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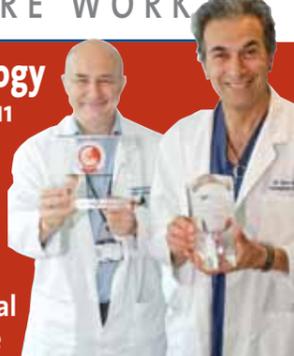
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VOL 20 ISSUE 4/11

AUGUST/SEPTEMBER 2011

Date for the diary...
11-13 October
The Global E-Health Forum – Hamburg 2011



Designing personalised healthcare

Improving the quality of healthcare, increasing the efficiency of the systems and ensuring patient empowerment - these are common goals worldwide when discussing the necessary transformation of healthcare systems to guarantee sustainable healthcare delivery in the future. The Global E-Health Forum – Hamburg 2011 will represent major stakeholders involved in designing personalised healthcare.

'E-Health is increasingly seen as a key enabler for this transformation and as a key enabler for the evolution process towards personalised healthcare,' says Ljubisav Matejevic, founder and honorary chairman of the Global E-Health Forum. 'Healthcare that is proactive, instead of reactive, gives patients the opportunity and responsibility to become more involved in their own health. The ultimate goal will be to shape preventive and diagnostic care to match each person's unique characteristics.'

The initiators of the Global E-Health Forum – the Hamburg Chamber of Commerce, IBM and ICC - have developed this platform to discuss e-health strategies, best practices and new services/patient-centric approaches in a global context. While the main target groups consist of CEOs, CIOs and CFOs of hospitals and clinics, the comprehensive programme will also attract representatives from government bodies, health insurance organisations, service providers, influencers from hospital and health management associations as well as representatives from universities/research institutes. Canada supports this year's forum as its partner country.



Key international speakers will include Richard C Alvarez, President and CEO of Canada Health Infoway; *Transforming Healthcare in Canada through E-Health*; Dr Eric M Liederman, Director of Medical Informatics, The Permanente Medical Group (USA); *Balancing Privacy Protection with Patient Care*, and Chai Chuah, National Director, National Health Board Business Unit, New Zealand Ministry of Health; *Sustainable Personalised Healthcare - Challenges and Opportunities*. Their strategy presentations and case studies will be complemented by workshops and an exhibition of solution providers.

Guided tours at hospitals will include various Asklepios clinics. In Germany, the Asklepios Group manages more than 100 facilities, almost 40 day hospitals, around 22,000 beds and 36,000 employees. Details: www.global-ehealth-forum.com

Whilst the UK's massive National Health Service's NPfIT programme saw some healthy successes – already delivered and integrated into the service are applications such as *Choose and Book*, *Electronic Prescription Service* and *PACS* – through the near decade of the existence of this mammoth project, involving a still evolving science, there have been unhealthy delays, overspending, cancelled contracts, and too much else.

For example, although the plan aimed for every patient to have an electronic care record by 2010, systems ordered by the Department of Health (DoH) from suppliers British Telecom (BT) and the US firm CSC are not all are likely to be in place until 2015-16, and reservations have been aired about that completion period.

In addition, among 4,715 NHS organisations in England expecting to receive a new IT system, over 3,000 are still outstanding.

Up to recently, around £6.4 billion has been spent on the programme and £5 billion more was earmarked for investment.

In September 2010, following a review of the NPfIT programme, the DoH concluded that 'a centralised, national approach is no longer required, and a more locally-led plural system of procurement should operate, whilst continuing with national applications already procured.'

This February, the death knell sounded louder following the release of a report from the National Audit Office (NAO) that revealed the state of the NPfIT, nine years after its launch. In a statement in May 2011, Amyas Morse, head of the NAO said: 'The original vision

UK government topples the dinosaur

Cut to size: The £12 billion NHS National Programme for IT (NPfIT)

Led by the then Prime Minister Tony Blair, the United Kingdom's Labour government proudly launched its National Programme for IT (NPfIT) in 2002, a forward-looking plan with huge budget to match. The following year the nation was awed by something akin to a gold rush, as information technology companies scrambled to compete for and gain healthcare IT contracts from the £12 billion project. Today, that ambitious programme has been abandoned or, on closer inspection, somewhat adjusted, *Brenda Marsh reports*

for the National Programme for IT in the NHS will not be realised. The NHS is now getting far fewer systems than planned despite the Department paying contractors almost the same amount of money. This is yet another example of a department fundamentally underestimating the scale and complexity of a major IT-enabled change programme.

'The Department of Health needs to admit that it is now in damage-limitation mode', he continued. 'I hope that my report today, together with the forthcoming review by the Cabinet Office and Treasury, announced by the Prime Minister, will help to prevent further loss of public value from future expenditure on the Programme,' he concluded.

In July a government white paper

announced its radical re-organisation of the health service.

In August, a Commons' Public Accounts Committee report called for the entire NPfIT, including plans for EPRs, to be dropped and, backed vociferously by Members of Parliament, criticised IT suppliers – BT and CSC – for failing to deliver what was guaranteed in their contracts.

The DoH has been negotiating with CSC for over a year, and is reported to have said that it might be more expensive to terminate the contract than to complete it. (According to CSC's annual report in June, the DoH paid the firm £200m in April, as part of an advance payment. There is a provision: that the firm, which is responsible for the implementation of iSoft's Lorenzo software in

three UK healthcare regions, will repay the sum upon NHS demand in September 'if the parties are not progressing satisfactorily toward completion of the expected contract amendment'.

BT, also accused of being unable to deliver according to its original contract, is additionally accused of demanding over four times the market rate for its services – it receives \$9 million for systems in each NHS site, 'even though the same systems have been purchased for under £2m by NHS organisations outside the NPfIT'.

Before mid-August, the UK Coalition Government (Conservative and Liberal Democrat) acted. It now intends to replace the world's most ambitious healthcare IT programme with a form of decentralisation that might at least save £700 million.

Health Minister Simon Burns said: 'We will allow hospitals to use and develop the IT they already have and add to their environment either by integrating systems purchased through the existing national contracts or elsewhere.'

The NHS now has matured applications that no longer need to be managed as projects; they can be controlled by the NHS itself. According to a DoH statement, *continued on page 3*

Russia's new healthcare legislation

The initial bill on *The basic principles of healthcare for the citizens in the Russian Federation* passed its first reading in the State Duma (the lower house of the Federal Assembly of Russia). Upper house: Federation Council of Russia). The current healthcare legislation came into effect in 1993. Since then, much has changed in Russian society, writes EH correspondent Alla Astachova

The law on mandatory medical insurance was recently adopted, bringing to an end the so-called 'patient bondage' in Russia's healthcare system. Formerly, someone in need of medical care could not freely choose a doctor but had to apply for medical assistance at the healthcare institution in the district where he/she was registered.

Today, whilst the mandatory insurance policy is valid throughout Russia, the implementation of the new regulations requires some additional measures.

In the past, residents of one region could not obtain medical assistance in other areas because inter-territorial payment schemes were not adjusted. Healthcare funding was not sufficient in 'poor' regions, which means that, for their residents, medical treatment in a clinic situated in a 'rich' district of Russia was not affordable.

According to Deputy Minister of Healthcare and Social Development, Veronika Skvortzova, the new law will abolish these differences in healthcare funding.

Moreover, it will introduce unified quality standards for medical care. The standards were drafted on the basis of clinical protocols and guidelines and present principal elements mandatory for healthcare in defined profiles.

A standard allows evaluation of the costs of medical care on a minimum/maximum scale and the definition of an average. Officers in the Ministry of Healthcare affirm that the above mentioned meas-

ures for the first time will enable them to calculate the actual funding requirements of Russian healthcare. It has always been common practice in Russia to finance public healthcare from budget leftovers and the estimates by healthcare officials were based chiefly on the amounts allocated by the government.

The new legislation also aims to remedy numerous problems that have accumulated in the Russian healthcare sector during the past 18 years. For example, finally pharmaceuticals might become available for patients suffering from 'orphan' diseases. Furthermore, the law will ban euthanasia and it includes a presumed consent provision for organ donation. The bill also proposes physicians' accreditation to improve the quality of care.

Nearly every single provision of the proposed law provoked controversial public debates. Professional associations of physicians, for instance, expressed their discontent with the mandatory accredita-

tion at the Ministry of Healthcare and Social Development.

At the same time, the most essential problem of Russian healthcare is not solved: insufficient funding. The funding gap expected for the coming years is estimated at 20-25% of the budget.

The members of Duma, who are now debating the bill, have many issues to consider. The parliamentary working group is expected to meet daily.

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Do you consider that your equipment is out-dated Yes No

relatively modern Yes No

state-of-the-art Yes No

Do you use/buy second-hand equipment? Yes No

If so, what do you use of this kind? _____

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Is your department linked to an external computer network? Yes No

Is your department involved with telemedicine in the community? Yes No

Do you consider your department is under-staffed? Yes No

Are you given ample opportunities to up-date knowledge? Yes No

Do you attend congresses or similar meetings for your speciality? Yes No

This information will be used only in an analysis for European Hospital, Theodor-Althoff-Str. 39, 45133 Essen, Germany, and for the mailing out of future issues and the EH electronic newsletter.

EH 4/11

NEWS & MANAGEMENT

Following 19 years at the German Federal Ministry of Health, in 2006 economist Georg Baum became Managing Director of the German Hospital Association (DKG) and in this capacity will attend the German Hospital Congress. In June this year he was also elected President of HOPE and as such will also lead the very first European Hospital Conference. Both events to be held during Medica in Dusseldorf



Visiting European healthcare professionals will be able to enter a strong debate on hospital-related politics as well as medical and economic issues at MEDICA this year when the 1st European Hospital Conference (EHC) will take place alongside the 34th Congress of German Hospitals.

