their 1999 guidelines, recently reviewed by Thomsen (Nephrol Dial Transplant 2005; 20 [Suppl 1]: i18-i22).

Lactic acidosis

The oral anti-diabetic agent metformin may inhibit lactate degradation. The story of metformin (a biguanide) induced lactic acidosis is intimately linked to the occurrence of contrast-induced nephropathy. A metabolic acidosis due to raised serum lactic acid may occur in severe hypoxic states, such as cardiogenic shock, or sepsis. In the late 1970s, a causal relation between intake of biguanides, acute renal failure and lactic acidosis was recognised as a class-effect. However, metformin does not cause renal failure, metformin and radiographic contrast agents do not interact, and lactic acidosis very rarely occurs in patients with normal serum creatinine. Nevertheless, since metformin is eliminated from the body entirely via the kidneys, any renal impairment, e.g. in contrast induced nephropathy, may lead to its accumulation.

Lactic acidosis in the context of CIN in patients with metformin-treated diabetes has an incidence of only 0.003%; importantly however, about half of cases have a fatal outcome. Patients at risk are those at risk of CIN, particularly those whose renal impairment is due to a diabetic state. As indicated, there is a correlation between the degree of renal impairment and the likeliness of CIN, as well as the state of hydration at the time of a contrast medium supported investigation. Irrespectively, since a normal serum creatinine does not necessarily imply normal renal function, occurrence of lactic acidosis may still ensue in such patients.

Advice differs in various parts of the world as to how contrast media administration should be managed in diabetics receiving metformin. Some believe that biguanides are contraindicated in any form of renal impairment and it may be argued that metformin is an inappropriate choice of agent in the

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context of even mild renal impairment; however, the agent has several important advantages over other oral antidiabetics, namely improving insulin sensitivity, reducing hunger and decreasing gastro-intestinal absorption of carbohydrates, while only rarely causing hypoglycaemic episodes.

In Germany, current advice still suggests that metformin is discontinued 48 hours in advance of a procedure while in the United States metformin may be stopped at the time of the investigation, providing a normal serum creatinine reading. The Royal College of Radiologists in their guidelines take the same view as the German and wider European authorities but differ in that patients who are to receive intra-arterial or doses in excess of 100 ml of contrast medium should also discontinue metformin 48 hours prior to examination, irrespective of a normal serum creatinine. There is agreement generally that metformin should only be recommenced when serum creatinine has been checked at least 48 hours post procedure and is found to be normal. Other advice relates to the prevention of CIN, specifically regarding the use of low-osmolar media and hydration.

Prophylaxis of anaphylactoid reactions

Adverse reactions to radiographic, i.e. iodinated contrast media in their most commonly used non-ionic form occur with an incidence of ≤ 4%. Although the most serious and occasionally fatal instances happen in no more than 0.04 to 0.22%, even such a small fraction of critical events amounts to a significant problem because of the frequent and rising use of these agents.

There has been considerable debate regarding the usefulness of prophylactic measures in patients at increased risk of idiosyncratic reactions, largely due to a lack of high quality randomised clinical trials. The only systematic review of published evidence on radiographic contrast media concludes first, that pooled data resulting in relative risk estimates demonstrate a significant reduction in the likeliness of an anaphylactoid reaction with H1-receptor antagonists (anti-histamines) when given immediately prior to a procedure. Second, by contrast, the same review lends less support for the pre-treatment administration of corticosteroids: A report by Lasser (1987) found a reduction in the incidence of reactions from 9.0 to 6.4%.

This study used ionic agents in comparison with placebo and administered 32 mg of Methylprednisolone at least 6 hours and again two hours prior to a contrast procedure. The incidence of severe reactions was reduced from 0.75 to 0.2%. The single study that satisfied all inclusion criteria of the above review was published in 1994 by the same author, now reporting on reactions to non-ionic iodinated media, but using the same prophylactic regime and finding incidences reduced from 5–2% overall and 0.87 to 0.17% for serious events. However, the latter was not statistically significant.

Interestingly, the incidences of serious events were surprisingly similar for both ionic and non-ionic media. Studies administering corticosteroids immediately or up to two hours before a radiographic contrast medium found no statistically significant effects – hardly surprising given that corticosteroids work by interfering with protein synthesis in the cell nucleus. Consequently, their maximum effect is not seen until after 2–8 hours.

To prevent allergic reactions, patients at high risk need to be identified and non-ionic agents be used in their care. Current practical advice has been given by Bush (2006): Previous reactions to contrast agents and a history of asthma or allergy are all predispositions, or make a subsequent reaction more likely. Prior anaphylactoid reactions are of particular concern, and one should aim to ascertain their type and severity. Bush asserts that 'pre-testing is not predictive, may itself be dangerous, and is not recommended'. Patients with previous mild reaction that needed no intervention may be given the choice of a prophylactic regime. Individuals who exhibited a rash, bronchospasm or laryngeal oedema should all receive prophylaxis. In cases of prior severe reaction, it must be seriously considered whether a radiographic contrast study is required. If found absolutely necessary, prophylaxis must be given and support from an anaesthetist should be arranged for the time of the procedure, including the immediate post-procedure period since reactions may be delayed up to 30 min. It should also be recognised that essentially the same advice applies to the use of gadolinium compounds in MRI. As indicated above, severe anaphylactoid reactions to gadolinium are rare, but recognised and potential risk factors include a previous reaction to iodinated contrast medium.

Conclusion – Agents used to modulate tissue contrast in imaging investigations may have pharmacological effects or provoke anaphylactoid reactions. The incidence of such events is generally low but some are severe and few occasionally fatal. Radiologists must therefore be aware of current advice on the recognition and prevention of these states. Current thinking focuses on NSF as a possible late serious adverse reaction to gadodiamide, however, it is unclear at present whether this represents a class rather than a specific agent effect. Principally, all serious adverse drug reactions should be reported through appropriate channels, for NSF a web-based registry has been established at Yale University. What unites instances of NSF, CIN and metformin-induced lactic acidosis is the impaired renal function of patients in whom these conditions occur. All patients receiving contrast agents should therefore be asked about a history of kidney disease, particularly diabetics. Special considerations apply in any emergency setting when some of the above advice may be waived.

**A referenced version of this article is available upon request by contacting the author at jlarsenmd@hotmail.com*

Blood products and radiofrequency identification (RFID)

Bar coding saves blood products

The Sato Corporation specialises in barcode printing – established in Japan, it pioneered the first hand labellers in 1962 and, in 1974, developed a printer able to print barcodes and OCR characters. Today, Sato produces data collection systems and labelling.

The firm points out that when a blood product is needed for transfusion, a nurse takes it from the refrigerator and must check it is the correct type. Then the receiving patient's identity must be checked. Before and after a transfusion the blood product's temperature must be checked, and so on.

In addition, when blood is taken from lab to operating theatre, then returned if unused, the product is mostly thrown away because the right temperature might not have been maintained. 'One blood bag costs €200 to €300, and a medium-sized hospital could throw away, from one department, €300,000 annually!' Sato points out, adding that, by using RFID with patient-ID and temperature logging, many lives and funds could be saved. Both the use of blood products in wards and the OT involve considerable paperwork. The barcode system cuts out:

- check patient ID and blood product
- record data about patient and nurse in case of adverse reaction, the protocol is displayed upon pda
- Record the treatment – Haemovigilance.

Sato adds that, after the blood returns to the lab, the temperature can be checked and if all was correct, the product can be re-used.

Gadofosveset trisodium (trade name: Vasovist) is the first approved blood pool contrast agent worldwide for the diagnosis of vascular disease, Bayer Schering Pharma AG reports. 'This innovative agent for use in magnetic resonance angiography (MRA) is unique among MR contrast media due to its capacity to prolong the diagnostic window for up to one hour. This characteristic is attributable to its ability to bind reversibly to serum albumin. Thus, gadofosveset has a much higher relaxivity and longer residence time in the blood than conventional extra-cellular agents. It is therefore not only suitable for conventional first-pass imaging in the arterial phase, but also provides brilliant ultra-high resolution MR images of blood vessels in the steady-state phase.'

In 2005, this product was approved for use in abdominal and peripheral MRA in the EU, Canada and Australia, and, in 2006, for whole body MRA in Switzerland.

From the Department of Radiology at the University of Bonn, Germany, Dr Winfried Willinek has reported obtaining MRA images with very detailed information of vascular structures, particularly in the periphery, when using this contrast agent. 'Significantly more vessel segments are depicted on ultra-high resolution steady-state images with gadofosveset, compared with the standard technique alone. This helps to guide interventions and may improve patient management especially in the critical patient in whom we need to identify more distal vessels that are potentially suitable for distal origin bypass surgery.'

The manufacturer adds that the contrast agent - which can be used for both dynamic and static imaging - might also open up new opportunities in MRA. 'The blood pool agent provides homogeneous contrast in both arteries and venous structures.

According to Dr Joachim Lotz, a radiologist at Hanover University Clinic, venous imaging is reliable, easy to use and of a consistently high quality. The reliability of the venous contrast produced is also the single most important aspect for diagnosis and for planning surgical or interventional procedures, especially in cases with highly pathologic venous alterations. Gadofosveset may, moreover, expand the potential of MRA in the detection of pulmonary embolism (PE) following deep venous thrombosis (DVT), a common and potentially life-threatening disease.'

At Grosshadern University Clinic, Munich, Dr Christian Fink explained: 'Following a single bolus injection the lungs can be dynamically imaged during first pass to assess perfusion of the lung. High spatial resolution pulmonary MR angiography during the steady-state also allows the detection of the embolus in the lung.' Finally, Bayer Schering points out, the diagnostic workup can be completed with MR venography of the whole body. The source of an embolus arising from an underlying deep vein thrombosis can be confirmed or excluded within one and the same examination.

