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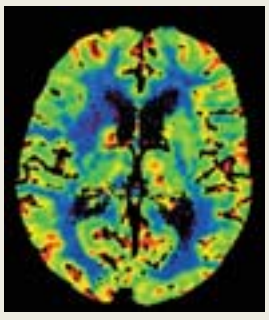

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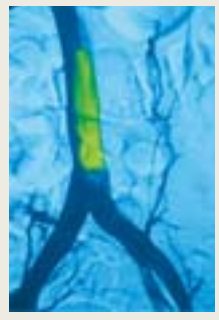

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Flu outbreaks and fears

Following the 1918 (Spanish H1N1) influenza pandemic - which killed perhaps 20 million or 20-40 million or, in other estimates, even 40-50 million people worldwide - two more influenza pandemics occurred, the first in 1957-58 (Asian, H2N2), was blamed for 70,000 deaths in the USA alone. The second (Hong Kong, H3N2) occurred just three and a half decades ago (1968-69) and was blamed for 34,000 US deaths.

Later incidents of limited spread include: In 1976 the H1N1 influenza A virus threatened, and referred to as 'Swine' flu because the possible intermediary between poultry and humans were pigs. The next year the same strain threatened again, but was dubbed 'Russian' flu and termed a 'benign' pandemic. In Hong Kong the colloquially named 'bird flu' H5NI emerged in 1997. In 1999 bird flu H9N2 was worrying. Then, in the Netherlands, bird flu H7N7 was recorded. None of these reached pandemic proportions. In late 2003 and 2004, the H5N1, first identified in birds in S. Africa in 1961, was associated with human illness and death in Asia.

Current estimates in the USA, in the case of a H5NI pandemic, are given as 36,000 deaths and 200,000 hospitalisations.

The World Health Organisation has stated that experts agree that another influenza pandemic is 'inevitable and possibly imminent'.

Pandemic panic sends feathers flying

AIDS, SARS and now H5NI; just a brief beginning or the end? As the virus moves towards Europe, and millions of birds are slaughtered, interest has risen in a Chinese herb, a patent-sharing controversy and drug stockpiling

Star Anise Photo: B Marsh

The rare herb *Star Anise** grows on small trees in a few provinces of China. It is used for its pungent (liquorice-like) flavour in cooking. But the seeds also contain a special ingredient - shikimic acid - and this has taken on world importance. The acid is used to make the drug Tamiflu (oseltamivir phosphate), the influenza treatment thought to be the only one currently available that might reduce the severity of an attack by the avian virus H5NI, the 'bird flu' that, in humans, has caused around 60 deaths and over a hundred illnesses so far. These cases are not many, but the cry of 'pandemic' is rising because infected birds have been suspected or confirmed in parts of Europe.

There is little agreement about the actual danger to humans - the threat to people would be serious only if the virus develops into a form that can spread from person to person.

The situation has raised a multitude of questions. Meanwhile, politicians and health organisations in Europe, as elsewhere, are under pressure to ensure that if a HFNI pandemic does occur, their populations will receive the best treatment available to combat this infection. Some are not so sure they want to join the panic zone. In Switzerland, Interior Minister Pascal Couchepin (with responsibility for health issues) has said that it is almost impossible for people to catch this influenza and he has criticized the 'hysteria' surrounding it.

Meanwhile, Markos Kyprianou, EU health commissioner, advised having enough antiviral medicine to cover 25% of the 450 million people in the union. Belgium's Health Ministry then suggested that the EU buy antivirals and not depend on individual governments to purchase them.

Meanwhile, 30 countries have placed extremely large orders with Roche for Tamiflu, among them France is reported as having 15 million doses of Tamiflu ready for

continued on page 3

Early warning system cuts hospital admissions

UK - The King's Fund has launched a computerised programme to provide an early warning system to identify patients with long-term conditions who are most at risk of admittance to hospital. A wide range of patient information - such as age, type of illness, and recent contacts with the National Health Service (NHS) is processed to work out which patients are most in need of care. Once prioritised, NHS care teams can then work with patients to help them maintain their health and avoid a visit to hospital.

King's Fund chief executive Niall Dickson said that if the programme is successful: '...the prize would be immense - better care of a higher quality delivered earlier to patients, fewer unnecessary hospital admissions and better use of NHS resources.'

The project was commissioned by Essex Strategic Health Authority (SHA), acting as lead commissioner for the country's 28 SHAs, the Department of Health and the NHS Modernisation Agency. The UK's National Health Service (NHS), and the King's Fund devised the programme with researchers at New York University and Health Dialog - a care management firm that specialises in analytics and chronic disease management.

The new software (available free to the NHS) is being further developed to incorporate data from community sources in addition to hospital data, and this final version is expected to become available early next year.

More IT & telemedicine: page 24

Top private hospitals acquisition

Germany - Fresenius AG has entered into an agreement to acquire Helios Kliniken GmbH, in Fulda, Germany. Helios is recognised for having medical quality standards of the highest level in the industry. With expected sales of around €1.2 billion in 2005 the company ranks among the largest and financially most successful private hospital chains in Germany.

The acquisition of HELIOS will establish Fresenius ProServe as one of the leading private hospital operators in this country and create a strong third business segment within Fresenius Group. 'The hospital management business in Germany has been our clear focus following the streamlining of Fresenius ProServe's operations in 2003 and 2004. The acquisition of one of the most successful German hospital operators is a unique opportunity to strengthen our position in acute care hospitals. Building on this strong position, we will capitalise on the excellent growth potential of the ongoing privatisation process in the German hospital market. Helios is an extremely well-managed company and is, just like Fresenius, strongly committed to deliver best-in-class medical treatment,' explained Dr Ulf M Schneider, Chairman of the Management Board of Fresenius AG.

Helios Kliniken GmbH is one of the leading private German hospital operators in terms of revenue growth and profitability. Since 2002, the company posted a compounded annual growth rate of 28% in sales. In 2004, Helios achieved revenues of €1,161 million, operating income of €95 million and net income of €66 million. The company owns 24 hospitals with a total capacity of about 9,300 beds. It is the only hospital chain in Germany that operates four maximum-care hospitals with over 1,000 beds each. The company has around 18,000 employees and performs about 330,000 in-patient and about 700,000 out-patient treatments annually.

The combined business will include 55 clinics with 2004 proforma revenues of around Ä 1.5 billion. The purchase price for 100 % of the HELIOS shares is €1.5 billion plus € 100 million for the net cash position. Fresenius will acquire 94 % of the HELIOS shares, 6 % will continue to be held by the Helios management. The acquisition requires antitrust approval. However, Fresenius anticipates completing the transaction at the end of this year.

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use in an outbreak. The country's National Institute for Public Health Surveillance also said that 100 million face masks have been bought and delivered, and 100 million more should arrive by the end of this year. (Two people suspected of having contracted the virus were hospitalised by French health authorities, but later released when tests proved negative).

Italy has 150,000 doses of Tamiflu, and has ordered six million more, according to Francesco Storace, the country's minister for health. However, he pointed out that there is medical debate as to whether Tamiflu would be effective in the event of any H5N1 illnesses.

In the United Kingdom, Liam Donaldson, the chief medical officer, announced that vaccine manufacturers are being invited to tender contracts to supply 120 million doses, enough for two shots per person in the country, once the pandemic strain is known.

Problem? Although Roche now makes Tamiflu at 13 sites worldwide, producing more than 100 million capsules annually, the demand is massive. To meet pandemic demands, Roche reported that it had doubled production of Tamiflu in 2004 and doubled it again in 2005, and planned to double it again in 2006. However, the firm has enough orders to exhaust its production capacity both this year and next. The very nature of production is also a problem (see the section on Star Anise)

Roche spokesman Alexander Klauser: "*Tamiflu has killed the bird flu virus in laboratory tests, but the results were more mixed when it was used on some of the 117 people who contracted the virus in Asia since 2003*"

Many countries have asked the World Health Organisation to pressure Roche to relinquish the patent so that a generic version of the drug could be produced and it would be 'cheaper'. Roche is now in discussions about licensing.

Drug costs and profits

Clearly this is a lucrative market for pharmaceutical companies. (On an online Roche-authorised site, 30 tablets are currently quoted as costing around 42 euros). Yet, in June, Gilead Sciences Inc, the California-based biopharmaceutical research company that invented the drug, delivered a 'Termination Notice ' to Roche for their 1996 Development and License Agreement for Tamiflu. In this action, Gilead said the result would be that the rights to Tamiflu held by Roche would revert to Gilead. 'Despite our repeated communication of concerns over the last several years, Roche has not adequately demonstrated the requisite commitment to Tamiflu since its launch in the United States nearly six years ago, nor has it allocated the necessary resources to realize the potential of the product as a treatment and preventive for influenza,' said John C. Martin PhD, President and CEO of Gilead Sciences. 'Gilead is taking this action in the interest of our shareholders and, importantly, because it is essential for public health that healthcare professionals and consumers have improved access to information about Tamiflu, as well as to the product itself.' (Details: www.gilead.com)

Nonetheless, this month (October), Gilead Sciences announced its third quarter 2005 financial results: total revenues $493.5 Million, up 51% over the third quarter of 2004. This resulted in a net income for the third quarter of 2005 of $179.2 million. The net income in the same period in 2004 was $113.2 million.

Apart from substantial increases seen among the firm's products, including its HIV product portfolio, in that period, royalty and contract revenues resulting from collaborations with corporate partners totalled $26.2 million - a 70% increase from $15.5 million in the third quarter of 2004. Gilead Sciences pointed out: 'The increase was primarily driven by royalties of $12.1 million received from F. Hoffmann-La Roche Ltd (Roche) for sales of Tamiflu (oseltamivir phosphate) recognized by Roche in the second quarter of 2005, compared to $1.7 million of Tamiflu royalties received in the third quarter of 2004...' (Other royalties were also mentioned).

Roche has also presented third-quarter revenues - showing a rise of 17%. The Swiss firm said sales of Tamiflu had more than doubled to 279m Swiss francs, compared with the same period last year. The company's overall sales for the three months to the end of September rose to 8.8bn Swiss francs.

Star Anise

Now that licensing by Roche might occur, how will it work, given that the essential herb is not largely grown - and processing is not easy? Suitable Star Anise grows in only four regions of China. The plant is harvested only between March and May. Roche buys 90% of that harvest. Each section of the Star Anise flower holds a seed (see photograph) - about eight per star. Enormous amounts of these seeds are needed to obtain sufficient shikimic acid to produce Tamiflu. A spokesperson for Roche pointed out that there is inevitably a shortage of the raw material.

When shikimic acid is extracted from the harvested seeds, in a three-step chemical process, at low temperature, it is converted into epoxide, then comes a dangerous part of the process, because the conversion of epoxide into azide involves a reaction that produces explosive material. Specialist companies do this and only handle the material in small quantities to reduce that problem.

Crystal strands of the active ingredient of Tamiflu are then produced and these are vacuum dried to be converted into capsules.

News roundup: Brenda Marsh

Health tourists

The extent to which patients resident in European Union (EU) Member States are able to obtain medical treatment in other EU Member States at the expense of their home Member States continues to be debated.

Various recent cases including *Geraets-Smits and Peerbooms* and *Müller-Fauré and Van Riet* have shown that, when 'medical tourists' move between EU Member States especially to access healthcare services in Member States other than their home States, national prior authorisation systems regarding such treatment abroad can be deemed to breach relevant EU legislation. This may occur where the grounds on which Member States' national authorities can refuse prior authorisation of overseas medical treatment and the restrictions on freedom to provide and receive services within the EU, which such systems can create, cannot be justified in the objective public interest. In certain circumstances, Member States' national authorities can therefore find themselves legally obliged to reimburse their citizens for the costs of treatment obtained in other Member States.

Clare Sellars, Associate at McDermott Will & Emery UK LLP, reports on current events in the cross border healthcare debate

The relevant case law has primarily concerned prior authorisation systems of Member States with public healthcare arrangements based on social insurance systems, both reimbursement schemes and benefits in kind schemes, however, it is unclear whether national health services based on benefits in kind systems are also affected in the same way, for example the UK's National Health Service (NHS).

Hopefully this issue will soon be clarified. In the case of *R (Watts) v Bedford Primary Care Trust*, the UK Court of Appeal has referred to the European Court of Justice (ECJ) the question of whether the NHS is obliged to authorise medical treatment for patients in Member States other than the UK, together with various subsidiary questions. One significant subsidiary question concerns one of the grounds often relied on by Member States when refusing prior authorisation of medical treatment abroad - the fact that authorisation can be refused because the same or equally effective treatment is available in the home Member State "without undue delay". Guidance on the interpretation of what "without undue delay" means in these circumstances has also been sought from the ECJ.

The hearing took place on 4 October and the Advocate-General's opinion is due to be published within the next weeks. Depending on the outcome of this hearing, the implications of the ECJ's decisions for all Member States, particularly those with national health services, could be significant.

** McDermott Will & Emery UK LLP (www.mwe.com) is a London-based limited liability partnership regulated by the Law Society and registered in England and Wales. The members are solicitors or registered foreign lawyers.*

Medical research challenged

A recent media briefing held by the *Journal of the American Medical Association* (JAMA) at Rockefeller University, NY, a world-renowned centre for research and graduate education in the biomedical sciences, addressed the hurdles medical research currently faces in the United States.

According to a study in the September 21 issue of JAMA (JAMA 2005. Vol. 294,11: 1297-1454), total funding for biomedical research in the USA doubled to $94.3 billion from 1994 to 2003, with the industry providing 57% of the funding and the National Institutes of Health providing 28%. Industry sponsorship from pharmaceutical, biotechnology, and medical device firms of clinical trials increased from $4.0 to $14.2 billion, while federal proportions devoted to basic and applied research were unchanged.

Presenting the study's findings, lead author Hamilton Moses III, MD, of the Alerion Institute, Virginia, emphasized the need 'to change the odds of the bets - don't put money through sales channels, but put it into translational research instead,' he urged.

'For all sponsors, the challenge is patience. Biomedical research is an inherently high risk and lengthy process. It would be helpful to remind those making financial decisions that the promise of earlier advances in the basic understanding of physiology in the 1920s and 1930s, or of biochemistry and microbiology in the 1940s, 1950s, and 1960s, took decades to unfold,' the authors write.

'The bone is always a little ahead of the dog', said Dr. Moses, citing two examples to underline his point: Penicillin took 15 years, from the time of discovery to wide availability for treatment; knowing insulin is central to diabetes did not speed things up either - it took 30 years from that understanding to become a treatment for diabetics.

'Enhancing research productivity and evaluation of benefit are pressing challenges, requiring more effective translation of basic scientific knowledge to clinical application, critical appraisal of rapidly moving scientific areas to guide investment where clinical need is greatest, not only where commercial opportunity is currently perceived, and more specific information about sources and uses of

Karen Dente
Reporting from the USA

research funds than is generally available to allow informed investment decisions. Responsibility falls on industry, government, and foundations to bring these changes about with a longer-term view of research value,' the authors wrote (JAMA 2005; 294:1333 - 1342).

Lead author Jordan J Cohen MD, of the Association of American Medical Colleges (AAMC), Washington DC, presented an article on the challenges that academic medical centers face. The present era, he emphasised, offers more promise in medical research than ever before. 'Contemporary science has deciphered the human genome, discovered some of the potential of stem cells, and unleashed the power of information technologies. Any one of these three historic scientific achievements would have the potential to effect a fundamental transformation in medicine; their confluence has created unprecedented opportunity for spectacular breakthroughs in human health,' the authors wrote.

Despite this promise for progress, many challenges to exploiting them also exist. A major challenge is the need to maintain public trust. 'If the public fails to trust in institutions, this is worrisome,' said Dr Cohen. Maintaining public trust includes managing financial conflicts of interest, protecting human subjects in clinical research, and managing high public expectations for life-saving discoveries.

Another big challenge to medical research is the widening gap between the costs of research and available funding sources, and the need to recruit and retain more physician-scientists to pursue translation research, he explained. Translational research entails applying concepts of the basic sciences to clinical medicine. With the industry compromising the principal research sponsors (57% in 2003, compared with 28% by National Institutes of Health) the need to maintain academic values while partnering with the industry is another major challenge. 'The ability to benefit optimally from the growing relationships with industry is heavily dependent on remaining true to fundamental academic values,' authors wrote.

'The degree to which medical schools and teaching hospitals are

Hamilton Moses III

successful in meeting these challenges will determine the degree to which the historic promise of modern medical science will be realized,' Dr Cohen pointed out.

In 2003, the USA spent c. 5.6% of its total health expenditures on biomedical research - more than any other country - but less than 0.1% for health services research. From an economic perspective, biotechnology and medical device companies were most productive, as measured by new diagnostic and therapeutic device per dollar of research and development cost. Productivity declined for new pharmaceuticals.

The future lies in remote monitoring

Patient monitoring device manufacturers are facing tough times in Europe, according to a new report 'Profiles of Key Participants in the European Patient Monitoring Market', produced by Aarati Ajay, Research Analyst at the global growth consultancy Frost & Sullivan. One of the reasons for this is the severe pressure on national governments to reduce the number of hospitals in their countries, the author points out. However, she also says that the market for patient monitoring devices is rapidly reaching maturity and future growth is increasingly becoming dependent upon the replacement of existing equipment. Therefore, Ms Ajay suggests, manufacturers of patient monitoring devices need to maximise replacement opportunities and increase expenditure on research and development (R&D) to produce advanced equipment that can replace existing devices.

Strategic acquisitions - to ensure growth, market expansion and new product lines - have been significant, says Ms Ajay, naming Abbott Laboratories as an example. (The firm first acquired Medisense then i-STAT, then, a year later Therasense (2004). 'Bayer Diagnostics and Lifescan, Inc also have a significant presence in the area of continuous blood glucose monitoring systems and provide strong competition to Abbott. Bayer's diabetes care division provides products from insulin pumps to blood glucose monitors while Lifescan is a leading expert in diabetes management.'

Remote patient monitoring - Intensive home care is likely to rise due to the aging baby boomers. Over 18% of Europeans are over 65 years old, and more likely to need disease management. 'Disease management systems are the future of patient monitoring,' concludes Ms Ajay, who pinpoints systems with inherent abilities to monitor and interact with patients as a key development. Remote monitoring also takes on more significance in view of already mentioned potential reduction in the number of hospitals.

Ms Ajay mentions in her report a number of companies that have taken a significant position in this field: Spacelabs Medical Inc, for its monitoring information systems; Welch Allyn Inc, for its lightweight multiparameter portable and ambulatory systems, and GE Healthcare for its non-invasive haemodynamic patient monitor - the world's first.

Report: Profiles of Key Participants in the European Patient Monitoring Market (B581-56). Full details: http://medicaldevices.frost.com

Perinatal medicine

In September the *5th International Congress for Perinatal Medicine*, was held in Croatia. In December, the German Society for Perinatal Medicine will hold its *22nd German Congress for Perinatal Medicine* (www.perinatal-kongress.de). In a timely interview with **Professor Klaus Vetter MD**, director of the Obstetrics Clinic at the Perinatal Centre, Vivantes Hospital Neukölln in Berlin, and Congress President of the 22nd German Congress for Perinatal Medicine, we initially asked: ***How is this field defined?***

Perinatal medicine is an interdisciplinary medicine for mother and child, the professor explained. It comprises the period before, during and after birth. This includes obstetrics, as part of gynaecology in general, and neonatal medicine as part of paediatrics and adolescent medicine. It also includes anaesthetics for pregnant women and newborns.

Prenatal diagnostics is diagnostics for mother and child during pregnancy. This comprises taking of blood pressure, urine testing to monitor kidney function as well as determining the mother's abdominal girth, and ultrasound scan diagnostics for the unborn child. The most commonly found problems in unborn children are growth problems, macrosomy and growth retardation; the most common problems affecting the mothers are, respectively, diabetes, high blood pressure and pre-eclampsia.

What does the future hold for prenatal diagnostics, particularly in the European economic area?

'We can assume that, in the future, prenatal diagnostics will be increasingly available during earlier stages of pregnancy, and that triage (determining future treatment and monitoring required to ascertain whether a pregnancy is progressing normally or not) will often be available in the first trimester.

From a general point of view, this may mean that women will feel increasingly encouraged in their decisions to become pregnant, because early triage appears to enable a closely monitored, 'customised' pregnancy. This may lead to a higher acceptance of pregnancy in general. However, it is difficult to say what effects this is likely to have on the European economic area.

What are the structural prerequisites for adequate perinatal care within the constraints of the diagnosis related groups (DRGs); integrated care provided by surgeries and hospitals (IV) and medical care centres (MVZ) in a European comparison?

The principle in Germany is that all pregnant women are entitled to the necessary perinatal care. This is set out in maternity guidelines developed by the Federal Joint Committee (www.g-ba.de), made up of providers (members of the German Hospital Association) and those funding healthcare costs. Currently, the DRGs do not actually support the care and treatment of pregnancy complications sufficiently. IVs and MVZs currently have no particular bearing on perinatal medicine. During the congress, a panel discussion will address this subject.

'The Small Child - causes, diagnostics, birth and postpartal therapy' is also on the agenda. At what stage in development do you talk about a 'small' child who is at particular risk?


Klaus Vetter

A child is considered underweight if it does not fall within the percentile curves, i.e. distributions of length, weight and head circumference at a certain age, and if its weight, depending on age, falls below the 10th percentile. If the child's weight is below the 3rd percentile, we talk about a significant growth retardation. To assess the situation - and ensure that the child is in no acute danger - it is vital to determine the cause. Modern biophysical diagnostic procedures, such as ultrasound and, in particular, non-invasive, functional examination procedures such as Doppler scans, have proved most suitable for this.

If there is a proven risk of complications, the birth should take place at a suitably specialised unit for mother and child; in very difficult cases this should be in a specialist perinatal centre. When choosing the date and place of birth we also need to consider the envisaged postpartal therapy, so that the lives of both child and, as the case may be, mother, are not endangered.

During pregnancy, birth and post birth - what does interdisciplinary co-operation entail?

Apart from pregnancies and births where no anomalies are detected, but that have interdisciplinary support, there are pregnancies where interdisciplinary co-operation is of utmost importance and can be life-saving. The specialist fields are prenatal medicine and obstetrics, neonatal medicine and anaesthetics for pregnant women, as well as the newborn.

Concepts in Germany - at least within the scientific societies and associations - orientate themselves on European models. For gynaecology and obstetrics this means the European Board and College of Obstetricians and Gynaecologists (EBCOG - www.ebcog.org). Large differences between countries are increasingly balanced through these international organisations - even when there might be very different conditions in individual cases. The 22nd German Congress for Perinatal Medicine, in December, will also contribute to this progress.

Contact:
knk.geburtsmedizin@vivantes.de

Under the microscope Dutch healthcare

The walls of Robbert Huijsman's office, on the fourth floor of one of Erasmus University's buildings, in Rotterdam, are festooned with posters. One of stands out from the rest; it contains a photograph of a battery and the text 'Erasmus charges you'. Certainly the professor himself is full of energy. He has been a professor at Erasmus for eight years, although he is now only 43 years old. Lecturing on Integrated Care Management, he demonstrates the enjoyment by the manner in which he discusses his subject: passionately! One push on the button and his enthusiasm pours out.

I head straight to the point. *How healthy is Holland*? His answer is as short as it is powerful: 'It could be better. No', he quickly reflected, 'the situation is not very glorious'. It all very much depends on where you live and that is very disturbing, because the type and quality of care should be uniform and there should be no difference between being admitted to a hospital in Maastricht or Amsterdam. Typically, when determining quality of care it is not just a question of whether one is working according to the latest professional views and guidelines but, even more importantly, how the patient is being addressed and served.

In this last aspect alone, despite all the policy ambitions, there still has not been a complete breakthrough. Consider this from the point of view and feelings of a patient; we should address him, or her, as a fit human being and not as some inferior number in a long row of cases. Also, it is of the utmost importance that various disciplines are attuned to one another in multidisciplinary teams, through which the '*learning ability*' of organisations will also be improved. Working in teams and banning the competence battle - that's the point - at all levels in care, among relief workers, hospital teams and other caretakers, as well as the ministry of health.

Care with the neighbours

On our question of how the state of care is delivered in other countries compared with the Netherlands, Professor Huijsman offered two examples. First he briefly sketched briefly the situation in Belgium, while making clear that the situation there does not really differ from that in the Netherlands. There is no single country that has complete control over all aspects of their healthcare systems, he pointed out. Of course there are observable differences in elements. First, the Belgians are more courteous towards their patients, as well as between themselves, giving each other full play, both socially and professionally, and this is recognisable in their healthcare delivery systems.

This does not mean that, in Belgium, as in Holland, a systemic change does not take place. The difference between the Belgians and the Dutch however is, that the Belgians achieve change without the discussions that are so characteristic of the Dutch. Dutch policy discussions can extend over and over, for many years, and then they still hesitate to execute their plans. Even then, it sometimes goes wrong!

'Next there is the British situation,' he continued. 'Healthcare is also good there, and well organised, but has also its own Achilles heel: i.e. a top-down policy, which means it is much easier to implement new regulations, but it does not mean that handling changes in this way creates the necessary support of the professionals.'

Compared with other countries, the Netherlands lacks leadership in healthcare management, both at national and the organisational levels. Without that leadership there will be absolutely no success; but who has the courage to make this a political item?'

Advice

At Erasmus, students are taught and research is carried out - this is no surprise to anyone. It also is no surprise that advice is given, whether demanded or not sought. When we asked the professor whether he ever advises the minister of health, a sort of twisted grin appears on his generally friendly face. 'I don't really see that the ministry feels much need for advice from people outside their own circuits in The Hague,' he responded. 'Pilots are started, but monitoring and evaluation of these experiments is not very high on the political agenda. Once, I heard a top employee at the ministry state that the vision that everything is now known; that all the knowledge is available and that all we need is implementation in the field. Orders for investigation, given to universities or research institutes, are virtually a past tense. Consultancy firms, with strong ties to the ministry, carry out implementation. The real glitch in working methods is the lack of a systematic agenda for research and development within the healthcare sector. Critically, monitoring and evaluation to improve policy is clearly less present. The ministry could improve its *learning ability*, by placing research back on the agenda again.'

Professor Robbert Huijsman, of Erasmus University, pulls no punches. The country needs greater integrated care and fuller governmental co-operation with healthcare professionals. *Interview: Michiel Bloemendaal, our Dutch correspondent*

Robbert Huijsman

The future

That things in the Dutch healthcare policy must change is crystal clear to Professor Huijsman. He mentioned as an example the changes in the nursing homes budget. '200 million euros extra was presented on a budget of five million euros, which means 200 million euros has to be divided between 350 nursing homes. What a joke! With such an increment, how could we possibly improve the quality of care!'

The government, he emphasised, does realise that the quality of Dutch healthcare is slipping. 'There is a need for entrepreneurial people and leaders to take care institutes in tow. They must introduce competition as an instrument. This also means that salaries must be higher than average - it's a matter of supply and demand. If you want a hotshot you must pay'.

Tomorrow's hospital

'Excellent, well-qualified people work in Dutch hospitals; they knock themselves out, and earn far more respect than they really get. This holds for doctors, nurses, heads of laboratories and general services alike, they do not get what they deserve.

'Despite that hard work, they have to ask themselves whether they are working on the right things, and if they are doing those things in the right way. Are the hospitals organised in the right way, or does one put too much trust into old structures, routines, functions and disciplines? Even here an eye must be kept on the process of a patient, from hospital admission right through to discharge and after care. Activity based structures must be changed to process-based, patient-centred chains of care, like clinical care pathways, connected to other suppliers in the whole care continuum. It is time to leave the old system and change from suboptimisation of activities to optimisation of care chains: it is not enough that everyone works as hard as he or she can, but the various services have to do so together, through which optimisation can be realised'.

Good examples of such systemic changes are stroke services or a 'mamapoli', he observed. 'Some years ago it was standard procedure that it took about three months before a treatment plan was made and executed. Nowadays, disease can be diagnosed and a treatment plan presented to a patient, in just one day, just because the efforts of several hospital departments are integrated into a *chain approach*. This new way of thinking about processes, instead of single activities, requires three cornerstones. First, one must think from the patient's viewpoint; second, one must think look at the best available knowledge. Finally, the involved disciplines must co-operate closely, in multidisciplinary teams, which cross over the traditional boundaries between disciplines, departments and organisations'.

Training

Do not suggest to Professor Huijsman that such a development cannot be realised overnight. On one hand, the outlined change in working and thinking must be introduced into hospitals; on the other, a lot has to be done through education. In 2002, Erasmus University had already begun, by introducing a master's degree in care management. A student who opts for this course (the first in Holland) is trained to be a bachelor of health sciences, in which he/she must tackle law, economics, healthcare insurance, care management and social-medical sciences. In the second phase, the master phase, a choice can be made in three directions: care management; health economics, policy & law, or health services research.