Directed by the German Hospital Association (Gesellschaft Deutscher Krankenhauser -- GDK) and led by Georg Baum (above), President of the European Hospital and Healthcare Federation (HOPE), the conference will open with an examination of the current European health policy and the impact of the EU patients' rights directive. Passed by the European Council of Ministers in February, these guidelines envisage patients having cross-border access to healthcare services, inclusive of a free choice of doctors and hospitals across the entire EU.

During our EH interview, the HOPE President expressed his particular pleasure that Luxembourg Health Minister Mars di Bartolomeo will attend the conference. 'With Mr di Bartolomeo,' he explained, 'we have an experienced EU health politician on our side with whom it will be a pleasure to discuss the shape of hospital organisation with the attending decision makers and experts.'

Feeling 'very honoured' that HOPE's European members have appointed him to lead the organisation for the next three years, George Baum added: 'Representing the interests of all European hospitals is a highly complex task. The European healthcare market is a very heterogenic entity, which comprises very different social security systems with very different structures, resources and national welfare systems. I see myself as the guardian of national responsibilities as well as a promoter of committed European policies.'

Asked about a potential conflict of interests in representing both the German Hospital Association

Following five years as Vice-President of AEMH, João de Deus (right) became its President in January 2010. In Lisbon, Portugal, he is Senior Hospital Doctor of Ophthalmology in Egas Moniz Hospital, and Professor of Ophthalmology in the city's Health Technology University. Among his many important appointments, and as Professor of Medical Ethics in the Catholic University of Lisbon, from 2006 to 2009 he served as Vice-President of Ethics Sub-Committee of CPME (Standing Committee of European Doctors)



When Georg Baum, President of the European Hospital and Healthcare Federation (HOPE) kicks off the debate on hospital-related politics and medical and economic issues at the European Hospital Conference (EHC), fellow participants will include Heinz Kölling, President of the European Association of Hospital Managers (EAHM) and Dr João de Deus, President of the European Association of Senior Hospital Physicians (AEMH). During our interview with Dr de Deus, he pointed out that AEMH, HOPE and EAHM hold different views on European healthcare policy, which is why he believes the debate at this year's 1st EHC will be 'very lively'.

'The EHC will offer a great opportunity for our societies to debate fairly and squarely,' Dr João de Deus explained, referring to the different views of the AEMH, EAHM and HOPE. 'Hopefully,' he added, 'we will come to some shared conclusions.'

Since 1963, the AEMH has provided a platform for hospital department heads and other physicians, aiming for cooperation and communication between national member delegations to improve understanding of the different health systems and reduce hospital care inequalities within the EU Member States. Today the organisation is the umbrella of 17 national member delegations. How does it accommodate the number of claims?

'Due to the different healthcare systems in the European States, the organisational structures of public health and healthcare work can vary a lot -- we deal with different problems from different countries. First, this means that we must gain a deep understanding of the national mismatch in order to support the interests of our national delegations,' Dr de Deus explained. Questions arising, he said, include: Is it a national health service? Is it a national or private insurance model? What are the working conditions for hospital doctors?

'On the other hand, one of our struggles is trying to harmonise these different systems, because patient safety and quality of healthcare in a cross-border environment, where health professionals and patients can move freely within the EU, is a priority for all our policy areas.' Generally, he explained, the AEMH divides its tasks in two -- supporting the positions of its national medical associations in relation to their own governmental health-

A date for your diary - 18 November The 1st European Hospital Conference

Where? At MEDICA 2011

(DKG) and the European Hospital Association, he said it actually works quite well. 'As our European healthcare systems are very much geared towards their own, national control mechanisms, at the DKG I look into issues around legally required provision, compensation systems and quality assurance measures etcetera. Of course there are also common grounds here on an EU level, regarding to the patients' rights directive. There are different opinions across HOPE member states as to how much freedom patients should be given regarding their choice of treatment abroad. In Germany, we don't have concerns because we can provide all forms of maximum care ourselves. However, there are countries with different national healthcare systems which fear they might lose patients. This includes countries with long waiting list problems, such as the Nordic countries and Great Britain, and Eastern European countries that are only just in the process of developing independent healthcare infrastructures.'

One effect of the EU patients' rights directive on hospitals is that they must prepare to receive streams of foreign patients, he pointed out, and that includes providing the necessary communication skills, within the hospital as well as for follow-up communications with patients' physicians abroad. 'Many hospitals are actually already responding to enquiries from abroad and also actively promoting their services abroad. We are already working with the Federal Ministry of Economics to promote Medicine made in Germany as an international brand. I think it is a legitimate approach for each country to offer its medical treatment capacities and qualities on the international healthcare market. The cross-border freedom of choice can actually promote quality competition amongst hospitals and doctors.'

Implementing the patients' rights directive
The directive requires that all EU Member

States provide transparency about their range of services, prices and quality of treatment. We are already well on our way with this in Germany; we introduced a hospital catalogue a few years ago that systematically informs about the range of treatment on offer, and the quality of results in all German hospitals. There will probably be a need for clarification on how services are being reimbursed. The directive envisages that patients will pay for their treatment immediately. However, there is also discussion as to whether it would be possible to process payment via the respective social security systems. I'm rather critical about this. Moreover, in countries that lack capacity for patient care, things will depend on how they handle the right of provision of their own medical insurance systems, that is, how they will handle their national guidelines on the authorisation of treatment abroad.'

Major challenges

The lack of qualified doctors and nurses, as well as younger medics, is a problem across Europe, resulting from demographic change, he points out, mentioning increasing intensive care for aging populations. Thus, there is discussion about an EU guideline on the recognition of qualifications, including stipulation that nursing qualifications will only be internationally recognised if candidates have previously attended school for 12 years. This would considerably damage, for example, Germany's current policy, which requires school attendance for only 10 years, and would prevent many motivated young people from entering nursing.

The European Hospital and Healthcare Federation (HOPE)
Founded in 1966 and initially aimed at knowledge exchange on best practices and networking among participating European hospitals, with the increasing importance of EU policies and healthcare provision in the Member States, HOPE's range of objectives gathered pace. Today it not only represents the interests of its member organisations at important EU institutions in Brussels, but also is increasingly involved in EU-funded research projects, as well as promoting the international exchange of experience among hospital leaders through the annual HOPE Exchange Programme.

Diverse views, similar aims

The 1st EHC will see three important organisations face up to their differences in what promises to be a great debate

care policies, and the Association's promotion of healthcare cooperation objectives on an international level within the framework of European Union.

Asked about any standards that could guarantee treatment quality and patient safety, Dr de Deus pointed out that there are three key strategies: 'First, the introduction of risk management routines; for example, by developing guidelines and indicators as a part of a quality assessment system in the healthcare sector. Secondly, the involvement of senior physicians in hospital management is crucial. Doctors take responsibilities for many hospital decisions that influence performance and quality of care and therefore inter-relate with other areas in the hospital and human resources, financial success, healthcare policy and economics.'

The third aspect is the evaluation of pre- and post-graduate education. Continuing professional development (CPD) is a major concern to our association with regard to quality assurance. Due to the increasing economic and financial difficulties in European hospitals, we observe a worrisome development in some EU member states, where primarily physician-directed tasks are delegated down the line to nurses and other non-physician staff members. Many governments support this task-shifting policy, because of the shortage of doctors in their countries and because nurses are much cheaper labour than highly trained physicians. However, we believe it's a dangerous threat to patient safety, if healthcare workers with no deep medical understanding do, for example, surgical operations.'

Is medical training harmonised in the EU?

'Unfortunately not,' Dr de Deus regrets. 'Whilst in the course of the Bologna Process the academic training in European medical faculties has reached a high international standard, we face a huge problem of harmonising medical training in the EU and therefore in a consistent recognition of professional qualifications in working life.'

'When it comes to specialisation, the countries have very different rules for training times, certification and validation processes. For instance, in some countries no official training programme exists for medical specialisation. This situation is unreasonable. Therefore, we have initiated a working group to deal with training, CPD and learning needs assessment.'

The migration of doctors within the EU also causes acute physician shortages in some regions. How could this trend be countered?

'From an individual's aspect, it's of great importance that doctors as well as patients can move freely within the EU. But the reason why doctors migrate to other countries are much too often bad working conditions with long

working hours and low payment. If European countries would assimilate much more in these points, the tendency of doctor shortages would decline. Good working conditions for doctors are also a major component in ensuring quality of care and patient safety. Excessive working time, poor or no rest after a long work period, understaffed teams, work overload, inadequate or outdated equipment, a lack of collaboration and communication among clinical staff, create not only a bad working atmosphere but also encourage sources of errors.'

'We deal with this problem also in the revision of the European Working Time Directive, in which, among other things, we demand the inclusion of a period of rest after a long period of work, exclusion of opt-out and the concept of "inactive period of work". We have elaborated and sent to the European Commission and European Parliament some common documents with other European Medical Organisations (Standing Committee of European Doctors, the European Federation of Salaried Doctors and the Permanent Working Group of European Junior Hospital Doctors) stressing our position about this proposal of revision.'

'Another problem in this context is that up to forty percent of medical students, after acquiring their university degree, don't choose a career in clinical medicine but go into research or free enterprise -- precisely because they are put off by the bad labour conditions in the physician's profession.'

Do some EU countries have more commendable healthcare systems than others?

'No system is perfect,' Dr de Deus believes, adding, 'but there are some better than others. France is certainly very advanced when it comes to unrestricted access to healthcare services. The patient can freely choose his doctor, specialist or hospital and the waiting lists are therefore much shorter than in other countries.'