Radiologist Professor Marco Essig, at the German Cancer Research Centre (DKFZ), Heidelberg, added: 'I see a great potential in the use of gadofosveset for MRA of supra-aortic and cerebral vessels.'

Steady-state imaging with gadofosveset displays relatively large anatomical areas with an excellent spatial resolution in the sub-millimetre range, whereas cerebral MRA with conventional extra-cellular agents can only be performed in about 30 seconds during first pass and with a substantially lower spatial resolution, the manufacturer points out. 'Moreover, gadofosveset-enhanced MRA is much less invasive than conventional angiography or computed tomography angiography (CTA).'

According to Professor Regina Beets-Tan of Maastricht University Hospital, Netherlands, the contrast agent might also prove useful in distinguishing malignant from benign lymph nodes in colorectal cancer, which no other contrast agent has been able to do yet.

Dutch hold 'mini' conference on tissue vigilance

To help improve transfusion safety, in accordance with EU Directive 2002/98/EC, the Dutch National Haemovigilance Office, TRIP, receives and analyses reports of transfusion reactions and promotes haemovigilance. The directive aims to ensure blood components are of comparable quality and safety in all EU member states, and there is a similar directive for human tissues and cells (Directive 2004/23/EC). In the latter, article 11 requires that Member States ensure they have a system to report, investigate, register and transmit information about serious adverse events and reactions.

TRIP is run by representatives of professional organizations and is therefore independent of blood and tissue establishments. Haemovigilance and tissue vigilance have many similarities. A tissue vigilance system can help to improve the quality and safety of tissue and cells and can learn form existing haemovigilance systems. In August 2006, TRIP launched the tissue vigilance pilot.

Haemovigilance, a system to collect data about blood transfusions, was shown at the ITEG in Berlin recently. It 'mini-conference' on tissue vigilance will take place on 9 May in The Hague (www.tripnet.nl).

OSMOMETRY

By **Ken Micciche** (right), Market Development Manager at Advanced Instruments

The clinical use of controls, materials and osmometry

Osmolality is a simple, rapid and relatively inexpensive procedure that is important in the diagnosis of many physiological conditions, because the measurement of osmolality often provides information that cannot be obtained by any other method.

Background

Freezing point osmometry measures the total solute concentration in a liquid. It is most convenient to describe freezing point as the concentration of particles in solution. Freezing point won't tell you how big these particles are, or what shape they have, or if they are charged. It will tell you how many you have. At low concentrations, freezing point is linear with the number of dissolved particles.

Low	240 mOsm/kg H2O	233-247 mOsm/kg H2O
Normal	280 mOsm/kg H2O	273-287 mOsm/kg H2O
High	320 mOsm/kg H2O	313-327 mOsm/kg H2O

Clinical Relevance

It is generally accepted that osmotic effects have a major place in the maintenance of equilibrium in the living body with respect to various functions and to the chemical composition of the fluids and tissues, examples: temperature, heart rate, blood pressure, water content or blood sugar. These effects occur within or between cells and tissues where they cannot be measured. One troublesome problem in clinical medicine is the maintenance of adequate body fluids and proper balance between extracellular and intracellular fluid volumes in seriously ill patients. Fluid and electrolyte abnormalities are not disease, but the manifestations of disease. Physiological mechanisms, which control water intake and output, appear to respond primarily to serum osmolality. Renal regulation of output is influenced by variations in rate of release of pituitary antidiuretic hormone (ADH) and other factors in response to changes in serum osmolality. These changes also serve as a stimulus to moderate thirst and are sensitive in order to limit variations in osmolality in normal patients to about 1%.

An increase in plasma osmolality of 1% will stimulate ADH release, which results in the reduction of urine flow and stimulates thirst, causing water intake to occur. This transfer of water through cell membranes occurs so rapidly that any lack of osmotic equilibrium between the two fluid compartments in any given tissue usually is corrected quickly. The rapid transfer of water does not mean that complete equilibration occurs between the extracellular and intracellular compartments throughout the entire body within this same short period of time. Fluid usually enters the body through the gut and then must be transported by the circulatory system to all tissues before complete equilibration can occur. In the normal person, after drinking water it may require 30–60 minutes to achieve reasonably good equilibrium throughout the body. Osmolality determines the physiologic acceptability of a variety of solutions used for therapeutic and nutritional purposes.

Using osmolality

Osmolality can be used for routine analysis and on patient samples requiring stat measurements. If screening for toxin ingestion is done, stat osmolality should be included as a rapid screen for low molecular weight toxins. Treatment of neurosurgical patients often requires calculation of osmotic gap to monitor mannitol therapy, to assure adequate dosage and to prevent toxicity. Evaluation of patients with alteration in serum sodium or abnormal urine output is facilitated by the measurement of osmolality. Because freezing point osmolality delivers a more accurate measurement of urine solute concentration, this is preferred over methods based on ionic strength or specific gravity. When stat results are required, results are available within a short time of specimen collection, which serves to minimise errors caused by loss of volatile substances or production of osmotically active compounds through in vitro metabolism.

Control solutions and materials

Control solutions and materials can be defined as a solution or patient specimen used solely for quality control purposes. Control products are widely available commercially in liquid, lyophilised form, packaged in small amounts suitable for daily use. They can be bought from the same companies that sell reagents and instrumentation. It is common for laboratories to purchase complete testing packages, which serve to enhance their quality control programme.

By purchasing from a sole source, differences in products and effects on method or instrument performance can be minimised. Good control materials should have the same matrix as the specimens being tested, so that they behave the same as the patient specimen. By developing materials to minimise alterations, a manufacturer can help to eliminate interferences in the testing process.

Liquid controls and materials such as Protinol – serum control, Renol – urine control, Clinitrol 290 – reference solution, and Osmolality Linearity Set, are designed to perform optimally. These are good value, as they reduce waste due to stability, eliminate vial to vial variability, and reduce operator errors that are frequently associated with the reconstitution process, all whilst enhancing laboratory quality and confidence in testing.

Basic quality control practices

CLIA '88 – Clinical Laboratory Improvement Amendments of 1988 are requirements for general quality control (QC) provisions and personnel qualifications for moderate complexity testing.

JCAHO – JCAHO follows CLIA '88 and mandates for moderately complex methods that external controls (usually liquid) be run to verify manufacturer's claims and to validate that no change occurred with the testing system. Labs must be certain that these results meet its acceptance criteria before patient results are reported.

CAP – Controls must be included with all tests, even those identified in CLIA '88 as waived. Cap requires an audit trail that ties patient results to both a positive and negative control each day of use.

Advanced Instruments ControLine products

These reliable, quality products help clinical labs to achieve the most accurate results with the only comprehensive set of control solutions and materials designed specifically for osmometers.

They can help laboratories avoid expensive workflow disruptions and ensure the reliability of patients' results. With a tighter tolerance than multi-analyte controls, it is easier for users to identify when action needs to be taken due to results found outside satisfactory control limits.

***Protinol** – Protein-based Serum Controls* is designed specifically for clinical laboratories testing blood samples and formulated to produce the most consistent, reliable results in the human serum range. Formulated at three levels, to allow users to comply with CLIA '88 quality control requirements, the product is premixed and ready to use in three, 3 mL vials per kit (see box).

Renol – Urine Controls. Renol is the world's only osmometer specific control solution for laboratories that test urine samples. The aqueous-based control material is manufactured to extremely tight tolerances for better repeatability and the most precise control over patient results. It comes premixed and ready to use in four, 3 mL vials of each value per kit. Formulation values include 300 and 800 mOsm/kg H2O. These concentrations are close to medical decision levels where performance is critical for the use and interpretation of the test.

To comply with CLIA 493.1218, labs should perform and document control procedures using at least two levels of control materials daily.

By utilising products designed specifically for osmometers and strengthening quality programmes, users will be able to track control results; identify shifts, trends, and random errors; apply control rules; and implement corrective actions.

Clinitrol – 290 Reference Solution and Calibration standards. These premixed and ready to use reference solutions and calibration standards meet CLIA 493.1217 regulations.

Labs will use Clinitrol 290 to monitor operator technique – particularly important with several shifts. Additionally, when following a calibration routine, Clinitrol 290 is a valuable tool for calibration verification. The calibration standards are manufactured to stringent NIST and ISO9000 quality systems standards, are stable, reliable, and accurate.

Osmolality Linearity Set. This product was designed to help clinical laboratories easily monitor instrument performance, which fulfils the CLIA 493.1213 requirement for establishment and verification of method performance specifications and reportable range of a laboratory method.

LAB TESTS

By **Henning von Eicke** of Roche Diagnostics GmbH

Low compliance with guidance harms patients

The key to all successful therapy is a correct and timely diagnosis; yet the value of laboratory diagnostics is often underestimated. At least that's the conclusion reached by an extensive analysis undertaken in the USA by a US consultancy, the Lewin Group (*The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care. July 2005*). Although many recommendations made by the study cannot be translated one-to-one from the US to the various European healthcare systems, nonetheless the analysis is extremely interesting for our hospitals, doctors and healthcare businesses.

On average, diagnostics accounts for only five percent of the costs of hospital treatment, although the results affect 60–70% of healthcare decision-making in a hospital. Therefore, in any cost-benefit calculation of *in vitro* diagnostics, it is not the direct costs that are ultimately decisive, but rather the huge potential for lowering follow-up treatment costs in the subsequent course of a patient's hospital stay. In the USA, for instance, there are some 1,230 evidence-based guidelines and, in more than one third of these, clinical laboratory tests play an important role. According to the US National Committee for Quality Assurance (NCQA), in 2004 alone, poor compliance with these, for diabetes, coronary heart disease, colorectal cancer and breast cancer, led to 56,200 avoidable adverse health events and 34,000 avoidable deaths. This translates into avoidable healthcare costs of 899 million US dollars.