For Professor Huijsman, everything should then improve - as long the ministry of health takes the advice!

CRIMINAL ADMISSIONS

Doctors can be trapped between their need for medical professional secrecy and the jurisdiction's need for a criminal investigation. **Michiel Bloemendaal** reports


Wilma Duijst-Heesters (foreground right)

The Netherlands - A public debate reopened recently regarding the position of medical professionals if they come in contact with patients suspected of criminal activity, or if information is acquired that could be relevant in a criminal case.

Medical professional secrecy protects a patient's privacy. The Dutch criminal code lays out how this is legally enacted. A starting point in the debate is that medical professional secrecy prevails over police interests.

Legislation is increasingly corrected in the interest of tracing criminals. The result is that information covered by professional secrecy often can be and is used to trace criminal activities, as is the case in sexual abuse, maltreatment of children, doubts about natural death and medical mistakes etc. So, it is now time to bring clarity to the relationship between medical professional secrecy and police investigation. Last September, Wilma Duijst-Heesters, doctor and lawyer, took her PhD on this subject at the University of Nijmegen.

Medical secrecy and the right to refuse to testify

Medical professionals have, as stated, a medical professional secrecy, and when appearing before a judge they can appeal for that right. However, that right can be 'out of order' for several reasons, including a legal demand or if a patient agrees, or there is a conflict of interests. Such a conflict exists if there is a danger to other people, and it could be resolved by placing the out of order rule. Abuse of professional secrecy, without good reasons (which hardly happens) can lead to a sanction of criminal law or an action on civil law. In written law a new development becomes visible in which 'serious interests' can lead towards interfering with professional secrecy.

Professional secrecy and tracing criminals

A nursing ward, in which a patient stays, is regarded by law as a house and can only be entered with permission or legal authorisation. However, an investigating officer is allowed to enter an operating theatre (OT) or doctor's surgery, even without the doctor' or patient's permission. According to Dr Duijst, this is a strange difference that should be legally repaired: police admission should only be allowed with a doctor's permission or the authorisation of the judge.

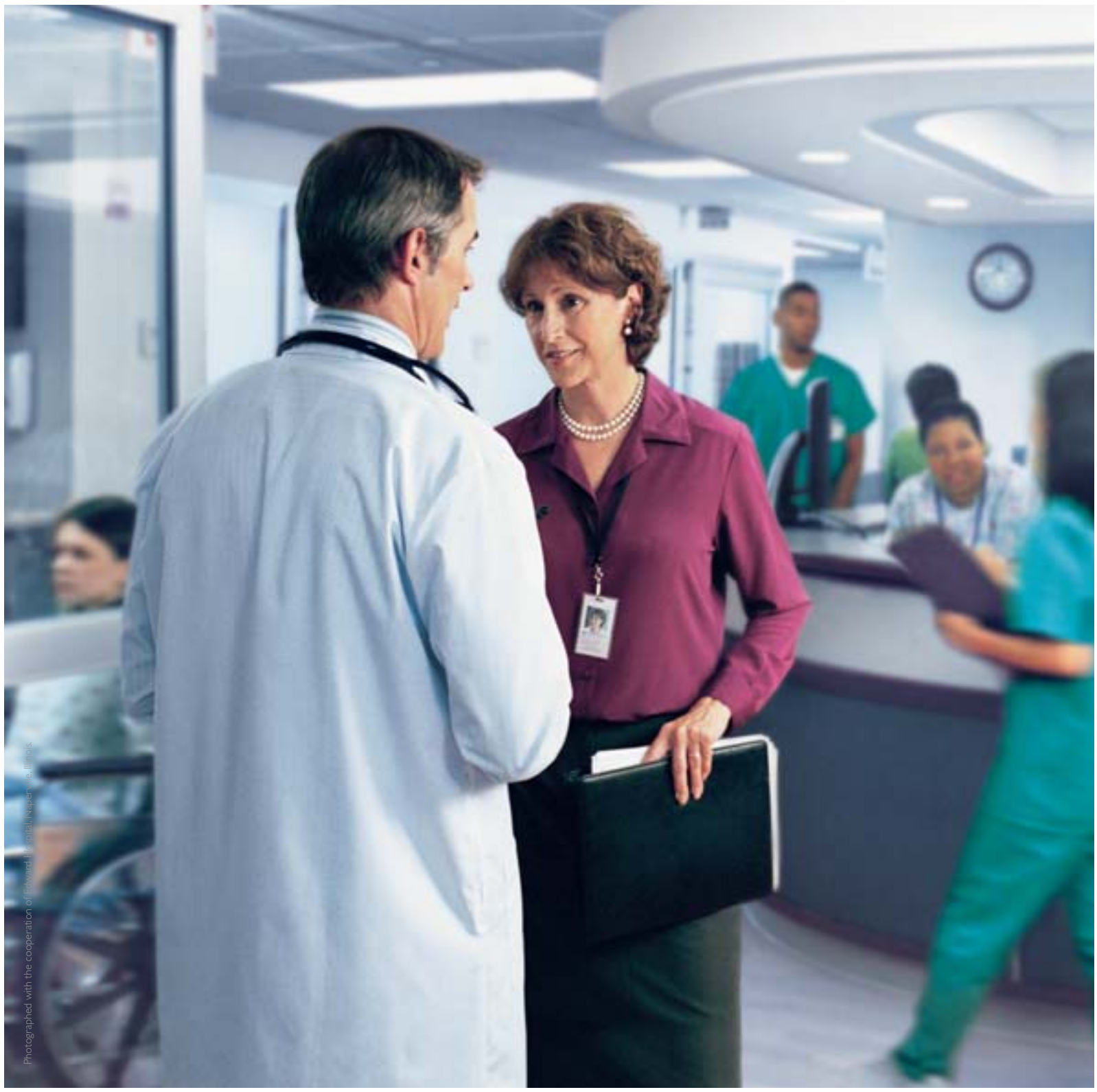
A hospital search and/or the confiscation of letters and other documentation are out of the question. This should also be the case for X-ray's, CT-scans and other information carriers.

Legislation that forces the medical professional to deliver information for a judicial search and control must be clear about what is going to be done with that information. As long there is insufficient clarity there cannot be an obligation (spoken of) to deliver information that is protected by professional secrecy.

As long as no legal obligation exists to over-rule professional secrecy, and as long as it remains the responsibility of the medical professional to decide whether or not to co-operate, a good relationship between professional secrecy and judicial investigation cannot exist.

Pacts

A number of Dutch hospitals and judicial authorities have made pacts in accordance with a private law, about how criminal procedures in hospitals can be arranged. These pacts are a result of discontent and obscurity about the way things had been organised up to now. When studying these pacts it soon becomes clear that a lot is wrong with them. Private law does not seem the ideal way to organise criminal procedures. The hospital where a suspect is staying is in a vulnerable position. On the one hand it depends on a doctor and, on the other, the law, and therefore it needs legal guarantees.



MULTIPLE LAUNCHES

GE to showcase new and advanced equipment at RSNA venue

GE Healthcare presentations at this year's RSNA meeting will include a significant number of imaging and IT developments.

These include the Discovery STE, which the firm describes as '...a breakthrough PET/CT imaging system that provides a wide range of clinically relevant capabilities and true hybrid imaging flexibility,' this is reported as allowing earlier, better diagnosis of cancer, heart disease, and neurological conditions, and the monitoring of treatment. In addition, the integrated Discovery Dimension Console aims to optimise workflow.

Also highlighted will be the Discovery VCT (64-slice) PET/CT system, which provides both anatomical and physiological information to help diagnose coronary artery disease.

Improvements in coverage and acquisition time in GE's Infinia Hawkeye nuclear medicine system have also been announced. The Infinia Hawkeye 4 (4-slice) focuses on lesion localization and attenuation correction, and the new Evolution for Bone suite of reconstruction tools for the Infinia with Xeleris functional imaging workstation is said to provide excellent image clarity and up to a 50% reduction in imaging time.

Xpress.cardiac results from collaboration between GE Healthcare and UltraSPECT. This is new Wide Beam Reconstruction (WBR) technology for faster nuclear cardiovascular imaging.

Also on show: the new PETtrace10, '...the world's highest capacity commercial cyclotron for PET radioisotope production,' which, the firm announces, provides the highest PET radioisotope production capability in the market.

GE Healthcare will also unveil a new family of scanners, to bring the benefits of LightSpeed VCT to a broader audience, such as community hospitals and outpatient imaging centres.

Lung VCAR, which systematically visualizes, isolates and quantitatively analyses lung nodules over a period of time, is another exhibit. So is the new 16-slice Wide Bore CT system to scan for radiation oncology, bariatric patients and interventional procedures - and incidentally, this is reported as having the most powerful tube available, and able to provide the accuracy of table movement for the largest patients - it is currently the only CT that can lift and scan a 650-pound patient.

Another exhibit will be the next generation Smart View advanced application for multi-slice CT systems, a fluoro technology to provide one of the fastest real time acquisitions available, with 12 frames per second. GEHC also says it has the shortest latency time on the market, and provides better control of needle placement during interventional procedures.

PACS - Centricity Radiology Business Intelligence dashboard software can provide detailed reporting of various processes in Radiology departments, aiming to compare current performance against preconfigured values and industry benchmarks, and so provide information about the use of various resources, e.g. scanners, patient waiting times, radiology staff performance and optionally providing information about equipment status (servicing etc).

GE reports that it is the only manufacturer of an entire mammography imaging chain of products - from tube, detector to review workstation. It will demonstrate the next generation platform of its Senographe mammography system and, at Chicago, also will unveil future plans in this field.

In magnetic resonance (MR) the Signa HD family has three new additions: Signa HDx 1.5T and Signa HDx 3.0T for the most advanced clinical imaging performance and Signa HDe 1.5T a smaller, more economical, but still powerful package.

New technologies introduced in Signa HDx include 32-channel architecture, ultra-fast reconstruction algorithms, breakthrough advancements in parallel imaging and new acquisition strategies. Clinical performance and productivity is maximized when combined with new enhancements to unique GE technologies such as PROPELLER motion-resistant brain, VIBRANT breast, LAVA XV body imaging, and TRICKS time-resolved angiography.

In this range, the new space-saving Signa HDe 1.5T MRI, should attract hospital buyers who seek superb diagnostic imaging, but need a small installation footprint and quick return on investment. The equipment has liquid cooling technology, and can be installed in a week in a single scanning room.

The Definium X-ray series will also be launched. The Definium 8000 is a fixed room digital radiography (DR) system that provides high image quality for the full range of traditional radiographic procedures. Definium AMX 700 is a mobile DR system, with digital flat panel detector technology that can be used for virtually any portable application. Applications include: Auto Image Pasting - to provide single panoramic views of the human anatomy, particularly spine/legs, without visible seam lines, and Volume Rad, providing 3-D high-resolution X-ray anatomical images that include abdomen/chest/spine. These applications complement GE's Dual Energy Subtraction, a clinical technique that eliminates bone obstruction from chest or abdominal images.

The Innova CT - which enhances GE's Innova 4100 and Innova 3100 cardiovascular interventional imaging systems - could help change the direction of medical imaging for surgical patients, according to Laura King, Global Vice President, Interventional, Cardiology and Surgery at GE Healthcare. 'We've combined the best of both worlds - taking 3-D medical imaging to the next level by bringing 3-D interventional images normally acquired during CT scans into the X-ray interventional lab.' Traditionally, she explains, interventional radiologists and surgeons competed for access to a hospital's diagnostic CT system to help guide their instruments in real time during an image guided medical treatment. Few hospitals today have a fully dedicated CT suite for CT-image guided procedures, in either radiology or surgery. The new equipment provides CT-like tissue visualization on Innova flat panel interventional X-ray systems as well as 2-D fluoroscopy during a single session of care, without moving the patient from one table to another.

GEHC also will showcase its new Volume Imaging Protocol (VIP) platform, which enables acquisition, optimisation and analysis of volumetric data. Radiographers can 'sweep across a target area of a patient's anatomy and collect true, raw data. After image acquisition, the radiologist can virtually re-scan the patient, by manipulating the raw data with new protocols and in a 3-D planar view, long after the patient has left,' the firm explains.

In addition to these products, contrast media for X-rays and CT are to be highlighted at the GEHC booth.

Single image/data management system integrates major medical fields

NEW

Luc Thijs

IMPAX Enterprise - a single image and data management system that draws together radiology, cardiology, orthopaedics, and women's care as the building blocks of an electronic medical record (EMR) - will be shown by Agfa's HealthCare Business Group at this year's RSNA.

This system combines IMPAX PACS 6.0 (Picture Archiving and Communication System), IMPAX RIS (Radiology Information System), SMMS (Solution Monitoring & Management Services), IMPAX Reporting, IMPAX Auditing and Integration Services.

Using it, medical personnel can use the internet to schedule radiology, cardiology, mammography and other clinical examinations; to access reports, images, and patients' entire electronic medical records using only a web browser, and they have a single sign-on, integrated work list an adaptive user interface with the ability to read and dictate reports over a LAN or WAN through access to traditional RIS.

IMPAX 6.0, an application for imaging-based planning, interpretation and results distribution, tightly integrated with the IMPAX RIS as a single workflow-based system to serve users inside and outside a health facility.

SMMS (System Monitoring and Management Services) is integrated to continually manage and monitor Agfa's applications, hardware, operating systems and databases in a hospital. If a problem arises, all those involved with the system are notified and a map is provided to quickly track and resolve the problem, at any time, due to the connection with Agfa's Global Support Centres.

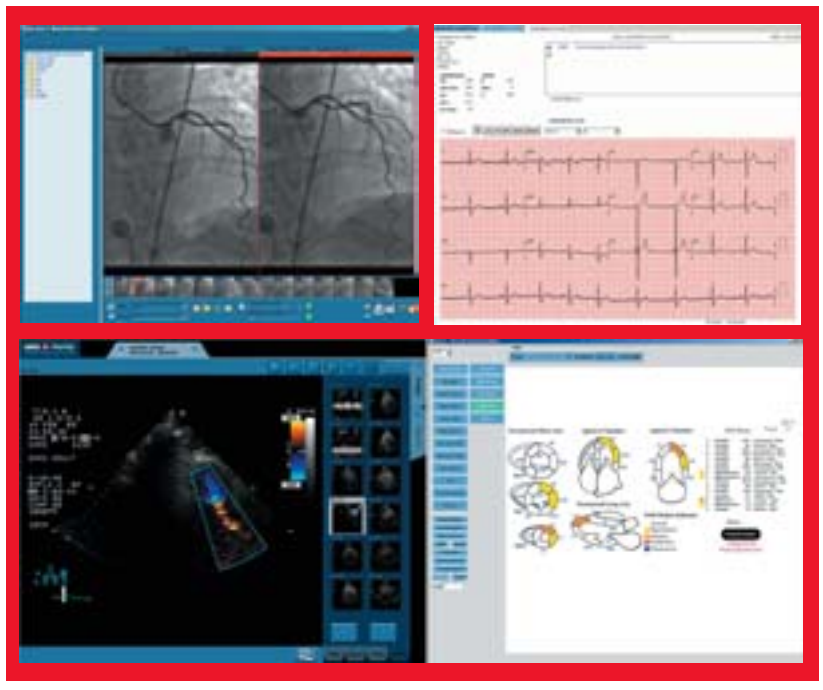
IMPAX RIS/PACS, for imaging centres and clinics, streamlines and integrates a comprehensive range of radiology, business and clinical information workflow that traditionally were manual or paper based. New innovations include embedded billing workflow, and an integrated Mammography Tracking module.

The systems provide pre-certification workflow, improving speed of insurance verification, authorisation and re-authorisation steps and reduce manual and paper processes, Agfa points out. 'Embedded document management within the RIS application, allowing quick user access to documents and electronic screening forms, including radiologist access from within the PACS

Single Desktop Integration to Agfa IMPAX PACS and TalkStation speech recognition allowing single log in, work list utilisation and automatic synchronisation between clinical information and images.'

The Agfa Heartlab portfolio

Beyond radiology, other image-intensive departments within the hospital include cardiology, orthopaedics, and surgery. Of these, cardiology presents a special set of challenges, said Luc Thijs, Agfa's Vice President and Director of Marketing, Radiology & Department Solutions. Cardiology's moving images produce large data sets and demand a system architecture that supports rapid access, flexible storage, and robust data protection.



'Information management needs are different between radiology and cardiology. Radiologists do not see a huge quantity of images, and their reports customarily have four or five lines describing problems, diagnosis, and recommendation. In cardiology, there are more direct examinations and a different approach,' Luc Thijs explained. 'You work much more with etiopathologies. A cardiologist's report will have 40 to 50 different kinds of measurements concerning the function, size and shape of the heart, or details about the valves and so on. A cardiologist needs all the data within the image record to make an effective diagnosis.'

With the acquisition of Heartlab, a leading designer and supplier of image and information networks for cardiology, Agfa meets these challenges with the Agfa Heartlab Cardiovascular portfolio, the world's first fully web-based cardiovascular information system. The new portfolio facilitates accurate cardiology diagnosis from a single point of access and enhances communication through the integration of cardiology, radiology, and the wider enterprise.

'In the past,' he continued, 'cardiology image data was captured by modality equipment and then results were manually written into the patient record. In a typical first generation of digital imaging, you'll find different echocardiology systems generating cardiac data and images, and you may find a mini PACS for the echo lab. On the cath lab side, you'll find the same. But there would be no integration. You would not be able to see the data generated in the echo lab and the data generated in the cath lab in the same digital record. And CT? Well, that's one step beyond!'

The Agfa Heartlab Cardiovascular system provides one uniform PACS combining all cardiac images and information. 'We take cardiology into digitisation,' Luc Thijs pointed out. In addition, because cardiologists typically need access to relevant radiology images, the system also provides connectivity for all the different disciplines. 'Having a unified patient file, with all the images and measurements available, is totally new - in Heartlab.'

RSNA 2005

Connecting for lifelong learning

By ***Professor David H Hussey***
MD, President of the Radiological Society of North America (RSNA) and clinical professor in the Department of Radiation Oncology at the University of Texas Health Science Centre, San Antonio, USA

The 91st Scientific Assembly and Annual Meeting of the Radiological Society of North America (27 November - 2 December, in Chicago) will offer representatives from many specialties and disciplines within radiology, and the entire healthcare arena, the opportunity to exchange information, share educational experiences and review new technology. This year's theme *Connecting for Lifelong Learning* was chosen to embody this vision.

It is imperative that radiologists, radiation oncologists, medical physicists and allied health scientists have a forum through which they can connect and cultivate innovative solutions for today's healthcare challenges. RSNA 2005 offers a broad spectrum of educational and professional activities unparalleled at any other medical imaging assembly. This valuable display of cutting-edge information and technology should not be missed.

New to the programme

A number of changes are being introduced this year, both in the content of the programme and the way it is presented. Just as technologies are changing medical treatment, technology is changing how refresher courses are structured and delivered at the RSNA annual meeting.

Refresher courses are the most popular feature of the annual meeting. Each year, about 300 refresher courses are offered, covering traditional and innovative topics in subspecialty areas. At RSNA 2005 there will be 136 new refresher courses, four new refresher course tracks, four new *Essentials of Radiology* courses and a new case-based review course in radiation oncology.

In the past, MR and CT had dedicated refresher course tracks. Beginning this year, the CT and MRI courses will be folded into tracks organised by organ system. For example, musculoskeletal MR will be included within the musculoskeletal imaging course track.

A special mini-course at RSNA 2005 will be devoted to advances in MR technology, pulse sequences and protocols. Thirty refresher courses reference MR in the title, and 64 additional courses include MR as a major portion of the course curriculum. A new *Essentials of Radiology* course will focus on abdominal MR. CT topics also have been expanded and folded into the diagnostic imaging tracks.

Four new refresher course tracks have been developed to address the current educational needs of imaging professionals. The new tracks are cardiac radiology, emerging technologies, radiology education and vascular radiology. The emerging technologies track will cover the latest in molecular imaging probes and molecular imaging modalities, as well as pertinent topics in molecular biology.

The radiology education track will include sessions on medical student and radiology resident education, teaching skills, delivering presentations, reviewing manuscripts, continuing medical education, electronic aids and self-assessment. The vascular track will feature the latest in vascular contrast agents and post-processing techniques for vascular imaging, MR angiography, CT angiography and digital subtraction angiography. It will also include presentations on vascular pathology in adults and children.

Also this year, the number of courses incorporating audience-response systems (ARS) will be increased to 15. All of the case-based review courses will also include ARS. ARS technology helps keep the audience involved in the presentation, and it allows the instructors to tailor their courses to the competency level of the audience. Instructors will be able to ask the audience questions and then see their answers on a screen. The instructors can then alter the course material based on the responses.

The popular, interactive case-based review courses in interventional, paediatric and neuroradiology were submitted to the American Board of Radiology (ABR) so that RSNA can offer these courses with self-assessment modules (SAMs). SAMs are needed to fulfil the ABR's maintenance of certification (MOC) requirements.

Other highlights

On **Monday**, the Eugene P Pendergrass New Horizons Lecture - ***Imaging in Drug Discovery: Emerging Roles and Challenges*** - will be presented by Lawrence Schwartz MD.

Tuesday will feature the Annual Oration in Diagnostic Radiology, ***Radiology - Back to the Future***, by William R. Brody MD PhD, and on **Wednesday**, K S Clifford Chao MD will present the Annual Oration in Radiation Oncology, ***Integration of Functional Images into Future Radiation Oncology Research and Practice***.

The RSNA annual meeting provides a significant opportunity for radiologists to acquire CME credits - as many as 83 credits can be earned during the course of the meeting. An MOC kiosk at RSNA 2005 will provide attendees with a dedicated location where they can ask questions about the MOC process, see demonstrations of RSNA products related to the MOC, and get information about other MOC resources.

For radiology administrators, Course 941 *Capital Asset Management: **From Acquisition to Replacement Strategies*** and Course 943 HIPAA: ***Ongoing Impacts and Re-inventions in Radiology*** should be of particular interest.

Finally, RSNA and the Society of Interventional Radiology (SIR) Foundation have collaborated to offer a 'meeting within a meeting' on interventional oncology at RSNA 2005. This Interventional Oncology Symposium will be held Monday, 28 November to Friday, 2 December. As with other RSNA programmes, the annual meeting registration fee includes attendance to this symposium. To reserve a seat, you should register for the days you plan on attending when registering for the RSNA meeting.

ROLES

The USA's radiology administrator

By ***Cynthia E Keen***

New CRAs at the AHRA annual meeting two years ago. Around 500 radiology administrators are now certified

In the USA, over 6,000 licensed hospitals provide radiology services. Responsibility for the management of a radiology department lies with a radiology administrator. The radiologist who serves as the department's chairman oversees the professional work of colleagues, supervises clinical research, and leads the direction to determine what diagnostic imaging services are offered. S/he represents the senior authority for diagnostic imaging in the hospital.

The radiology administrator's role is to make the department work, which involves responsibility for the hire, promotion, schedules and supervision of radiology technologists (radiographers), division supervisors, and all support staff. The administrator also maintains federal and state accreditation, regulatory, radiation safety, quality control and patient privacy/security standards. Other tasks include resolving problems and managing conflict resolution; developing (and adhering to) the capital and operational budgets; evaluating and recommending new equipment, negotiating with vendors, and supervising service contracts and equipment maintenance.

As departments convert to near-filmless and paperless operations, the radiology administrator has had to become IT knowledgeable - for RIS, PACS and speech recognition implementation and management. S/he also supervises coding and financial reimbursement for performed procedures, and is expected to create workflow protocols and schedules that optimise all the resources, to enable a department to generate as much revenue as possible. As a minimum requirement, a radiography administrator is expected to be a licensed and experienced radiographer.

With so much responsibility for a position with such diverse, important responsibilities, it is interesting to note that no formal academic programme exists in the United States specifically to train radiology administrators. Like apprentices of master craftsmen, the would-be radiology administrator typically works as a radiographer for years. Clinical education is augmented with college business courses to obtain the financial and management acumen appropriate for running multi-million dollar enterprises. An increasing number of highly motivated administrators earn MBA degrees.

Members of the AHRA signing the agreement with Kodak representatives. The firm pledged $1 million over five years to support the certification programme

In 2002, the 3,750-member American Healthcare Radiology Administrators (AHRA), the professional association for North American hospital radiology department and imaging centre administrators, initiated a certification programme, supported by a $1 million grant over five years from Kodak Health Imaging. Official CRA certification combines on-the-job experience with successfully passing a rigorous written examination testing knowledge of asset resources management, fiscal and operations management, and human resources management. To date, approximately 500 administrators have voluntarily earned certification.

Scanning the biggest patients

USA - The first Aquilion LB, made by Toshiba Medical Systems, has been successfully installed at Beth Israel Deaconess Medical Centre (BIDMC) in Boston.

This completely re-designed 16-slice CT features the largest available bore (90 cm), and widest Field-Of-View (70 cm) to scan patients of all sizes in various positions. The Indexed Patient Positioning System (IPPS) tabletop also allows the use of all patient positioning accessories commonly used in radiation therapy. The combination with a breast board allows a patient to be scanned with an incline of 25°. In addition, the machine's new, larger gantry opening allows patients to place their arms comfortably overhead during scanning.

Dr Edward Holupka, director of physics at BIDMC, Harvard Medical School, said: 'It's paramount to have the technology required to accurately obtain the information we need, regardless of patient positioning or size issues.' This equipment, he added, overcomes the problem of repeatable patient positioning.

The QuantumPlus detector is the only large bore detector that provides three different slice-width acquisitions: 0.5 mm, 1.0 mm and 2.0 mm

The imaging facilities of the X-Ray simulator have also been expanded to high resolution 3-D CT-imaging.

Based on the Toshiba's Quantum Multi-Row detector, which offers slices as small as 0.5 mm, Toshiba built the QuantumPlus detector that enables Aquilion LB to acquire isotropic images with voxels of just 0.35 mm^3.

Carotid artery disease

Multi-slice CT of the neck and skull base

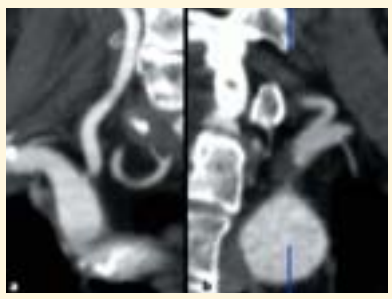
By **J Larsen** MD FRCR, University Department of Neuroradiology, Goettingen, Germany

The development of multi-detector row helical acquisition CT scanners has advanced our ability to examine pathologies of the neck and skull base very considerably. Recent advances in multi-slice CT (MSCT) technology are relevant to a spectrum of challenging imaging tasks in this body region. The improved spatial resolution is critical, e.g. to the evaluation of the thin bony membranes of the facial skeleton, assessment of dysplasias of the ossicular chain or staging of perineurovascular spread of neoplastic processes. The improved temporal resolution is not only of practical help when critically ill, unco-operative patients or children require CT imaging but also of essential importance when we consider that the time span of arterio-venous transition is no more than about seven seconds. In this respect, non-invasive CT-angiography (CTA) may serve, for example, to accurately assess tumour vascularisation, or to demonstrate the site of bleeding in cases of uncontrollable epistaxis.

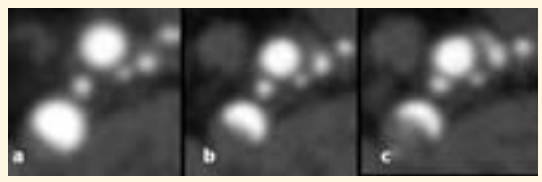
However, the greatest impact of MSCT may have been on the evaluation of carotid artery disease. The vast majority of referrals for CTA certainly are in the setting of symptomatic ischaemic or haemorrhagic stroke. Applications at and below the skull base in the acute setting comprise the search for a source of arterio-arterial embolism, in particular the assessment of carotid artery stenosis, it's site, length and degree or haemodynamic significance as well as plaque composition and documentation of possible stenosis in the proximal arterial tree which may make access to the symptomatic stenosis during secondary prophylactic procedures difficult.