'Luxemburgers are also very content with their statutory health insurance system. However, because this is a very small state it has some peculiarities that make it difficult to transfer to larger states.'

'Generally, the economic state of a country gives evidence about a good working healthcare system only to a limited extent -- as recently could be seen in Portugal. In addition, nowadays we see an increasing number of liberal healthcare systems in Europe. In particular, in East European countries the privatisation of hospitals quickly progresses towards Americanisation circumstances, which make hospital access for non-insured patients more difficult and jeopardises labour guarantees and the power of physicians in their workplace. We have to wait and see where this will lead in the future.'

PURCHASING DIAGNOSTIC SYSTEMS

Manufacturers urged to add environmental impact to product details

The acquisition of large diagnostic imaging equipment is clearly expensive – but further costs also result from their energy consumption and maintenance, as well as hidden costs due to complicated, labour-intensive handling, removal and disposal of old equipment, etc. often not considered during purchasing.

Making ecological aspects more transparent during acquisition and including these in the equipment calculations is the focus of a cooperation project for integrated product policies (IPP) in medical technology, initiated by the Office for Urban Development and the Environment in Hamburg. Hospital and clinic representatives in northern Germany, and those from companies such as Siemens, Philips, Agfa and GE Healthcare, and other German associations, e.g. the ZVEI (German Electrical and Electronics Manufacturers Association), linked up to establish which ecological criteria should be included in the evaluation of the use of medical devices.

From the project *Ecological Product Information for Diagnostic Imaging Equipment* a catalogue* of criteria, listing 27 points, was developed. The catalogue enables diagnostic imaging equipment buyers to ask manufacturers about the most important ecological criteria and therefore contribute towards a standard of information that ensures better comparison of important criteria for the environment and for purchasing budgets.

The initiative is encouraging medical technology manufacturers to include the project results in their product descriptions. The advantages of the developed standards are obvious: Independent of the purchase price, hospitals and surgeries can identify potential savings in an environmentally friendly manner and, in the long term, be able to identify cheaper equipment.

Along with a marketing gain, manufacturers will also gain insights into the customers' expectations of the equipment, which may then influence product development.

Refurbished diagnostic equipment is also attractive to budget conscious healthcare providers. To ensure safe and fully functioning second hand equipment, COCIR (European Coordination Committee of the European Radiological, Electromedical and Healthcare IT Industry) developed its *Green Paper on Good Refurbishment Practice*. Among the members, Siemens has an advantage with its *Proven Excellence Programme*, which guar-

antees customers quality comparable with a new system at up to 30% lower purchasing cost. Around 90% of the materials of the initial products are used for refurbishment.

Dr Freimut Schroeder of the Medical Solutions Environment, Health and Safety Division at Siemens in Erlangen, heads the Working Group Environment at COCIR. He emphasises: 'Product-based environmental protection on the part of the EU must start during the product development phase. All diagnostic and imaging equipment in medicine should be supplied with comparable information about its environmental performance.'

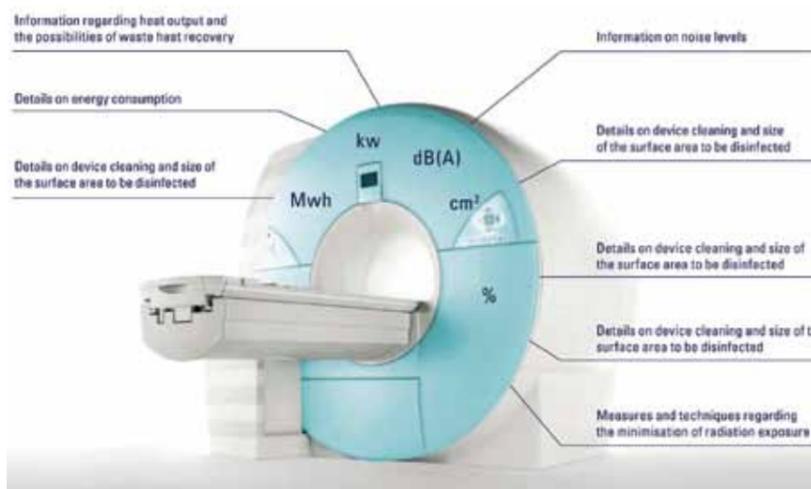
In recent years Siemens' refurbishment sites at Forchheim in Germany and Hoffman

Estates in Illinois, USA, implemented the processes set out in the Green Paper.

Positive reactions were also received from NEMA (National Electrical Manufacturers Association, USA), JIRA (Japan Industries Association of Radiological Systems), MIISC (Medical Imaging & Information Systems Council, Canada), the US Department of Commerce, and the Chinese Hospital Association.

COCIR is now collecting feedback from all partners to develop the second version, which will form the basis for a future international standard.

*English version: www.klima.hamburg.de/ipp-medizintechnik
Report: Anja Behringer



UK Governments topples the dinosaur

continued from page 1

NHS local organisations now can themselves 'introduce smaller, more manageable change, in line with their business requirements and capacity. NHS services will be the customers of a more plural system of IT embodying the core assumption of "connect all", rather than "replace all" systems. This reflects the coalition government's commitment to ending top-down government and enabling localised decision-making.'

Until a review report expected to be aired in September and focusing on the NPfIT's Summary Care Records system (aiming to implement a national electronic patient records application), no one knows whether this will also face further cuts.

A decade is a long time in information technology. Since the NPfIT began, electronic communication has advanced so rapidly that perhaps the UK's elephantine healthcare IT project became more of a dinosaur, doomed from the start from a technology climate change. Certainly much has been learned and progress made, but the ultimate lesson appears to be that small has more chance of survival, and in that smallness it has to be the people 'on the ground', in this case healthcare IT users, who control their individual institutions communication needs, though still able to use a larger communications infrastructure as needed.

The decentralisation of government IT should prove faster to implement as well as enjoy standardised, interconnected systems – becoming nothing too big to survive.

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Referral management and referral cooperation

Referral cooperation is of particular strategic importance to hospitals and the referring doctors are important 'anchors in the market'. They ensure continuous demand from patients and ensure their quality care after discharge.

Around 70% of patients follow their GPs' referral recommendation. 94% of patients use their GP as a source of information on issues of medical quality (37% frequently, 57% occasionally), 85% ask their specialists (19% frequently, 66% occasionally).

However, specialist doctors are also important referrers: 74% of patients ask their GP for immediate referral to a private specialist when a diagnosis is unclear.

Referral management represents a special strategy to sustain development and safeguard a hospital's referral potential. Its objective is to attract and work in the long term with those doctors who can be classed as 'successful referrers' (graph 1) i.e. who:

- look after a large number of cases
- have medically interesting and economically attractive case structures
- enjoy above average popularity (friendliness, helpfulness, understanding, etc.) among patients
- are competent
- are interested in developing their own patient market by providing innovative services.

Referral management corresponds with medical care (social empathy), quality of accommodation and care as well as service. After a hospital stay, a patient who complains to his GP about one of those aspects counteracts any strategy of direct referral care. A quickly despatched doctor's letter does not make up for unfriendly care or the need for surgical revision (graph 2).

Referral management and referral marketing are part of the marketing strategy of the hospital and are design objects as well as design elements of the marketing mix.

The view of the referring doctor

Successful referral management rests on a win-win basis. In as much as the hospital is very interested in working with medically effective and economically attractive referrers in the long

'New market dynamics' in healthcare, with characteristics such as crowding out, internationalisation of medical services, increasing transparency of services due to the media, and price-oriented reimbursement systems, enforce quality-promoting and cost-reducing labour divisions as well as cooperation of all players in healthcare provision. Professor Wilfried von Eiff (right), from the Centre for Hospital Management, University of Munster, Germany, outlines approaches to cope with these demands



term, a referring doctor will always be aiming to cooperate with those hospitals that provide added value for his surgery and his patients. Doctors particularly value these service characteristics from cooperating hospitals:

- Outstanding medicine with the option of obtaining second opinions
- Quality of hygiene management, particularly regarding infection risk (norovirus, Clostridium difficile, MRSA)
- Participation in the know-how and development of experience through training, observation and residency

around the clock availability of current patient status information, joint development of treatment plans for aftercare. This includes the availability of the diagnosis upon discharge or no later than 24 hrs later.

- Quality and safety of pharmacotherapy (microbiology for antibiotics treatment, presence of a clinical pharmacist in the treatment team).
- Room design and equipment that ensures privacy and confidential doctor/patient talks.
- Real-time, direct referral of the patient back to the referring doctor.

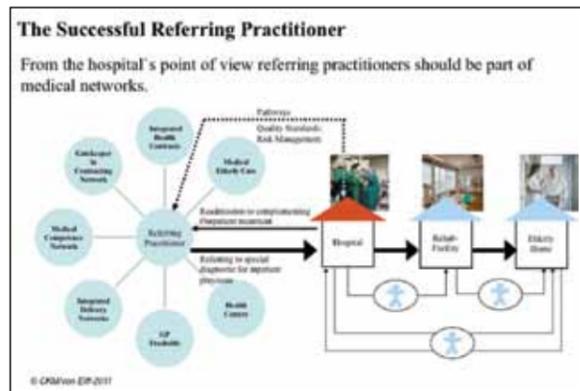
- Medication management to ensure continuous, stratified drug therapy.
- Real-time availability of medically relevant information for follow-on treatment by the referring doctor.