The Lewin report cites case studies drawn from a thorough review of the literature to illustrate the impact of diagnostics on the quality of healthcare, the use of resources, the effectiveness of medical treatment and healthcare costs. According to the report, US hospitals, for instance, spend some twelve billion dollars annually on the hospitalisation of patients with a false-positive diagnosis of heart attack, while between two and ten percent of those patients who have in fact suffered a heart attack are mistakenly sent home again. Testing for troponin – the gold standard for diagnosing heart attacks – reduces treatment costs by 900 US dollars per patient compared with patients who are diagnosed only for standard parameters, such as creatinine kinase or myoglobin. According to the Lewin Group study, hospitals could save up to 30% of follow-up costs if they were to routinely test patients with acute chest pain for troponin in their emergency wards.

One informative case study – only published in 2006 and therefore not included in the Lewin report – discusses the laboratory marker NT-proBNP for the diagnosis of chronic heart failure. The Siebert et al. study (Cost-effectiveness of using N-terminal pro-brain natriuretic peptide to guide diagnostic assessment and management of dyspnoeic patients in the emergency department; Am J Cardiol 2006; 98: 800-805), describes 599 patients admitted to the emergency department with dyspnoea and then followed up over a period of 60 days. The study concludes that the costs of hospital treatment could be decreased by 9.4% if the doctors knew their patients' NT-proBNP value. This decline in costs was due mainly to the shorter period of hospitalisation, but also to a 58% reduction in the use of echocardiography.

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FAST TRACK surgery

'The term fast track surgery refers to a combination of findings from current, high quality studies of anaesthetics, surgery and perioperative care for a certain medical indication,' explained Professor Schwenk. 'The evaluation of these findings is then transformed into a certain path of treatment followed through all the treatment stages, i.e. from admission to a hospital, all the way to out-patient aftercare. In short, fast track surgery is a procedure specific, evidence based and inter-professionally optimised course of therapy.

'Although there is already an established procedure for a certain indication, the initial reason why such a treatment path should be developed can be explained using colon surgery as an example. With traditional treatment, postoperative general complications such as pneumonia or cardiovascular complications, tend to occur in every third or forth case. Obviously the question arises as to how these postoperative problems can be minimised. This is the basic question that must be dealt with by all the medical disciplines involved - in this case surgery, anaesthetics, nursing care and physiotherapy. Having looked at medical findings from all over the world, they research and define what can be classed as evidence based and what can then be implemented in hospital. Results are then summarised in a catalogue. In the case of colon surgery, the treatment path is as follows: A patient can drink up to two hours prior to surgery, no colon preparation, regional abdominal anaesthesia via thoracic peridural catheter, additionally general anaesthetic, minimally invasive surgery or transverse opening of the abdominal wall. The patient is aggressively mobilised out of bed by the evening of the day of surgery. There is no infusion or drainage and the patient can eat normally the next day. On the second day after surgery the patient is fully mobilised, and from the fifth day onwards the patient can be discharged. With this treatment plan we have been able to lower the rate of complications in colon surgery to only 10% and have cut the length of individual hospital stays by half.

'As this treatment plan has resulted in standardisation of processes, even though there are still individual aspects for each patient, it is easier to calculate treatment costs. Deviations from the "normal course" are significantly lower than those occurring with traditional methods, which is particularly important for planning integrated care with doctors in surgeries outside a hospital. Moreover, the treatment path ensures a streamlining of procedures and prevents, for example, redundant examinations. Finally, the lower rate of postoperative complications results in lower follow-on costs.

'Of course fast track methods require investments, such as intensive staff training, so that the methods can be successfully implemented in practice. Often the structures required for successful implementation must be created, such as the setting up of acute pain services. All in all, these investments pay off in the medium term, particularly for patients.'

So why is 'fast track' still infrequently used?

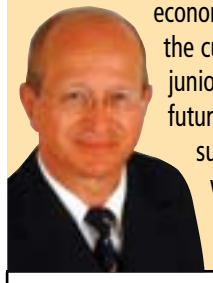
'The exact number of surgeions fast-tracking patients in Germany is unknown. Only 24 hospitals in Germany are undergoing a joint internal quality assurance programme offered by the Charité. On a European level a working group represents the fast track principle, which is known as Enhanced Recovery After Surgery (ERAS), and hospitals in Denmark, Sweden, Scotland, Norway and The Netherlands are participating in that programme.

'We mustn't forget that there are probably some hospitals already using this method without being aware of it and without having a specific term for it. I believe fast track surgery will gain more importance in the future and that it will also be implemented for other medical indications. But, whoever opts for fast track needs to be aware that the method has to be continuously advanced. Once developed, any treatment path must be checked regularly to include any relevant new findings. Fast track surgery is a continuous process that adapts to new medical findings.'

Although everyone talks of 'fast track surgery', in most cases the term is not correctly used. The name might appear to be a reference to speed but, in this case, 'fast track' refers to therapy optimisation. The fact that patients recover 'faster' due to optimised therapy is really just a very positive 'side effect'. *Meike Lerner*, of European Hospital, discussed the method with **Professor Wolfgang Schwenk** (below), Associate Clinical Director at the Clinic for General, Visceral, Vascular and Thoracic Surgery, at the Charité University of Medicine Berlin, and one of the pioneers of fast track surgery.

Changing operations and work patterns

Under the banner *Surgery and Changing Systems,* the 124th Congress of the German Society for Surgery (1-5 May. ICM Munich) promises to be a stimulating programme. According to its President and Secretary General, respectively **Professor H U Steinau** (left) and **Professor H Bauer**, the focus will not only be on current operating procedures, interdisciplinary problem cases, and troubles with surgical provision under changing economic conditions, but the current situation for junior surgeons and future prospects for surgeons in Germany will come under scrutiny.



Along with advanced training courses, a training laboratory, video presentations, careers advice, satellite symposia to simplify the collation of clinical data, the forum will present a platform for young scientists.

The new forum-panel also will define the ethical basics of experimental and clinical research.

On 2 May, the congress will merge with the Congress on Accident and Emergency Medicine, organised by regional branches of the Professional Medical Associations in Saxony and Bavaria, to present and discuss aspects of rehabilitation, MRSA and particularly nosocomial illnesses acquired by operating theatre staff.

NB: For those who could not attend the congress the contents of the clinical and experimental sessions will be presented on the Society's website (www.dgch.de), and in publications from the DGC and the BDC.

Knowing the right procedure

DGCH promotes studies for evidence-based medicine (EbM) in surgery to establish guidelines

Research from the USA and The Netherlands has shown that 30-40% of patients do not receive the scientifically proven best treatment for their condition, and about 25% of patients receive unnecessary treatment. Evidence-based medicine (EbM) serves to evaluate the use of diagnostic and therapeutic services. In an ideal case it ensures patients always receive the best possible medical treatment, the DGCH points out. 'Researchers also identify ineffective or less effective therapies through relevant studies. All of which could save patients receiving unnecessary, ineffective or even damaging treatment and cut costs for healthcare systems.

EbM also can be used as a record of the effectiveness, or superiority, of an operative procedure.' However, Professor Bauer, secretary general of the DGCH in Berlin, points out: 'Essential progress in surgery has so far rarely been achieved through methods used in evidence-based medicine.'

Researchers mainly obtain scientific evidence through examinations of different, randomly distributed patient groups - so-called randomised controlled studies (RCTs). These are generally carried out 'blind': Neither doctors, nor patients, are aware which medication is being tested, which produces constant test conditions and forms the basis for meaningful comparisons. In 2000, a survey of clinical studies of surgery showed the percentage of RCTs to be only 2.8%. Of course, in surgery it is almost impossible to 'blind' patients and doctors. What can be achieved in drug trials using placebos can hardly be replicated as 'pretend' surgical operations. That would be unethical.

With its study centre (SDGC) and linked network of five regional centres (CHIR-Net) the DGCH promotes large, multicentre clinical studies in surgery. 'The necessary repeatability and comparability of procedures require a high degree of standardisation, not only for the surgical operation but also for the entire peri-operative treatment regime,' Professor Bauer explains. The SDGC is able to meet these complex scientific, methodical and ethical requirements by carrying out national studies. In this way, the DGCH promotes patient-oriented research in Germany and contributes to the realisation of treatment procedures with proven effect and evident benefit for patients.

Source: www.dgch.de

EH: Surgery Update logo photograph courtesy of Trumpf

New device leads airway management evolution

i-gel, a new single-use, supraglottic airway device designed for quick, easy insertion, also comes ready to use. Intersurgical, its UK-based manufacturer, reports that the device '…. accurately positions itself over the laryngeal framework to provide a reliable perilaryngeal seal without the need for an inflatable cuff'. For greater safety, it also incorporates a gastric channel; an integral bite block to reduce the possibility of airway occlusion, and a buccal cavity stabilizer to aid rapid insertion and eliminate the potential for rotation.