The socio-economic impact of stroke disease on western societies is vast and well documented. Much work has been done to advance our ability to document in particular prognostically significant parameters that characterise carotid stenotic disease: Calcified plaque has been

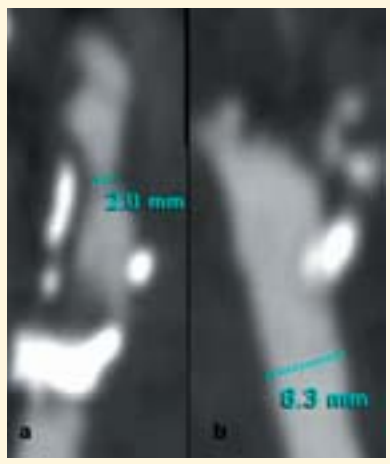
Right:: 1. Proximal cervical artery disease: Multiplanar reformations of a CTA-data set demonstrate tight stenoses of the origin of the right vertebral artery (a) and left subclavian artery (b)



Below: 2, Eccentricity of luminal narrowing: Transverse axial source images of CTA-data set showing increasingly eccentric and narrowed carotid artery lumen on consecutive images (a-c)

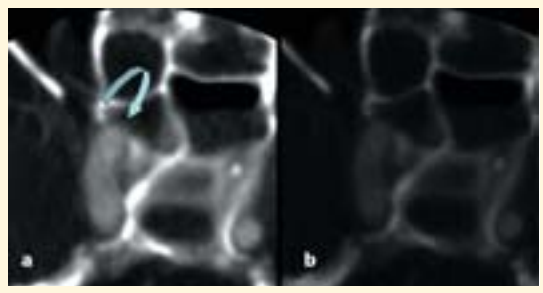


Right: 3. Measurement of carotid stenosis: Thin-slice MPR images - the diameter of the stenosis (a) is subtracted from the diameter of the common carotid artery lumen just proximal to the stenotic segment (b) and the result divided by the CC-diameter: 4.3/6.3 = 68%

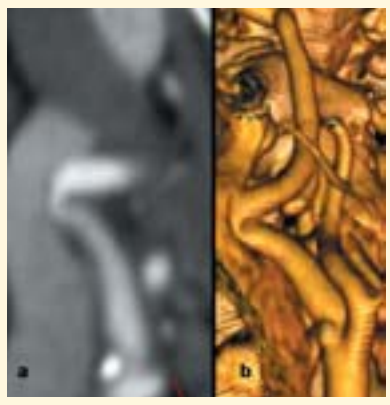


Below: 4. Looping and coiling of vessels: 3D-volume rendered CTA-images of subpetrous looping of the left internal carotid artery (a) and coiling (b) in a different patient: in the axially reconstructed section, the internal carotid artery appears three times

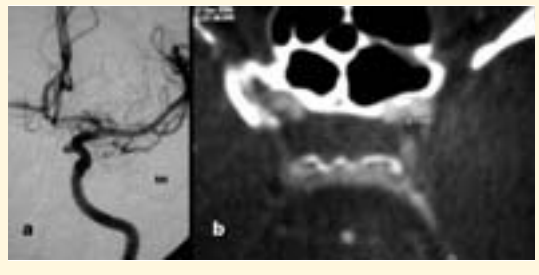
Below: 6. Sphenoid protrusion of internal carotid artery: Axial reformat of CTA-data set in 'calcified vessel' (a) and bone window settings (b) show lack of a bony membrane between the vessel wall and the right compartment of the sinus (arrow)



Right: 5. Arterial kinking: MPR- (a) and 3D-volume-rendered (b) images of CTA-data set indicate a high-grade kinking of the right internal carotid artery, resulting in functional stenosis

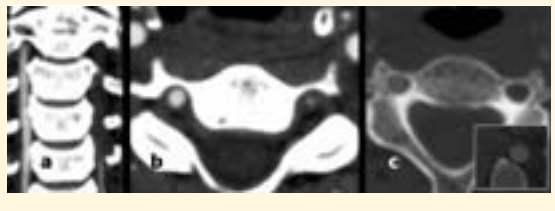


Below: 8. Aneurysm in the carotid siphon: Working projection of digital subtraction angiogram (a) at time of intervention and MPR of CTA-data set with measurements of aneurysm sack

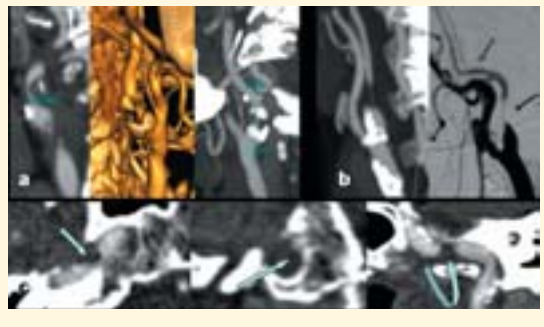


Below: 7. Skull base aneurysm: Axial reformats of CTA-data set in 'calcified vessel' and bone window settings (left and right respectively) at the level of the skull base (a) and slightly more cranially (b) demonstrate an essentially thrombosed giant internal carotid artery aneurysm on the left (a) as well as a smaller still perfused aneurysm on the right (b)

Below: 9. Vertebral artery dissection: Multiplanar reformats of CTA-data set: Coronal image shows discrepancy in the opacification of the vertebral arteries (a). Fusiform luminal narrowing could be due to hypoplasia on the left (b), however, bone window settings show symmetry of transverse foramina, suggesting that there is dissection of the vessel wall - proof: spinal osteophytes in the vicinity of the abdominal aorta only occur on the side opposite to the side of pulsation (inset)



Below: 10. Carotid artery stenoses: CTA-images of patients with a high-grade stenosis of the origin of the internal carotid artery (a), a longer and haemodynamically significant narrowing (b; note the reduction in vessel calibre and opacification distal to the stenosis in the angiographic image - perfusion pressure is reduced here) and a short but high-grade stenosis of the intrapetrous portion of the internal carotid artery (c; straight arrows): MPR-sections may falsely suggest vessel occlusion (curved arrow).



shown to be less symptomatic and therefore possibly more stable than a soft one. This has been confirmed by MRI studies of plaque morphology. It could be demonstrated further that the volume of calcium within carotid plaque correlates with the degree of luminal narrowing. In addition, important technical comments were made by Claves and colleagues who established that an accurate measurement of carotid stenosis depends upon the density value of the blood-contrast medium mixture as much as window settings.

Assessment of carotid stenosis

The initial evaluation of the arterial system in the neck is usually carried out using Doppler-ultrasound. This shows carotid plaque as the morphological correlate of the stenosis as well as the flow acceleration across it, which allows an estimate of its degree. However, on anatomical as well as technical grounds we require a more robust method that has, in our experience, been realised with modern CTA.

A volume scan is obtained in the caudo-cranial direction. For the assessment of the extracranial arteries, acquisition starts at the aortic arch, which allows the use of bolus-triggering software. Intracranial scans are started just below the skull base and triggered visually once contrast medium inflow is observed. In both instances scans are extended to cover the course of the callosomarginal arteries. Intracranial scans are performed with 0.5 mm collimation with no more than 1.0 mm used extracranially. From the volume data sets overlapping 0.5 mm transverse axial 'source images' are calculated routinely. Because of the complex image reconstruction algorithms in MSCT, consideration of manufacturers recommendations e.g. with respect to the choice of pitch etc. has been advised.

Review of the axial reconstructions alone is insufficient for the proper evaluation of a CT-angiogram. Rather a systematic stepwise image post-processing is recommended. While the patient remains on the examination table, a brief review of the source images may however be performed in order to ascertain the technical quality of the examination while gaining an overview of the gross pathology. Afterwards dedicated multiplanar reconstructions (MPR) are made on a medical imaging workstation to bring out detailed findings. Finally, 3-D reconstructions may be created for demonstration purposes only, since the degree of luminal narrowing on rendered images is highly variable depending upon window settings.

The emphasis in the evaluation of the data set is on its systematic approach. For example, demonstration of a stenosis at the origin of a proximal artery is highly relevant to the report of a skull base aneurysm if the stenosis may make access during coil embolisation difficult (Fig. 1). Careful and systematic review of all vessels throughout their course in the source images is therefore required in the first instance. With respect to carotid stenosis, multiplanar reformations should be as thin as possible and the plane of sectioning aligned with the angulation of the course of the vessel at the point of maximum stenosis. Thin slicing is of such importance since stenoses commonly fail to assume an hourglass-like configuration but are frequently eccentric or ragged, i.e. the apparent degree of stenosis depends upon the plane of sectioning such as it depends upon the projection in conventional angiography (Fig. 2). The minimum short axis of a luminal stenosis should therefore be measured7. In other words, maximum intensity projections are not suited to the accurate reporting of carotid stenotic disease with one exception: they are useful when choosing the length and calibre of stents prior to stent-protected percutaneous transluminal angioplasty of stenoses while serving as 'eyeballing'-review image at the time of the procedure.

Actual measurement of carotid stenosis is carried out according to the protocols of the large international series, namely the NASCE- and ECS-trials. However, it has been shown that the so-called common carotid-method is consistently the most reproducible (Fig. 3).

Anatomical variants and common pathologies

There are many clinically and, in particular, therapeutically relevant variants of normal arterial anatomy in the neck. These include looping and coiling of vessels (Fig. 4). Kinking, even to a degree of significant luminal narrowing, may also occur (Fig. 5). Such variants may be interpreted as a consequence of years of untreated arterial hypertension similar to the elongation and unfolding of the thoracic aorta. It is also recognised that the carotid artery may protrude into the sphenoid bone. The osseous membrane to the sinus may then be eroded, which is highly relevant to functional endoscopic sinus - as well as pituitary surgical procedures (Fig. 6).

Common pathologies of carotid artery disease include aneurysms, dissection of the arterial wall and stenoses. Aneurysms may involve both the skull base (Fig. 7) or the carotid siphon. Thin MPR-images allow measurement of aneurysm dimensions relevant to the choice of the first coil for the embolisation procedure (Fig. 8). These are equally suited to demonstrate sites and extent of dissections (Fig. 9). Appearances of carotid stenoses vary widely. As indicated above, their site, length, degree or haemodynamic significance as well as plaque composition are relevant to the choice of possible therapeutic interventions (Fig. 10 a-c).

** Adapted from an oral presentation, 4th Multislice CT Symposium, Charité, Berlin, August 2005*

By ***Dr Fabian Kiessling***, Head of the Division of Molecular Imaging, Department of Biophysics and Medical Radiation Physics, German Cancer Research Centre (DKFZ)

Molecular MRI
Moving into the clinic?

Molecular imaging has been defined as the non-invasive visualisation of cellular and molecular mechanisms in vivo. While 'molecular imaging' has been carried out for decades in nuclear medicine (e.g. thyroid scintigraphy, bone scintigraphy and FDG-PET) its popularity rose just a few years ago with the publication of studies showing the feasibility of target specific imaging in MRI, optical imaging, and ultrasound. For clinical use, MRI is a particularly attractive tool for molecular imaging approaches, due its broad variety of applications, excellent tissue contrast and higher spatial resolution, compared with nuclear medicine techniques. However, it must be considered that the sensitivity of MRI to contrast agents is over 10,000-fold lower than that of nuclear medicine techniques, which require dedicated labelling strategies of target structures in vivo. So far, it is uncertain to what degree specific MR-imaging can really be transferred into the clinic.

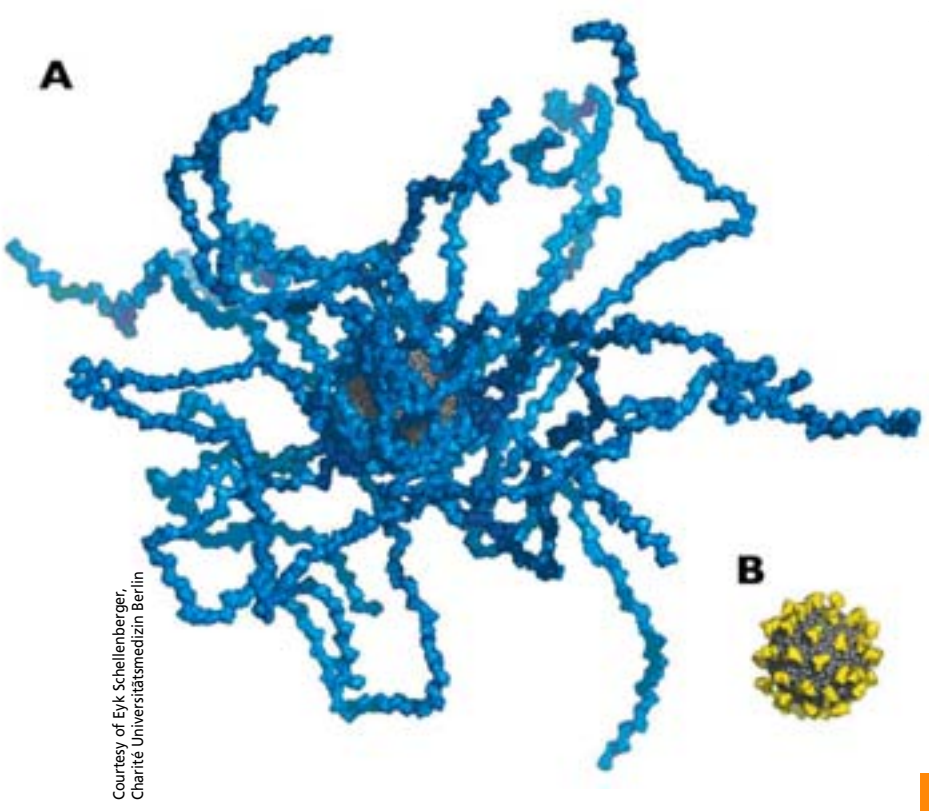
Superparamagnetic iron oxide particles (SPIO) and ultra-small superparamagnetic iron oxide particles (USPIO), amplify the MR signal considerably, compared with established Gd-based contrast agents, due to the crystalline structure of thousands of iron ions. SPIO and USPIO, which accumulate intracellularly, are usually used for specific and cellular MR imaging. These dextran or carboxydextran coated SPIO regularly show high hepatic uptake and are clinically used for liver imaging (e.g. Resovist, Schering, Berlin). For specific imaging it is desirable that the unspecific uptake by the liver and the RES is low and the size of the particles is small. Among those particles are citrate coated, very small, superparamagnetic particles (VSOP), developed by the Ferropharm GmbH (Teltow, Germany; fig. 1). These particles show good biocompatibility and have already entered clinical evaluation as contrast agents for MR-angiography and cardiac MRI.

Nano AG is a multicentre project with partners from the industry (Siemens, Erlangen, Germany; Ferropharm GmbH, Teltow, Germany; Schering AG, Berlin, Germany; Mevis GmbH, Bremen, Germany) and scientific institutions (Charité Universitätsmedizin Berlin, Germany; University of Freiburg, Germany; German Cancer Research Centre, Heidelberg, Germany) funded by the German Ministry for Education and Research (BMBF) and co-ordinated by Arne Hengerer from Siemens AG (Erlangen, Germany).

The primary aim of Nano AG is to develop target specific VSOP and imaging strategies to visualise dangerous vulnerable plaques in arteriosclerosis using MRI. In addition, it will be investigated whether these contrast agents can also be used translationally, e.g. to detect angiogenesis in cancer. In contrast to most previous projects, it is not the aim of Nano AG to show only feasibility of molecular MR-imaging concepts, but to develop specific contrast agents that can subsequently be applied in patients. Superparamagnetic particles, which are used for this purpose, must fulfil important requirements: First, to be non toxic and highly biocompatible. Second, high T1- and/or T2-relaxivity are required to allow visualisation of the targets in vivo by MRI. Third, small particle sizes are desired to improve extravasation, target binding in vivo and if possible renal elimination.

Nano_AG project particles will be provided by Ferropharm GmbH, which specialises in superparamagnetic iron oxide particles for MRI. In the course of the project the physical characteristics and pharmacokinetic properties of the particles will be tailored to the particular application. VSOP will be functionalised by coupling them to ligands to make them bind to arteriosclerotic plaques. Finally MR-imaging techniques will be optimised and postprocessing algorithms for the MR-data will be developed.

Summary - Nano_AG is a unique interdisciplinary project that combines world-class expertise in probe design, application development and engineering in a cross industry collaboration including renowned academic sites. Specific MR contrast agents will be synthesised for the imaging of early thrombotic plaques. The virtual team will ensure that these functionalised VSOP fulfil the regulations for clinical contrast agents and it is the declared aim that these specific compounds are ready for clinical evaluation after funding ends. Thereby the consortium aims to help in early diagnostics and risk stratification of the 'vulnerable patient' by providing a diagnostic solution (contrast agent and imaging hardware & software) for a hitherto unmet medical need.



Courtesy of Eyk Schellenberger, Charité Universitätsmedizin Berlin

Size comparison of conventional dextran coated SPIO (hydrodynamic diameter above 20nm) with the new citrate coated VSOP (about 7nm).

Tobias Schaeffter PhD, Principal Scientist, Philips Research Laboratories, Hamburg, ***Arne Hengerer PhD***, Director molecular MR, Siemens Medical Solutions, Erlangen, and ***Andreas Briel PhD***, Eisenherz project manager, Schering Research Laboratories, Berlin, describe...

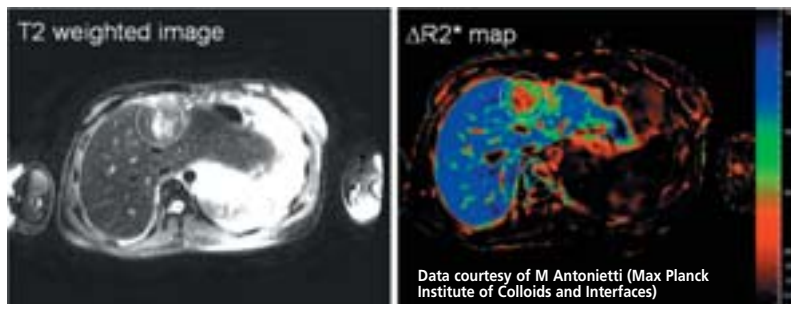
The Eisenherz project

Recent developments in genomics and proteomics have tremendously increased our knowledge on the molecular processes of diseases. This feeds the hope that the susceptibility of an individual to many diseases can be predicted and that these diseases can be diagnosed at a much earlier stage and more individually designed therapies can be developed. Molecular imaging aims at the early detection and quantification of molecular processes associated with disease by using sensitive imaging methods together with targeted contrast agents. In order to make this vision happen, an interdisciplinary effort between different academia and industries is necessary.

The Eisenherz project is funded by the German Ministry of Education and Science (BMBF) to develop new targeted MR contrast agents and MRI technology that enables clinicians to detect cancer cells earlier, to stage the cancer, and ultimately, to quantify therapy effects of individual cancer treatments. This has massive implications for cancer management and could have sizeable cost-saving implications for hospitals.

In order to achieve these goals, Eisenherz has created an alliance for nanotechnology in cancer - a partnership between academic institutions, two of the leading medical imaging companies, Philips Medical Systems and Siemens Medical Solutions, and Schering, the leading contrast agent and pharmaceutical firm. The three-year research project, which began on 1 September 2005 under the leadership of Schering in the *Nano-for-Life* framework of the German Ministry of Federal Research, aims to translate German excellence in nanosciences to commercially viable medical products and processes.

To develop contrast-enhancing agents for molecular imaging is one major challenge facing the pharmaceutical industry today. Classic contrast agents primarily document the anatomy. For pathophysiological examinations using differential diag-



Liver tumour: Image from University Hospital Muenster that demonstrates the use, in patients, of quantitative MRI developed by Philips Research Hamburg with an approved agent from Schering for the detection of cancer

Siemens to produce preclinical contrast agents

Dr Arne Hengerer

By ***Dr Arne Hengerer***, Department of Molecular Imaging/ Magnetic Resonance at Siemens Medical Solutions

Advances in the non-invasive visualisation of biological processes at the cellular and molecular level are mandatory for MRI to be competitive in the age of molecular medicine. However, many molecular targets are expressed in considerably low concentrations. In recent years, new contrast agent concepts have enabled mMRI (molecular MRI), and molecular imaging has commanded attention from beyond the field of nuclear medicine. In cardiac diagnostics, innovative contrast agents (e.g. VSOP) will pave the way towards a significant improvement in early detection of inflammatory disease within the vessel wall, and therefore will bring significant improvement in the medical treatment for patients at risk for sudden cardiac death.

The Nano-Ag consortium intends to foster cardiac mMRI. We will develop imaging solutions (including contrast agents and imaging hardware and software) that will provide an additional level of information at the molecular or cellular level. Thus we will extend cardiac MRI further, beyond the anatomical and physiological level. By acquiring new parameters for risk stratification we will address the so far (unmet) needs of cardiologists, today a customer group that uses MRI sporadically. Advancements developed within the Nano-Ag will translate into more powerful MRI scanner generations, not only after market launch of VSOP's in the future, but sequentially as we proceed in the project. Better protocols for cardiac MRI including navigators, sophisticated postprocessing tools, etc. will be commercialised as soon as possible.

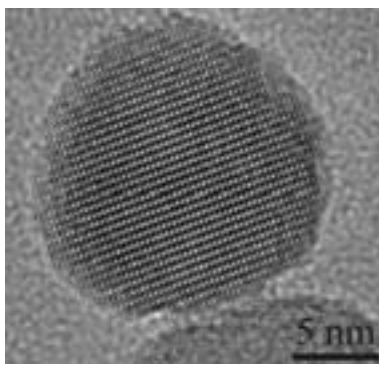
Last but not least, this is the very first time that Siemens is becoming actively involved in preclinical MR contrast agent development - an investment for the future of our business.

In conclusion, we foresee a substantial growth potential within our established customer base and, on top of growth, within a new customers group, driven by innovative contrast agents (and new applications) of MR.

nostic techniques, in other words, characterising the development of a disease, they are only suitable to a limited degree. Molecular imaging selectively tracks down molecules and cell structures to be able to establish proof of diseases at a very early stage - and then to make decisions on a highly individual treatment.

The next straightforward vision of medical imaging quite clearly lies in the concept 'Find, Fight and Follow'. In radiopharmaceuticals we are already pursuing the approach of a triad consisting of early diagnosis, therapy and therapy control. Building a bridge between therapy and diagnosis opens the field of 'Theranostics'. With a 'Find, Fight and Follow' strategy, the tissue of interest first can be imaged via target-specific contrast particles. In a second step, the same particles, now combined with a pharmacologically active agent, can be used for therapy. And finally, monitoring of treatment effects is possible by sequential imaging.

Beside radiopharmaceuticals, utilising the nanotechnological concepts of colloid- and interface science imaging on a molecular level can also be achieved via MRI using tiny magnetic iron oxide particles



Nanoparticle: Atoms become visible! High Resolution Transmission Electron Micrograph (HRTEM) of a magnetic iron oxide nanoparticle. Recent progress in nanotechnology enables the controlled manufacturing of nanoparticles of certain nanoscaled sizes, crystal structures and architectures. This can be the basis for new ultra-sensitive contrast enhancing systems (better probes or tracers)

coupled to target-specific ligands. Schering has many years experience in the field of contrast agent development and an already approved nanoscaled iron oxide MRI contrast agent called Resovist, in the market since 2001.

The device manufactures major strategic aims include supporting R&D in molecular medicine through the development of new ultra-sensitive imaging systems capable of observing phenomena at the molecular level, supporting the work of academic groups, and forming collaborations with contrast-agent and pharmaceutical companies.

In particular, sensitive detection of a contrast agent in large volumes has to be developed to detect cancer cells with targeted contrast agents. In addition, the development of quantitative MRI is seen to be crucial for assessing disease progression or regression after therapy. Classical MRI usually allows only qualitative assessment of pathology by obtaining T1, T2 or T2* weighted images. By contrast, the mapping of relaxation times provides a quantitative estimation of the local contrast agent concentration. In addition, *pharmacokinetic (PK) modelling* is a valuable tool for objectively assessing contrast agent uptake in tissue. For this, mathematical schemes are developed that represent complex processes within the body. Quantitative MRI together with advanced PK modelling gives a valuable indication of, for example, the behaviour (uptake rate) of a tumour before and after therapy. Therefore, this technology has a high potential for an objective evidence of the effectiveness of therapy and can be used for individual dosage.

The project focuses on breast and prostate tumours - the most relevant cancer types. Therefore, targeted nanotechnology based contrast agents, common among these cancer types, will be developed by Schering in collaboration with the Max-Planck Institute of Colloids and Interfaces (Prof. Antonietti) and the start-up company Capsulution NanoScience AG. Regarding the dedicated tools and methods to characterise nanoscaled systems, the project will be supported by NanoLytics GmbH - a Berlin-based nanotechnology characterisation laboratory.

The developed contrast agent will be tested at three different hospitals for the different cancer types. The University Hospital Muenster (Professors Heindel and Bremer) will work mainly in the field of breast cancer. The detection of cancer cells will be tested and cross-validated with optical fluorescence tomography on animals. The Technical University (TU) Munich (Professors Schwaiger, Wester and Botnar) will focus on the detection of prostate cancer cells and will cross-validate the detection with positron emission tomography. The German Cancer Research Centre Heidelberg (DKFZ, Prof. Semmler, Dr. Bock) is evaluating the newly developed nanoscale contrast agents on various cancers models and will develop new animal MR-coils for clinical MRI scanners.

Since the hospital Muenster and TU-Munich are working with Philips equipment, these two sites are closely collaborating with Philips Research in Hamburg, whereas the DKFZ is collaborating with Siemens Medical Solutions in Erlangen. Both imaging industry partners (Philips Medical Systems and Siemens Medical Solutions) are working on standardisation issues, e.g. reference measurements for new, targeted contrast agents, and their limit of detection.

Eisenherz is a unique interdisciplinary consortium for the improved cancer management by means of Molecular Imaging: the early detection, the quantitative diagnosis and the selection of an appropriate treatment of cancer. This integrated approach has a high potential to improve the quality of life in future.

Computed tomography and acute stroke

By Imanuel Dzialowski MD

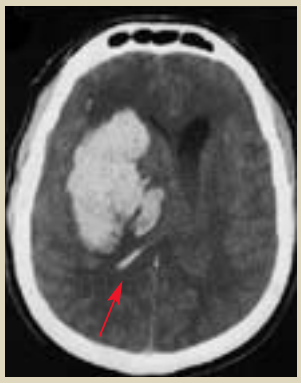
In February 2005 Dr Imanuel Dzialowski became a Postdoctoral Fellow, on the Calgary Stroke Programme, at the Department of Clinical Neurosciences, in Foothills Hospital, Calgary, Alberta, Canada, following a wealth of neurology and neuroradiology training, experience and stroke research in the University of Technology, Dresden, the Humbold University, Berlin, and the University of Essen.

He is also co-author of a dozen papers/abstracts, printed in the publications Radiology, Intensivmed, Stroke, Journal of Neurology, Cerebrovascular Diseases, Aktuelle Neurologie, Journal of Neuroimaging.

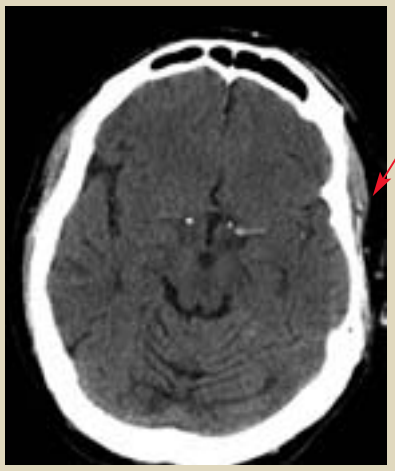
Patients with an acute stroke syndrome present with hemiparesis, hemisensory loss, hemianopia, speech disturbance, or impairment of consciousness. The two most common causes are cerebral ischaemia and intracranial haemorrhage. Less frequent differential diagnoses include migraine, seizure, cerebral venous thrombosis, focal encephalitis, demyelination disorder, or tumour. Brain imaging is necessary to assess the exact diagnosis and the acute pathophysiological state of the brain. Both will guide treatment and will finally determine the patient's clinical outcome.

Computed tomography (CT) has been revolutionizing the understanding and treatment of stroke since its introduction into clinical practice around 30 years ago. Magnetic resonance imaging is another upcoming imaging modality with even greater potential to study the brain in acute stroke. However, it is not yet widely available in most countries and its feasibility in severely affected patients is still limited.

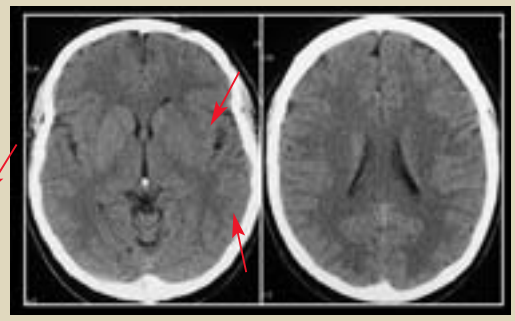
Despite the enormous progress CT has conveyed, stroke scientists must ask whether its use really improves patients' outcomes. Kent and Larson proposed five levels of clinical efficacy for assessing diagnostic technology: 1) technical capacity 2) diagnostic accuracy 3) diagnostic impact 4) therapeutic impact, and 5) patient outcome. This article addresses the question of which pathology CT is able to assess in patients with acute stroke; how accurate this information is; and whether imaging with CT has any impact on stroke diagnosis, stroke treatment, and finally on the clinical outcome of patients.