Summary

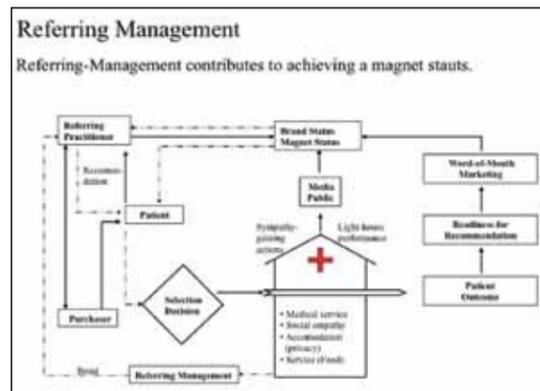
Referring doctors are the 'anchors' for hospitals in the market for medical services.

Referral management

- should be a central, strategic hospital task, to ensure its long term, economically stable survival
- needs to be strategically developed and carried out by an organisationally established, professionally designed specialist function with knowledge of medical processes. It should not be 'caretaker' management
- needs to be hospital- department- and people-specific, i.e. every consultant and specialist registrar needs to carry out referral management based on the strategic requirements
- can be achieved through different cooperation models: Integrated care, the portal-hospital concept, gatekeep-



Graph 1: Successful referrers who have themselves integrated into efficient networks are medically discerning and of economic interest



Graph 2: Referral Management contributes towards the development of a market status; market status and quality of a hospital's referral management in turn impact on the referral recommendations among GPs

and integration into knowledge management (specialist article matching on ICD basis, case-related article research, information on adverse drug reactions, aftercare guidelines etc.)

- Smooth, non-intrusive organisation of patient care, particularly regarding admission and discharge management through a case manager,

these interfaces work, the more qualified the medical result, the better the patient outcome and higher the satisfaction among patients and their referring doctors.

Three important aspects to the interface between out- and in-patient care need particular organisational solutions:

- A consistent point of contact for the referring doctor.

er-concept, community health centres and centres of competency. The concepts aim to achieve the best possible, medically-appropriate patient care at sustainable cost.

Referral controlling helps to monitor the qualitative and financial effects and to derive measures for referral care.

Further details: von.eiff@uni-muenster.de

The role of hospital management consultants

'Public hospitals are not yet acknowledging the necessity of engaging management consultants in the same way as private institutions. Management



and organisational consultancy is particularly important in hospitals as it is not just undertaken for the benefit of staff but also the benefit of the patients" explains Verena Krassnitzer, Vienna-based management consultant and supervisor, organiser and coordinator of a pool of supervisors for temporary assignments to the Vienna Hospital Association KAV. With 12 hospitals, 11 geriatric care centres and a care home, KAV is one of the largest hospital associations in Europe.

Management consultancy aims to analyse organisational processes, communication structures, decision-making and power structures in organisations in cooperation with the employees and, where necessary, to change them. Often it is not possible to draw a clear line between consultancy, supervision and coaching. 'In many cases we are commissioned to carry out a supervisory function in a hospital department when in fact all we do is management consultancy,' she points out.

Typical situations where management consultancy is required are in the implementation of new processes or merging teams or departments. For example, in a psychiatric department in a hospital in Lower Austria, the consultant and the in-house hospital team developed and implemented a new daily routine, a new form of team briefing and a new structure of cooperation with external institutions. Management consultants can also help with severe and persistent conflicts within teams. 'High sickness rates and large staff turnover, the results of bullying or burn-out, point towards something not being quite right on a ward or in a department,' Verena Krassnitzer points out.

A large potential for conflict is inherent in the system of collegial leadership, typical in Austria as well as Germany. In this, there are separate hierarchies for doctors and nurses; the medical head of a department therefore cannot give instructions to nurses because they report to the respective charge nurse and nursing directorate. 'Cooperation between doctors and nurses is therefore often less than perfect,' she points out.

For this and other reasons she believes that working with executives is particularly important. On the one hand, management consultancy can only work if executives believe in it: 'If the medical head of a department or the charge nurse says "This is humbug" then consultancy becomes difficult. The leadership team has to be sat around a table so that mutual trust can be established, otherwise it's not possible to work together successfully.' On the other hand, in hospitals more than in other organisations, hierarchy is based on expertise, meaning it is not leadership skills that determine whether someone is appointed to a leadership position, but professional competence.

'If a doctor who is excellent from a professional perspective takes up a leadership position, he or she suddenly has to deal with issues that have nothing to do with his/her professional expertise,' the consultant emphasises. 'Being in a leadership position means making decisions, communicating with others, thinking strategically. A leader must be rock solid, should resonate with the staff and must be part of a team as well as its counterpart.'

Vienna recently announced a comprehensive hospital reform to be completed by 2030. Five of the city's 12 hospitals are to be closed, with many departments moving over to other existing hospitals or into the new Vienna North Hospital, opening in 2015. The remaining hospitals are to be transformed into centres of excellence for specific medical specialties and harmonised with one another.

With this in mind, Verena Krassnitzer predicts: 'There will be a big demand for management consultancy.'

Report: Ronald Bäcker

Correction: European Hospital 3/11 - Page 15

Article: Dose discussion - How low can you go?

We apologise to our readers and GE Healthcare for a misleading error in our last issue. Two captions were reversed in this feature.

As you will see from these images and captions, the ASiR reconstruction is far clearer than the FBP reconstruction.

Crohn's disease follow-up exam



FBP Reconstruction



ASiR Reconstruction

3.2 mSv* effective dose (DLP: 192 mGy.cm) 70 to 84 mAs, 120 kV

*Obtained by EUR-16262 EN, using an adult abdomen factor of 0,015*DLP and a pelvis factor of 0,019*DLP

A date for the diary... 5-8 October SALZBURG, AUSTRIA

The European Health Forum Gastein

Founded in 1998, the European Health Forum Gastein is Europe's leading health political conference, attracting 600 participants from around 60 countries. Beyond the EU, its leading role is underlined by the participation of active members from the GUS states, south-eastern European countries and Taiwan, Christian Pruszinsky reports.

The event has become an international meeting place for top-level healthcare politicians, managers and scientists from all over the world, EHFG president Professor Günther Leiner points out. 'When it comes to health political discussion and the exchange of information on the highest level then the EHFG is probably unique in Europe.'

This year, in Salzburg, intensive dialogue between those in politics, administration, science and research, economics, civilians, with key players from the EU member countries as well as others in the WHO region Europe.

High-ranking speakers will include: John Dalli, EU Commissioner for Health and Consumer Policy, Maire Geoghegan-Quinn, EU Commissioner for Research, Innovation and Science, Ewa Kopacz, Minister of Health of the Republic of Poland (EU presidency country for the second half of 2011), Bertel Haarder, Minister of the Interior and Health, Denmark (EU presidency country for the first half of 2012), Taiwanese Health Minister Chiu, WHO Europe director Zsuzsanna Jakab and Austrian Health Minister and host of the event Alois Stöger.

With English the main congress language, there will also be simultaneous translations into English, German and Russian during the plenary events, and most parallel panel meetings and workshops.

Under the slogan Innovation and Wellbeing - European Health in 2020 and beyond, six parallel panel meetings and



Günther Leiner

14 workshops will deal with health politics, patient-related and socio-economic issues in an interdisciplinary and cross-border context, and key topics in research and pharmaco-

logy, medical technology, IT and last, but not least, with aspects of the economic orientation and financing of systems.

Prevention

A key topic will be 'non-contagious diseases', which cause 86% of deaths in Europe and represent the biggest problem for healthcare systems. In 53 countries within the WHO region of Europe, cardiovascular diseases, chronic respiratory diseases, diabetes and cancer make up 77% of those diseases. 'Lifestyle diseases' are also the central threat to health in emerging nations and developing countries; the current global status of the WHO for the previously mentioned groups of diseases shows that they are responsible for 63% of all 57 million deaths worldwide,' Prof. Leiner points out. In an interview with EH correspondent Christian Pruszinsky he described this development as particularly irritating because most of those diseases go hand in hand with known risk factors, such as lack of exercise, unhealthy diet, alcohol abuse and smoking, all of which could be avoided.

'Consequent prevention can save millions of lives,' he says, adding that there is an enormous need for action among health politicians. According to WHO estimates, in 2020 there will be annual 7.5 million deaths annually caused by smoking, an annual 3.2 million deaths due to lack of exercise, 2.8 million deaths due to obesity and 2.5 million deaths through alcohol abuse. However, currently 97% of healthcare expenditure goes towards the

treatment of diseases and a mere 3% is invested in prevention. Prof. Leiner demands political decisions on a national and international level to limit tobacco consumption, lower the daily intake of salt by an average 3g, eliminate trans fats, reduce saturated fats and promote exercise via transport policies.

The EHFG president believes that instead of the current, very decentralised decision-making structures in the medium to long term there ought to be enhanced EU competency in questions of healthcare through step-by-step development of transnational cooperation: 'A lack of common, EU health policies is out of line with current requirements.'

Further key topics at the congress will look at health through innovation and design, Health in 2020 - European healthcare concepts and future strategies, the European innovation partnership for active and health ageing, trends in health technology assessment and future personalised medicine. Other focuses will include, for example, health security, chronic diseases, medical innovation, optimising adult vaccination, migration and health and healthcare financing.

European Health Award 2011

As an acknowledgement of transnational healthcare initiatives in Europe with significant potential for quality improvements and increases in efficiency, the 14th EHFG will award the €10,000 European Health Award. Important criteria will be the participation of several countries, transferability of results to other countries and immediate benefit for large parts of the population or patient groups.

This year's shortlisted projects: ECORN-CF, Child Safety Report Cards, the IMAGE Project, HeartScore and the Move for Change Campaign

Siemens describes its new and advanced technology at AACC 2011

Automation and IT establish a path to increase the laboratory's value to clinicians

The health of the laboratory/clinician relationship has always served as a good indicator of the overall quality of a given healthcare network. Historically, labs focused 'heads down' on delivering excellent test results, but today appear to be expanding their horizons to partner with clinicians for better patient care. And, for their part, clinicians expect more from laboratories now than five, 10 or even 15 years ago, because patient and testing volumes are ever increasing and diagnostic testing has to meet clinicians' needs for faster, more accurate and error-free analytical results on a daily basis. To meet these rising expectations, laboratories are automating and rely on diagnostics IT and data management.