'The **i-gel** is a truly unique airway device. It represents the culmination of years of extensive research and development,' says Intersurgical, which is inviting EH readers to see the device at Stand 20 in *Euroanaesthesia 2007*, 9-12 June, in Munich, Germany.
Details: www.igel.com

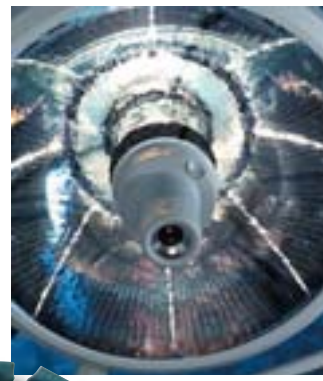
NEW

With a power range up to 200 W, Bowa's new electrosurgical unit, ARC 200, is equipped with the well-recognised ARC Control, which regulates power output to just the necessary minimum, unrelated to tissue type, cutting speed and surface.

When combined with the Argon beamer ARC Plus, the ARC 200G becomes a superior

HF-workstation, with reliable ignition even below 10 W: 'A great addition for any endoscopic tower,' Bowa says.

Bespoke operating theatres



'We have 40 square metres for a surgical unit. Please supply a Supersuite'

'Supersuite' describes a valuable service provided by Berchtold, specialist manufacturer of operating theatre lights (e.g. Chromophare), camera systems, monitor arms, surgical tables (Operon) and equipment management systems (surgical and anaesthesia booms, but not the device control units). For the company not only sells and installs its individual products, such as the simple anaesthetic pendant soon to be installed at the Siemens Radiography suite in Kent and Canterbury Hospital, but also runs the Supersuite service to undertake the planning, design and installation of integrated, customised operating theatres – notably the 10 in use at Krefeld Hospital, Germany, and 12 at Baylor Regional Medical Centre in Plano, Texas.

Supersuite can produce an up and running operating theatre in 6-15 weeks, depending on size and other factors. 'Generally speaking, Berchtold supports the structure of the operating theatre,' explained Judith Szarmach, Marketing & Communications Manager at Berchtold. 'We design where our lights, tables, booms, etc. would best be located. We don't manufacture device control units, but we manufacture the system where the device control units can be placed, so we team up with partners for integrated services, including imaging and device control and visualisation, such as from Storz, S&N, etc.' Additionally, should a hospital want other, perhaps specialist equipment, Berchtold also sources and supplies it.

Supersuite specialities include orthopaedic surgery, advanced laparoscopic surgery, general and neuro surgery and cardiac surgery.

Further details: www.berchtold.de

Pioneering vertebral procedure

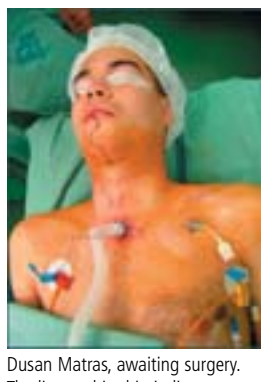
By Rostislav Kuklik

Czech Republic - In 2001, when doctors at the Motol Faculty Hospital first saw Dusan Matras, he was diagnosed with a thyroid gland problem. However, they later found he had a tumour. Six years later, Dusan has become the first in the world to undergo a unique surgical procedure on the vertebral column in the neck area.

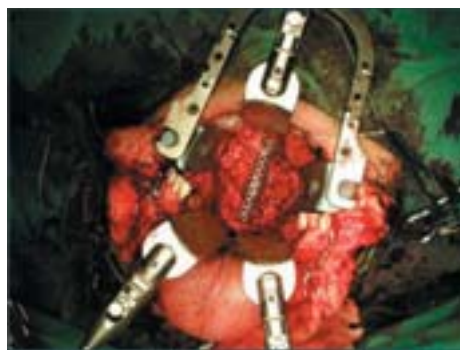
Dr Jan Stulík, who heads vertebral surgery at Motol, explained that the patient originally had thyroid gland neoplasm, and this had been removed. However, five years later a vertebral metastasis was found in the second cervical vertebra. After lengthy discussions, then planning, the Motol team decided to remove the entire C2 vertebra (axis) – a risky procedure. All previous efforts to do this have resulted in partial brain damage because C2 protects two large brain vessels, one of which had to be sealed off.

The Prague surgeons became the first to successfully complete such an operation without destroying any arteriae vertebrales or damaging the patient's brain. The team first worked from the back of patient's neck, removing the arcus posterior vertebrae. Three weeks later they removed the remaining C2, by centrally splitting the lower jaw (mandibula). They fixed C1 (atlas) and C3 together using a metal fitting enclosed in bone implants taken from the patient's pelvis. At the same time, to support the nerves and large vessels, they replaced the missing C2 frontal area with a titanium inlay.

Thus the surgeons removed the whole vertebra without harming the vital structures running through the spinal canal and secured almost the full physiological movement range of patient's head - 11 hours after surgery. 'I have just slight difficulties turning my head to the furthest left and right positions, but otherwise everything is absolutely perfect,' 27-year-old Dusan told the waiting press.
Details (no translation): http://www.fnmotol.cz/html/zdravotnicka_pracoviste/zp.php?lang=cz&id=17



Dusan Matras, awaiting surgery. The line on his chin indicates entry area to reach the lower jaw bone

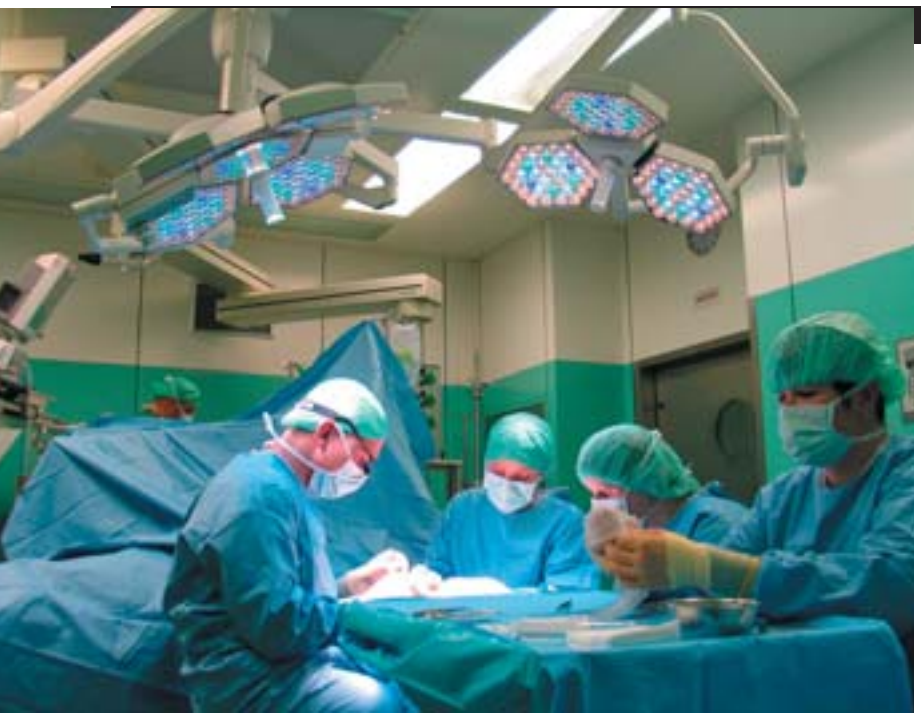


Patient's open mouth reveals the mandibula split in two and a metal staple that joins C1 and C3

See saw blades on the Web

Komet Medical has developed rotating and oscillating instruments since 1923. In its 'Evolution' range the various sized, hardened, stainless steel saw blades are compatible with common drive systems, and suit both knee and hip endoprosthesis: 90mm length for knee; 50mm-70mm for hip. A varying material thickness makes vibration in the saw blade template impossible, Komet points out.

To provide the obligatory evidence these reprocessable blades are in fact clean after cleansing and disinfection, with an independent company Komet developed a validated reprocessing method. These individual reprocessing steps can be viewed at: www.kometmedical.de.



Studies confirm adjustable colour temperatures benefit surgeons

After their debut at the 2005 Medica trade show, the first LED lamp made by Trumpf Medizin Systeme (iLED) found new users worldwide. In the USA, the light also received two prizes at the *Healthcare Facilities Symposium & Expo*, which recognises extraordinary innovations in the health industry. However, it was even more important for their inventors to scientifically prove the quality of the iLED.

Trumpf decided to commission two studies, to ascertain the degree that adjustable colour temperature influences our visual performance and also whether its iLED sufficiently meets hygiene standards for the operating theatre (OT).

Colours for more vision

Currently, the iLED is the only operating light that can have its colour temperature adjusted to any OT situation – from warm red 3,500 Kelvin to cool blue at 5,000 Kelvin. An independent lighting institute conducted a study in which 30 test subjects had to identify standardised vision test characters on a colour background under both the iLED 5 and gas-discharge lamps. Results: Under the iLED, the characters were considerably clearer with weak colour contrasts. In most cases, the test subjects had the best vision at 4,000 to 4,500 Kelvin and, with a blue background, at 3,500 Kelvin. In addition, they preferred the iLED, even when the colour temperatures of both lamps were the same (4,000 Kelvin) – because the iLED's light was more evenly distributed. For surgeons, this means that the iLED helps them to better distinguish between healthy tissue and diseased tissue that is slightly off colour. For a red wound location the surgeon's eyes are relieved by a high colour temperature, for a blue wound location, a low colour temperature.

Best ratings for hygiene

Professor Seipp, at Germany's Centre for Hygiene and Technical Public Health, tested how well the iLED met the hygiene regulations in the OT under real-life conditions and in strict compliance with EU directives. His findings: The iLED 3 is one of the best lamps that is compatible with an air-handling ceiling that he has ever tested - because it generates very little turbulence that would disturb the irrotational, laminar flows in the OT and thereby impair the room's cleanliness. This means that the light is also well suited for sensitive medical disciplines, such as orthopaedics and bone surgery, in which absolute sterility is top priority. The iLED's excellent ratings come from an open, compact form, low laminar flow surface and minimal temperatures on the lamp body.