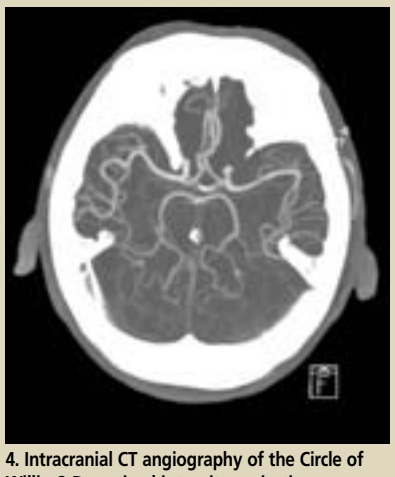
1. Example of an acute intracerebral haemorrhage into the basal ganglia. Note intraventricular extension (arrow) and considerable mass effect with midline shift to the left



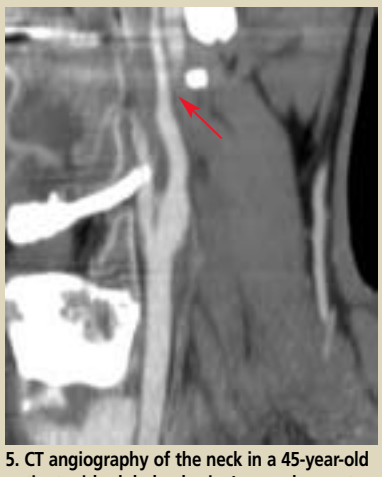
2. Left hyperdense middle cerebral artery sign



3. Obscuration of the lentiform nucleus (long arrow) on the left in a patient with acute left middle cerebral artery syndrome. Note the clear loss in density of the lentiform nucleus and the anterior part of the head of the caudate nucleus (short arrow) only 1:15 hours after symptom onset. Upper slice (image on right) does not show signs of infarction yet



4. Intracranial CT angiography of the Circle of Willis. 2-D maximal intensity projection



5. CT angiography of the neck in a 45-year-old patient with global aphasia. Image shows stenosis of the left internal carotid artery (arrow) typical for extracranial arterial dissection

Technical capacity of CT in acute stroke

Based on changes in X-ray attenuation, non-contrast CT is capable of detecting the following changes:

- Intracranial haemorrhage appears clearly hyperdense, e.g. as parenchymal mass or filling of the subarachnoid space (figure 1)
- Thrombo-embolic arterial occlusion; well-defined hyperdensity in the course of the middle cerebral artery (figure 2)
- Ischaemic brain oedema; hypodensity of grey or white matter manifesting e.g. as 'loss of cortical ribbon' or obscuration of the lentiform nucleus (figure 3).

Adding intravenous contrast media, CT can assess intracranial vessel status (CT angiography, images 4 and 5) and brain parenchyma perfusion (perfusion-CT, image 6).

Diagnostic accuracy

Because CT was the first modality that could image the brain in-vivo, a reference standard for CT findings in acute stroke has seldom been available. However, surgery or autopsy regularly confirms the CT finding of intracranial haemorrhage.

In cerebral ischaemia, hypo-attenuation on CT is highly specific for irreversible brain tissue damage. In its very early stage, ischaemic oedema might be too subtle to be detected by the human eye. However, even within three hours from symptom onset, CT is positive in about 40-60% of patients.

CT has *diagnostic impact* by reliably differentiating between haemorrhagic and ischaemic stroke. In addition, it is used to differentiate among types of cerebral ischaemia like territorial infarcts caused by emboli, infarcts in end-supply areas or 'watershed areas' often associated with major artery occlusion or stenosis, and disseminated small infarcts caused by small vessel disease.

Therapeutic impact

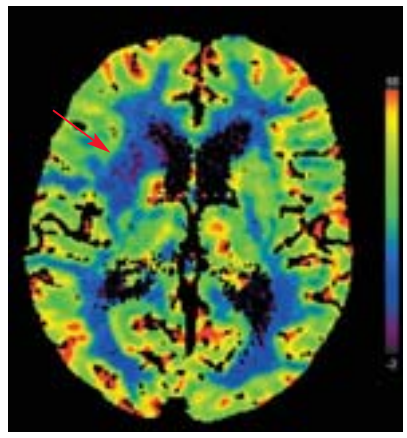
For the first time in history, CT enabled identifying patients suffering from cerebral ischaemia. As a consequence, specific treatment like thrombolysis could be tested. CT has thus an enormous therapeutic impact just by differentiating between ischaemic and haemorrhagic stroke.

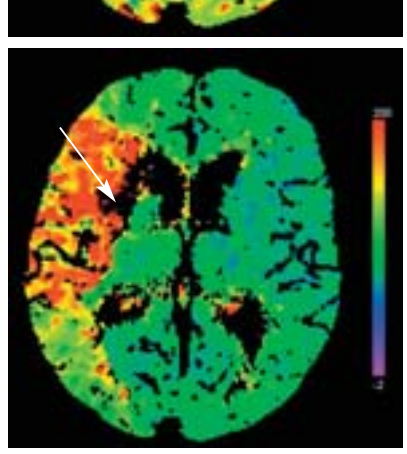
In acute cerebral ischaemia, the only treatment that is proven to improve clinical outcome is intravenous thrombolysis with recombinant tissue plasminogen activator (rt-PA) applied within three hours of symptom onset, or intra-arterial infusion of pro-urokinase in patients with MCA occlusion if applied within six hours of symptom onset. In selected patients, the time-window for intravenous thrombolysis can be extended to up to six hours from symptom-onset and CT identifies those patients at risk for thrombolysis-related secondary intracerebral haemorrhage.

In acute haemorrhagic stroke, prothrombotic treatment with Factor VIIa appears to be a therapeutic option in the near future.

Impact on patient outcome is the most important criterion for the usefulness of a diagnostic test showing that it leads to a change in patient management that improves patient outcome. CT enables thrombolytic therapy and thereby reduces likelihood for disability by at least 30%. Each prevented disabling stroke saves estimated lifetime-costs of around US$90,000.

In summary: CT is the current standard of care in acute stroke since it impacts stroke diagnosis and therapy and thereby improves patient outcome.





6. Perfusion-CT: parameter image of cerebral blood volume (CBV) on left and time-to-peak (TTP) and right. Red-colour-coded lesion on TTP suggests area of markedly delayed blood flow with non-measurable flow in the left lentiform and caudate nucleus (white arrow) corresponding to a small area of decreased CBV (black arrow).

Scans and strokes

Greece - The *Clotbust* trial recently demonstrated that continuous 2-MHz Transcranial Doppler Ultrasound monitoring of acute intracranial artery occlusions safely enhances systemic thrombolysis in stroke patients. At the *European Federation of Neurological Societies* (EFNS) September meeting, in Athens, many presentations attested to the growing use of non-invasive imaging modalities in neurology.

- French stroke specialists (Tours hospital, Abstract P1058) found that creating a specialist stroke unit reduced delays in hospital admissions, imaging, and length of hospital stay, but access to MRI was crucial for this scheme's success.
- Neurologists from Nordland Central Hospital, Bodo, Norway reported that early Perfusion-CT scans in acute stroke might predict the potential benefit of thrombolysis in individual patients (Abstract P2001).
- Using functional magnetic resonance imaging of patients with mild cognitive impairment, Finnish neurologists showed that function and metabolism of cortical neuronal networks are already compromised prior to manifestation of dementia (Abstract P2174).
- High-resolution cerebrovascular duplex ultrasound is enabling studies of vessel wall morphology, plaque development and vascular remodelling, reported Dr Stephen Meairs, University Of Heidelberg, Germany. Combined with other vascular imaging modalities (CT, CTA, MRI and MRA) outcome and prognosis in stroke patients can be predicted. Dr Meairs believes that ultrasound mediated gene therapy will be a future weapon against stroke.
- Stroke infarct volume quantified via magnetic resonance diffusion weighted imaging appears to predict both short-term (24-hours) and long-term (90-days) clinical outcome, according to neurologists at The Stroke Centre, University Hospital, Olomouc, Czech Republic (Abstract SC210).
- A combination of functional and structural imaging with neuropsychological testing should be able to provide highest diagnostic specificity in diagnosing dementia, according to neurologists from Ludwig-Maximilians University Hospital Munich, Germany (Abstract P2103).

BRAIN NEGLECT

Some patients who suffer a right-hemisphere stroke develop 'neglect' syndrome, in which they ignore the entire left side of the body and objects around it. The deficit is caused by abnormal activation in intact areas of the brain connected to the damaged areas, rather than by the original damage itself, according to a paper in the November issue of Nature Neuroscience http://www.nature.com/nn/)

Using functional magnetic resonance imaging (fMRI), Maurizio Corbetta and colleagues, at Washington University School of Medicine, St Louis, MO, USA, scanned 'neglect' patients

- **immediately after a stroke**
- **when these patients were impaired in detecting targets on their left side**
- **several months later, when the patients were much better at the task.**

They found that an undamaged brain area in the right hemisphere - the dorsal parietal cortex - did not activate at all in the first scan, but did activate strongly later, when the patients' performance improved. This area is normally involved in shifting attention, and is connected to the temporo-parietal junction and prefrontal cortex, areas that are damaged in spatial neglect.

Their results suggest that behavioural deficits might result not from actual damage to a brain area, but from alterations in activity in brain areas connected to the damaged region.

HIV thins the brain

Almost 40% of HIV/Aids patients have neurological symptoms. A study by Dr Paul Thompson, of the University of California, Los Angeles, and colleagues at the University of Pittsburgh (*Proceedings of the National Academy of Sciences*) has demonstrated that the brains of participating AIDS patients were 10-15% thinner than those of healthy people. The team suggest that the use of 3-D MRI scanning might help to identify early changes in neurologically asymptomatic patients with HIV who might benefit most from neuroprotective agents.

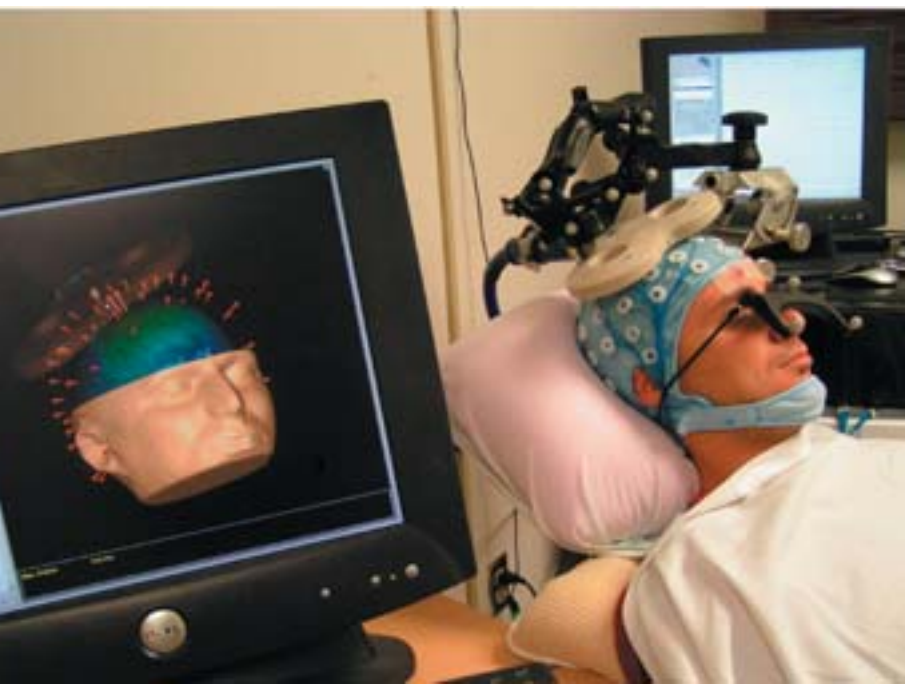
According to studies, at least two in five HIV/AIDS victims suffer cognitive impairments, ranging from minor deficits to dementia, but the pattern of brain damage caused by the virus has not been fully understood.

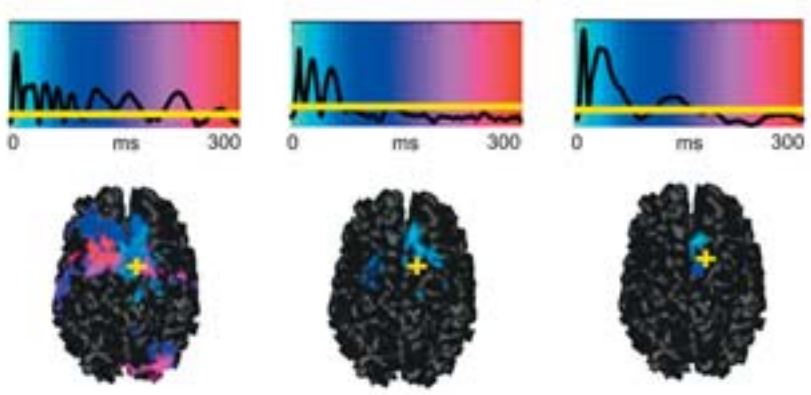
The brains of 26 AIDS patients were compared with those of 14 healthy people. The AIDS patients had 10-15% thinner brain regions, including the primary sensory, motor and pre-motor cortices, whether they took anti-HIV drugs or not. The thinned tissue, shown by brain mapping, correlated with the cognitive and motor deficits that the patients displayed in the many brain function tests use.

New navigated brain stimulation technique

Aiding consciousness research

By ***Marcello Massimini*** MD, PhD, of the Department of Psychiatry, University of Wisconsin, Madison, USA





We know that the presence and the anatomical integrity of the thalamo-cortical system are critical for consciousness to emerge. However, our everyday experience also suggests that consciousness is something that can come and go, grow and shrink, and that it depends strictly on the way our brain is functioning. Indeed, everyone is familiar with the impression of nothingness that we experience upon awakening from dreamless sleep - the sense that we were not even there, nor, as far as we are concerned, was the entire universe. Interestingly, even during the deepest stages of sleep when our conscious experience is extinguished, our brain does not shut down and the thalamo-cortical system remains very active. So, what is the fundamental ability that the brain looses when consciousness fades?

In designing an experiment that could address this question we were guided by a theory, the *information integration theory of consciousness*, recently formulated by Professor Giulio Tononi, at the Department of Psychiatry, University of Wisconsin. According to this theory, what matters for consciousness is the ability of the brain to integrate information, which, in fact, depends on the ability of the different areas of the thalamo-cortical system to effectively talk to each other.

Testing this hypothesis with an experiment was not easy, because we needed to find a way to 'knock' directly on one cortical area and record how this area then communicates with the rest of the brain. Adding to our difficulties, we needed to do this while subjects were falling from wakefulness into sleep. Our solution was to use a new Navigated Brain Stimulation (NBS) technique produced in Finland by *Nexstim Ltd* (www.nexstim.com) that combines transcranial magnetic stimulation (TMS) and high-resolution electroencephalography (hr-EEG). TMS allows stimulating the human cerebral cortex, directly and non-invasively, while hr-EEG enables the recording of how the entire brain responds to that stimulation.

The results were very clear. During wakefulness the activation of one cortical area was promptly transmitted to other connected areas in the thalamo-cortical system and echoed in these brain regions for a long time. As soon as the subject entered sleep, the initial activation, although very strong, remained localized to the stimulated area and died away rapidly. Thus, during sleep, different elements that make up the thalamo-cortical network became isolated and unable to exchange information. This change may be the key difference between the awake, conscious brain and the sleeping, less conscious brain. Similar changes, more subtle or more pronounced, might also occur in some pathological conditions such as schizophrenia, dementia or in comatose patients, as well as in subjects under the effect of anaesthetics. Thus, the ability to measure directly in humans the degree to which cortical areas can talk to each other when consciousness is affected can be important in clinical neurology and psychiatry.

Co-authors: F Ferrarelli; R Huber; S Esser; H Singh; G Tononi

Imaging for war zones

CR equipment is mobile and ready to move

From left: Dorian Cook, National Sales Manager Ferrania LifeImaging, with Surgeon Commander Peter Buxton, Squadron Leader Martin Coleman and Captain Catriona Eaton

Ferrania Imaging Technologies is supplying the British Army with computed radiography (CR) equipment for use in Basra, Iraq.

Two LifeInVision CR systems, along with two LifeJet printers, two mega pixel monitors, especially rugged laptops, and robust Hardigg cases in which to transport all the equipment.

One system is installed at the Royal Naval Hospital, Haslar, and the other is in use at the forward field medical centre in Basra.

According to Ferrania, this system represents a big step forward and offers massive benefits for the army's medical teams, particularly in the field. 'Previously, they had been using traditional X-ray technology, with all the inherent problems of transporting the necessary chemicals and equipment, not to mention the difficulty of keeping chemicals stable in the heat of Iraq and the limited space in which to store all the materials and equipment. By contrast Ferrania's LifeInVision CR system with its laser scanning ability, erasable phosphor plates and advanced image management software, offers complete, flexible and multi-purpose imaging solutions. The unit can quickly and easily produce high quality images of any body part. Images can be stored for convenience on CDs or even memory sticks for simplicity and mobility.'

In addition, the firm points out that the whole system is fully portable, a valuable feature in a busy, space-limited environment. Details: www.ferraniait.com

ELECTROMEDICAL DEVICES

PUBLISHED BY
EUROPEAN HOSPITAL

STATE-OF-THE-ART ELECTROMEDICAL MANUFACTURING

German engineering has a valued history, which continues and ever advances. Today, the importance of the ***Made in Germany*** stamp on electromedical technology is underlined by the combined annual turnover of €3 billion - two thirds derived from exports - of companies associated with the *German ZVEI Association for Electromedical Technology*

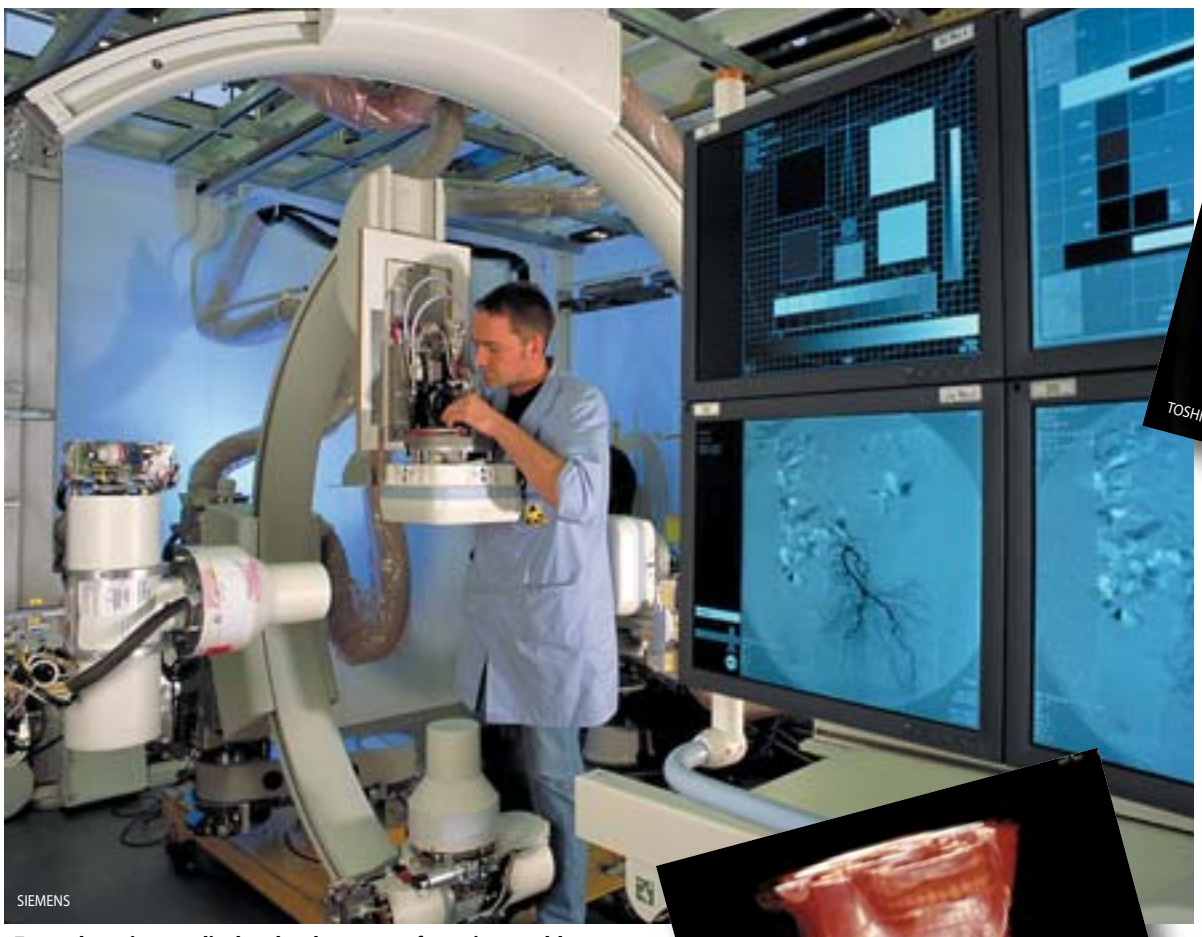
Valued worldwide

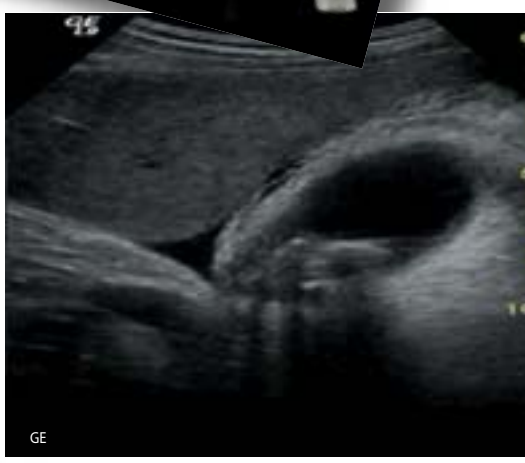
Setting a high standard of technical reliability, the country's electromedical manufacturers continue to provide solutions that optimise and accelerate medical care in hospitals and surgeries. The equipment is used in preventive medical care; for precise diagnosis via state-of-the-art imaging systems; to monitor patients and support life-saving organ functions.

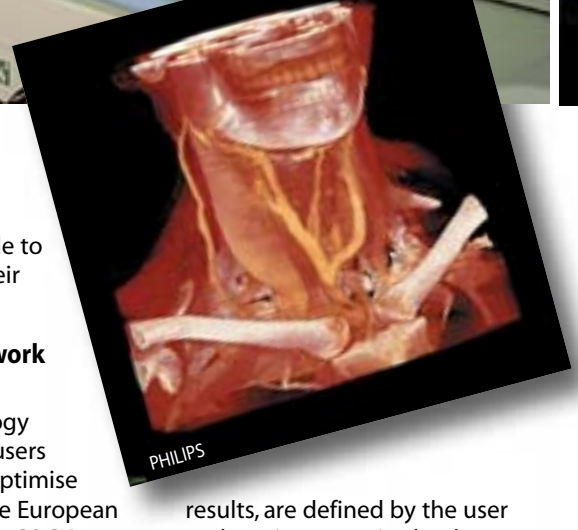
In addition, the country's information technology (IT) regulates the entire patient-oriented chain of processes. From initial examination and electronic prescription, to hospital admission-treatment-discharge, and any aftercare and rehabilitation - networked software can ensure a seamless exchange of information to improve workflow, as well as produce a complete electronic patient file, archived centrally. This, combined with the hospital information system (HIS), in the future could enable automated therapy recommendations (e.g. contra-indications), as well as therapy monitoring and control due to an improved identification of false alarms.

In addition, manufacturers' access to hardware, for 'remote device service and diagnosis' means there is not only direct online support for medical technicians, but fewer onsite visits and therefore lower operating costs.

In IT there have also been innovations in patient and user security.







Ever advancing medical technology manufacturing enables doctors to delve deeper into the body's innermost secrets

Improved imaging and therapies

The World Health Organisation (WHO) has reported that quality ensured mammography screening could achieve a reduction in mortality of up to 35%. Consequently, many EU representatives and European doctors have argued the case for quality-ensured mammography screening according to European guidelines. This could be greatly improved by using digital rather than analogue mammography systems.

CT scans enable very precise, diagnostic insights into the morphology of the body. However, if a tumour is detected, generally it is impossible to tell whether the lesion is benign or malignant. Positron emissions tomography (PET) scanners present that differentiation.

Deposits in arteries can lead to constrictions, or complete blockages. This can be alleviated in a minimally invasive procedure, using a balloon catheter and fitting a stent.

Three-dimensional (3-D) images of coronary vessels, provided by modern angiography equipment, show the position, size and angles of constrictions or calcifications of coronaries with great accuracy.

These are just a few examples of medical developments that can now improve patient care. They enable more effective and efficient healthcare, and are available now. However, only the healthcare services themselves can decide to take advantage of their development.

Industry and users work together

The medical technology industry and its end users have taken steps to optimise processes through the European umbrella organisation COCIR - and, in Germany, via the ZVEI Association. Doctors and medical companies have also united in the *Integrating the Healthcare Enterprise* (IHE) to solve the problems of interoperability of primary systems. Clinical processes, such as a request for diagnosis and transmission of the results, are defined by the user and put into practice by the industry, an initiative that has produced such success that it has been copied across Europe. Clinical departments, e.g. cardiology and the laboratory, are already integrated and, in the future, this will extend, for example, to pathology and surgery.

** The **German ZVEI Association for Electromedical Technology** represents about 100 companies that produce 90% of the country's imaging and other electromedical equipment.*

Apart from political lobbying in the interest of this high-tech field, the Association also co-ordinates the exchange of information and experience in all relevant business areas. Information regarding market developments during the last few years can be accessed at: www.zvei.org/medtech (Branchen-information).

*The association also represents members at a European and international level through active involvement in the European umbrella organisation **COCIR** (www.cocir.org), which, among other activities, focuses on European legislation originating in Brussels. COCIR also tackles topics such as the EU-recognised licensing procedure for medical technology products in relation to partner associations in North America and Asia.*

The world's medical electronics market is worth around Euros 40 billion (2004)

MARKET LEADERS

1 USA 2 JAPAN 3 GERMANY

GERMANY

Imports	**€2.45 billion**
Exports	**€5.22 billion**

Export markets	
Europe	43%
USA/America	34%
Asia	20%
Africa	2%
Australia	1%

Share of export turnover	
1980	47%
2004	62%

In 2003, German public healthcare expenditure was euros 136.2 billion.The country has 82 million inhabitants and 37 million employees. Of these, four million work in healthcare (11 %).

MEDICAL ELECTRONICS TURNOVER

Total: Euros 1.2 billon (1,121) - two-thirds for diagnostic imaging equipment

In euros	2004	1999*	changes
Imaging equipment	438	521	- 16 %
Medical electronics	294	338	- 13 %
Ultrasound	263	244	+ 8 %
Nuclear	17	22	- 23 %
Miscellaneous	109	103	+ 6 %
Total	**1121**	**1228**	**- 8.7 %**

Turnover share for imaging systems (2004)

Ultrasound	42%
MRT	20%
CT	16%
Angiography	9%
X-Ray	7%
Nuclear	4%
Fluoroscopy	2%

Total MRT systems worldwide (2002) 25,210
Installations per million population

Japan	42	
USA/Canada	39	
Germany	19	*(plus 42 % since 2000)*
UK	8	

Total CT systems worldwide (2002) 41,000
Installations per 1 million inhabitants

Japan	87	
USA/Canada	32	
Germany	30	*(plus 15 % since 2000)*
UK	8	

Ultrasound (sonography) systems used in Germany: about 40,000
Average age of the country's medical electronic systems

	2001	1998
Over 10 years	34 %	51 %
6-10 years	43 %	21 %
Up to 5 years	23 %	28 %

Data source: ZVEI, 6/2005

CONTRAST AGENT INJECTORS

NEW

Save time! Don't change media containers

In 1982, ***ulrich medical*** - a 3rd generation family concern based in Ulm - presented the first contrast agent injector for CT examinations. Twenty years on, ulrich not only offers a high-end portfolio of contrast agent injectors - many installed on the fastest MSCTs - but it also has a highly active international distribution network.