Dave Hickey



Derek Kelly

Because hospital-owned laboratories and their clinician counterparts share so many of the same needs (e.g. reducing costs through improved workflow, delivering quality, error-free results, establishing evidence-based protocols, and migrating to integrated data-sharing platforms), how then are automation and diagnostics IT giving labs the power to establish a path for improved turn around time, results quality and enhanced value to clinicians?



Susan Dawson

During a Panel Discussion held by Siemens Healthcare Diagnostics at the 2011 AACC and ASCLS Annual Meetings and Clinical Lab Expo, Dave Hickey, CEO of the firm's Chemistry, Immunoassay, Automation and Diagnostics IT Business Unit, moderated panellists from the Swedish Covenant Hospital in Chicago, IL: Susan Dawson, Clinical Laboratory Manager, and Dr Derek Kelly, VP Medical Management of CMO, CMIO.

As Dr Hickey explained, the IT portion of this equation helps ensure faster results delivery and better quality testing through data management, process management, patient identification, and laboratory information system (LIS) platforms. To help illustrate this he pointed to several existing Siemens solutions, including the new syngo Lab Data Manager that connects multiple analysers to a single interface, contributing towards decreased turn around time (TAT) and ultimately, faster diagnosis by clinicians.

Dr Hickey also highlighted Siemens' Patient Identification Check (PIK) solution as an example of where IT can promote data transparency, primary tube sampling and trace-ability, equalling error reductions and therefore, increased quality.

Automation, then, helps laboratories realise efficiency

without sacrificing quality. By helping to manage peak load times, results are completed on time and turnaround time goals are met. Plus, process efficiency reduces the number of tubes and labour steps for sample processing, thereby improving cost performance. And because advanced automation solutions also provide access to expansive test menus for screening, diagnosis, prognosis, and

monitoring of disease, the disease diagnosis process becomes exponentially consolidated.

But not everything is about improved turn around time and cost efficiency. Labs are also increasingly involved in patient care decisions.

At Swedish Covenant Hospital, the laboratory has not only steadily implemented IT and automation solutions into their workflow over the past 10 years,

but also continuously seeks additional ways to partners with clinicians for better patient care. Because IT and automation has helped free the lab to focus on critical results, patient care and clinician collaboration, Swedish Covenant's clinician community has come to rely on Susan Dawson's team of laboratorians for help in ordering the right tests as well as reviewing and interpreting test results. 'At the ICU, we are

highly dependent on the lab and typically we need everything stat,' says Dr Derek Kelly. 'Working closely with the lab and ensuring it knows how their work impacts patient care directly is very important.'

Long term, laboratorians and clinicians have a combined future as the increasing dialogue plays a role in an improved patient treatment path. This elevates quality of patient results, shares cost reduction and bolsters hospital competitiveness.

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Trends and technology at the AACC 2011

This year's catchwords: workflow, speed and outcome

Improving workflow and routine



Thermo Fisher introduced the Thermo Scientific Indiko, a fully automated, compact chemistry analyser that recently received clearance from the USA's Food and Drug Administration (FDA) and is designed for routine clinical chemistry applications that include drugs-of-abuse testing and

therapeutic drug monitoring.

The firm also highlighted an improved liquid chromatography/mass spectrometry (LC/MS) workflow for immunosuppressant analysis, designed to improve productivity in clinical research applications. Within that, the Thermo Scientific Versette

automated liquid-handling platform is used to simplify the sample-handling method, whether the research chemist is transitioning from handheld pipetting or establishing an integrated system. The workflow also incorporates the latest release of Thermo Scientific TraceFinder 1.1 software, designed for use in clinical research and forensic toxicology testing.

TraceFinder software has been specifically adapted for use on the Thermo Scientific Transcend system, known for its Turbo-Flow technology and multiplexing capability. Multiplexing allows up to four independent HPLC channels to connect to a single mass spectrometer, reducing cost and increasing clinical research laboratory flexibility and productivity.

Innovation. Powered by You



Under the slogan 'Innovation. Powered by You', the large range of clinical diagnostics products from Siemens reflected its attitude to customer input in the firm's innovative systems, adaptable automation options, assays and next generation diagnostic IT products. Among these was the new Immulite 2000 XPi Immunoassay System, which has a continuous, random-access analyser with enhanced hardware and software features, as well as the Dimension EXL 200 Integrated Chemistry System. This is the newest addition to the Dimension family of analysers for lower-volume labs with access to LOCI Advanced

Chemiluminescence Technology.

Also on show, the Siemens intelligent sample management solution VersaCell System, which helps create specific, needs-based workstations between multiple analysers.

For assays, the firm demonstrated, for example, the Advia Centaur Vitam D Total assay as well as new assays for HIV antibodies or thyroid disease. In the Diagnostics IT field, the latest Siemens solution is the new syngo Lab Data Manager, which offers advanced data management capabilities, auto verification, quality control and simplified connectivity to lab instruments, LIS, automation and remote services.

High speed and ultra-high throughput

Beckman Coulter showed its AU5800 ultra-high throughput chemistry system, which provides speed, reliability and scalability and was introduced in Europe at the IFCC in Berlin in May this year.

In figures, the AU5800 performs up to 2,000 photometric chemistry tests per hour for a single modus.

With a four-unit configuration, labs can achieve up to 8,000 tests per hour and can gain even more efficiency by adding a dual ISE flow cell that increases maximum throughput of nearly 10,000 tests per hour, the company reports.

The system can be used as a stand-alone instrument or is designed for connectivity with the



company's automation solution, further allowing for the potential integration with the clinical information systems and immunoassay testing platforms.

The AU5800 series offers a clear and customisable upgrade path enabling laboratories to add components as their workflow

demands increase, the firm adds.

Beckman Coulter, Inc. is now a member of the Danaher group of companies installing more than 275,000 clinical and research systems in laboratories, hospitals and other critical care settings globally.

Solutions for mid & high range laboratories

Ortho Clinical Diagnostics launched its Vitros 4600 Chemistry System for mid-to high-volume laboratories.

This provides configurable, expandable automation solutions using proprietary technologies such as MicroSlide, MicroTip,



An award winning system

Luminex Corporation, recently named *Most Innovative Company of the Year* by American Business Awards, and winner of *Business Innovation of the Year* for its Magpix system, presented the Luminex xTAG Gastrointestinal Pathogen Panel (XTAG GPP). This recently received CE marking and was used as a first line screen for patients in Germany during the E. coli crisis that had a significant impact across Europe.

Additionally, last month Luminex entered into a global distribution agreement with Life Technologies for the award winning Magpix system and completed the acquisition of EraGen Biosciences, strengthening its leadership position and expanding its capabilities in the molecular diagnostic market, the firm reports.



FREE The mobile app that answers patients' medical test

Debuting at the AACC meeting was the first free mobile application to help consumers decipher their own medical tests. Created for use on an iPhone, iPad and Android smartphone, the *Lab Tests Online* app connects to a site promising to provide reliable, unbiased information that enables them to have more informed conversations with their doctors.

The peer-reviewed Lab Tests Online site was launched in 2001 by the American Association for Clinical Chemistry (AACC) as a joint project between the laboratory industry and the laboratory professional community. The content is developed and approved by a volunteer team of laboratory professionals to provide patients with detailed test descriptions, condition descriptions cross-linked by related tests, and articles

about testing and test reliability.

'Lab Tests Online was designed to help patients and caregivers make sense of the many clinical lab tests that are part of routine care,' explained Dr D Robert Dufour, AACC's executive editor of Lab Tests Online. 'The site helps consumers take responsibility for their care by learning more about these tests that help save lives and improve the quality of life.'

The patient-centred site is acknowledging its 10 years as a standard for patient education by developing a mobile app for Apple and Android smartphones and tablets, and by increasing its social media presence. Both will debut next month at the AACC Annual Meeting and Clinical Lab Expo.

The website already provides two million visitors a month with informa-

tion needed to discuss their tests with their doctors. With 17 versions of the site online or in development – including translations in Chinese, Spanish and French – almost one-third of the world's population can now learn from Lab Tests Online in their native language.

Elissa Passiment, executive vice president for the American Society for Clinical Laboratory Science (ASCLS) and a member of Lab Tests Online's Editorial Review Board since its inception, said: 'Lab Tests Online is the ideal resource to help patients understand why their doctors ordered certain tests, so they can have intelligent conversations with them and be more active participants in their healthcare.'

A collaboration of 17 laboratory professional societies and organisations in the U.S. and Canada, the site's content is

Early stage HIV infection test



Abbott unveiled the i-STAT 1 Wireless Point-of-Care Testing System, a hand-held device that potentially saves time by allowing caregivers to perform critical tests at the bedside and transmit test results immediately to the patients' electronic medical record for physician review.

Abbot also focused on HIV, transplant and vitamin D diagnostics as well as laboratory informatics solutions. Since the launch of

Architect HIV Ag/Ab Combo assay last year, early stage HIV infections are detected much sooner. This is a chemiluminescent microparticle immuno-assay for simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV-1 group M and group O) and/or type 2 (HIV-2) in human serum and plasma. It is intended for use as an aid in the diagnosis of HIV-1/HIV-2 infection in subjects age two and up and pregnant women, including acute/primary HIV-1 infection.

This assay is the first test approved in the USA that can simultaneously detect both HIV antigen and antibodies. At this year's congress researchers presented their observations and experiences collected when using the test.