The iLED underwent many tests. The manufacturer reports that its vital features include variable colour temperature (3,500 to 5,000 Kelvin) for greater colour contrast and better tissue differentiation; even light field with almost no shadows on the surface and at depth without refocusing; minimum 20,000-hour life cycle of LEDs due to a new optical light system; very good depth illumination and spatial perception; sterile operation for dimming, colour temperature, endo light and camera functions; cold, infrared-free light despite high light output of up to 160,000 lux, and finally, optimal outage prevention thanks to a new optical light concept.

Electron intra-operative therapy

Developed by Professor Umberto Veronesi, breast cancer specialist and former Minister of Health in Italy, in certain cases electron intra-operative therapy (ELIOT) could become a substitute for postoperative radiotherapy. As the new method undergoes clinical tests at the Breast Centre, Milan, *Meike Lerner* of European Hospital spoke with radio-oncologist **Professor F-J Prott** about current results and ELIOT's potential future in oncology

'ELIOT means that single-fraction radiation of 21 Gy is delivered directly to the tumour bed during a surgical intervention, to a depth of about 3 cm,' Professor Prott explained. 'Due to this procedure the procedure takes about 30 minutes longer than usual, but post-operative radiation therapy is no longer needed. Consequently, for most patients, the treatment is complete, with hospital discharge, and they don't have to undergo out-patient radiation therapy, which could take up to six weeks.

'Since post-operative radiation of the entire breast and the surrounding tissue is no longer indicated, ELIOT is suitable only for a clearly defined group of patients. These parameters must be present: the patient is older than 50 years; the tumour is not larger than 2 cm (T1) and no lymph nodes are affected (N0). The histological degree is maximum G2 and there must be no indications of metastases. The surgeon has to be extremely careful to remove any traces of tumour-carrying tissue.

'Due to today's advanced diagnostic methods, the number of early detections and thus of T1/N0 tumours is increasing constantly. However, many women with such early detected tumours are under 50 years old, so are not eligible for this kind of intra-operative radiotherapy.

'Despite these limitations, the first clinical results are very promising. A study at the Milan Breast Centre, involving 1,600 patients, showed that only 2.8% of the women suffered fibroses and the recurrence rate was 1.6%. That means, compared with conventional methods, ELIOT showed 1-2% less fibroses and even 2% less recurrences. However, these figures are only valid for Milan. It remains to be seen whether other hospitals will be able to achieve similar results.

Currently, ELIOT is only used for research. In view of its apparent advantages, when might it be clinically introduced?

'It's without a doubt a very interesting method and there is a clear trend towards ever more targeted and precise radiation therapies, moving away from large area radiation. However, we must acknowledge that the conventional method – breast-conserving surgery followed by about 30 radiation sessions – is also very successful. Moreover, we were able to reduce side effects, particularly skin changes on the breast, so we have a method that's tried and true and which has been constantly improved. As far as the current status of ELIOT is concerned, I'd rather go for "never touch a running system". Having said that, I also want to point out again that ELIOT means there is only intra-operative radiation. As a boost, I mean an addition to whole-breast radiation therapies, intra-operative methods are allowed and may be applied outside studies. That means, during surgery a boost of about 10 Gy is applied and a conventional breast radiation therapy of about 46-50 Gy follows. This procedure reduces the post-operative radiation by one week, that's five sessions.

In short, I look very optimistically upon ELIOT and I think it's an important goal to make breast cancer therapy as stress free as possible. Nevertheless, we must not act prematurely, that means long-term and large-scale studies are needed before the method is introduced in to everyday practice. In my opinion that will take another few years of intensive research before we might be able to use ELIOT without reservation in every day oncological work.'

Professor F-J Prott, Director of the RNS Clinic, St Josefs-Hospital, in Wiesbaden, Germany

Ultrasound-guided regional anaesthesia and pain therapy – a painstaking technique

Watching an ultrasound-guided needle move towards a nerve can help an anaesthetist and a pain therapist, as well as increase their success rate. Nonetheless, few physicians use this option in interventional pain therapy. *Meike Lerner* of European Hospital spoke with **Dr Urs Eichenberger**, hospital consultant and director (ad interim) of pain therapy at the anaesthesiology polyclinic, University Hospital Bern/Inselklinik, and asked why this technique is so rarely used in interventional pain therapy and what the future holds for this technique

'Ultrasound-guided interventional pain therapy originates in ultrasound guided regional anaesthesia,' Dr Eichenberger explained. 'The traditional method for partial anaesthesia – that is, detecting the nerve with electricity and then injecting anaesthetic – has a drawback. It shows only if the needle tip is close to the nerve. But what you really want is to transport the drug to the nerve, not the needle. With ultrasound we can visualise and localise nerves and guide the needle all the way to them, thus reducing the risk of damaging the nerve and neighboured structures. Obviously, as an anaesthetist you know where the nerves should be, but there are anatomical variations that can only be recognised with ultrasound. Moreover, you can watch the anaesthetic spread live, so to speak, and see whether it reaches the target. With the traditional method the success rate of very experienced physicians is up to 95%. With ultrasound I'm sure we can increase that rate.

'The method was transposed to pain therapy from regional anaesthesia, and the advantages are obvious: With chronic pain patients we usually diagnostically block nerves to localise the source of the pain. Before, we did this blindly - we injected large doses of anaesthetic, up to 10 ml. With the help of ultrasound we can reduce that dose to about 1-2 ml because we can target certain nerves and don't have to spread anaesthetic over a large area. For a patient this hopefully means better diagnosis. Furthermore, dose reduction in regional anaesthesia – where larger doses are used – means a lower risk of side effects and allows us to block several regions of interest at the same time, both arms, for example. With a dose of 40 ml per side we cannot do this – as that dose would be toxic.

'Ultrasound-guided pain therapy is particularly interesting for very sensitive regions, such as the cervix. Very close to the targeted nerves you find a lot of different vulnerable structures. Today ultrasound can visualise small nerves down to a diameter of 1-2 mm. One example is the possible visualisation of the nerves innervating the cervical facet joints. Consequently, we can position the needle right next to the targeted nerve. The traditional method to block these nerves is based on X-ray images, which show only the neighbouring bone structure. While this gives an indication of the nerve pattern you do not recognise anatomical variations, both of the nerves and of surrounding structures you don't want to damage.'

Why is this apparently successful method so rarely used?

'In regional anaesthesia the method is used quite often, and in a lot of hospitals. In pain therapy the targeted nerves are smaller and therefore more difficult to detect by ultrasound. In ultrasound you recognise the very small nerves only if you have excellent anatomical knowledge and know where these nerves run. You need an experienced eye to correctly interpret the images. And we should not forget: With the exception of cardiac anaesthetists, the anaesthetists and pain therapists using this method often lack experience in reading ultrasound images. This is an entirely new field for the discipline.

'There is also another problem in pain therapy. There are so many anatomical regions we have to deal with. In pain therapy we have too few cases for special interventions, so it's more difficult to build up experience.

'In some ways, ultrasound-guided work is a paradox: it facilitates the therapy, but only if you already have the necessary know-how. So, as a physician, you have to master your trade perfectly. Ultrasound will not automatically turn a physician into an excellent pain therapist – you have to be an excellent physician to begin with. Handling the technology is something that has to be learnt and exercised in seminars and workshops. In anaesthesia particularly, there's currently a huge demand for training, and a trend towards ultrasound-guided methods, which will increase over the next few years.

'The next step is obviously to spread the method. We are currently one of only a few centres to offer this pain therapy. In anaesthesia the situation is somewhat different. Here the method is better known, and I expect, in the future, it will be a normal procedure in all regional anaesthesia applications for which it is suitable and the rate of success could be augmented and complications could be reduced significantly.

Further details: urs.eichenberger@insel.ch

Telemedicine

Systems for today and tomorrow

'New communication technologies are gaining increasing influence in medical engineering, within the context of the continuous further development and refinement of surgical treatment methods,' software firm Richard Wolf points out. 'One of these modern communication standards is video-conference/telemedicine. Here, video-conference equipment represents the communication platform of physicians and specialist medical departments. It facilitates live communication from clinic to clinic, the exchange of specialists' experience and provides support in the education and training of the medical practitioners of tomorrow.'

When integrated in the teleconference system, it permits '… intra-operative, bidirectional communication of specialists (e.g. surgeon-histologist) for high-quality patient treatment with at the same time cost-oriented clinic management,' the firm continues, adding that the key factor in the ***core*** integration solution, which it develops, is '… the simple, intuitive menu guidance for the routine use of this technology. Rational use in the operating room workflow is possible only by this interactive operation'.

Details: core.info@richard-wolf.com

FDA clears sale of patient-controlled ventilator

Neurally adjusted ventilatory system promotes spontaneous breathing

The US Food and Drug Administration (FDA) has given 510(K) clearance to Maquet Critical Care of Solna, Sweden, to market its Servo-i ventilator with the NAVA (Neurally Adjusted Ventilatory Assist) option. Sales of the system, which aims to treat and monitor neonatal, infant and adult patients, should begin this year. In addition, current Servo-i users can upgrade their system with NAVA.

In this new approach to mechanical ventilation, to improve synchrony between patient and ventilator the patient's own respiratory centre can control the ventilator. Signals from the brain's respiratory control centre are transmitted through the phrenic nerve to the diaphragm, where a catheter captures the electrical activity (Edi) and feeds it to the ventilator. The ventilator responds by providing the requested level of support to the patient. As the ventilator and diaphragm work with the same signal, the coupling between the two is virtually instantaneous.