'Unlike common syringe injectors,' ulrich explains, 'all our injectors are based on the special roll pump system. Pre-loading syringes is not necessary because injection is made directly from the media container, a feature that allows big storage bottles to be mounted. So several injections can be made consecutively without loading or decanting media. This comfortable handling contributes to a high patient turnover, as well as the saving of time and costs for disposables. In addition to the economic performance and consumption, the construction principle of a roll pump system reliably ensures the hygienic safety for multi-dosing.'

In addition to its CT injector ***ohio tandem***, the company has now developed the ***ohio M***, to also provide the tandem function for MRI examinations. This means two different contrast agents can be chosen without a time-consuming change of media containers. 'Because two of the three media accesses can be equipped with different contrast agents, the optimal contrast medium, plus NaCl for each patient or examination, can be chosen without re-organising the daily workflow,' ulrich points out.

CANopen technology

Medtron AG, which designs and markets high-performance contrast agent injectors for use in CT, MRI and angiography, constantly aims to meet the demands of the latest scanner generations and advancing medical requirements, along with patient comfort and cost effectiveness. 'Injection systems for simultaneous or sequential injection of contrast agent and saline solution, meets those demands,' Medtron points out. 'We recognised at an early stage the chances of CANopen technology and were the first to support an interface based on this standard.'

Based in Saarbrücken, Medtron has qualified partners in many countries who distribute and maintain the firm's devices and corresponding disposables - e.g. syringes, automatic filling kits or specially designed customer solutions.

CONTRAST at the right time – at the right place

Mammography

Greater control plus comfort

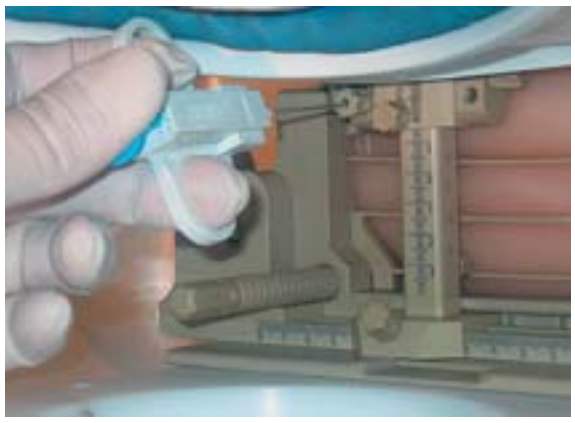
Immobilisation of the female breast for diagnostic examination and biopsy is one of the prime foci of the Noras Company. In 1996 the predecessor of the firm's well-known MR-BI 160 Biopsy Unit was submitted for a patent; today over 500 of these are at work worldwide.

Based on resulting clinical experience, this unit and other products have been further developed: the MR-BI 160 PA Unit consists of a padded patient support table and a variation of the ***MR-BI 160 Unit***. Using this version, imaging can be carried out with the spine coil and/or other coils of an existing system, for example.

The device immobilises the breast under examination and provides needle guidance during a biopsy. Immobilisation is realised by the compression unit, which can be rotated by 360° parallel to the frontal plane for optimum accessibility to the lesion. Noras also points out that a further development of the well-known ***PE 162 Positioning Unit*** is used for needle guidance and offers access to areas close to the axillary region (chest wall).

System independence, simple assembly and disassembly and easy cleaning (the system is 100% plastic), plus comfortable patient bedding, are among the unit's many other advantages. Additionally, the components of the biopsy unit are made of Peek and can be reused after disinfection/sterilisation.

** A special Noras adapter permits use with the Vacora Vacuum Biopsy System of the C R Bard Company.*



The tabletop film processor

NEW

Ecomax - a brand new plug and play system for analogue X-ray film processing - is being launched at the RSNA by the Oberstenfeld-based company ***Protec Medizintechnik GmbH & Co. KG***. The firm reports that this concept of mounting all components that substantially influence image quality (e.g. pumps, heaters, guide bars, rollers etc.) has resulted in:

- optimised image quality due to a brand new tank design
- reduction of wasted chemicals due to oxidation, because of smaller tank sizes (environment-friendly and money-saving for consumables)
- less required space, due to the more compact overall processor design
- easier access to components that require regular maintenance saves time and reduces maintenance costs
- preset, optimal parameters ensure consistent good results.

To be marketed early next year, Protec adds: 'Ecomax convinces with its simplicity, its design and the image quality it produces.'

Protec entered the X-ray film processing market in 1984, then, in 2001, in order to play a major role in digital growth, the firm set up ***Protec medical information systems***. Today the company has a worldwide dealer network of dealers that sell its products in almost 100 countries, accounting for an export share of over 90%.

Mobile patient positioning table with quick-change battery

The bucky table is an inexpensive tool for X-Ray departments. However, due to the increasing use of movable stands, especially combined with digital imaging receptors, further requirements for a patient positioning table arise. Along with tabletop movements in XYZ directions, to optimise the advantages of movable stands, table movement is desirable with a patient in the room. To this end, ***Provotec GmbH & Co. KG***, based in Espelkamp, has developed the ***Prognost XPE*** - a mobile patient positioning table with motorised elevating and floating tabletop that allows variable patient positioning as well as the optimal use of modern X-ray tube/image receptor combinations.

Not having a line cable makes the ***Prognost XPE - Akku*** particularly comfortable, Provotec also points out. 'A rechargeable battery (accu) supplies sufficient energy for moving approximately 120 patients up to desired working heights. While one accu supplies energy to the table, another is loaded in the loading station. This is very user-friendly, because the accus can be changed simply, quickly and without a tool. Even if charge signals are overlooked and the accu is "suddenly" empty, changing it takes only seconds. The loaded accu can be removed with one hand from the loading station and replaced in the Prognost XPE - Akku against the empty one.'

New diagnostic software

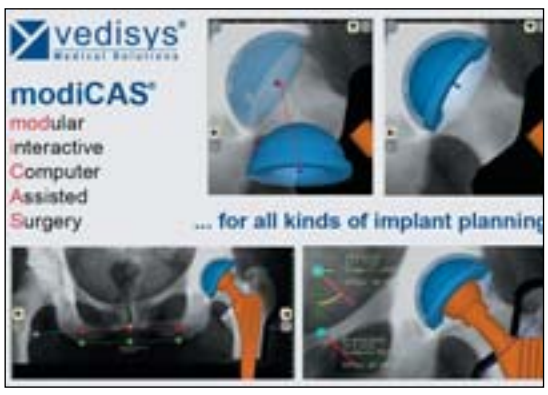
Making a second appearance at the RSNA, ***Medos AG***, of Langenselboldis, is demonstrating MD-Jade 2, its radiology diagnostic workstation, and the new Software MD-Jade 2. Developed by MeVis Diagnostics GmbH & Co KG, as a joint venture, the system's core - a '***Task-focused Diagnostic System - ADS***' - has been put onto a completely new technological foundation, Medos reports. 'By means of the incremental pre-processing of the new ADS, the advantages of pre-processing are used to full capacity, leading to a significant acceleration of data transfer and interaction, particularly with large data sets, while remaining flexible in dealing with newly incoming series.'

Established in 1978, to design and develop medical information systems, by 1984 around 200 of this firm's systems were installed in university hospitals, general hospitals and large radiological practices. In 1998, the firm introduced its multi-media electronic patient documentation, which enables data supply from external IT-Systems via secure web technology. Following the first installation of its PACS, in 1999/2000, this system also became widely used in large university and general hospitals, as well as large radiological practices.

With several regional centres in Germany, as well as a subsidiary in Denmark, in May this year Medos, as part of Sweden's Ortivus Group, was listed on the Stockholm stock exchange.

Integrating imaging and management systems

Enjoying its specialist role in the integration and tailoring of imaging and management systems specifically for hospitals, private clinics and practices, ***Vedisys Medical Solutions*** explains: 'We provide much better communication - internally and externally - in other words ***Direct image access at any place, any time, instead of manual transport***, snail mail or even Taxi. A substantial part of our solution is a high performance, reliable and modern image management system that significantly reduces costs for X-ray films, chemical processes as well as all the archiving and distribution costs of films and patient records.'



By working on full integration within existing infrastructure (hard/software) Vedisys points out that customers can reduce their hardware investment to a minimum as well as '.... upgrade existing HIS or RIS systems with the features of a perfectly integrated image management system that works directly in the desired electronic patient record'. Optimal image and patient record distribution throughout a hospital, innovative web-technologies, and most secure archive solutions are framed with digital radiography and mammography systems, information and digital voice recording/recognition systems, as well as economic, high quality paper print solutions, the firm points out, adding: 'Vedisys stands for the best of breed products and solutions from one strong partner!'

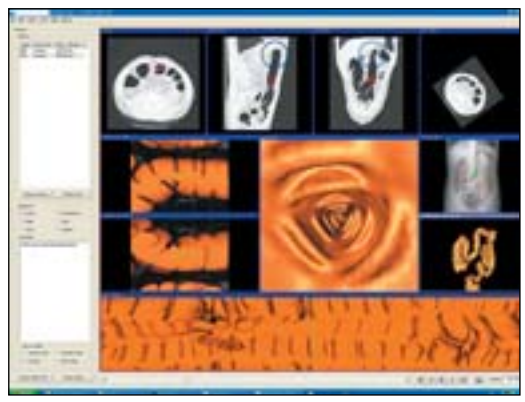
New in the firm's product line is a pre-operative planning system named **modiCAS** (modular interactive computer assisted surgery) for implant planning. Unlike many systems on the market, this is not only 2-D, but also utilises 3-D CAD implant data from various vendors which, the firm explains, enables far more precise planning and documentation of implant surgery.

Based in Griesheim, near Frankfurt, the firm provides a team of software developers, service engineers and a sales force for direct consultation, integration and maintenance.

Full automation accelerates uptake of virtual colonoscopy

Although 3-D rendering of the colon eliminates invasive endoscopic probing and thus potential perforation, the adoption of virtual colonoscopy by physicians has been slow - mainly because using the software proved too time-consuming. A fully automated system promises to remove that problem.

Developed by a team of computer scientists in co-operation with radiologists at the Clinical Radiology Institute of LMU (Klinikum Grosshadern), *Rendoscopy Gentle Colon* is intuitive software that accelerates visualisation of the whole colonic mucosa.'The entire 3-D-Post-Processing is fully automated, without any need for interaction by a doctor or assistant,' the Rendoscopy team explains.'This applies to the Multi-pathfinding as well as to endoscopic image generation and the view behind-the-folds-images'.



The colon mucosa is examined using an ultra low dose technique, so the mucosa assessment is in no way restricted. In addition to a virtual intra-luminal view, this provides a view behind the folds. (Splitting the colon provides it without distortion, whereas flattening the colon leads to artefacts). Consequently 'blind areas' can now be assessed.

The Multipath Tracking System finds each path in the 3-D dataset without manual interaction. If the gas-filled colon is blocked by fluid or a collapsed colon part, the part of the colon before and behind the collapsed part can still be examined. After scanning, axial slices are automatically transferred to the Rendoscopy workstation and surface calculation of the colonic mucosa and splitting of the colon along the track also occur automatically. Full cross-sectional imaging data (MPR and oblique use) is updated as tracking continues.

Rendoscopy 3-D imaging algorithms create surfaces with practically no partial volume effect, so images have a far higher technical contrast resolution than 2-D axial cuts. The 1 Voxel spatial resolution (0.3 mm) on 3-D surfaces provides the physician with a very powerful zoom view on the colon mucosa.

A physician can choose to make an interactive examination, or to assess images in paper or electronic form (e.g. PACS assessment console, intranet or CD-Rom).

The software utilises DICOM data from advanced multislice CT scanners, such as those made by GE, Toshiba, Siemens, Philips and Hitachi. Rendoscopy's documentation operates smoothly with all common PACS systems, such as Agfa Impax, GE Centricity, Siemens Magic View, systems produced by Sectra, Philips, Kodak, Cedara, etc.

Added to these benefits, virtual colonoscopy means no sedation for patients. Obviously, all things considered, many gastroenterologists are calling for virtual colonoscopy to be recommended as a front line screening examination.

**The same intuitive solution from Rendoscopy exists for virtual bronchoscopy and traumatology*

PACS plus selenium technology

The medical information technology (IT) firm ***medigration company*** specialises in PACS picture archiving and communication systems (PACS) and provides, for example, customised and vendor independent small to mid-size solutions. Established in Erlangen six years ago, medigration's products include:

F: Radiography
- 1710 Radiographic units, digital

L: Film and Image Management
- 3380 PACS
- 3385 PACS components
- 3387 Paper print equipment
- 3395 Teleradiology

R: DICOM-Compliant Systems
- Data storage
- PACS

ImageBroker, medigration's main product is a complete system for digital short and long-term storage of all DICOM image objects with integrated image distribution via intranet. 'We also offer a DICOM review workstation (**ImageVision**) including 3-D as well as DICOM PaperPrint Server and CD-Imager,' the firm adds. 'Our newest innovation is a Direct Digital Radiography system that features ***Selenium*** technology - a fast, intuitive system ideal for all general radiographic examinations.'

Seamless enterprise-wide IT

Based in Karlsruhe, ***medavis GmbH*** has been developing system solutions for radiology since 1994. 'As a well-reputed and experienced supplier for radiology IT solutions, especially RIS and PACS, we cover the entire workflow of findings and of all related processes. Therefore we combine ease of use and efficiency with a seamless integration into enterprise wide IT structures - all over the world,' the firm says.

The ***medavis RIS*** - designed to manage all radiology data - exchanges information with systems from various manufacturers. To that end the firm uses HL7 and DICOM standards and provides modules that harmonise with and complement each other, and they also can be integrated independently of one another in existing structures.'We support our participation in the IHE Initiative not only with our compatible products but we are also a driving force in its design. We also regularly demonstrate our performance capability at every IHE Connectathon.'

The ***medavis PACS*** is known for its excellent integration into medavis RIS and its high speed, the firm points out. 'Due to its flexible interfaces it can be easily integrated into an existing system infrastructure. The modular structure and modern distributed system architecture enable free scaling and configuration according to individual requirements.'

History, images and report dictation

all-in-one workstation

Great Britain - Hereford's County Hospital is the country's first to upgrade to a fully operational Kodak RIS/PACS platform that can extend beyond the hospital into the wider community. 'The system went live in June and, said Malcolm Williams, Radiology IT Manager for the hospital, it is now a 'roaring success as a functioning clinical platform connected to all modalities'. The hospital's previous Kodak System 4 PACS worked well, he added, explaining the hospital's progression to the latest System 5 with RIS when it became available. To ensure a smooth roll out, Kodak will continue to work with individual clinicians within the Hereford NHS Trust as the new system integrates fully into their workflow. So far, users are said to find it very intuitive, and more user friendly, and they add: 'The manipulation tools for diagnostic reading are excellent.'

Designed to increase radiologists' reporting efficiency, the system avoids the need to access separate ones. Previously, a radiologist had to access patient demographic details and history on RIS, images on PACS, then dictate a report into a third system. Now the whole process is launched instantly and simultaneously, with everything displayed at one workstation.

The hospital now intends to incorporate Philips SpeechMagic voice recognition. The implementation of the Kodak RIS 2010 web module, interfaced to patient demographics and the PACS is also proving a huge advantage for clinicians requesting reports. The new RIS can accommodate paper based, paper light (scanning requests) and electronic requesting. The RIS 2010 web module has provided users outside radiology with the ability to track a complete radiology episode, including image availability, preliminary dictation and final verified reports.

Next, the hospital intends to widen access to the community by distributing patient booking, appointment details, images and clinical reports to referring physicians and General Practitioners within Primary Care Trusts.

Cancer scanners may not solve problems

UK - Despite the announcement of a £20 million investment in high-tech scanners, which could double the seven positron emission tomography (PET) scanners used in the country's National Health System (NHS) in England. However, it is not clear how many new scanners this budget will buy because there has been no decision, as yet, about what proportion of fixed and mobile scanners will be ordered and where they will be based.

With predictions that the demand for scans will quadruple by 2008, cancer charities say even more scanners will be needed. At the Macmillan Cancer Relief organisation, its CEO, Peter Cardy, speaking for several cancer charities, said that, whilst the new funding was welcome, it would not go far enough. 'The UK lags behind the rest of Europe and the US in the provision of PET,' he pointed out, adding that the NHS currently needs at least 15 scanners to meet the needs of cancer patients. In certain areas of the country, because of the distance to the few scanners, patients are often not even referred for scanning.

Although there was reassurance from the present Health Minister, Rosie Winterton (Labour) that the NHS Cancer Plan (providing more investment and staff) is reducing cancer deaths, the Shadow Health Secretary Andrew Lansley (Conservative) pointed out that, due to tight hospital budgets, they might have to struggle to use the scanners they receive.

Although Europe has many female paediatric and gastrointestinal radiologists, few women become interventional radiologists. ***Professor Malgorzata Szczerbo-Trojanowska*** is among that minority. When the former ECR President Professor Helen Carty retired from the congress, Prof. Szczerbo-Trojanowska became the only female Member of the Board of the European Congress of Radiology. Daniela Zimmermann, Executive Director of European Hospital journal, asked the professor about her choice of career and future prospects for women in this field

Member of the Board of the ECR Professor Malgorzata Szczerbo-Trojanowska, is Chairman of the Department of Radiology and Head of the Department of Interventional Radiology, at the University Medical School, in Lublin, Poland. The professor has carried out research in Italy, the UK, Sweden and Germany and is a member of many Polish radiological organisations, as well as the Cardiovascular and Interventional Radiological Society of Europe and the International College of Angiology. 172 of her papers, and 11 monographs, have been published in scientific journals

Women in Radiology

Women radiologists are not rare in Poland, Professor Szczerbo-Trojanowska explained. 'They became interested in the field many years ago, when only X-ray machines were available. Due to the X-ray exposure, the job description stipulated shorter hours and two weeks extra holiday time. Today, given advances in equipment, and therefore reduced X-ray exposure, I expect, and hope for changes because, many radiologists who work those short hours opportunistically seek additional jobs elsewhere.'

Are women radiologists well accepted by male counterparts in Poland, or are they perceived as a potential threat?

'Those who achieve a high standard in their practice or performance are fully accepted. They are so very much involved in the profession that they don't want to compete with the men, or take their places. However, there are quite a number of women in leading positions - as heads of departments and chairs of societies,' she pointed out, adding: 'However only few women chose interventional radiology. Being an interventional radiologist, is hard work. You have to stay in the operating theatre or cath-lab for many hours, wearing heavy aprons, mask and cap. So it is a stressful, hard job.'

For a year before becoming the only woman ECR Board Member, she had enjoyed the presence of the former ECR President Professor Helen Carty. 'Professor Carty's professionalism was so high that there wasn't a single problem that could arise because she's a woman. If you want to compete with a man you must be a good radiologist and an open minded, tolerant person. Professor Carty has such a great personality that she managed the Board and complex European issues smoothly. I really admired the way she ran the ECR Board as its chairman. She was very diplomatic, and absolutely excellent. It's probably something I could not achieve. She had another advantage: we use the English language for discussions. If that's your mother tongue you can be very precise and sometimes when things are very difficult you need a lot of diplomacy to find the right word to express thoughts, or a way to argue with someone, so as not to offend him. Professor Carty had a very delicate way of convincing opponents. Also, I think women generally are more tender, cautious, delicate and diplomatic than men. Along with diplomacy they pay more attention to details, because excellency is made of small details. Men will often go straight forward, not caring about particulars. This may lead to failures,' she pointed out.

Does Professor Szczerbo-Trojanowska want to become ECR President?

'Ambitions always run high. We say: If you go step by step then you gain an appetite. But you should develop a way of waiting and looking and talking to people and to make your way slowly. Some individuals are driven by too high ambitions, I favour modesty and criticism in modulation of ambitions. I am convinced that success of ECR should come before ambitions of an individual. Quite early on, in Poland, I became head of a department, and then quite soon took a chair of radiology at the university where I work. Then I had the great honour and pleasure to be the first woman to become president of the Polish Radiological Society, It all happened in a natural way. I suppose I did not compete with the men, but I was simply promoted higher and higher step by step. I gained experience in being in a society, working first on a Board, then in various sections, then becoming chairman of small sections, and so on. And I had a few new ideas. I had observed my society for many years and thought it is time to change many things - the statutes, for example - which a lot of people actually wanted, because my election occurred along with the political and economic changes in Poland. Traditionally, the presidents served two terms up to 6 years, so a society did not develop as quickly as it should. The first year is for running in, the second you have to do something, but then, if you are to be routinely re-elected, you think there's no need to make a big effort. So I introduced changes; one was to have no re-election. The president has one term and knows that it is the only period he or she can contribute to the society, introduce new ideas. Then someone else takes over.

'I succeeded with most of my ideas. We changed a lot of paragraphs in our statutes. I convinced most of the Board Members that it was a good way to change a society. For example, we changed our journal, quickly. In one year an old-fashioned journal became a very modern one. We also radically changed our education system, radiology specialisation and examination. So, in a short time, many things occurred that convinced people that this was a good direction in which to proceed. I was not forcing the changes - I had the feeling that almost 100 percent of the board wanted and supported changes, and everyone came up with their own ideas. It was time to become up-to-date.'

The ECR is of course very different from a national society. It deals with radiologists in the diverse countries of Europe. 'For many years, especially before we changed our system, we knew that countries such as Poland and Hungary could not have adequate presence in European radiology, due to politics and economics. Europe was divided,' the professor observed. 'Since most countries are now joined in one Europe I thought it would be easier for radiologist from Eastern countries to appear on the scene, but I thought this process would be quicker. At the ECR there are not enough moderators of sessions or members of sub-committees from East European countries; most are from Western Europe. I've had lots of discussions with presidents and Board Members about this, and was told that nominations come from sub-committees and sub-specialisation societies. Obviously for years scientists from Western countries were well known. But when I looked at statistics I found that for example the number of abstracts accepted from Poland ranked in the first ten countries with highest contribution,

Radiologist Professor Malgorzata Szczerbo-Trojanowska (left) in discussion with Daniela Zimmermann

but it did not correspond with the involvement as moderators or sub-committee members.

As a member of the Board I feel it is my responsibility to stress existence and potential of Central and East European radiology. I am convinced that their increased involvement will strengthen ECR.

Asked whether radiologists in Poland must become more management oriented as in other EU countries, the professor explained that the healthcare system has not changed that much in her country in the last few years. 'We have a domination of the national health care. Private services are growing but still very limited. Private insurance is planned for the future. Procedures in my department are paid via national healthcare insurance, and their number is strictly limited. You may have limit of a hundred procedures a month, but there are 150 to do. That's a problem. It can be dramatic, because I must decide whether to do a certain procedure for a patient immediately or place him on a waiting list. This is a very uncomfortable situation.'

Has she ever considered a political career?

'Definitely not! However my position in the Polish Society was in a way political. We had meetings in the Ministry of Health, and that's how we tried to improve radiological services. We wrote a lot of letters and reports on current situation. We were pointing to the necessity of establishing standards of radiology in various departments, in big and small cities.

The professor points out to the Health Minister many of the standards and ideas operating in European countries. 'I say: "Have a look. We should follow those well functioning solutions". These are the arguments used, she said. 'However, up to now, the consequences are not satisfactory. But if we make at least some steps in the right direction, progress will come. In ten years we could not reach the same level of solutions as Western Europe. We not only needed to change the system of politics and economics, but also people's mentality, because fifty years in Eastern Block covers more than one generation. So it will take time, but it will come.'

What does she consider the most exciting radiological development today?

'Molecular imaging, because present imaging reached anatomical and morphological accuracy close to that of anatomy lab. It means that again radiology will go beyond typically diagnostic imaging of organs to cellular and functional imaging, having a major impact on medicine in future. Radiology will again push the development of treatment. We did not expect this years ago.

'Interventional radiology, introduced by vascular radiologists, promoted radiology into treatment. We can now offer attractive alternatives to surgical interventions and completely new therapeutic solutions. I think radiology is at the moment one of the most exciting specialities.'

Finally, we asked why the professor had chosen this field, since initially she had hoped to become a surgeon, because her father was one. 'When I married a neurosurgeon the thought of one more surgeon in the family led me elsewhere,' she replied. Inspired by a tutor who had a vision that interventional radiology would flourish in the future, the professor said she realised this field was a little akin to surgery and felt she had found the right compromise. I also felt I would have more contact with patients than other radiologists.'

In 1970, at Lublin's Medical University, she qualified with distinction as a physician, and in 1976 gained her PhD and became a Board Certified specialist in diagnostic radiology. In 1977 she became an assistant professor at the Department of Interventional Radiology, University Hospital Lublin.

How did her father react to her work?

'When I told him in early seventies that it is better to do a percutaneous nephrostomy rather than an open nephrostomy, he asked: How could you puncture a renal pelvis through the kidney, just percutaneously, just under fluoroscopy? You should open it, he said, you should take a look. Then he said: Try it! He was very impressed when we did the first nephrostomy and it worked.

Now aged 58 years, the professor reflected: 'My father and husband have always been supportive, because, as a radiologist I provided diagnoses to neurosurgeons - and now we even co-operate closely, because I treat patients with vascular lesions of the brain, such as aneurysms, AVM's, percutaneously, doing embolisations. So the number of the patients who have open surgery to clip an aneurysm is decreasing, but we can propose the best treatment option for each patient.'

Does her intensive work plus society and political involvements encroach on her family life?

'It's impossible for a doctor to close the hospital door and stop thinking about patients. There are many difficult cases to think about every day, day and night,' Professor Szczerbo-Trojanowska observed. 'However, being a family of two doctors makes it easier to understand each other and easier to accept that a telephone call in the night means one of them has to leave home to treat an urgent case. It has also been accepted by my two sons.'

Telemedical co-operations

Italy • Spain • Denmark • Belgium

When Claudio Dario, the CEO of Treviso Healthcare Structure, decided to take his hospital departments into the 21st century by experimenting with telemedicine applications he brought about huge improvements for providers and users alike.

In 2003, *Escape,* the first telemedical project - later extended and renamed TelemedEscape - was up and running in Treviso Healthcare Structure, and it has since been adopted by other Italian healthcare divisions in other regions to provide a service for three million potential users.

This completely digital system of signing, transmitting, delivering and storing clinical documents, maintaining the privacy and the security of healthcare data, brings big healthcare delivery advantages, including the fact that patients can read their results on the internet (35% of patients now download results) or by post (11% receive results directly at home).

Claudio Dario

The *Health Optimum Project* - Closely connected to TelemedEscape, this is interdisciplinary, with clinical partners from Italy's Veneto Region, Spain's Aragon Government, and Denmark's County of Funen, and with technological assistance and support provided by the Partners Telemedicina Rizzoli (Italy), and TB Solutions Technology Software S.L. (Spain), organisational assistance and support by PriceWaterhouseCoopers (Italy), and the Project Manager is Health Information Management (Belgium). It is approved and co-funded (budget € 2,200,000,00) by the European Community within the eTEN programme.

Health Optimum is validating the re-engineering of healthcare delivery via telemedicine - tele-counselling, tele-laboratory, virtual referral, tele-care and shared clinical data. It aims to re-organise processes, standardise clinical and technological procedures and manage patient documentation digitally.

A wide variety of specialties have been tested in this project, namely neurosurgical tele-counselling and tele-laboratory in Veneto, tele-diabetes, tele-cardiology in Funen and tele-haematology, tele-radiology, tele-oncology, tele-endocrinology, tele-nephrology, tele-cardiology and tele-laboratory in Aragon. At the root of these tele-counselling initiatives lies the need to provide prompt consultancy by specialists for urgent medical cases and also to provide services for citizens living in hard-to-reach, remote areas.

The Treviso Healthcare Structure

During a tele-consultation an emergency department specialist, using a digitally signed electronic request containing all necessary clinical data and images, asks a tertiary hospital specialist for an opinion, and that centre of excellence sends back a digitally signed opinion. An addition specialist in the circuit can also be consulted, for example one on duty in another tertiary hospital, or the Head of a Department who, through a remote connection, can view the data even from home.

For the Tele-laboratory applications a new generation of instruments allowing tests to be carried out onsite and to show the results immediately at the patient's side, make for a simplified workflow and cost reduction. The system is based on a palm-size device (POCT - Point of Care Testing), which interacts with a portable PC equipped with a specific software application. Test results collected on the spot can later be uploaded onto the hospital server for certification by the laboratory using a digital signature.

The clinical partners are presently working on field trials and collecting results. A preliminary market survey has been carried out and also a Business Plan has been drafted based on the ex-ante situation and with the results of the field trials, it is being constantly refined. A quality of care impact assessment is also underway to compare ex-ante and ex-post indicators.