MicroSensor, Intellicheck and e-Connectivity Interactive System Management, which offers real-time access.

Additionally the company introduced a new immuno-diagnostic assay, the Vitros Intact PTH Assay, for quantitative detection of parathyroid hormone. The assay measures intact parathyroid hormone levels and uses one protocol for both routine and intra-operative testing with results available in 18 minutes, the company reports.

The Vitros iPTH Assay runs in a fully automated, random-access format on the Vitros ECi/ECiQ and 3600 Immunodiagnostic Systems and can also run on the Vitros 5600 Integrated System. Equivalent analytical results are generated across all three systems.

AACC 2012 will take place between 15-19 July, in Los Angeles, California

questions

reviewed by an editorial board composed of representatives from AACC, ASCLS, American Society for Microbiology, Clinical Laboratory Management Association, College of American Pathologists, American Society of Clinical Pathology, Association of Molecular Pathology, and 10 other member organisations.

Susan Leclair, chancellor professor at the University of Massachusetts Dartmouth and ASCLS board member who helped found ASCLS' Consumer Information Response Service, which uses another group of volunteer laboratory professionals to answer questions from Lab Tests Online users, added: 'Every now and then you hear back from people, something like, "Thank you. It was the first night's sleep I've had in months". That's what makes it worthwhile.'

* <http://www.labtestsonline.org/>.

Hospital develops its own app Doctors' smartphones access lab results and all relevant patient data

An original computer application that enables access to electronic patient records (EPRs) instantly via doctors' smartphones has been designed by the IT team at the Holy Name Medical Centre in Teaneck, New Jersey, USA. The app also offers direct phone links to a patient's nurse and emergency contact person via iPhone, Android, Blackberry and other mobile devices.

Dubbed MicroHIS, the technology is a component of Holy Name's internal com-

puter system, WebHIS, and is available free to its medics, providing information for physicians to make patient care decisions without delay, while affording them the convenience of reviewing their patients' charts and speaking to a patient or key members of the care team.

As soon as lab and radiology reports, vital signs, and other aspects of the medical record are posted to the 361-bed Medical Centre's computer system, the doctor can access them by clicking on

the MicroHIS icon and logging on to the secure network. Then a list of his patients and essential medical data appears – with any abnormal test results flagged.

By touching the patient's bedside phone number the doctor is instantly connected to the patient's room. He can also search for a patient by hospital unit, and when found, he simply adds the patient to his own list with a touch.

Mike Skvarenina, the hospital's Assistant V-P for IT, said that the Centre has been writing its own software for clinical applications for many years, chiefly because although manufacturers produce similar technology there are differences in personalisation and service. The real advantage in doing it themselves: 'We can react in a heartbeat to feedback from our staff and are

in total control of our application and its functionality.' Ever open to further development of MicroHIS, he pointed out: 'There's a feedback button on the app through which staff can make suggestions to us.'

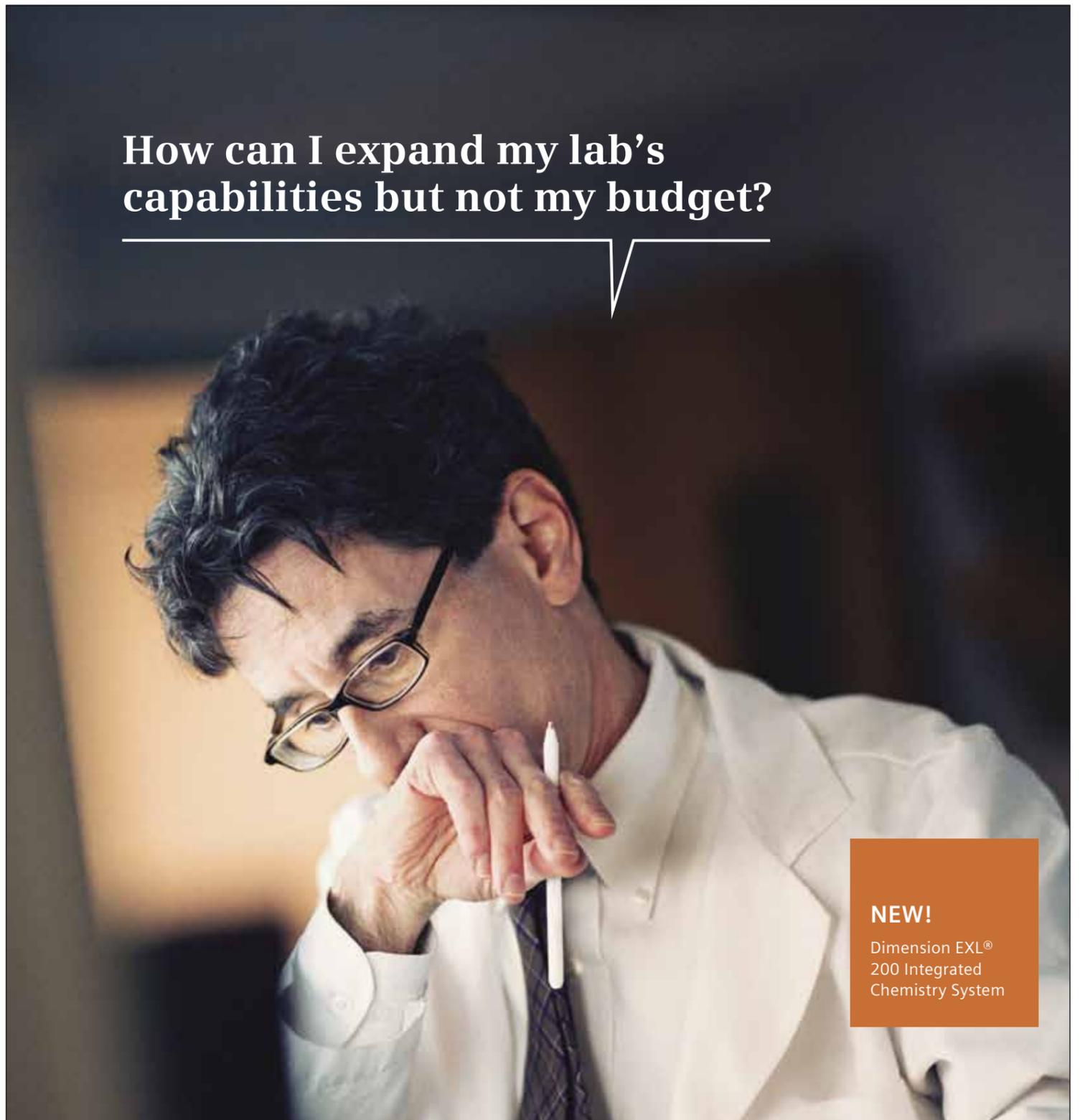
The flexibility of the MicroHIS means that IT staff can modify the system and the functionality of an application in as little as 10 minutes to an hour, he added, whereas it could take weeks, months or longer when working with a vendor.

Recently MicroHIS was upgraded to receive out-patient reporting and doctors have asked IT staff to add operating theatre schedules.

Although MicroHIS has met with great success, there are current plans to market it commercially.

Report: Mark Nicholls

How can I expand my lab's capabilities but not my budget?



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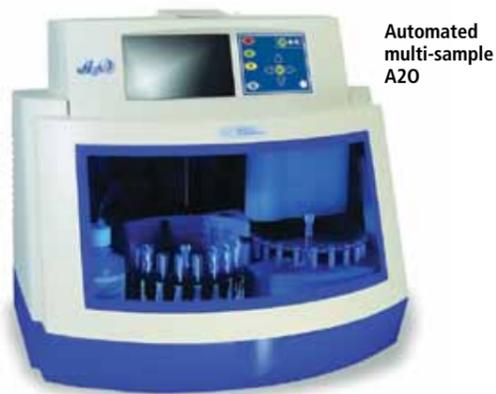
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Trends and technology at the AACC 2011

Freezing point osmometry

Advanced Instruments was showing its new fully-automated, multi-sample A20 Advanced Automated Osmometer, which incorporates over 50 years of applied technology experience in the field of freezing point osmometry, the company points out.

The A20 combines a functional design, exceptional analytical performance, and an intuitive software control package that is both powerful and elegantly simple to operate, the firm adds. Every aspect of the A20 has been intelligently engineered to automate osmolality testing fully – and with ease and simplicity. For today's busy laboratories, being asked to achieve



Automated multi-sample A20

more results faster, yet with fewer resources, this could prove a desirable choice.

The company reports these A20 features:

- Touch-screen user interface: With a menu driven operating system, intuitive software control, and multi language capability, operating the A20 is simple.
- Direct sampling from the primary sample tube: Eliminate the need of the technician to do any liquid handling and pipetting, minimises sampling errors and improves accuracy of test results.
- Intelligent liquid handling technology: Featuring liquid level sensing, crash detection, self-cleaning pipette, and a simple fluid management system. These features provide flexible sample processing while minimising sample carryover and cross-contamination.
- Automated multi sample capability: A 20 position primary sample tube carousel intelligently designed to accommodate the most common sample tubes sizes and low volume insert sample cups.
- Positive Sample Identification: An integrated bar code scanner with software control provides effective sample management and eliminates transcription errors. The onboard printer provides additional sample identification and results reporting benefits.

A new MRSA test



Alere introduced its new PBP2a test, a rapid, lateral-flow assay that detects the PBP2a protein found in MRSA directly from *Staphylococcus aureus* isolates. It is a cost-effective, targeted approach to identifying MRSA, the firm points out. Providing results in five minutes, the assay uses samples from cultures (wound, skin, urine, etc.) and has built-in quality controls on every test strip.