In addition to being a distinct mode of ventilation, NAVA also enables a complete evaluation of the neural respiratory control by capturing the electrical activity of the diaphragm (Edi). The Edi signal can be used as a unique monitoring tool, as it provides information on respiratory drive, volume requirements, the effects of ventilatory settings, and to gain indication for sedation and weaning.

Christer Ström, Director Ventilator Program, Maquet Critical Care, said: 'We are proud to introduce the most progressive advancement within respiratory therapy since the introduction of mechanical ventilation 30 years ago.'

Details: www.maquet.com

Merge Healthcare

US firm localises IT systems for European countries


Beth Frost-Johnson

Some 23 years ago, when William Mortimore set up a firm to focus on connectivity, a tool called MergeBox (which allows modalities to speak to other networks) inspired him to name his new business. 'Bill Mortimore was one of the individuals involved in the development of the DICOM standard,' explains **Beth Frost-Johnson** Senior Vice President of Marketing at Merge Healthcare. 'He is considered one of the early gurus of digital medical imaging.'

As medical imaging has expanded, Merge Healthcare has stayed on the leading edge, she points out. Building on the connectivity success, the company developed a PACS infrastructure by 1997. In 2002, Merge Healthcare then acquired eFilm Medical, '…producer of eFilm Workstation, the most widely used diagnostic desktop software in the world,' Beth Frost-Johnson explains. 'It's used in 84 countries, and is often a clinician's first introduction to digital reading.' This became the first visualisation component of the PACS solution. 'As Merge realised that customers needed a RIS/PACS to really manage workflow, we worked on acquiring RIS Logic, one of the leading United States RIS companies in the imaging centre market. Our growth strategy led us to a merger in 2005 with Cedara Software, very well known in the industry for providing leading edge imaging technologies and engineering services to OEMs [Original Equipment Manufacturers] worldwide. Our most recent acquisition was the technology from aXigate, an Electronic Patient Record company based in Paris.'

In September of 2006, Kenneth Rardin joined as President/CEO. In conjunction with the senior management team, carried out an intensive analysis of Merge Healthcare and the market potential, which resulted in a company reorganisation. Beth Frost-Johnson explains: 'Although we've had a European presence with our Netherlands and Paris offices, we decided a more dedicated and comprehensive approach in the European, Middle East and Africa (EMEA) market made sense, and formed the Merge Healthcare EMEA division. This division now brings a comprehensive product portfolio, with RIS/PACS and clinical applications, mammography, orthopaedics, PET/CT and Electronic Patient Record (EPR) in Europe. I'm very proud of the analysis and research we put into our product line selection for the European market.'

RIS Solutions

'As part of our market analysis, we asked ourselves: *Does our product line make sense in the European market?* Our PACS functions well within European workflow, but our RIS was created for US imaging centres and their US-based workflow. So, to ensure that our products meet the needs of the European market, we chose to partner with Medavis. In our portfolio we offer Fusion RIS GL, which is the rebranded Medavis RIS, to have a fully integrated system; we're working with Medavis to fully integrate their RIS and the Fusion PACS. We chose Medavis because they created software that has been designed for easily localisation (local billing and local languages). They currently have about 120 installations throughout Germany, Switzerland, China, and the UK. Their solutions are easily configured for regulations, finance and the business model of a specific country.'

PACS Solutions

'The way we developed our PACS is very interesting,' says Beth Frost-Johnson. 'We used a process called concept engineering. We went out and spent two days individually with multiple radiologists from imaging centres, large hospitals, small hospitals, multi-sites and single sites. One day we just observed how they work; the second day we asked questions such as: *What don't you like in the way you work – not just the software, but what drives you crazy?* The second question was: How do you want to work? We transcribed all that information, and then had squadrons of people review it using highlighters, and sticky notes. They filled an entire room with the customer's voice. We found that users can't always articulate the specifications, but if we can understand what is difficult and what challenges them, then we can translate that pain into a product specification. Our PACS was built on what our customers told us. Oftentimes when a radiologist sees our PACS they say: *'Wow. You know how I work!'*

This understanding comes from both the firm's development process and experience, she adds. 'Merge and Cedara have been developing radiology software for over 20 years, so we have a depth of expertise. Secondly, Cedara works with many of the major modality manufacturers etc., so we can see what's coming down the road two, three or five years from now, and ask: *What impact will that have on workflow a year or two later?* Who would have thought studies would be the size they are today? People may have been designing a PACS three years ago, but did they really have an understanding of the impact that these new acquisition modalities would have? I think we have a real advantage in understanding which road those modality manufacturers are going down, with the ability to change our forthcoming workflow applications accordingly.'

Clinical Applications

'Our Merge Mammo, which is a vendor neutral, multi-modality mammography workstation that allows our users to read studies acquired by any brand of digital mammography modality, and from any type of modality.

'Then also if someone is starting out with digital mammo and they decided later that they want to do MRI, ultrasound – a single workstation, vendor neutral, multi-modality. It makes a lot of sense, so we're rolling that out in Europe, along with our orthopaedic product, for surgical planning, templating, etcetera, all digital and our PET/CT workstation. So our roadmap plan is to also integrate all the clinical applications into the workflow, so all a radiologist has to do is Sit, read, sit, read, sit and read. The system will be smart enough to know what kind of study it is, and open up the study and the relevant priorities in the appropriate tool.

'One of the advantages to Merge Healthcare is that we have our dual strategy of selling our solution and services to OEM's as well as end users. We have centralised product development and product management, which leverages our expertise for both of these markets. Cedara sells clinical applications to the companies that compete with our direct end user business. From a business perspective, if revenue comes in both ways that's good for our financial health. It's a model that works well for us, because we hope to see our mammography product – seen as Merge Mammo or under other names – as a standard in the industry. That's our business strategy.'

Based on an interview by Daniela Zimmermann

E- for education

Italian association upgrades web-based medical and laboratory programme

Italbioforma's Scientific Director and coordinator of the Scientific Committee is **Dr Antonio Goglio**, (left) professor and director of the School of Microbiology and Virology, University of Milan, and director of the department for the prevention and surveillance of infections at the Riuniti di Bergamo Hospital.

Members of the committee include:
Giuseppe Banfi – Healthcare Director at the Galeazzi Orthopaedic Institute in Milan and Supervisor of the Italbioforma training programme
Claudio Farina – Director of Microbiology, Azienda Ospedaliera 'San Carlo Borromeo Hospital', Milan
Luigi Ferrari – Haematologist
Carlo Franzini – Clinical biochemist at the Medical & Surgery Faculty, Università degli Studi, Milan
Federico Maggi – Laboratorio TOMA Advanced Biomedical Assays SpA, Busto Arsizio (VA)
Fiorenzo Pastoni – National Order of Biologists
Roberto Rescaldani – Faculty of Medicine, University of Milan-Bicocca

Milan – Founded in 2001, Italbioforma is a non-profit association focused on medical training – including specialist distance learning. The group has the direct cooperation of the French Ministry of Health, promoted by Professor Adrien Bedossa of Bioforma, who is also president of a French association that has, for years, trained laboratory technicians.

Between 2003–2005 Italbioforma began to present distance learning and scientific updates on its website (see below), using QconLine – an evaluation of clinical cases. Eleven programmes covered bacteriology, hemal and non-hemal parasitology, mycology, haematology, spermiology, histopathology, citopatology, immuno-haematology, cytogenetics and electrophoresis. Each aimed to constantly update professionals with an immediate evaluation of their diagnostic performances in various sectors of laboratory medicine. 10 clinical case reports were published monthly, over the year, and included microscopic and macroscopic images simulating what was observed in the laboratory; educational literature from experts to train and help with further understanding of each clinical case; at all times the possibility of direct contact with an expert to clarify doubts and compare personal experiences and, finally, constant access to educational archives with images, cards and experts' comments. To make the programmes accessible at a European level, QConLine was presented in Italian, French (ControlImage), Portuguese, English, Spanish and Rumanian.

QconLine suspended

However, disregarding its success, QconLine, was suspended at the end of 2006, because Italbioforma wanted to widen its horizons and make its FAD programmes compatible with the training objectives of national and regional interest. Thus it purchased FE.E-Learning for online training, and compatible with AICC standards. In recent months, Italbioforma has been defining new training programmes.

Also thanks to important partnerships with e.g. the National Order of Biologists (ONB) – already accredited as the provider – Italbioforma will soon offer not only its own ECM distance learning courses but also courses already available from other providers – e.g. the FAD Criteria of Quality: conceptual and technical evolution of normatives produced by the ONB, with Italbioforma's technological partnership.

Organization of distance learning courses, particularly online courses, with a national or regional plan for the continuous creation (education/training/updating) of healthcare operators: Italbioforma is registered with the Ministry of the Health as a provider for the creation of distance training events and is accredited by the ECM (Educazione Continua in Medicina).

Italbioforma also aims to provide information and modernise medicine and healthcare. For each year a section has been activated on the association's site dedicated to the SOPs – i.e. the translation into Italian of methods and national standards in clinical fields. These publications became possible through collaboration with the Health Protection Agency. Besides the SOPs, Italbioforma has dedicated a section of its site to medical laboratory news, edited by Professor Ferruccio Mandler, who has also retained interesting and useful news items dating from May 2003. All the priceless scientific information in the SOPs section is made freely accessible to the public.

In 2004, Italbioforma's System for Quality Management was successfully audited according to the European & International standards of UNI EN ISO 9001:200, and it is certified by Certiquality (certificate no. 7039) to organise and implement distance learning projects in medicine and health. Italbioforma also wants the on-line ECM programmes to be accredited as soon as the ministry has defined modalities for accrediting the FAD.