Begun in May 2004, the Health Optimum project should be completed in January 2006, with an important final conference taking place in Palazzo Franchetti, Venice. There, internationally renowned telemedicine experts, present either physically or virtually, will participate in discussions, see the illustrations of H.O. applications and demonstrations of the telemedicine services.

A newly founded *Telemedicine Observatory* Consortium is to be launched at the event. Nineteen Veneto Healthcare Structures, covering a population of about 3.5 million people, voluntarily worked together to draw up its constitution. Among its aims is to share tele-medical know-how and to reproduce and adapt best practices to medical-legal organisational standards and international technological standards.

by ***Dr Eduardo de la Sota***

HEALTHCARE TECHNOLOGY UPTAKE

Spain - General information concerning the country's healthcare is held at the Instituto Nacional de Estadística (INE), a legally independent, administrative, autonomous institution assigned to the Ministry of Economy to regulate statistics activity (demographic and economic censuses, national accounts, demographic and social statistics, and other indicators). The healthcare information includes: Hospital Morbidity Survey, Hospital Indicators Statistics, Death statistics according to cause of death, Collegiate health professionals, survey on Disabilities, Impairments and Health Status, National Health Survey, Health and Sexual Habits Survey, In-patient healthcare institutions, Obligatory Notifiable Diseases and Other aspects related with health.

The Ministry of Health, via the Institute of Health Information, provides information on Health Statistics, Reports and compilations, Standardisation and Coding, Main Figures of the National Health System and Centres and Services of the National Health System (Health Centres, Hospitals, Blood Banks and Transfusion Centres).

Spanish Healthcare Registries - Imaz et al. (2005) from the Carlos III Health Institute, studied the Spanish Healthcare Registries within the 1997-2002 period. 107 healthcare registries were identified, most providing local or regional coverage (71%). Areas with the largest number of registries were related to death statistics (17%) and cancer (16%). 298 publications were retrieved, which analyse data produced by the registries, most of which study the frequency and distribution of the events recorded (58%) and, less frequently to conducting healthcare technology assessment studies (24%). Nonetheless, important areas without any records and improvement elements related to the use of healthcare registries for healthcare technology assessment were detected.

Internet use - A survey conducted by Lorenzo & Mira (2004) among 302 doctors in eight Spanish hospitals revealed that they consider the internet to be a tool that enhances the doctor-patient relationship. New technologies are accelerating the substitution of a paternalistic style by one in which a patient has access to more information and resources. There appears to be a favourable attitude towards seeking a second opinion through the internet, although not towards patient' chats'.

Sanz Arrufat et al. (2004), from Albacete, analysed 452 hospitals with 100 or more beds; 198 (43.8%) hospital web pages and 52 (11.52%) pharmacy department websites were found. The contents of pharmacy department sites were usually deficient. The authors think that telepharmacy, or pharmaceutical care for outpatients using novel information technologies, remains underdeveloped in Spanish pharmacy departments.

Telemedicine - Gonzalez & Castro (2005) from the University of Santiago, searched the Medline database for publications about telemedicine from 1966 to 2003. The first publication appeared in 1988 and publication output showed a sudden increase starting in 1995, reaching a maximum in 2002 with 21 publications. The mean impact factor of the journals in which the publications appeared was 0.961. Production of telemedicine publications in Spain has followed the same temporal course as observed worldwide. There is an unequal geographical and institutional distribution of publications. The highest production is concentrated in a few institutions and only a small number of authors show steady research activity.

Interestingly, the Bioengineering and Telemedicine Group (Technical University of Madrid), has developed a new model for care of chronically ill patients based on home care supported by remote monitoring technology and telemedicine. The monitored variables include non-invasive blood pressure, blood oxygen saturation, ECG, spirometry and respiratory rate. The telemedicine system includes a home-based patient unit and a management centre that received information from the home units. The chronic care management centre was installed in two hospitals, in Spain (Barcelona) and Belgium (Leuven). The promoters expect this to result in significant cost-savings and a better quality of care.

Healthcare Economic Information - The Catalan Agency for Health Technology Assessment and Research has described economic evaluation studies carried out in Spain and published during the last 20 years. 87 studies were included in the review. According to the methodology, the most frequently used technique was cost-effectiveness analysis. The authors observed that, in most cases, some weaknesses could be pointed out: absence of any objective directly linked to the decision-making process, a non-explicit perspective, no inclusion of indirect costs, or clinical and economical data not currently collected. They conclude that future research studies should improve methodology, increase the dissemination of results and use more sophisticated economic analysis techniques.

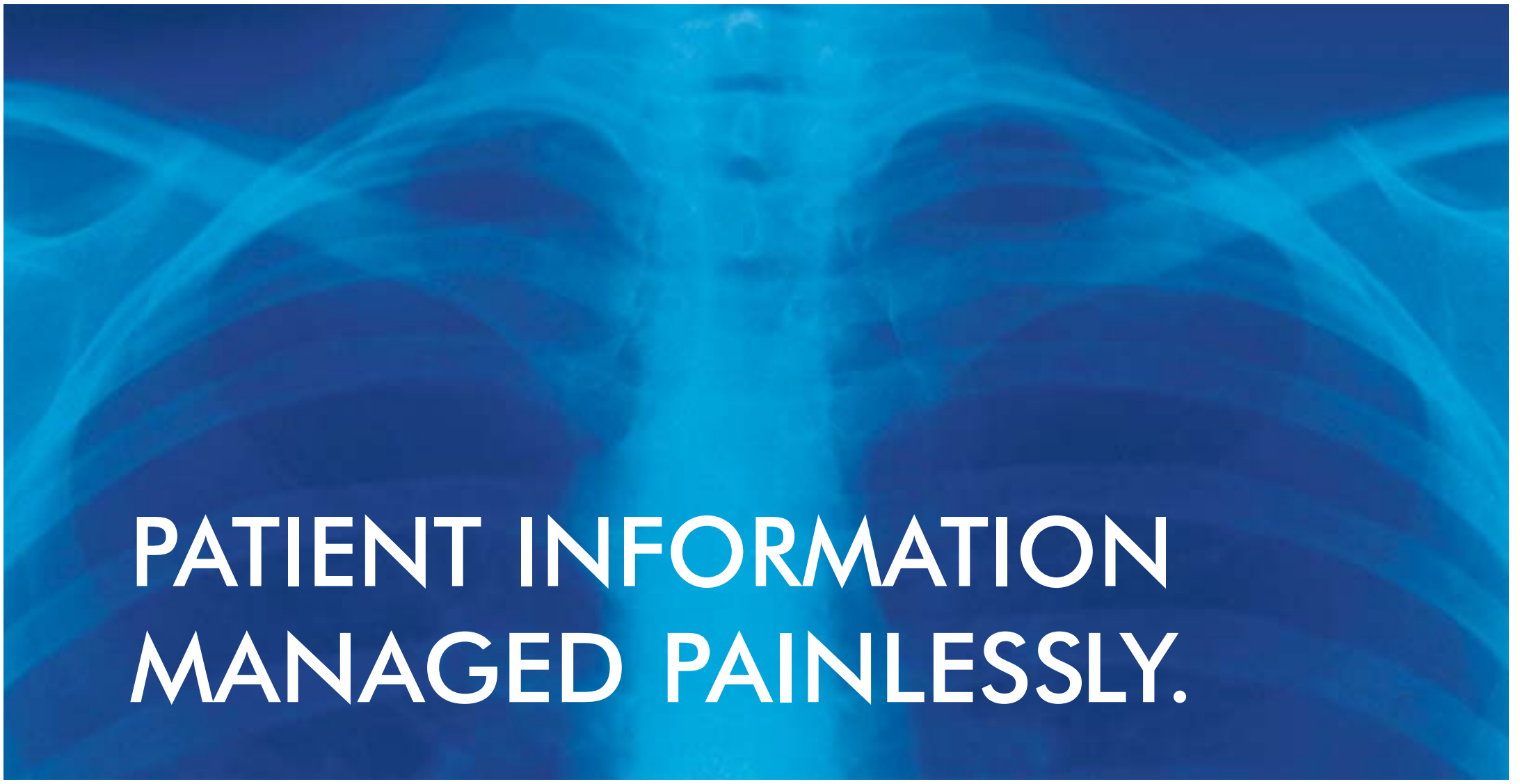
Llano et al. (2002) implemented a qualitative analysis of organisational innovations in Spanish public hospitals. They recovered the opinion of CEOs and physicians on the organisational innovations that affected more than one level of health management interventions, and found out that physicians showed increased interest in organisational innovations, while CEOs were ambivalent about their changing role and respective responsibilities. There appeared to be evidence of resistance to change, and probably innovations are needed in the style and characteristics of management structures (composition, functions and responsibilities).

UK's biggest single wireless network

The largest single wireless network, covering 7,000 users in eight hospitals, has been installed by the California-based firm Aruba Networks WLAN technology in the University College London Hospitals (UCLH) NHS Trust. The network has three Aruba 5000 mobility controllers and over 300 centrally managed access points.

Security - Aruba protects patient data by adopting a centralised multi-layered security strategy, whereby any user or device attempting to connect to a corporate system is authenticated and checked for potential threats before being allowed onto the UCLH network. Additionally, all encryption is implemented by a centralised hardware-accelerated encryption engine rather than in individual access points.

This development is in line with the NHS Trust's plan to become completely paperless in the next few years.



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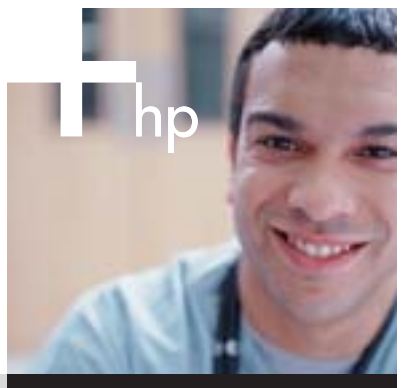

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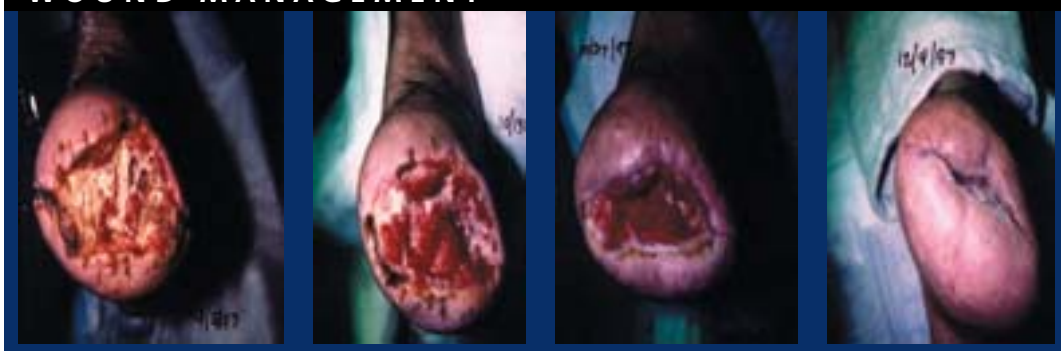
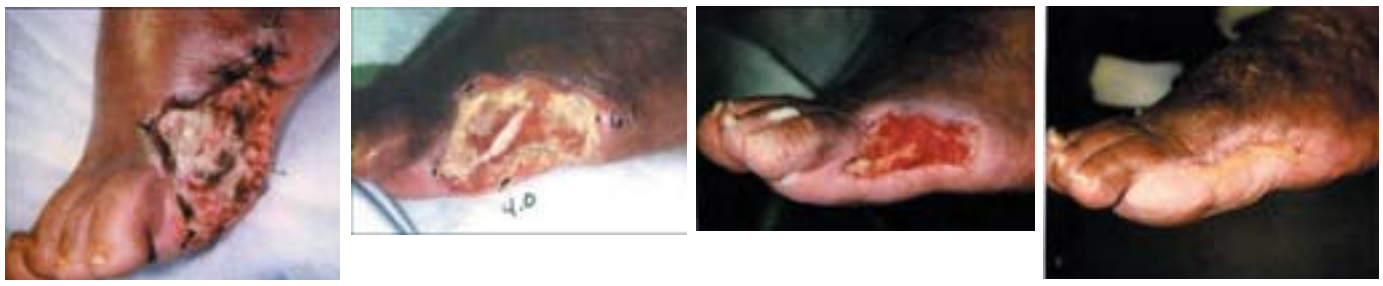


Left: A 57-year-old African American female, NIDDM with severe peripheral vascular disease and multiple Wagner grade III ulcerations on the distal foot, transmetatarsal amputation, subsequent referral for HBO when dehiscence and recurrent infection occurred. PtcO2 study revealed PO2 values below 20 mmHg on room air, PO2 values during HBO in 400s. Angiogram revealed diffuse, multilevel disease with no options for intervention. Closed with 32 HBO treatments and aggressive local wound care

Right: Latin-American male, aged 40 years, IDDM with renal transplant, s/p L 5th ray amputation with wound dehiscence, amputation for critical ischaemia, granulated after 20 HBO and 8 weeks of VAC therapy was closed, the final photo is on a late follow-up to show quality and durability of wound healing with HBO



Hyperbaric oxygen treatment

Rationale and effectiveness in the non-healing diabetic foot ulcer patient

In the chamber: patients wearing masks and hood tents

By ***Peter HJ Mueller*** and ***Robert A Warriner III***

Problem wounds represent a significant and growing challenge to our healthcare systems. The incidence and prevalence of these wounds are increasing in the population resulting in growing utilisation of healthcare resources and budgets expended. Foot ulcers in patients with diabetes contribute to over half of lower extremity amputations in the USA in a group at risk representing only 3% of the population. In response to this challenge specialised programmes have emerged designed to identify and manage these patients, using a variety of new technology to improve outcomes. Hyperbaric oxygen treatment has been increasingly utilised in an adjunctive role in many of these patients coinciding with optimised patient and local wound care.

Hypoxia in Wound Healing Failure

Normal wound healing proceeds through an orderly sequence of steps involving control of contamination and infection, resolution of inflammation, regeneration of the connective tissue matrix, angiogenesis, and resurfacing. Several of these steps are critically dependent upon adequate perfusion and oxygen availability. The end result of this process is sustained restoration of anatomical continuity and functional integrity. Problem or chronic wounds are wounds that have failed to proceed through this orderly sequence of events and have failed to establish a sustained anatomic and functional result. This failure of wound healing is usually the result of one or more local wound or systemic host factors inhibiting the normal tissue response to injury. These factors include persistent infection, malperfusion and hypoxia, cellular failure, and unrelieved pressure or recurrent trauma.

The hypoxic nature of all wounds has been demonstrated, and the hypoxia, when pathologically increased, has correlated with impaired wound healing and increased rates of wound infection. Local oxygen tensions in the vicinity of the wound are approximately half the values observed in normal, non-wounded tissue. The rate at which normal wounds heal has been shown to be oxygen dependent. Fibroblast replication, collagen deposition, angiogenesis, resistance to infection, and intracellular leukocyte bacterial killing are oxygen sensitive responses essential to normal wound healing. However, if the periwound tissue is normally perfused, steep oxygen gradients from the periphery to the hypoxic wound centre support a normal wound healing response.

Measurement of Wound Hypoxia

Transcutaneous oxygen tension ($PtcO_2$) measurements provide a direct, quantitative assessment of oxygen availability to the periwound skin and an indirect measurement of periwound microcirculatory blood flow. The application of $PtcO_2$ measurement in the assessment of peripheral vascular disease has been well described by Scheffler and its application to wound healing problems by Sheffield. This technology allows objective determination of the presence and degree of local, periwound hypoxia serving as a screening tool to identify patients at risk for failure of primary wound or amputation flap healing. It can also be used during assessment of patients with lower extremity wounds as a screening tool for occult peripheral arterial occlusive disease.

Physiology of Hyperbaric Oxygenation of Wounds

Regardless of the primary aetiology of problem wounds, a basic pathway to non-healing is the interplay between tissue hypoperfusion, resulting hypoxia, and infection. A large body of evidence exists which demonstrates that intermittent oxygenation of hypoperfused wound beds, a process only achievable in selected patients by exposing them to hyperbaric oxygen treatment, mitigates many of these impediments and sets into motion a cascade of events that leads to wound healing. Hyperbaric oxygenation is achieved when a patient breathes 100% oxygen at an elevated atmospheric pressure. Physiologically, this produces a directly proportional increase in the plasma volume fraction of transported oxygen that is readily available for cellular metabolism. Arterial PO_2 elevations to 1500 mmHg or greater are achieved with 2 to 2.5 atm abs with soft tissue and muscle PO_2 levels elevated correspondingly. Oxygen diffusion varies in a direct linear relationship to the increased partial pressure of oxygen present in the circulating plasma caused by hyperbaric oxygen therapy. This significant level of hyperoxygenation allows for the reversal of localised tissue hypoxia, which may be secondary to ischaemia or to other local factors within the compromised tissue.

In the hypoxic wound, hyperbaric oxygen therapy acutely corrects the pathophysiology related to oxygen deficiency and impaired wound healing. A key factor in hyperbaric oxygen therapy's enhancement of the hypoxic wound environment is its ability to establish adequate oxygen availability within the vascularised connective tissue compartment that surrounds the wound. Proper oxygenation of the vascularised connective tissue compartment is crucial to the efficient initiation of the wound repair process and becomes an important rate-limiting factor for the cellular functions associated with several aspects of wound healing. Neutrophils, fibroblasts, macrophages, and osteoclasts are all dependent upon an environment in which oxygen is not deficient in order to carry out their specific inflammatory or repair functions. Two groups of induced responses occur:

1) Improved leukocyte function of bacterial killing, antibiotic potentiation, and enhanced collagen synthesis occur during periods of elevated tissue PO_2.

2) Suppression of bacterial toxin synthesis, blunting of systemic inflammatory responses, and prevention of leukocyte activation and adhesion following ischaemic reperfusion are effects that may persist even after completion of hyperbaric oxygen treatment.

In addition, vascular endothelial growth factor (VEGF) release is stimulated and platelet derived growth factor (PDGF) receptor appearance is also induced. The net result of serial hyperbaric oxygen exposures is improved local host immune response, clearance of infection, enhanced tissue growth and angiogenesis with progressive improvement in local tissue oxygenation, and epithelialisation of hypoxic wounds.

Diabetic Lower Extremity Wounds, the Prototype Hypoxic Wound

Lower extremity ulcers and amputations are an increasing problem for people with diabetes. Up to 6 per cent of all hospitalisations for diabetics include a lower extremity ulcer as a discharge diagnosis. When present, an ulcer increased hospital length of stay by an average of 59% compared to diabetics admitted without lower extremity ulcers. Finally, once an amputation occurs, nine to 20% of diabetic patients will experience an ipsilateral or contralateral amputation

Peter HJ Mueller MD is the lead Clinician at London Hyperbaric Medicine Ltd, and a consultant at Whipps Cross University Hospital, London

Robert A Warriner III MD, FACA, FCCP, ABPM/UHM, CWS, is Chief Medical Officer of Praxis Clinical Services in Anaheim, California and Emeritus Medical Director and Founder of the Southeast Texas Centre for Wound Care and Hyperbaric Medicine, in Conroe, Texas

within 12 months and 28-52% within five years. The cost of care for a new diabetic foot ulcer has been calculated to be $27,987 in the two years following diagnosis.

Management, likewise, has been extensively described and includes careful attention to identification and management of infection, aggressive surgical debridement, evaluation and correction of vascular insufficiency ambulatory off-loading, and glycaemic control. While a full discussion of these interventions is beyond the scope of this review, they form the basis of effective diabetic foot ulcer management and must be applied consistently if adjunctive interventions are to provide an additive value. Other interventions have recently been advocated including topical application of a recombinant human platelet derived growth factor (PDGF-BB, becaplermin), bio-engineered human monolayer fibroblast grafts and bi-layer fibroblast and keratinocyte grafts, and negative pressure wound therapy (wound vac). Clearly, regardless of the interventions applied, limb salvage rates improve when care is applied in a multidisciplinary setting using comprehensive protocols for care.

Local wound hypoxia plays a pivotal role in diabetic wound healing failure and limb loss as evidence by the report by Pecoraro that when periwound $PtcO_2$ values were below 20 mmHg they were associated with a 39 fold increased risk of primary healing failure. While aggressive distal lower extremity bypass grafting and lower extremity angioplasty have contributed to increased wound healing and limb salvage rates, technical grafting success does not necessarily equate with limb salvage. Hyperbaric oxygen treatment offers an intriguing opportunity to maximise oxygen delivery in the setting of minimal or insufficiently corrected blood flow.

Table 1. Wagner Grading System for Diabetic Foot Ulcers

Grade 0:	Intact skin
Grade I:	Superficial without penetration deeper layers
Grade II:	Deeper reaching tendon, bone, or joint capsule
Grade III:	Deeper with abscess, osteomyelitis, or tendonitis extending to those structures
Grade IV:	Gangrene of some portion of the toe, toes, and/or forefoot
Grade V:	Gangrene involving the whole foot or enough of the foot that no local procedures are possible

Clinical Experience with Hyperbaric Oxygen Treatment in Diabetic Lower Extremity Wounds

Since 1999 there have been eight published independent evidence-based reviews that have addressed the effectiveness of hyperbaric oxygen treatment in problem, chronic wounds. These reviews have evaluated the results of:
1) Four randomised controlled clinical trials of hyperbaric oxygen treatment in diabetic lower extremity wounds.
2) Two randomised controlled trials in non-diabetic leg ulcers or where wound healing was not the outcome indicator.
3) Two non-randomised controlled trials in diabetic lower extremity wounds.
4) One prospective case series of hyperbaric oxygen treatment and infra popliteal angioplasty in diabetic lower extremity wounds
5) Eight prospective or retrospective uncontrolled case series in diabetic lower extremity wounds.

In the controlled trials, 334 patients were included in the hyperbaric oxygen treatment arms and 582 patients in the control arms. In the cases series, 1590 patients were reported. There were additional small retrospective series that were not included in this review.

In general, while specific selection criteria for inclusion for hyperbaric oxygen treatment were not provided, inference from the description of patients included can be made that most were Wagner grade (Table 1) III or greater ulcers since 'diabetic gangrene' was frequently mentioned as a descriptor of patients included. Hypoxic transcutaneous PO_2 values were not mentioned as an inclusion criterion for selection for the randomised controlled clinical trials.

In summary, the available evidence supports classifying the use of adjunctive in hyperbaric oxygen treatment for diabetic foot ulcers meets the requirements for AHA Class I definitely recommended based on Level A evidence of positive randomised controlled trials with statistically positive results. In the broader category of hypoxic wounds, based on the absence of trials using measured tissue hypoxia as a patient inclusion criterion, adjunctive hyperbaric oxygen treatment meets the requirements for AHA Class IIb acceptable and useful with fair to good evidence for support based upon limited level clinical trial data but with substantial level B non-randomised retrospective case series where $PtcO_2$ values were reported but not used for inclusion, animal models with very reasonable extrapolations from existing data, and rational conjecture and historical acceptance. Randomised clinical trials should be performed to better define a 'hypoxic' wound as a unique wound category and the value of hyperbaric oxygen treatment in this setting.

Hyperbaric Oxygen Treatment Protocols

Treatment protocols vary depending on the severity of the problem and the type of hyperbaric chamber used. In larger multiplace chambers, treatments are delivered at 2.0 to 2.5 ATA for 90 to 120 minutes once or twice daily. In monoplace chambers patients are usually treated at 2.0 ATA. Patients with serious infections may require hospitalisation for intravenous antibiotics and better diabetes control. Hyperbaric oxygen treatment in such cases is usually rendered twice daily for 90 minutes. Once stabilised most of these patients can be treated on a once daily basis as outpatients. When infection is controlled, blood flow optimised (wherever possible), other interventions that may hasten tissue growth and wound closure such as negative pressure wound therapy (wound vac), bio-engineered tissue grafts, or surgical reconstruction or closure can be used in combination with adjunctive hyperbaric oxygen treatment to hasten recovery. The October 2000 Office of the Inspector General report to the Department of Health and Human Services identified that active physician oversight of hyperbaric oxygen treatment led to improved outcomes.

Utilisation Review

Hyperbaric oxygen treatments are performed at 2.0 to 2.5 ATA for 90 to 120 minutes of oxygen breathing. The initial treatment schedule is dictated by the severity of the disease process. In the presence of limb-threatening infection after debridement or incompletely corrected peripheral arterial occlusive disease, patients may require twice daily treatments. Once stabilised, treatment frequency may decrease to once daily. Utilisation review is required after the initial 30 days of treatment and at least that frequently thereafter.

Cost Impact

Hyperbaric oxygen therapy as an adjunct to medical and surgical treatment of difficult problem, chronic wounds, particularly diabetic lower extremity wounds, has been shown to be cost effective in limited reviews, especially when compared to major lower extremity amputation. Preventing a below the knee amputation by salvaging a ray resection or transmetatarsal amputation of the foot or preventing an above the knee amputation by preserving a below the knee amputation represents a satisfactory outcome in these high-risk patients. Wounds healed with adjunctive hyperbaric oxygen treatment have also demonstrated excellent durability.

Outlook

Considering the existing evidence, the Jury of the ECHM Consensus Conference on hyperbaric oxygen in the treatment of foot lesion in diabetic patients, held in London (December 1998) stated: 'There is some evidence from a number of trials, each of which suffers from methodological problems, to support the use of HBO in ischaemic limb-threatening problems in diabetic patients. Patients with diabetic foot problems warrant treatment by foot care teams with careful evaluation of metabolic, neuropathic and vascular factors. Potential candidates for HBO may include those with Wagner grade 3 to 5 lesions treated unsuccessfully by standard methods when amputation seems a possibility.'

A result of the meeting was the recognition of the urgent need for a collaborative international trial for the application of HBO in diabetic foot lesions. This study is now well advanced in Europe as a multi-centric, prospective, controlled, randomised project to evaluate the efficacy of HBO in the healing of foot lesions in diabetic patients. This had been designed by the Working Group 4 of the COST Action B14 (www.oxynet.org), which was co-ordinated by the Research Foundation of the European Commission until March 2005. Results of that study should become available in the near future.

Photo: Ian Mason

From left: Dr Alexander Cohen, Dr Juan Arcelus and Prof Michel-Meyer Samama

As hospital administrators and clinicians across Europe are urged to take action to cut these unnecessary deaths - experts call for screening of surgical and medical patients, and thromboprophylaxis for those at risk. ***Ian Mason*** reports

Fatal blood clots claim 500,000 EU lives annually

Pulmonary embolism following venous thrombosis claims over 500,000 lives in the EU annually, according to a new study. The need for preventive measures is clear, since most premature deaths due to blood clots are avoidable, says Dr Alexander Cohen, on behalf of the *Venous Thrombo-embolism (VTE) Impact Assessment Group in Europe (VITAE)*.

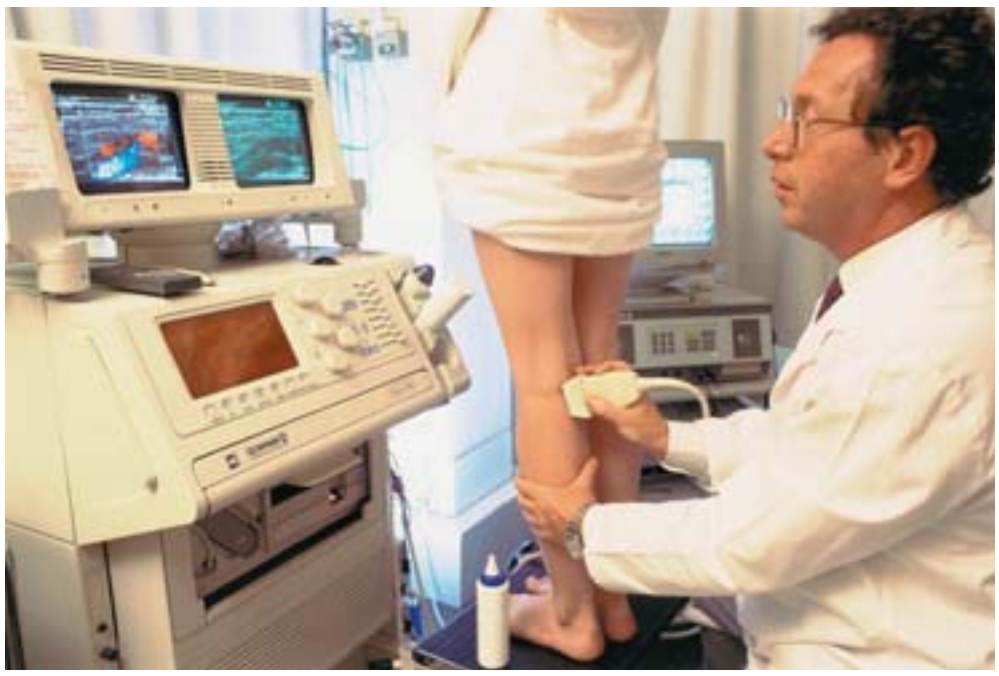
'VTE kills more Europeans each year than breast cancer, prostate cancer, HIV/AIDS and road traffic accidents combined,' said Dr Cohen, of Guy's, King and St Thomas School of Medicine and King's College Hospital, London, UK. 'The direct cost of VTE to EU healthcare systems exceeds three billion euros annually.'