Questioned about the advantages of digital over computed radiography systems, Jim Burns pointed out that these are obvious in dose, productivity and image quality, for example. 'DR technology either delivers better image quality at the same dose as CR or similar image quality at lower dose than CR. DR also allows for very quick availability of preview images, so that the radiographer can be certain, within seconds, whether good image quality or the correct posi-

the DRX detector is qualified for nearly all the established systems in the world. And, with our recent acquisition of Quantum Medical, we have even more opportunities to serve the value-tier market by integrating our detector into their floor standing X-ray solution, the Q-Rad system.'

In other cases, hospitals cannot afford to retrofit their systems to DR all at once, Jim Burns pointed out. 'That's why we make sure that all our products user interfaces are the same. So when a radiographer

From CR to DR

Keeping pace with an accelerating evolution

Breathtaking though the rate of improvement in medical imaging systems may be, many hospitals remain locked into their various evolutionary stages – depending on their needs and capabilities. With its versatile portfolio, Carestream Health, provides choices to meet their diverse circumstances. Daniela Zimmermann asked Jim E Burns, Carestream's Director of Advanced Development and Strategy, and Helen Titus, the firm's Worldwide Marketing Manager for Digital Capture Systems, about today's coexistence of Computed Radiography (CR) and Digital Radiography (DR) and what the future holds for digital X-ray systems

tion is achieved, or not. While with CR, it can take minutes before you see the first image results, because you have to position the cassette behind the patient, take the shot, bring the test cassette to the scanner – maybe on a totally different room or floor – and then wait for the image to enter the PACS.'

In terms of clinical importance, he believes DR is particularly beneficial in intensive care units '... where every second counts in diagnosis and where patients are least movable. Some of these patients can also be very heavy and therefore it simplifies processes enormously if the staff can determine quickly and easily if image quality levels are adequate. We have also found that ICU staff utilise one of the special features of both our CR and DR solution, called Tube and Line Visualisation Software for amplified visualisation of tubes and lines in thorax and abdominal radiography. The programme generates a specially processed companion image to make objects very noticeable to the practitioner, so he can check for correct positioning of tubes and lines.'

For the same reason, Helen Titus added, DR presents a big advantage in surgery. 'Clinicians take our DRX-Mobile system with them into the operating room to get instant X-ray images. They use it for even very simple applications, like looking for so-called "leave behinds", sponges or tools that might have been left inside the body.'

So why do hospitals still buy CR technology? It's mainly due to cost, Helen Titus believes: 'For some smaller facilities, which handle lower patient volumes, digitising the image with CR is still a good choice – and Carestream offers some products to bridge the gap between the costs of CR and DR. For instance, our DRX-1 System allows customers to keep the existing analogue X-ray equipment, such as a generator, wall stand or bucky table, and just upgrade the detector. The DRX-1 detector is the same 43 x 35 cm size and thickness as any standard existing film or CR cassette. This means,



Jim Burns



Helen Titus

uses a CR system in an out-patient clinic and then changes to the DR system in the ICU, he finds the same working environment. Because of the high DR productivity, we also have customers who find they only need three DR instead of four CR systems, which is another way to minimise total costs. Or, they might have two detectors in a room and for a certain period of the day take the detector out with them on their intensive care rounds. So they can essentially share detectors in various systems and therefore make the best out of their capital equipment.'

The DR market is certainly expanding, Helen Titus confirmed, adding: 'Interim solutions, like our DRX-1 system, allow the market to grow even faster. In terms of the pace of adoption, the US, Canada, Western Europe and China are leading the way. On the other hand, we face the first DR replacement systems of rooms that started very early with digitisation. Nevertheless, we believe CR will also stay the right choice for other facilities, for a long time.'

In the future, when DR costs fall, Jim Burns believes emerging markets, such as Latin America or some Asian countries, will follow suit. 'The market-based dynamic has changed over the last 18 months, with many companies entering the detector sector. This competition will push prices. In addition,' he predicted, 'there will be technical improvements making the systems more robust and affordable. Among other things, manufacturers are already considering backplane structures other than glass for the digital detectors. Because they are the cost drivers of radiography systems, the bright future of DR will depend on the accessibility of detectors.'

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Ultra High Field Magnetic Resonance

European and North American experts share their developments

2011 brought a second year for European and US scientists to meet up at the Annual Scientific Symposium on Ultra High Field Magnetic Resonance, held at the Max Delbrück Centre for Molecular Medicine Berlin-Buch (MDC), Germany, to present and discuss their recent findings. Along with technical improvements, the main issues of the one-day gathering were cardiac, cerebral and molecular MR imaging. *Bettina Döbereiner reports*

Multichannel transmission and ultra high field enhance spatial resolution

Since last year, significant improvements in image resolution from 7-Tesla ultra high field magnetic resonance (UHF MR) scanners have been achieved by replacing the multi-channel radio frequency (RF) system of four coils with 16 coils. Compared to MR systems in clinical use (1.5 and 3-T scanners with their common body coil) the current multi-channel



David G Norris



Thoralf Niendorf



Sonia Waiczies



Bernd Ittermann



Kamil Ugurbil



Daniel K Sodickson

transmission in 7-T increases the image resolution by factor five. 'It's like transforming a 10 megapixels camera into one with 50 megapixels,' explained Prof Thoralf



Jeannette Schulz-Menger

Niendorf, one of the event-organisers and head of the Berlin Ultra High Field Facility (B.U.F.F.) at the MDC, where he and his team are currently working on a 32 coil-system.

Imaging the 'forgotten' right ventricle

In combination with the MR-stethoscope, an acoustic cardiac triggering device (presented at last year's meeting) the enhanced resolution of multichannel system will provide improved imaging of the heart. Prof. Jeannette Schulz-Menger, co-organiser of the meeting and cardiologist at the Charité University Medicine and the Helios Clinic, presented the first images of the right ventricle of hitherto unachieved quality – elusive due to sensitivity and spatial resolution constraints present at lower field strength.

The brain: Columns and layers

For a long time, brain studies at 7-T studied only small regions in great detail. 'Now technical developments have made it possible to examine the

whole brain with a high image quality and very high spatial resolution', allowing the examination of 'activation patterns at the spatial level of the building blocks of computational architecture: the cortical layers and columns', explained Professor David G Norris, from the Donders Centre for Cognitive Neuro-imaging at Radboud University in Nijmegen, The Netherlands, during his talk.

This development promises better understanding of psychiat-

ric diseases, explained Professor Kamil Ugurbil, from the Centre for Magnetic Resonance Research (CMRR), University of Minnesota.

Future directions

Exciting possibilities in UHF MR research were outlined by Professor Daniel K Sodickson, from New York University, USA. 'Research will involve extracting unique information that currently resides in what are now seen as UHF artefacts – namely the distur-

tions of electromagnetic fields and hence of MR images caused by the presence of tissue.'

Molecular MR imaging

A new topic during the conference was molecular MR imaging, enabling imaging on a cellular and even sub-cellular, i.e. microscopic scale. Proton imaging is no longer the 'one and only', as Prof Niendorf explained in an interview. 'We promote the so called heteronuclear imaging, using fluorine atoms, for example, but also sodium, carbon or phosphor nuclei.'

A recent result, from an inde-

pendent research group, set up in late summer of 2010 at the MDC, and led by molecular biologist Sonia Waiczies, was able to detect and neatly portray the lymphatic system of mice with the help of injected fluorine-marked cells. Even sentinel lymph nodes could be distinctly identified, which will certainly be of great use for future early-stage cancer diagnosis.

Event organisers: Prof Thoralf Niendorf from the B.U.F.F. at the MDC, Bernd Ittermann from the PTB, a national metrology institute provided scientific and technical services, and Prof Jeannette Schulz-Menger, Cardiologist from the Charité, University Medicine and Helios Clinic.

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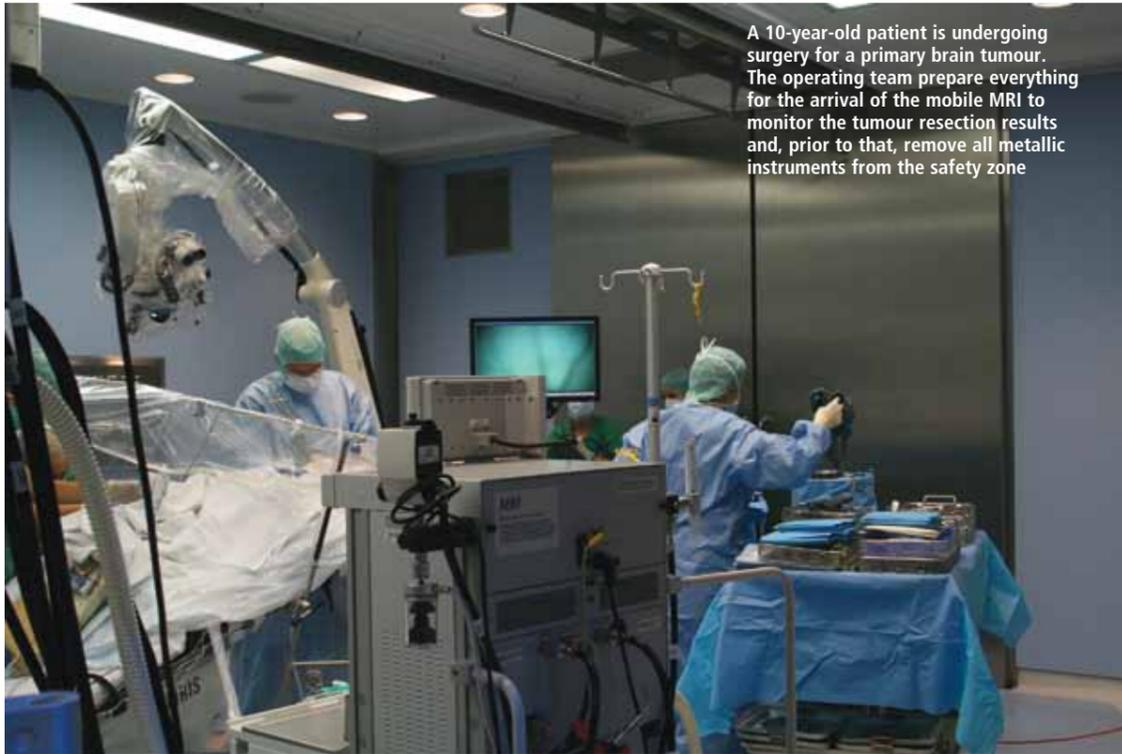
When Professor PD Dr Dr Marcos Tatagiba operates the recently installed five ton, ceiling mounted MRI scanner in the operating theatre at the Neurosurgery Clinic in University Hospital Tubingen, he will be using systems technology currently unique in Europe.