In 2004 the association collaborated with the FIASO (the Italian Federation of Sanitary Hospital and Institutions) during the ECM experiments for the FAD, making available to FIASO all its technical and scientific knowledge and experience from about three years of management and publication of QConLine.

Since 2005 Italbioforma has been accredited by FON.TER, a multi-professional fund for continuous education of out-source contractors – companies that provide services to healthcare structures. (www.fonter.it).

Between 2002 and 2005 Italbioforma had organized FAD events (ControlImage) for French analysis laboratories, with the contribution of the French Ministry of Health, through Bioforma.

In addition, Italbioforma proposes itself as ECM provider and/or professional co-provider for other scientific bodies that share the same learning objectives.

Continuing in this direction, the association goes beyond its consolidated and positive collaboration with the National Order of Biologists and is also consolidating collaborations with AMCLI and the CIRM. It is also evaluating a possible collaboration with ANISAP.

Based on information from our Italy correspondent Danilo Camisasca
Further details: www.italbioforma.org

DICOM module integrates Zeiss systems with PACS

Image data (mainly radiological) generated by the OPMI Pentero and MediLive MindStream Systems from Carl Zeiss can now be integrated into a hospital's picture archiving and communications system (PACS) via a DICOM* module

It's a definite benefit for the user,' said Dr Hans-Joachim Miesner, Business Unit Manager for Neuro/ENT of Carl Zeiss Surgical GmbH.. 'Integration of the DICOM module into OPMI Pentero and MediLive MindStream at long last makes the PACS-compatible archiving of intra-operative images a simple procedure. The devices are operated via the familiar user interface of the two ZEISS systems. The user's work is greatly simplified. For example, he or she can send the data from PACS systems directly to OPMI Pentero and MediLive MindStream at the push of a button.'

** The international standard, DICOM = Digital Imaging and Communications in Medicine – guarantees interoperability between different medical devices, irrespective of their system platforms. In addition to one or more images, the DICOM dataset contains information such as the patient's name, gender, date of birth or instrument parameters. Thus DICOM has become the basis for electronic image archiving in hospitals.*

ICT IMPROVES PATIENT SAFETY

By **Dr Veli Stroetmann**, of empirica, Germany, a research and consulting firm that focuses on businesses and healthcare IT developments

Improving patient safety and quality of care is of key importance for European citizens, and both the European Commission and Member States (MS) expect great benefits from new, information and communication technology (ICT)-based healthcare solutions. Our European *eHealth for Safety* study (www.ehealth-for-safety.org) identified the potential benefits induced by the use of ICT along the full continuum of care, and provides a fresh perspective for advanced research in this area.

About 80% of medical errors begin with miscommunication, missing or incorrect information about patients, or lack of access to patient records. In England, an evaluation showed that lost or poorly completed records are a major factor in patient safety incidents. It is widely believed that moving from a paper to an electronic patient record (EPR) system would be the key to improving patient safety. In recent years, one of the most important developments in many European Member States has been the planning and implementation of electronic health record (EHR) systems at the national, regional and local level. EHR systems can fundamentally improve safety by supporting the continuity of care, from GP offices to hospital care, long-term settings, and even home care.

The European *eHealth IMPACT* study (www.ehealth-impact.org) showed that eHealth could indeed lead to better and safer healthcare, also rendering at the same time considerable economic benefits. An intriguing example of a successful large-scale deployment is IZIP, the nationwide Czech EHR system. This allows instant access to comprehensive patient information independent of the location of the citizen, supports continuity of care and achieves a significant reduction in duplicative examinations, tests, etc. (estimated at 7%).

The large-scale deployment of eHealth infrastructures also facilitates the broader implementation of other ICT tools that improve patient safety, such as Computerised Physician Order Entry (CPOE) or Decision Support Systems (DSS). DSS are built into most CPOE systems, providing basic advice regarding drug doses, allergy flagging, interactions etc. CPOE systems are a key technology to reduce medical errors. The e-pharmacy system at a UK hospital applies a combination of e-prescribing, e-dispensing (robot system), e-stock-management and e-procurement for out-patients and discharged patients. Validated benefits include fewer prescribing errors, fewer dispensing errors (29% down from 30 to 21 per 100,000 packs), and shorter response time for urgent prescriptions (increase from 37% within one hour to 89%).

In this context, we must also mention computerised adverse event systems that monitor the occurrence of instances that could lead to adverse events and alert the clinician accordingly.

Experience shows that integrated systems, e.g. a combination of DSS, CPOE and alerting, are better accepted by professionals than stand-alone solutions. A key barrier to the wider diffusion of these systems is user acceptance. A deeper understanding of the complex cognitive and socio-technical interactions characteristic of healthcare processes will result in the design of even better systems to support safer outcomes in the hands of busy or poorly resourced physicians. Overall, ICT is an enabler that can revolutionise healthcare processes, and a key component of a safer healthcare environment. However, it is only one component, and management and cultural issues deserve the same attention. Moreover, a holistic vision and strategy, also taking into account organisational factors, is mandatory if safety is to be strengthened for all – be they healthy citizens or patients in need of the health service.

Europe's expanding IT healthcare

The growing use and successes of IT in several industry sectors has strongly influenced the healthcare sector, according to Research Analyst Rahul Philip Mampallil, in a report for the markets consultancy firm Frost & Sullivan (www.healthcare.frost.com). 'Solutions supporting healthcare are witnessing consistent growth as they align the complete channels of operations in the healthcare system. Moreover, with pressure from governments to develop a seamless capability across Europe – the need to have a completely linked healthcare network in the region – will offer growth opportunities to healthcare IT vendors.'

Computerised drug prescriptions and administration in hospitals and primary care trusts are '…performing with a high level of success and ardently support a cost/benefit value proposition,' Rahul Mampallil concludes. 'Customised stand-alone solutions are witnessing increasing pressures on growth due to intense competition from enterprise solution providers,' he adds. 'These solutions are generally provided for services such as nursing, pharmacy, laboratory and radiology. Although enterprise and individual hospital IT solutions are both present in the healthcare system, demand for each solution will depend on the approach of hospitals. The success and stability of these solutions will be determined by the integration capability of their software modules.'

The report notes that global IT companies are a big challenge for Europe's own domestic IT suppliers, and advises they develop solutions that can be easily integrated, because healthcare organisations appear to prefer enterprise solutions supplied by global vendors.

Currently, Europe's governments are taking initiatives such as the Connecting for Health (CfH) by the National Health Service (NHS) in the United Kingdom and the Dossier Medical Personnel (DMP) in France. These projects are commissioned on a large scale and will increase the usage of hospital IT solutions, the report points out.

Speech recognition

Philips seeks standardised medical terminology

Last year the European Commission, DG Health and Consumer Protection, observed that the health sector still lags behind other industries in introducing systematic safety processes and recommended the introduction of the electronic medical record (EMR).

The prototype for a voice recognition system, intended to link with the EMR and help reduce medical errors resulting from wrong medication, improper treatment, or incorrect or delayed test results, has been developed by the Netherlands firm Philips, working with Health Language Inc.

Named Interop 6.1, the system identifies findings, diagnoses, drugs, allergies and other relevant information in dictated reports and formats them for upload to the EMR. 'The solution further generates codes that support the classification of medical conditions and the structuring of clinical data, such as the World Health Organisation's International Classification of Diseases (ICD) codes and the Systematised Nomenclature of Medicine (SNOMED) codes,' Philips explains. 'Healthcare communities need to standardise existing systems and augment them with new, integrated solutions, focused on the patient,' said Marcel Wassink, managing director for Philips Speech Recognition Systems. 'The ability to exchange data accurately, effectively and consistently is key to eliminating cross-organisational boundaries and ensure the uniform and secure availability of critical information.'

Reward for silent 'sentry' guarding babies

A system that aims to prevent newborns from being swapped or kidnapped in hospitals, has received the RFID Award in the German Innovations Prize 2007, granted by Initiative Mittelstand, an association for small and medium businesses. The winner, BabyGuard WLAN Video, is the only baby protection system to be given an industry award in Germany.

Without using microwaves, but using harmless radio frequencies to detect newborn babes and their mothers, transmission works with three encryption levels: WEP, WPA and WPA-2, with real time video streaming to mobile devices, such as a PDA and laptop, via WLAN. When connected, whichever the mobile device, it can also control camera rotation and zoom. The real time videos are seen on the mobile with a slight delay of 0.5 seconds. Signals on similar, or even the same, frequencies do not jam the connection. When launched at the computer fair CeBIT 2007, the system performed without quality loss, despite having about 240 other 'hot spots' nearby.

BabyGuard WLAN Video was developed by the Hanover-based firm Syntron, which specialises in the integration of security systems, in collaboration with Munich-based Siemens Enterprise Communications.
Further details: www.syntrongmbh.de

Left: Dr Andreas Brielmaier, of Siemens, with Ralf Schwirzheim of Syntron demonstrating BabyGuard during Cebit 2007

NB: This commentary (left) was written as part of the eHealth for Safety study. It reflects solely the views of the author. The European Community is not liable for any use that may be made of the information it contains. I would like to thank colleagues from the ICT for Health Unit, EC, for continuous support to this topic.
E-contact: veli.stroetmann@empirica.com

network

Most hospitals across Western Europe possess IT systems for administration, he adds. Installation of clinical solutions will take place over the next few years, according to the needs of hospitals and primary care trusts.