Failure to prevent thrombosis is now the single most common cause of medical negligence litigation in the USA, and cases in the EU are now soaring, he cautioned.

'Hospital administrators and clinical directors need to check they have adequate protocols in place. In many EU countries government regulators are looking closely at the problem of VTE, and audits may soon be mandatory, ' he added.

The VITAE study - the first major attempt to establish the burden of VTE across the whole EU - shows that the annual toll of fatal and non-fatal symptomatic VTE, which includes pulmonary embolism (PE) and deep vein thrombosis (DVT), exceeds 1.5 million events annually in the European Union. This figure includes 543,500 deaths, 435,000 cases of PE and 684,000 cases of documented symptomatic DVT.

The VTE burden is probably much higher than these figures suggest, because in many cases it is clinically silent and difficult to diagnose. Most fatal PEs remain unrecognised as post mortems are rarely performed. 'More than 70% of fatal PEs are only detected during post-mortem examination,' said Professor Juan Arcelus, Department of Surgery, University of Granada Medical School, Spain. Patients should be screened, and if at risk, considered for thromboprophylaxis - this includes surgical patients and medical patients with restricted mobility, such as those with myocardial infarction, heart failure, stroke, acute infection or acute rheumatological disease - it is not often appreciated but PE kills three times more medical, than surgical patients.'



Duplex ultrasound has proved a popular, non-invasive, painless and cost-effective method for the investigation of deep vein thrombosis

Dr Marie-Antionette Sevestre, Service de Medicine Vasculaire, CHU Amiens, France would like to see greater use made of Duplex Ultrasound Scanning in the diagnosis of DVT. 'It is an accurate, non-invasive and cost effective technique that accurately identifies the site of the thrombus and helps stratify risk, but at the moment, many more patients who need scanning are not scanned,' she said.

Professor Michel-Meyer Samama, Hotel-Dieu University Hospital, Paris, France, has authored several influential textbooks on clinical thrombosis and hypercoagulable states. He says that too many relatively young patients die due to lack of adequate prophylaxis. 'VTE is a silent disease that prematurely takes live although available and effective prophylaxis and treatment exists.'

Preventive treatments for DVT include early mobilisation, sequential compression devices and stockings to prevent blood clotting, and anticoagulants and/or blood-thinning drugs.

DVT results when a blood clot inside a deep vein, commonly located in the calf and or thigh. PE a potentially life-threatening complication occurs when a fragment of a blood clot breaks loose and travels to the lungs.

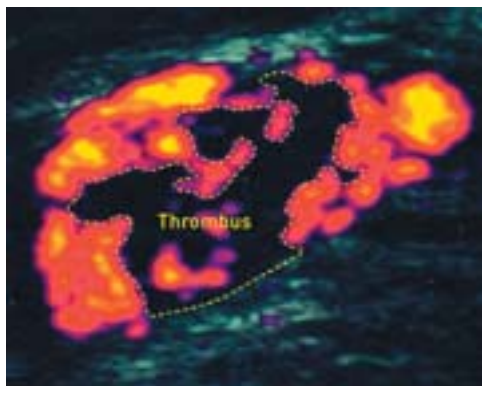
Venous thrombo-embolism: The facts

Venous thromboembolism (VTE) is caused by the formation of blood clots that partially or completely block a vein. The most common form is deep vein thrombosis (DVT), occuring when clots form in deep veins, usually in the legs.

Parts of the clot may break off and lodge in the arteries that supply the lungs, forming a pulmonary embolus (PE) - a medical emergency that can cause irreversible damage to the lungs and which frequently results in death

Risk factors for DVT and PE include: increasing age, prolonged immobility, stroke, or paralysis; previous VTE; cancer and its treatment; major surgery; trauma; obesity; varicose veins; cardiac dysfunction; and pregnancy.

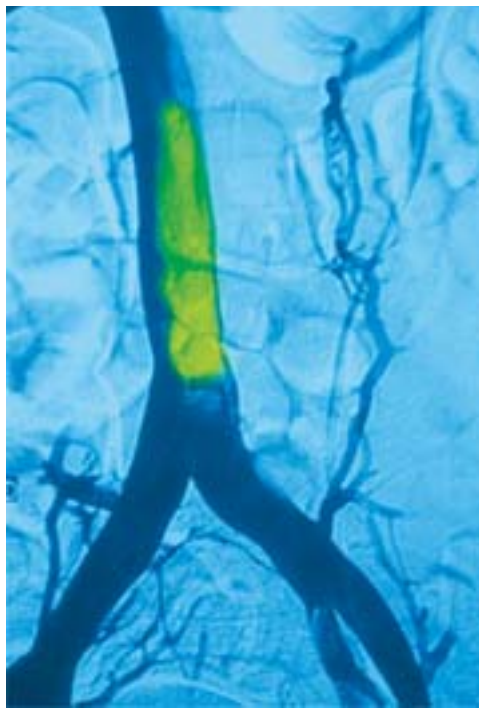
The risk of developing DVT after hip replacement has been estimated to be as high as 50% of patients when thromboprophylaxis is not used. The use of thromboprophylaxis can reduce this risk to between 10 and 15% of patients.



Duplex colour scan: Transverse axis view of a femoral vein partially blocked by a thrombus, which appears black, surrounded by blood (orange-red on the scan)

Despite the high risk of VTE in patients undergoing major surgery, some 40% or more of these patients still do not receive effective thromboprophylaxis.

Patients who suffer DVT are at risk of developing post-thrombotic syndrome (PTS), a painful, unpleasant and potentially disabling condition often resulting in the development of leg ulcers, which are persistent and difficult to heal.



Venography showing thrombus in a deep vein

The United Kingdom's House of Commons Health Select Committee recently published recommendations for the prevention of VTE in hospitalised patients. These included:

- On admission to hospital all patients should be counselled on the risks of VTE and undergo a risk assessment to determine if drugs should be administered
- Awareness should be raised among medical practitioners of the extent of the problem: all physicians and surgeons are to be informed if their patients contract VTE after they have been discharged from hospital
- Thrombosis committees and thrombosis teams should be established in each hospital to promote best practice and to be a source of education and training for all staff

VTE prevention

Thromboprophylaxis is available in both mechanical and pharmacological forms. For patients with moderate to low risk of blood clots mechanical prophylaxis may be used instead of, or in combination with, pharmacological prophylaxis. Mechanical methods of thromboprophylaxis include pneumatic calf compression and compression stockings. **Surgical patients** (especially those undergoing orthopaedic surgery) and medical patients classified as medium or high risk may be given anticoagulants to decrease the risk of blood clots.

Pharmacological agents for thromboprophylaxis include unfractionated heparin, LMWH, thrombin inhibitors, oral anticoagulants, and specific factor Xa inhibitors.

Many surgeons now advocate that prophylaxis after joint replacement should continue after the patient is discharged from hospital (extended prophylaxis). The duration of extended prophylaxis depends on the risk category of the patient and the treatment that is undertaken.

Extended prophylaxis normally lasts for five weeks but in high-risk patients, or in those who have previously experienced DVT, prophylaxis can be administered for a significantly longer period.

In a double-blind, placebo-controlled trial the risk of DVT/PE was reduced by 63% in acutely ill medical patients treated with enoxaparin when compared with placebo, without increased major bleeding. Enoxaparin reduced the risk of VTE by up to 50% in patients undergoing high-risk surgical procedures versus unfractionated heparin.

THE EUROPEAN TISSUE ENGINEERING PROJECT

The project European clinical engineering project (funding just under €25 million) is expected to make human tissue grown from stem cells available for transplant in the next four years. The technology will be developed to treat heart failure, diabetes, chronic ulcers and neurodegenerative diseases in particular.


Prof David Williams

Funded by the European Commission and led by the University of Liverpool and Italian pharmaceutical company Fidia, this tissue-engineering project will draw together experts in 23 academic and industrial groups across Europe.

'For tissue engineering to be successful clinically, it has to be able to generate exactly the right type of tissue, specific to a patient, in a cost-effective manner,' explained Professor David Williams, Director of the UK Centre For Tissue Engineering at the University of Liverpool. 'This is not really being achieved anywhere in the world yet, but this major new project will bring together a team, with critical mass, and a range of expertise from stem cell biology to bio-manufacturing processes, including ethics and business models.'

Tissue Engineering involves taking human cells - such as stem cells - from blood or bone marrow and encouraging them to produce new tissue through the use of growth factors. The Liverpool researchers have been developing methods of growing a variety of tissue, including human arteries, from adult stem cells. The arteries could be used, for example, to replace blocked arteries in those suffering coronary heart disease.

The new project - *A Systems Approach to Tissue Engineering Products and Processes* (STEPS), is one of the largest research contracts in Europe and a major part of the EU's Framework Six programme.

** The University of Liverpool is one of the UK's leading research institutions. It attracts collaborative and contract research commissions from a wide range of national and international organisations valued at more than MARY - €13 million annually.*


The Leica M520 F40

Photo: Leica Microsystems

Smooth action stand has smart brakes

The Leica M520 OptiChrome - used in microsurgery - now features a compact stand: the Leica F40. Using OptiChrome technology, the equipment has a working distance up to 470 mm, provides 30% higher depth of field, and 30% higher light intensity. Six electromagnetic brakes are fitted to the stand, and vibrations are low. It also comes with a stable space-saving foot.

The firm adds that the system provides perfect balance and stability and is easy to manoeuvre. 'Neurosurgery, otolaryngology surgery or spine surgery require the highest level of expertise and concentration on part of the surgical team,' Leica points out, adding that the Leica M520 surgical microscope facilitates this task due to its exceptional bright illumination and outstanding depth of field that reduces refocusing to a minimum. 'The slim design of the Leica F40 stand represents innovation and art in engineering. High-precision bearings and perfect aligned joints allow for a homogenous mobility that was previously reserved for premium systems. When you move the stand for the first time you'll be surprised by its smooth motion. Smart brakes and soft motion are the magic words of this new technology.

'Even with the large range of the swing-arm, the stand remains extremely low in post oscillation,' the firm reports. 'Post oscillation is prevented by the Leica EBS technology (electromagnetic brakes system) on six axes. This allows the microscope system to remain steady, especially during one-hand operation. Comfortable working is ensured by the system's high flexibility in any possible posture.'

A small, solid base forms the stable foundation. Combined with a large all-around handle, any positioning at the operating table is easy. 'The stand fits into any surgical environment, and the surgeon can communicate perfectly with the team during their work. Xenon illumination and electronics are integrated at the rear and are easily accessible,' Leica adds. Along with this, interface solutions also allow compatibility with Neuronavigation/IGS systems.

First Cyberknife centre opens

Germany - A new centre has opened in Munich to provide what is reported as a pain-free and patient-friendly treatment of tumours. The Cyberknife Centre is led by Dr Alexander Muacevic and PD Dr Berndt Wowra, in co-operation with Professor JC Tonn, at the neurosurgery department, University Hospital Munich.

CyberKnife, combines digital image-guidance robotic surgery with a high-precision radiation device, Dr Muacevic explained. Its design derives from the original concept of a frameless alternative to frame-based radiosurgery, and it has three key components:

- an advanced, lightweight linear accelerator (LINAC) (used to produce a high energy (6MV) 'killing beam' of radiation)
- a robot that can point the linear accelerator from a wide variety of angles
- several X-ray cameras (imaging devices) that are combined with powerful software to track patient position. The cameras obtain frequent pictures of the patient during treatment, and use this information to target the radiation beam emitted by the linear accelerator.

The robot is instrumental in precisely aiming that device. If a patient moves during treatment, the cameras detect the change in position and the robot compensates by re-targeting the linear accelerator before administering the radiation beam. This process of continually checking and correcting ensures accurate radiation targeting throughout treatment. Thus, the tumour receives a concentrated dose of radiation while minimising exposure to surrounding normal tissue. With sub-millimetre accuracy, the CyberKnife treats vascular abnormalities, tumours, functional disorders, and cancers of the brain and spine, the maker reports, summarising: 'CyberKnife replaces the stereotactic head frame with a patient-friendly image-guided localisation system. This technology has the added benefit of enabling the system to be used for radiosurgical applications outside the brain. Radiosurgery can now also be applied to spinal tumours. It is difficult if not impossible to perform these other procedures with standard frame-based radiosurgical systems.'

Patients benefit from greater comfort (there is no invasive head frame), and treatment free of surgery or anaesthesia, and no hospital stay or rehabilitation.

ACUTE LUNG INJURY

The *Symposium on Acute Lung Injury* - From Basic Science to Bedside Application, sponsored by MAQUET and held in Strasbourg, drew over 250 participating intensive care specialists from 20 countries, and the delegates came from Europe, North America and Asia.

At the event, chaired by Professor Arthur Slutsky, renowned researchers presented cutting-edge understanding of the mechanisms and therapies related to ventilator-induced lung injury. Speakers included Professor Luciano Gattinoni, Professor Stefan Uhlig, Dr Jesús Vilar, Dr Fernando Suarez Sipmann, Professor Rolf Hubmayr, Professor Michael Quintel, Professor Marco Ranieri and Assistant Professor Gary Nieman.

The purpose of the symposium was to stimulate migration of scientific knowledge into clinical practice, and Maquet, which produces the Servo ventilation range, reports that this was accomplished by lively interaction between speakers and audience. The company has produced a symposium lecture CD to document the sessions, and a summary report of the symposium and interviews with speakers and participants. These will be featured in the next issue of Maquet's *Critical Care News* magazine.

New concept offers ten-year guarantee for hip and knee joints

Germany - From the beginning of 2004, integrated contracts became possible between different healthcare providers, aiming to overcome barriers between in and out-patient sectors, improve co-operation, and optimise overall treatment, through higher quality yet shorter treatment. With falling numbers healthcare funds could also save money.

A new contract between the German medical fund Techniker Krankenkasse (TK) and the Bavaria-based hospitals Rummelsberg, Hessing Stiftung and Orthozentrum München aims to fundamentally improve treatment for hip or knee surgery patients. 'Best results for the patients and a long durability of the artificial hip or knee does not only depend on surgery alone,' explained Helmut Heckenstaller, head of the TK country division in Bavaria. 'Our contract makes sure that all steps are perfectly intertwined: intensive preparation for and with the patient, including special training before the surgery as well as the engagement of an experienced surgical team, immediate rehabilitation after the operation and ambulant aftercare.'

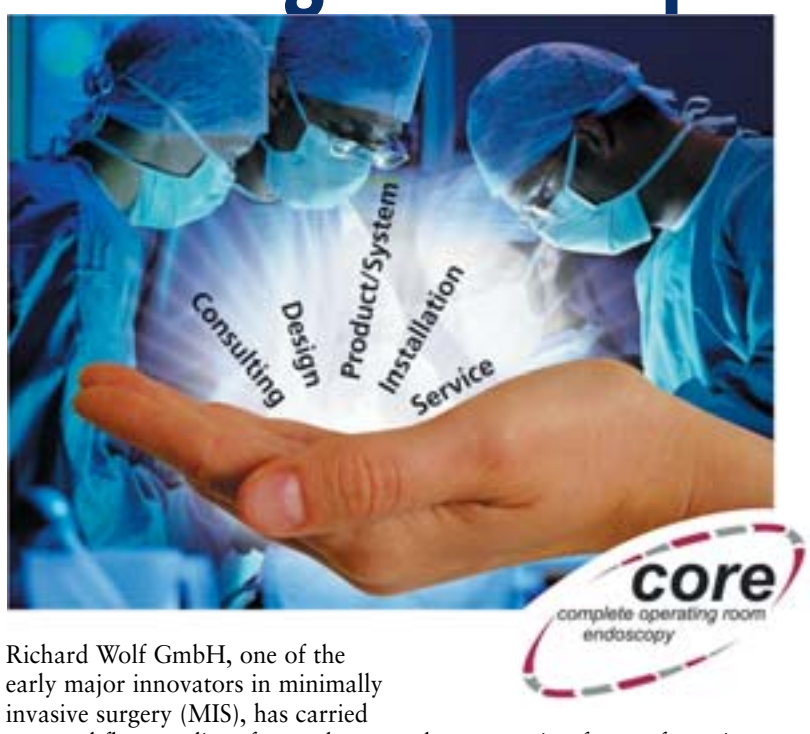
To ensure long-term success of the treatment, patients receive aftercare within the following four years where specialists check whether the artificial joint fits correctly.

Due to these measures, the three participating hospitals will even provide a ten-year-guarantee. If within this period of time the artificial hip or knee joint becomes loose or has to be replaced, the hospitals bear the expenses - at least to an extent. The orthopaedic hospitals hope that this quality-contract will improve their image and also attract more patients.

Participating health funds: Gmünder Ersatzkasse (GEK), Krankenkasse für Bau- und Holzberufe (HZK), Krankenkasse Eintracht Heusenstamm (KEH).

Helmut Heckenstaller, Techniker Krankenkasse

core integrates the operating theatre



Richard Wolf GmbH, one of the early major innovators in minimally invasive surgery (MIS), has carried out workflow studies of everyday operating theatre (OT) procedures and continuously provided adaptations, refinements and solutions for medical teams, which resulted in the firm's development of ***core*** - a complete OT concept that centralises control via its modular, integrative structure.

The system's main task is to network individual theatre devices and provide interactive monitoring. Thanks to standardisation - the widely adopted communications standard CAN Open BUS protocol is used - an excellent platform for continuous integration of further components has been developed. 'Vendor-specific communications interfaces that were often used in the past are losing importance,' the firm points out.

'The networking of the devices and the unique visualisation and operating concept allow the centralised control of the entire system from one central operator panel. core brings with it a further significant increase in efficiency in the form of voice control that is not dependent on the speaker. This allows the direct operation of devices such as cameras, light and OR table from within the sterile field of the operating theatre and provides the basis for immediate intra-operative preparation of the OR report. The consistent use of this module ensures the immediate postoperative availability of the electronic operating report, including images of findings, and allows increased efficiency in the documentation from a forensic perspective.'

This, the firm adds, leads to a further pillar of core: The medical image management system (PACS system). 'With Medimage, complete, digital patient picture and document management is possible. Starting from workstations for picture acquisition, processing and archiving and progressing to server, network and telecommunications solutions, it provides every form of image data management, as well as tailored, customised solutions. Medimage unites all types of pictures, films and reports from radiology, cardiology and surgery. The possible intra-operative visualisation of pre-operative image data (X-ray, CT) on suitable monitors in the operating field of the physician plays just as great a role in cost reduction as in increased operating safety.'

The system can be variably installed in ceiling supply units, distributed nurse stations and mobile system trolleys, and theatre tables and other peripheral devices can be integrated.

'An essential part of our company philosophy is to maintain close customer contact and to concentrate on precise implementation of customer requirements. Solutions in which usefulness and efficiency are in the foreground,' the firm emphasises.

The core team also provides specialist consultation and planning services, and additional services include the organisation of installation '... and commissioning of the customer's system solution and formulation of tailored service concepts'.

Richard Wolf will be demonstrating its latest concepts at this year's **MEDICA, in Dusseldorf. (Hall 10, Stand D57)**

Demineralised bone matrix products

Switzerland - IsoTis OrthoBiologics has entered into a three-year non-exclusive worldwide distribution agreement for its demineralised bone matrix products DynaGraft II and OrthoBlast II with Lifetek LLC and Endoplant AG, two subsidiaries of PLUS Orthopaedics Holding AG. The IsoTis products will be marketed and sold by Lifetek OrthoBiologics under the brand names Nexus and Nexus IC. European distribution will be primarily through the PLUS Sales Organisation. Lifetek OrthoBiologics will handle sales in other countries, directly or through third-party distributors. The Nexus Products were launched internationally last week at the worldwide SICOT meeting in Istanbul, Turkey. Financial details were not disclosed.

Lifetek OrthoBiologics, a global manufacturer and distributor of human tissue products used in orthopaedic and neurosurgery, was established in 2002. The firm's CEO, Michael Evertsen, said that the agreement gives his firm the ability to market proven products, and, he added: 'The Nexus and Nexus IC product line will give us access to the growing DBM market and an important opportunity to expand our product offering to surgeons.'

PLUS Orthopaedics AG, of Rotkreuz, Switzerland, is a globally operating, privately held orthopaedics firm, manufacturing implant systems for hip, knee and shoulder joints, surgical navigation systems and products to treat orthopaedic trauma.

The usefulness of musculoskeletal MRI

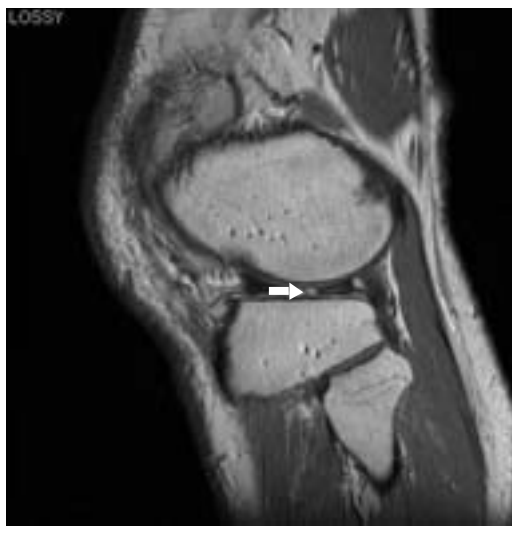
By ***Thomas H Magee***

Musculoskeletal MRI has been used for non-invasive diagnosis of joint disease since the 1980's. In our practice we have seen a continual increase in the utilisation of this imaging modality. Our surgeons have found it very useful in predicting which patients will benefit from surgery as opposed to those who will benefit from physical therapy. Additionally, MRI aids the surgeon in pre-surgical planning, and this can reduce the time required for the patient in the operating room, thus helping to reduce surgical risk. In our experience, musculoskeletal MRI has been useful in excluding patients from surgery. A patient with a negative MRI seldom has positive findings at surgery.

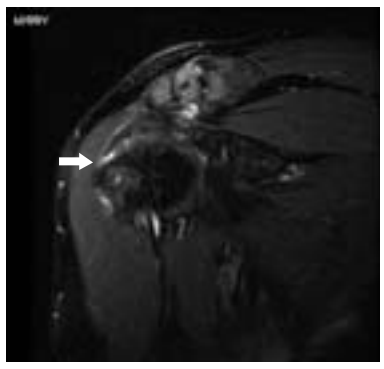
The inherent soft tissue contrast and high spatial resolution of MRI available on high field scanners allows for very accurate diagnoses. Musculoskeletal also has been useful for determining the extent of disease in soft tissue and bony tumours - often not well seen on conventional radiograph or a CT scan. Often, a bone scan can demonstrate increased radiotracer uptake in such cases, but lacks the specificity of MRI. A bone scan will demonstrate increased uptake in trauma, infection or tumour. MRI will demonstrate very specific findings in tumours that help differentiate them from trauma or infection.

MR is useful in demonstrating the presence and extent of infection, which helps guide the right course of action in treating infections. The treating physician is better able to determine whether surgery will be beneficial or whether the infection can be treated with antibiotics only.

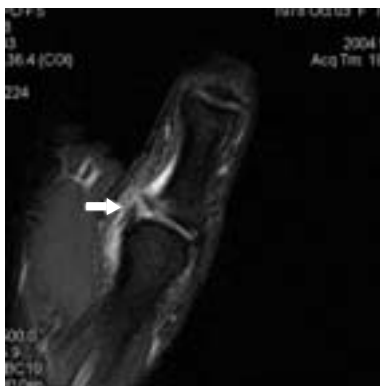
Overall we have found MR to be a highly accurate non-invasive diagnostic test for early and specific diagnosis of many types of musculoskeletal disease, and this has significantly improved the treatment of patients with many types of musculoskeletal disease.



In this sagittal MR image a small radial tear of the meniscus is clearly seen (arrow)



A small supraspinatus tendon tear is clearly seen in this coronal MR image (arrow)



A tear in the ulnar collateral ligament is visualised well by MR examination (arrow)

About the author

Radiologist Thomas Magee is a known figure at radiology gatherings, including the Radiological Society of North America (RSNA), where last year he was Moderator for the Musculoskeletal Knee Internal Derangement session. He is Board Examiner for the Musculoskeletal Section of the American Board of Radiology, and has authored and presented many research papers and manuscripts, and organised a number of radiological exhibits.

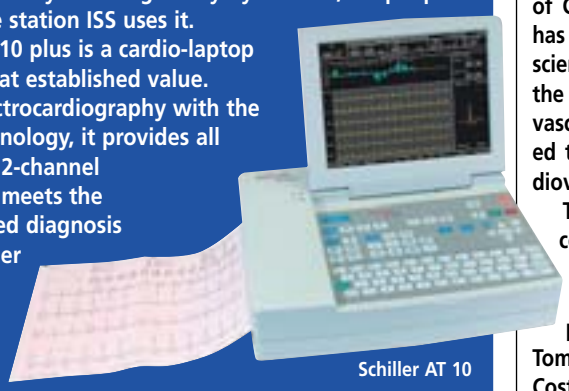
For the past five years, he has worked at Excellence in MRI, which runs centres in Melbourne, Merritt Island and Orlando, Florida.

Memberships: International Skeletal Society, Skeletal Society of Radiology, RSNA, ARRS, ACR, International Society of Magnetic Resonance in Medicine, and the Clinical Magnetic Resonance Society.

The laptop CARDIOVIT AT-10 plus Top Performance in Laptop Format!

A compact diagnosis station introduced in 1993 - the AT-10 - was far ahead of its time, and even today is used globally by over 20,000 people. Even the international space station ISS uses it.

The newer CARDIOVIT AT-10 plus is a cardio-laptop that continues to provide that established value. Combining the basics of electrocardiography with the benefits of information technology, it provides all functions of a high-quality 12-channel electrocardiograph and also meets the requirements of an integrated diagnosis workstation, its maker Schiller explains.



Schiller AT 10

This communication concept makes for an extremely flexible tool. Made in a compact, laptop design, with high-resolution colour display, plus the integrated 12-channel ECG recorder, the device also provides pacemaker detection and resting ECG measurement. It also has a rechargeable battery for mobile use, and the Schiller Communication Module (SCM) for integration with practice systems or HIS.

Various software options are available, including:

- Resting ECG interpretation for children and adults
- Thrombolysis software
- EXEC ergometry software (fully automatic ergometry, average cycles, ST measurement, rhythm recording, detailed report)

Details: www.schiller.ch

The fate of EU cardiovascular research

Thomas Lüscher

Sweden - As Thomas Lüscher, of the University Hospital, Zurich, observed during September's European Society of Cardiology (ESC) meeting, our role has been significant in cardiovascular science, from its humble beginnings in the 17th century to advances in cardiovascular therapies that have accelerated to a point whereby almost all cardiovascular disorders are treatable.

Today, however, Europe's pharmaceutical companies are beginning to shift research out of Europe, heading for the US, India and other parts of the world, according to Sir Tom McKillop, CEO of AstraZeneca. Costs are a considerable consideration in such moves. In China funding for research and clinical trials is a fraction of what is needed in Europe. However, he argued that although drug development may be more costly, the long-term benefits are worth the expense - if Europe is willing to pay.

Europe's drug manufacturers are calling for funding similar to that available in the USA, as well as for less bureaucracy. Günter Verheugen, the EU Commissioner for Enterprise and Industry, agreed. Europe's pharmaceutical industry he said, '... once the bastion of European innovation and the pharmacy of the world, is increasingly under threat, and Europe must decide whether we want to be a leading player in pharmaceutical innovation, or whether we simply step aside and let others do this job'.

However, it is not that simple as the recent EU Clinical Trials Directive (CTD) appears to be hampering clinical research rather than enhancing Europe's chances of being a world leader in research and development.

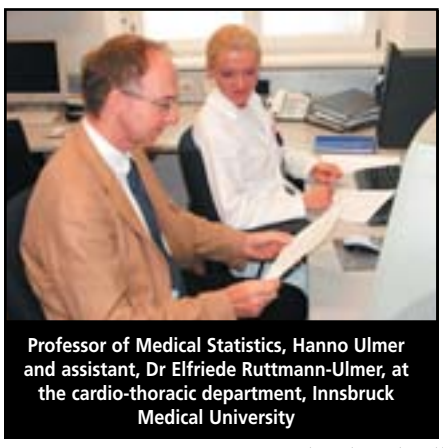
Bryan Williams, of Leicester, UK, pointed to an ESC survey, carried out this year, which found that academic researchers believed clinical research was vital if cardiovascular medicine was to thrive in Europe, but that the number of European trials would be halved due to the CTD. However, he argued that the CTD aims to protect the rights, safety and well being of patients, to simplify and harmonise the administrative procedure, to harmonise and make trial conduct more transparent, and to guarantee the credibility of results. Despite its good intent, the CTD makes great administrative demands on researchers and institutions that need to find sponsors and secure authorisation and validation for their programmes. Researchers complain that they spend their time trying to meet EU requirements, rather than carrying out vital research.

The Framework Programme 7 (FP7) offers hope, because it aims to double funding compared to FP6. According to European Commissioner, Octavi Quintana-Trias, from the European Commission's Health, Research Directorate General, FP7 will establish a European Research Council to fund and harmonise research, which should make Europe a more attractive area for critical inward investment, and will ensure that it continues to play a central role in research and development in life sciences.

Test could reveal CD death risk

Austria - A simple blood test may identify people who have an increased risk of dying from cardiovascular disease, according to research published in *Circulation: Journal of the American Heart Association*. The test measures gamma-glutamyl transferase (GGT) - an enzyme produced primarily by the liver - and catalyses glutathione, the main antioxidant in the body. The enzyme is elevated in some forms of liver disease, so physicians use GGT levels to detect liver damage and alcohol abuse.

Analysing data from a long-term study involving over 160,000 Austrian adults, the researchers found that the higher a person's blood level of GGT, the greater the risk of cardiovascular death. The levels are given in units per litre (U/l) of blood. Normal low is less than 9 U/l for women and less than 14 U/l for men. A moderately high value for GGT is 18 U/I for women and 28 U/I for men. High levels (two-fold elevated) are more than 36 U/I for women and 56 U/I for men.



Professor of Medical Statistics, Hanno Ulmer and assistant, Dr Elfriede Ruttmann-Ulmer, at the cardio-thoracic department, Innsbruck Medical University

'People with high GGT had more than a 1.5-fold risk of dying from cardiovascular diseases in comparison to people with normal low levels of GGT,' said Hanno Ulmer PhD, senior author and associate professor of medical statistics at the Innsbruck Medical University. 'For people under 60 years of age, this risk is even higher, amounting to more than two-fold. Over the past decade, some small studies have suggested a link between high GGT and cardiovascular disease.'

Several years ago, Italian researchers reported that elevated GGT could indicate early atherosclerosis. Dr Ulmer and his colleagues investigated those findings, examining medical data collected from 1985-2001 from 163,944 (98.4%) of the then-enrolled volunteers in the Vorarlberg Health Monitoring and Promotion Programme - an ongoing study in Austria's westernmost province that examines risk factors for chronic diseases.

The participants included 74,830 men and 89,114 women, aged 19 or older when they entered the study, and had been followed for an average of 11 to 12 years.

After controlling for known cardiovascular risk factors, the team found that GGT was an independent predictor of fatal heart disease or stroke.

Other key findings in the study:

- At enrolment, 21.9 percent of men and 15.6 percent of the women had elevated GGT.
- Of the 6,990 deaths that occurred among the volunteers, 43.3 percent resulted from heart disease or a stroke.
- Among all men, the risk of cardiovascular death was 28 percent higher for those with moderately high GGT, compared to men with normal levels of the enzyme, and rose to 64 percent for those with highly elevated GGT. In women, the increase in risk ranged from 35 percent to 51 percent.
- In men, elevated GGT had a statistically significant association with death caused by chronic coronary heart disease, congestive heart failure, ischaemic stroke (caused by a blocked artery in the brain), and hemorrhagic stroke (caused by a ruptured blood vessel in the brain). Researchers found no significant correlation with acute heart attacks caused by a blocked artery, sub-acute coronary heart disease, or other cardiovascular disease.
- Women with elevated GGT had an increased risk of death from all cardiovascular diseases. However, the association with hemorrhagic and ischaemic strokes was not statistically significant.
- GGT proved a strong predictor of cardiovascular death, third behind smoking and hypertension but ahead of high levels of blood sugar, cholesterol and triglycerides.

Ulmer cited two mechanisms that might explain why GGT can indicate cardiovascular disease. The first, originally proposed by the Italian researchers, is that high GGT shows the presence of atherosclerosis. The second is that it's related to the ill effects of heavy drinking on blood vessels.

'Beyond its role as an indicator of liver function, GGT is very likely to predict cardiovascular disease,' he said. 'Since GGT is correlated with established risk factors, the known ways of preventing the disease might also be effective in lowering GGT levels.'

Because the study participants were overwhelmingly white Austrians, the team could not say whether their findings hold true for other racial and ethnic groups.

'Both epidemiologic and experimental studies should be performed to confirm these findings, Dr Ulmer suggests. 'GGT should be included as a major parameter in future cardiovascular intervention studies'

In an accompanying editorial, Michele Emdin MD, of the cardiovascular medicine department at the National Research Council, in Pisa, Italy, wrote that elevated GGT might help identify people with 'the most risky combination for the vulnerable plaque, and the best medical strategies for the stabilization of lesions, rather than percutaneous or surgical.'

(Study co-authors: Elfriede Ruttmann MD; Larry J Brant PhD; Hans Concin MD; Gunter Diem MD; and Kilian Rapp MD).*

The EuroAction Intervention Team from Sweden

PREVENTIVE CARDIOLOGY

Nurse-led multidisciplinary teams can lead to reduced CVD risk factors

The EuroAction project - an initiative of the European Society of Cardiology (ESC), which is solely funded by the pharmaceuticals firm AstraZeneca - is the largest demonstration project in preventive cardiology, involving staff in busy general hospitals in Denmark, the Netherlands, France, Italy, Poland, Spain, Sweden, and the United Kingdom, and over 10,000 patients and their families.

Early results from the project clearly indicate that implementation of the Joint European Societies' Guidelines on CVD Prevention by nurse-led multidisciplinary teams can, through a family-based, behavioural approach, lead to measurable improvements in lifestyle and related factors, thus reducing the risk of future cardiovascular events.

EuroAction patients and partners achieved improvements in lifestyle, other cardiovascular risk factors and in the use of cardio-protective medication. Patients stopped smoking, reduced their consumption of saturated fats, increased daily intake of fruits/vegetables, and achieved greater levels of physical activity. Other CVD risk factors (e.g. weight/shape, blood pressure, and blood fat profile) all improved, and the vast majority were prescribed cardio-protective medicines. Patients' partners also adopted a healthier diet and increased their physical activity with corresponding reductions in weight/shape, blood pressure and blood fats.

Speaking at the European Society of Cardiology in Sweden, this September, Professor David Wood, Imperial College, London, UK, and EuroAction Principal Investigator, said: 'EuroAction signals a new dawn in preventive cardiology, making it accessible to the vast majority of coronary patients and their families.'

The EuroAction programme successfully reached out to a majority (73%) of all eligible coronary patients, and most (84%) completed the programme. All types of coronary patients were targeted, from those with an acute coronary syndrome (65%) through to stable angina (35%). A majority of the patients' partners/spouses (77%) also attended the programme.

Assisted by EuroAction teams, over half (58%) of the patients who were smokers prior to their coronary event had stopped by the end of the hospital programme. One in five partners also stopped smoking cigarettes.

Considerable improvements were seen in the dietary habits of both patients and their families; saturated fat consumption levels of patients decreased by almost 16% (12% in partners), with 68% of patients (62% of partners) reaching the target of less than 10% saturated fat within their daily diets. EuroAction patients increased their consumption of fruit and vegetables by an average of 155 grams each day (113 grams each day for partners), with a 23% (25% in partners) improvement against baseline in the amount of patients eating the recommended daily amount of 400 grams of these types of foods. EuroAction patients increased their consumption of fish with 58% (71% of partners) eating oily fish three times or more each week.

EuroAction patients and families also became more physically active. A quarter of patients were regularly active (20% of partners) according to the Caspersen and Powell Classification; an absolute increase of 11% compared to baseline (5% in partners). Over three quarters (86%) of patients (83% of partners) reported themselves to be highly active according to the International Physical Activity Questionnaire (IPAQ), an improvement of around one-fifth against baseline. Objective measures confirmed these self-reported improvements with a step counter showing an increase of 1362 steps (739 for partners). Assuming an average of three feet per step, this equates to patients walking around an extra three quarters of a mile each day.

Cardio-protective drug therapies were widely prescribed with 95% of patients taking antiplatelet drugs, 79% on beta-blockers, 58% on ACE inhibitors/ angiotensin receptor blockers, 19% on calcium antagonists and 86% on statins.

One-year results from EuroAction's hospital and primary care arms are expected in 2006.

By ***Professor Thomas Hummel***, of the Smell and Taste Clinic, Department of Otolaryngology, University of Dresden Medical School, Germany

Smell

Professor Thomas Hummel, MD PhD, left school at 18 years of age and ran a restaurant for two years, before beginning his medical studies at the University of Erlangen. Later, he gained a doctorate in pharmacology and toxicology.

The sense of smell exhibits numerous peculiarities. Odorous sensations, and most importantly, flavours, are typically not only brought about by the olfactory system, but other sensory channels are also involved in this chemosensory perception, namely the gustatory system, mediating sensations like sweet, sour, salty, bitter, and umami, or the trigeminal system mediating sensations like tickling, tingling, stinging, or burning. Thus, smells or, even more so, flavours are the result of the integration of sensory information through many different channels.

Humans express approximately 350 olfactory receptors. Every olfactory receptor neuron only expresses one single olfactory receptor gene. Further, axons from all olfactory receptor neurons expressing the same olfactory receptor project to two specific glomeruli in each olfactory bulb. This organisation is called glomerular convergence. Olfactory receptors are not selective for only one odorant but numerous molecules may bind with varying affinities to a certain olfactory receptor. Thus, odorants are typically not only recognised by one but by several olfactory receptors simultaneously, according to their particular chemical properties. At the level of the olfactory bulb this leads to a specific activation pattern for each odorant, which is believed to be responsible for the discrimination between different odorants.

Other than other sensory systems the majority of the olfactory fibres does not cross to the contralateral hemisphere but projects ipsilaterally to the brain. Second, most olfactory fibres bypass the thalamus and project very early and directly to the pyriform cortex, amygdalae, and entorhinal cortex, which are implicated in emotional and memory processing. This particular anatomy is claimed to be responsible for the emotions and memories produced by many odours. In addition, the olfactory system exhibits amazing plasticity on several levels: On the level of the epithelium, olfactory receptor neurons are continuously replaced throughout lifetime. Similarly, on the level of the olfactory bulb interneurons are being replaced constantly (accordingly, the volume of the olfactory bulb decreases in cases where sensory input to the bulb is lost, e.g. following head trauma with severed fila olfactoria). Such plasticity provides a basis for adaptive capabilities of this system, which allows humans to adjust quickly to environmental challenges. It is also the basis for recovery of olfactory function following destruction of olfactory receptor neurons, e.g., following infections of the upper respiratory tract.

In a clinical context testing of olfactory function is important as many people misjudge their olfactory capabilities. To this end, standardised systems are readily available, e.g. the *Sniffin' Sticks*. Apart from simple, but effective screening test, these test kits contain subtests for odour identification, odour discrimination, and odour thresholds. In addition, electrophysiological techniques like olfactory event-related potentials allow to objectively measure whether subjects perceive an odour or not. Such techniques are important when it comes to the diagnosis of olfactory loss - which is not a rare finding. In fact, 5% of the population are anosmic! The highest incidence of olfactory loss is found in the age group above 65 years, indicating that we typically lose olfactory abilities as we age.

Accordingly, the quality of our lives decreases as we age, especially because we are less able to enjoy sophisticated (or not so sophisticated, but delicious) foods and drinks. In addition, people with loss of olfactory function experience hazardous situations like eating spoiled foods or not recognising smoke or gas leaks.

Apart from 'aging' as a significant cause of olfactory loss, there are four other major causes: (1) sinunasal disease, e.g., chronic sinusitis or nasal polyposis, produces a gradual decrease of olfactory function; (2) olfactory loss is found after head trauma, and here particularly frequent after occipital trauma; (3) infections of the upper respiratory airways, e.g. a cold or a flu, and (4) neurodegenerative disease like Alzheimer's disease of Parkinson's disease. Interestingly, olfactory loss is an early sign of Parkinson's disease preceding motor symptoms by several years. This symptom is so reliable that in patients with signs of Parkinson's disease but normal olfactory function the diagnosis should be revisited.

With regard to therapy, relatively little can be done in patients with olfactory loss. Patients with sinunasal disease can be treated through surgical or anti-inflammatory regimens using both systemic and local corticosteroids. In patients with post-traumatic or post-infectious olfactory loss so far no conservative treatment has been established. However, recent studies show that training of the sense of smell (the rigorous practice of daily sniffing of four odours in the morning and evening over a period of 4-6 months) is beneficial to patients with olfactory loss. In addition, approximately 40-60% of patients with post-infectious olfactory loss and 10-20% or patients with post-traumatic olfactory loss experience recovery of the sense of smell over a period of 1-3 years. Considering the therapeutic void it appears important to counsel patients with regard to their prognosis.

NEW

3-D biophotonic imaging

USA - The IVIS 3D Imaging System, said to be the first commercial three-dimensional (3-D) biophotonic imaging system, has been launched by Xenogen Corporation at the 4th Annual Meeting of the Society for Molecular Imaging (SMI), held in Germany.

The bio-tech firm, which holds intellectual property rights in biophotonic imaging, reports that this, the most advanced system it offers, was designed to '... provide even higher quality, more predictive data earlier in the drug discovery and development process'.

Evaluation units of the IVIS 3D systems have been installed at several medical institutions, including the Children's Hospital Los Angeles and the Hospital for Sick Children in Toronto, Canada.

Professor Mark Henkelman, professor, Departments of Medical Biophysics and Medical Imaging, Canada Research Chair in Imaging, and director, Mouse Imaging Centre, Hospital for Sick Children, said the system '... enables us to see what's happening to cells inside a mouse, from multiple views and in real time. It is an extremely sensitive camera, and it's now the only way to get data on patterns of emitted light in animals - data we didn't have before. This technology will help us understand gene expression in mice and thus, better predict gene expression in humans.'

Using the firm's systems scientists can visualise, track and understand biological processes in living animals, in real time. The technology incorporates luciferase, the enzyme that makes fireflies and some bacteria glow, into living animals. Illuminating biological processes allows real-time visual exploration and analysis of gene expression, cellular pathways, drug/target interactions and the mechanism of action of drugs.

'The IVIS 3D Imaging System provides a full 3-D diffuse tomographic analysis of bioluminescent light sources in living animals as well as two-dimensional multi-view fluorescent imaging capabilities,' Xenogen explains. 'The system captures and processes numerous views/orientations taken around the mouse to provide researchers with better spatial representations of the light sources (e.g., cancer metastases, inflammatory markers). It is designed to enable researchers to more accurately pinpoint where and when a drug candidate has an effect on or is affected by a normal or disease process. The detailed surface topography measurements provided by the IVIS 3D Imaging System are ideal for co-registering with other modalities such as CT and MRI.'

MIGRAINE PREVENTION

Ian Mason reports from Athens

Professor Hans-Christoph Diener

Greece - 50% of all migraine sufferers are incapacitated during a migraine attack, which also results in countless working hours lost and schedules disrupted - a management headache. Patient satisfaction with current migraine treatments is also very low, according to results from a pan-European patient survey presented at the European Federation Neurological Societies (EFNS) meeting in Athens (September).

The *'Migraine Experience'* survey (Abstract P2131) analysed the impact of migraine on 2,061 people in the UK, France, Spain, Italy, Germany, Switzerland, Sweden, Finland, Norway and Denmark.

Seven out of ten migraineurs reported that attacks isolate them from everyday life and half reported feelings of misery, helplessness, frustration, stress and defeat. 81% reported that social life stops during a migraine attack and 54% said it impacts on their ability to care for the family. Over 50% said they would like to live without the constant worry of another migraine attack, and would welcome better prevention measures.

Prevention - Results from two clinical trials presented in Athens demonstrate that patients with frequent migraine who were treated with Topamax (topiramate) for up to 14 months showed a persistent reduction in the frequency of migraines (Abstract P2138). In addition, analyses from the three 26-week placebo-controlled pivotal trials of topiramate in migraine prevention showed that the drug improved health-related quality of life (Abstract P1158). Dr Domenico D'Amico (Neurological Institute C Besta, Milan, Italy) said: 'While acute treatments can lessen migraine symptoms once it has started, these trials show that using topiramate as preventative therapy reduces the frequency of attacks.'

The drug's most common side effects included paresthesia, loss of appetite, fatigue, nausea, taste alteration, diarrhoea, cognitive side effects and weight loss. The most common adverse events leading to drug discontinuation were fatigue (1.8%), paresthesia (1.6%) and language problems (1.6%).

The study, conducted at five sites in Germany, Italy and the UK, showed that the spray achieved the primary endpoint of headache relief at 30 minutes with significantly higher response compared with the placebo (Abstract P2140).

The study's lead investigator, Dr Peter Goadsby (Institute of Neurology, London) said the new treatment would offer an acceptable alternative for fast-acting relief of pain. A spokesman for its manufacturer, AstraZeneca, said that the company will discuss the new data with licensing authorities.

LAB-ON-CHIP FOR RAPID BACTERIAL DIAGNOSIS

Mobidiag bio-analyst Marika Karjalainen, sample testing with the Prove It diagnostic platform

Finland - A newly-launched lab-on-chip for DNA-based detection of sepsis-causing bacteria has been launched that uses a diagnostic panel from the Helsinki firm Mobidiag running on the STMicroelectronics (Boston, USA) In-Check platform. The firms report: 'The In-Check platform hosts a pathogen panel developed by Mobidiag to identify ten sepsis-causing bacterial species as well as methicillin-resistant strains of Staphylococcus aureus from positive blood culture samples,' the firms report. 'The diagnostic panel has been designed to optimise the choice of antibiotic therapy in combination with results from Gram-staining, an empirical comparative method of differentiating bacterial species. As a result, highly accurate and rapid results from the ST/Mobidiag solution will reduce the risks of antibiotic misuse and help physicians select the right treatment as early as possible.

'ST In-Check lab-on-chip platform amplifies clinically relevant DNA samples by Polymerase Chain Reaction (PCR) and has an integrated custom low-density micro-array. Microreactors buried in the micro-electro-mechanical-system (MEMS) chip carry the mixture of sample and reagents, while on-chip heating elements perform the temperature cycling. Silicon's low thermal capacity and the In-Check design features significantly reduce reaction times and costs, compared with standard laboratory equipment. The risks of cross-contamination inherent in conventional analysis methods are minimised, too, as the PCR and analysis is performed on chip in an encapsulated, self-contained unit.

'The lab-on-chip interfaces to the Thermal Control System (TCS) that actuates, monitors, and adjusts the parameters of the reaction. The TCS unit comprises five control modules with independent thermal protocols and random access capability. Optical signal acquisition is performed by a dedicated portable reader and processed by ST's specialised bio-informatics software, which can be installed on any PC and operates with Mobidiag's clinical reporting user interface. This software package allows users to easily monitor and control the reaction processes, analyse results, and generate reports compliant with MIAME (Minimum Information About a Micro-array Experiment) standards for unambiguous interpretation of data from DNA tests.'

Following a year of joint development, based on early prototypes, Mobidiag is now validating the first units of In-Check lab-on-chips, which contain the control instruments. Clinical trials are planned for early 2006, and the final product should be launched later in the year.

Flow sensors for medical device manufacturers

TSI Inc. provides a complete line of mass flow meters and flow sensors to measure air and other gases (O_2, N_2 and N_2O). Designed for easy integration into new product designs, these devices save engineering time, reduce development costs and help get new products to market faster, TSI reports.

The Flow Sensors measure flow, pressure and temperature, all in one instrument, and they are fast (four millisecond response), accurate (± 2% of reading) and have a low pressure drop, the firm points out.

A dedicated European service facility recalibrates and repairs TSI instruments and, TSI adds, the experienced personnel ensure fast turnaround (typically 3-5 days) to ensure instruments are not out of use for long. (Details: tsiabservice@tsi.com).

Single handed from dictation to document

Continuing Royal Philips Electronics SpeechMike concept of in-built dictation microphone, playback speakers, dictation control and PC navigation, the firm's new *SpeechMike Pro* and *SpeechMike Classic* include intuitive navigation tools, which makes these the first dictation devices to feature a scroll wheel for both navigation and volume control, Philips explains. 'This allows users to move through forms or documents using only one hand. The unique optical trackball offers unparalleled navigation accuracy and requires no additional cleaning. Clearly visible LEDs indicate record, insert and overwrite mode, making operation simple.'

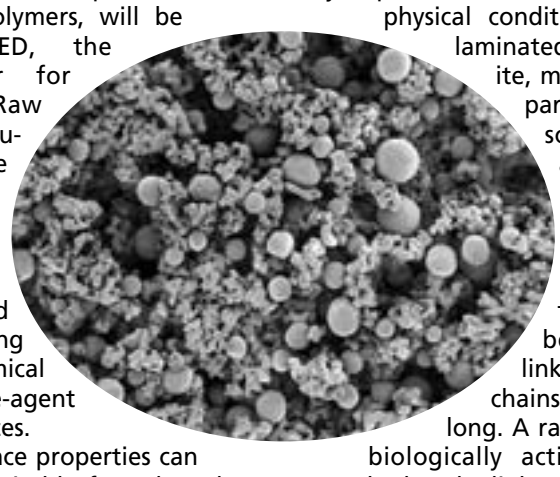
Ergonomically designed, the Classic comes with a programmable 4-Position-Switch and the Pro has programmable push buttons. ('The larger buttons provide greater sensitivity, enabling customers to use the dictation devices without looking away from the computer screen,' Philips adds. 'The controls on these lightweight devices also have been carefully positioned for use by those with smaller hands or who are left-handed.) For integrators, advanced versions with four programmable function keys have been added to the range, enabling users to control additional applications as required. The microphones have a wide frequency and sensitivity range, Philips also points out.

Playback - Volume can be controlled directly and sound quality is said to be crystal-clear.

SpeechMike products are based on the latest USB 2.0 technology and are the first dictation devices to comply with the EU's *'Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS)'* directive, which will take effect in July 2006.

SpeechMagic - Philips has added a new component to the SpeechMagic platform to enable it to work in Citrix environments. This results in a more efficient documentation workflow and enabling the centralisation of IT administration, the firm reports. 'By centralising applications and data delivery the systems can provide an extremely high level of security (no files stored locally), which improves personal data protection. 'By adding bi-directional audio capabilities, Citrix enabled the digital recordings to be uploaded and Philips developed a real-time speech recognition channel. This channel improves the usability of dictation hardware, such as SpeechMike, and allows for the deployment of the full range of speech recognition features within a Citrix environment. Numerous authors can now dictate simultaneously anywhere within the Citrix network and either delegate the dictation to a secretary, or correct it themselves.'

POROUS POLYMERIC MATERIALS



Porvair Filtration Group, which produces an extensive i-Vyon porous polymers, will be exhibiting at ComPaMED, the International Trade Fair for Components, Parts and Raw Materials for Medical Manufacturing, held alongside MEDICA, 16-18 November, in Dusseldorf, Germany. The polymers are used in applications involving fluid transfer, filtration and chemical separation, including sample preparation for chemical analysis, chemical wicking, re-agent support and diagnostic devices.

Modification of their surface properties can also make these materials suitable for a broader range of applications; for example, i-Vyon media can be made permanently hydrophilic or hydrophobic over a wide range of chemical and physical conditions. 'i-Vyon can also be laminated and formed as a composite, making a family of materials particularly suitable for bioscience industries,' Porvair adds. 'The internal surfaces of i-Vyon can be functionalised with a wide variety of chemical groups - e.g. CO, -COOH, & -NH2. The functionalised material can be further modified with linker molecules with carbon chains from 2 to 20 carbon atoms long. A range of chemically active or biologically active species can then be attached to the linker, making this form of i-Vyon an extremely useful support for organic synthesis and biochemical applications.'

Black, beautiful and practical

Inspired by requests from physicians, as well as the US TV show 'Scrubs', MDF instruments decided to elevate instruments from their classical steel appearance and feel. Developing an updated design in co-operation with users of the firm's MDF 767 stethoscope, a smooth, black design resulted: the BlackOut Stethoscope. This has 'highly satisfied' everyone, the firm reports, particularly with its acoustics when identifying the finest heart sounds. In addition, NBC viewers who watch 'Scrubs' now see the show's hospital personnel using the BlackOut Stethoscope.

A full set of the black medical instruments are available, including the MDF808B Aneroid (for professionals) and MDF 808 Aneroid (for home users) blood pressure units; the Taylor Percussion hammer MDF505, and various types of stethoscope (the MDF767 Sprague Rappaport; MDF747 Dual head, and MDF727 nurse stethoscope). Also available: blood pressure units (7), reflex hammers (7) and nylon cuffs (12), plus various types and models of stethoscope (18), all of which come with a spare diaphragm, non chill ring, spare ear olives and ID tag for personal identification.

See them at MEDICA (Hall 13 - Stand A04) in November

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Phone: +49 (0)211 7357 532
Fax: +49 (0)211 7357 530
e-mail: info@european-hospital.com

www.european-hospital.com

Editor-in-Chief Brenda Marsh
Art Director Mary Pargeter
Executive Directors Daniela Zimmermann, Reiner Hoffmann
Editorial Coordination Denise Hennig
Founded by Heinz-Jürgen Witzke

Correspondents
Austria: Christian Pruszinsky. ***Czech Republic***: Rostislav Kuklik. ***Germany***: Anja Behringer, Annette Bus, Heidi Heinold, Max Heymann, Holger Zorn. ***Great Britain***: Brenda Marsh, Peter Howieson. ***The Netherlands, Belgium***: Michiel Bloemendaal. ***Poland***: Pjotr Szoblik. ***Spain***: Eduardo de la Sota. ***USA***: Karen M Dente, Cynthia E Keen, Ivan Oransky, Craig Webb.

UK editorial address
55 Wey Meadows,Weybridge, Surrey KT13 8XY

Subscriptions
Janka Hoppe, European Hospital, Höherweg 287, 40231 Düsseldorf, Germany

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Advertising:
Ted Asoshina, Japan, +81 3 3263 5065
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C.K. Kwok, Hong Kong, +85 2 2890 5510
C.H. Park, South Korea, +82 2 3644 182
Hanna Politis, USA, Canada +1 301 8696 610

Germany
Head Office Düsseldorf
European Hospital, Höherweg 287, 40231 Düsseldorf, Federal Republic of Germany
Tel: +49 211 7357 531, Fax: +49 221 7357 530
e-mail: dz@european-hospital.com

GB, Scandinavia, BeNeLux, France
Simon Kramer, Willem Alexander Plantsoen 25, 2991 NA Barendrecht
Tel: +31 180 6172 26, Fax +31 180 6200 20
e-mail: sk@european-hospital.com

Hong Kong, China
Eastern Source Int. Media Centre, C K Kwok, 25/F Great Smart Tower, 230 Wanchai Road, Wanchai, Hong Kong
Tel: +85 2 2890 5510, Fax: + 85 2 2895 1443

Japan
Echo Japan Corporation, Tetsuzo Asoshina, Grande Maison Room 303
2-2 Kudan Kita, 1 Chome Chiyoda-Ku
Tokyo 102, Japan
Tel: + 81 3 3263 5065, Fax: +81 3 3224 2064
e-mail: ta@european-hospital.com

South Korea
Far East Marketing Inc,
Room 103-1011, Brown Stone,
1330, Baekseok-dong, Ilsan-ku,
Goyang-si, Gyunggi-do, Korea 410-360
Tel: +82 2 730 1234, Fax: +82 2 732 8899
e-mail: ch@european-hospital.com

USA & Canada
Media International, Hanna Politis, 8508 Plum Creek Drive, Gaitherburg, MD 20882, USA
Tel: +1 301 8696 610, Fax: +1 301 8696 611
email: hp@european-hospital.com

Taiwan
Jurassic Communications Corp., Ben Chen,
2F-3, No. 147, Lung Chiang Rd., Taipei 104, Taiwan R.O.C.
Tel: +886 2 8712 2385, Fax: +886 2 8712 2618
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