Emerging European Opportunities in Hospital IT (M020-48) is part of the F&S Healthcare & Life Sciences IT Subscription, which also includes research on European Patient E-booking Systems Markets, Healthcare Applications of Smart Cards in Europe, Solutions Supporting Pharmaceutical Distribution Channel in Europe. To order this report e-mail rmtheodore@frost.com, giving your name, title, company name, phone number, and full address.

THE MOTION C5 a mobile clinical assistant for nurses

NEW

Following international pilot studies, Intel Corporation and Motion Computing have released the Motion C5 – a mobile clinical assistant (MCA) for use by nurses.

Motion Computing's C5 is the first product based on Intel's MCA platform, the firm reports, adding that this is part of its efforts to better connect clinicians to comprehensive patient information in real-time. The lightweight, spill-resistant, drop-tolerant and easily disinfected MCA includes wireless connectivity to access up-to-date, secure patient data and physician's orders; radio frequency identification (RFID) technology that enables rapid user logon; a digital camera to enhance patient charting and progress notes, and track wound healing; and Bluetooth technology that helps capture vital signs.

To refine their applications for use on MCA, Intel and Motion Computing report that they worked with electronic patient record (EPR) and other clinical software companies such as Allscripts, Cardinal Health, Cerner Corporation, Eclipsys Corporation, Epic Systems Corporation, GE Healthcare, iSoft, McKesson, Nexus, Siemens Medical Solutions and Welch Allyn.

Intel also conducted a range of pilot studies in hospitals worldwide, including Salford Royal NHS Foundation Trust in the UK, El Camino Hospital in California and Changi General Hospital in Singapore.

To understand the platform's usage, usefulness and usability in the context of real clinical work practice, social scientists from Intel's Digital Health Group conducted ethnographic studies of clinicians who used the MCA at each hospital. As Paul Otellini, Intel president and CEO, pointed out: 'The mobile clinical assistant was defined and shaped by the clinicians who will use it.'

During the first European pilot of this new type of computerised device, at the Salford Royal NHS Foundation Trust, phlebotomists (those who collect patients' blood) and elderly care staff spent four weeks testing the MCA in an elderly care ward. Staff nurse Jenny Quilliam, said: 'The MCA enabled me to have on the spot access for inputting patient details at the bedside. I could look up results, check and make referrals as part of the ward round and support case conferences by having quick access to patient details.'
Details: www.intel.com/healthcare/mca

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European Hospital's team greeting visitors at ECR 2007

EUROPEAN HOSPITAL

Again raising its Western profile – and going East

Along with our European Hospital publications, members of our team often appear at medical trade shows, manning our own exhibition stands. So far this year these venues have already included the ECR (European Congress of Radiology), 9–13 March in Vienna, and the KIMES medical equipment fair in Seoul, Korea, from 15–17 March.

Our stand at KIMES was an ideal starting point for European Hospital to look beyond Europe and hone in on trends and developments in Asia. In return, Korean visitors took considerable interest in our issues and news of European healthcare.

However, we are long established at the ECR in Vienna. Nonetheless, again we found a lively interest in our publications, particularly the special issue EH @ ECR, handed out at the stand and at entrances to the congress. The scientific programme and products exhibition again provided many new ideas for radiology topics for future editions.

We also used the event to attract high-profile speakers to contribute articles for European Hospital.

Our 4th Hospital Management Symposium was also a great success (See box and our website).

Now we are looking forward to meeting more of you at future medical and healthcare events.


Our flagship publication prompted many to linger

European Hospital's 4th Hospital Manager Symposium

Topical presentations on management, IT and finance in radiology sparked lively discussions among the 300 participants of our symposium for hospital managers, which we organise jointly with the ECR.
Amid the exclusively medical-oriented presentations at this leading radiology congress, the symposium has established itself as an event that looks at radiology from another – albeit extremely important – perspective. High-profile speakers from hospitals and the healthcare industry focused on finance, fundraising, key trends in medical archiving systems and much else – issues that hit home because smart management and finance strategies as well as carefully selected IT solutions play an ever increasing role in hospital success.
Readers who missed these presentations can access live recording from the symposium at:
www.european-hospital.com/cooperations/


Welcoming the symposium audience: Christian Herold, President of ECR 2007

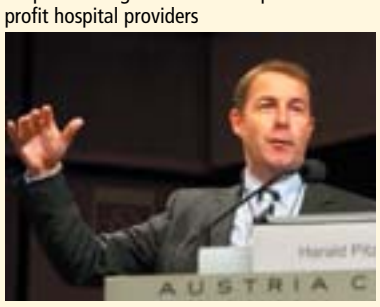
Rainer Braunschweig, MD, Director of the clinic for diagnostic imaging and interventional radiology, BG-Kliniken Bergmannstrost, Germany, spoke on local and national IT concepts


Diagnostic imaging and financing private diagnostic facilities in Poland was the focus of Jacek Brzezinski MD PhD, of Helimed Diagnostic Imaging, in Katowice, Poland


Hartwig Jaeger MD PhD, Director for Corporate Development with Vivantes, explained how taking a new approach to hospital management could help not-for-profit hospital providers


Responsible for the development of enterprise storage solutions at Hitachi Data Systems in Germany, Georgios Rimikis PhD discussed secure, effective archiving of clinical data


Sabine Eidmann, of Comprendium Leasing GmbH, belongs neither to a bank nor manufacturer: she showed 'off the beaten track' concepts; refinancing via capital markets



Harald Pitz, MD and Vice President for Industry Business Unit Healthcare, Higher Education & Research at SAP AG, spoke on business models and processes in healthcare


Peter Mildenberger, MD of the Radiology Clinic at Johannes Gutenberg-Universität Mainz, Germany, spoke on the management of IT implementation


Nikos Maniadakis, MD, General Manager & President of the University General Hospital of Iraklion, Crete, Greece spoke of coping with rising costs using various financing methods


Jan Schillebeeckx, Head of Radiology, Imelda Hospital, Belgium, showed how 'business intelligence' helps a hospital to maintain high annual productivity – and patient/staff satisfaction


What are the latest trends in medical archiving systems? During the symposium Bernard Algayres, of Eastman Kodak´s Health Group, provided answers


Fundraising only means asking for money, said Peter Fletcher, Director of Philanthropy at the University Hospital Birmingham, UK. *You will receive what you ask for!*

54,000 visitors, 1,038 exhibitors = increasing success

KIMES 2007


Choong-jin Kim President & CEO

During four days in March, 54,000 people visited the four huge exhibition halls that housed the *23rd Korean International Medical Equipment Show – KIMES 2007*. 'We've grown by 11% compared with last year,' said **Choong-jin Kim**, President & CEO of the exhibitions organiser Korea E & Ex Inc. 'Most visitors are interested in new trends in medical technology and were very happy with what was exhibited.'

Globally, although there are several bigger, more internationally recognised medical shows KIMES has a difference: alongside western medical equipment it exhibits oriental medical products. 'We'd like our exhibition to bring West and East closer to each other, so that the different cultures and traditions can enrich one other,' said Choong-jin Kim, 'KIMES is not only a platform for exhibitors, distributors and buyers; we also offer a comprehensive education programme; the exchange between doctors and industry is important to us. We want to meet the needs of users and keep up with developments in medical technology. We also work closely with the Korean Government to make Korea attractive for the worldwide medical market, to make KIMES more international. More than 30 sessions were held throughout the show period, organised by us with the media and exhibitors of KIMES 2007.

'The hospital management conference for specialist physicians, for example, was organised by Korea E & Ex Inc and *The Korean Doctors' Weekly*. KIMES co-organiser KMDICA (Medical Devices Industrial Coop. Association) and KMDIA (Korean Medical Devices Industry Association) held over seven seminars on medical regulations and policies in Korea. Also, the Korean Small & Medium Hospital Association and exhibitors successfully held a seminar for targeted interests groups and, KOTRA and Korea E & Ex Inc held the *NHS Medical Device Procurement Conference* for Korean manufactures exporting to Britain.

'We'd like to build on this even further. Our objective is to offer a similar variety in medical technology, products exhibition and education as that found at MEDICA, held every year in Dusseldorf. Maybe we'll succeed in becoming the MEDICA of Asia. It would be a great goal – I think we are well on our way.'

Changed eating habits abet obesity

In Europe today, obesity is assuming epidemic proportions. Indeed, the number of our obese citizens has tripled during the last twenty years, and their numbers are still increasing. If nothing is done, the World Health Organisation (WHO) expects that, by 2010, there will be around 150 million obese European adults (20% of the population) and 15 million obese European children and adolescents (10% of the population).

Part of the reason behind this development is our changed eating habits: European citizens eat too much and do not exercise enough. In addition, the food we eat is too fatty and too sweet. Scientists consider the increased intake of fat to be one of the main causes of increasing obesity figures. The proportion of animal fats in our food increased from 20% to 43% over the last two decades. According to the WHO, Europeans consume, on average, 150g of fat per head per day. 80g is the maximum daily amount recommended as part of a healthy diet.

Additionally, the increased range of foods now on offer tempts us to eat more. According to the WHO a woman needs about 2,000 kcal a day to maintain her weight; men need about 2,500 kcal. In 1961, people had an average 2,300 kcal at their daily disposal; by 1968 this had increased to 2,800 kcal. By 2015 it is likely to have increased to over 3,000 kcal a day.

Another factor that is promoting obesity: At the beginning of the 20th century our annual intake of sugar was less than 5kg per person – these days, in Europe, that figure is somewhere between 40 and 60kg. At the same time, we do not consume enough fruit and vegetables.

The strategy for addressing this obesity epidemic according to the WHO should have the following three cornerstones: Decreased consumption of fat and sugar, increased consumption of meals based around fruit and vegetables and increased physical exercise.