Carrying out around 3,200 surgical operations annually, the hospital ranks among the largest in Germany and, since 2004, it has seen continuous modernisation to provide most up-to-date medical technology. In spring this year, following a complex installation that began in October 2010, this was complemented by the intra-operative MRI scanner. 'Despite the high-tech equipment in the clinic the patient always remains at the centre of things,' Prof Feigl pointed out.

The new iMRI system includes an HF cabin, which protects the operating theatre from interfering frequencies from outside, and a steel frame on which the 1.5-Tesla magnet runs in 90 seconds from the opened magnet bay (called the 'garage' by the Tubingen team) to the operating table.

15 April saw the official opening of the iMRI unit with the IMRISneuro system, and the €5 million operating theatre, named after Prof Garnette Sutherland.

Since then the team has been operating on one patient per day. The main indications for treatment are primary brain tumours, Professor Feigl explained. 'Low grade glioma, in particular, do not absorb contrast media. Visually the tissue often looks just like normal brain tissue. Previously, until the point where the first post-operative image was available the day after surgery, there was no absolute certainty that the tumour had been completely removed



A 10-year-old patient is undergoing surgery for a primary brain tumour. The operating team prepare everything for the arrival of the mobile MRI to monitor the tumour resection results and, prior to that, remove all metallic instruments from the safety zone

IMRIS arrives in Europe

IMRIS Inc. based in Winnipeg, Canada, has been offering image guided therapy solutions for neurosurgery, the neurovascular and cardiovascular fields since 2005.

The mobile MRI scanner technology was developed in the 1990s by Dr Garnette Sutherland, neurosurgeon at the Foothills Hospital in Calgary, together with Dr John Saunders at the Canadian National Research Council (NRC) Institute of Biomedical Sciences in Winnipeg.

50 customers in North America, the Asiatic-Pacific area and now in Europe are already working with the IMRIS systems, which are available in individual room configurations.

The second neurosurgical installation will be carried out in September at the Clinatex Hospital in Grenoble, France, under Professor Alim-Louis Benabid. For the first time in Europe, Grenoble will have a two-room solution consisting of an operating theatre and a room for diagnostic imaging.

The flying magnet

Installed: Europe's first mobile MRI scanner for intra-operative imaging in Europe

but, with the new system, we are now the first neurosurgical clinic in Europe able to monitor during surgery, whether or not the resection was successful, without the need to move the patient, which is what needs to be done with stationary magnets.'

Today, the neurosurgeons carry out everything directly in the operating theatre, from planning imaging procedures

to postoperative imaging, all in close cooperation with the neuroradiology department under medical director, Professor U Ernemann. This has particular advantages for brain surgery, Professor Feigl said. 'As soon as surgical access to the tumour is carried out, and then during the operation while the tumour tissue is removed, the brain moves – a process known as "brain shift".

colour-coded Gauss lines around the operating table indicate which zones have which magnetic force.

The acquisition of specialist, non-magnetic operating theatre equipment is not necessary. When the magnet is 'parked' behind closed doors in the room next door – the magnet bay – all instruments can be freely used in the operating theatre.

Promising prospects

The iMRI unit in Tubingen has a special volumetric neuronavigation system

(MedSurgical, Sunnyvale California). The difference from conventional navigation systems is that all image layers can be merged so that the entire volume of the skull can also be intra-operatively reconstructed in 3-D.

The system also makes it possible to make layers of tissue transparent. The neurosurgeon can look into the patient's cranium with the system's pointer before the cranium has even been opened to plan the safest surgical access.

Important functional data, acquired pre-operatively, such as information on cerebral areas relating to motor function and fibre tracts, are also shown to ensure that the smallest possible surgical access is carried out whilst full functionality is maintained.

In the future, the team also plans to carry out MRI imaging with the IMRISneuro system intra-operatively, because tumours in the central region of the brain can shift the normal anatomy to such an extent that the normal landmarks for certain functional areas in the brain lose their significance. It is also important to show the cerebral paths originating in these function- or motor specific areas as they also may have shifted.

Further areas of application are interventions for epilepsy, deep brain stimulation, surgery on the pituitary gland as well as surgery for vascular malformations such as aneurysms and AVM. 'We are at the very beginning of our scope of experience with the new system,' said the professor, adding: 'We're really just getting started.'



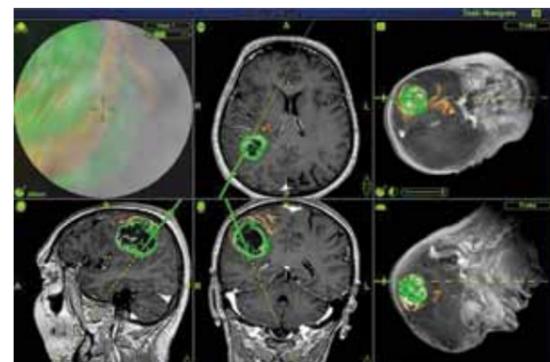
The steel doors opens and the magnet moves towards the patient on rails installed in the ceiling

The pre-operative images, which are required for neuronavigation, then no longer match with reality and must be updated.

'After the operation, we produce a postoperative MRI image that would normally have to be carried out separately the next day. We then merge the pre-, intra- and postoperative MRI images into a before and after series at the workstation, which allows precise presentation of the outcome of the operation.'

Safety first

Before the steel door between the magnet bay and the operating theatre opens and the MRI scanner is moved to the special, non-magnetic operating table via a switch, the team carries out a standard safety check, for which they received special training. With the help of hard copy and soft copy checklists they ensure that all ferromagnetic instruments and equipment have been placed outside the five Gauss line. Three



Intra-operative imaging of neuronavigation: Changes to transparency make it possible to clearly distinguish between the tumour (green) and the fibre tracts (brown) displaced by the tumour. The left upper window is a virtual endoscopic view showing the fibre tracts displaced by the tumour



During her visit to the University Hospital Tubingen, EH reporter Karoline Laarmann met Hartmut Warnken, Vice President & General Manager at IMRIS Europe, and specialist neurosurgeon PD Dr Dr Guenther C Feigl

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Determination of the rest- and total energy requirement made easy!

Obesity and malnutrition – doctors and nurses are increasingly confronted with these problems and their associated complications. The solution seems quite simple: the patient needs to gain or lose weight. But what daily energy intake is needed to achieve the desired target weight?

The determination of the rest energy requirement via methods of indirect calorimetry outside the field of scientific research is also very complex. Therefore, the rest and total energy requirement in daily medical routine is calculated based on scientifically developed formulae – it that takes up time and staff resources.

The determination of the rest and total energy intake becomes easy with the *seca 360°* wireless system. Two modes of diagnostic support are available within the network. The 'energy' module of the PC software *seca analytics 105* provides information about this. The only information needed is the patient's height and weight, sex, date of birth and PAL value (physical activity level), which can be transmitted wirelessly.

At the same time, this module can also calculate the recommended daily energy intake and works as a therapy planner for a target weight or a target BMI that needs to be calculated.

The *seca 360°* wireless system can also determine the energy requirement without the help of a PC. In a single step, height and weight are assessed via the *seca 285* measuring station. The patient's sex, age and PAL value are entered manually via the measuring station display. The thermal printer *seca 465*, or the wireless printer advanced *seca 466* receive the data and calculate the rest and total energy requirement – without any additional expenditure of time or use of staff resources.

Various references are available for the calculation of the rest and total energy requirement for both options, based on the site of operation.

For Germany, Austria and Switzerland the calculation is preset based on formulae by Mueller et.al. For all other European countries the WHO 2004 reference is recommended.

The calculation of the rest and total energy requirement can be used for children and adults. This means that the practice-oriented system can also be effectively utilised by paediatricians who are increasingly facing over- or underweight children.



The seca 285

At the 21st European Neurological Society meeting, this May in Lisbon, Portugal, around 3,200 experts met to discuss new developments in neurology. These included ever-increasing role of biomarkers in neuroscience, particularly in the management of multiple sclerosis. **Massimo Filippi, Director of the Interdepartmental Research Programme *BrainMap* and the Neuro-imaging Research Unit at the Scientific Institute and University Vita-Salute, Ospedale San Raffaele in Milan, Italy, discussed some of those current findings in an interview with *Karoline Laarmann***

'The field of neurology is mainly constituted of diseases that are complex and frequently have a multifactorial pathogenesis,' Professor Filippi explained. 'Biomarkers help clinical neurologists to understand which type of disease is present, what prognosis can be given to the patient and which therapeutic steps should be taken.'

Biomarkers are surrogate measures that can serve as indicators for specific biological states, salutogenetic or pathogenetic processes or responses to pharmacological treatments. Today, the two main aspects in the use of biomarkers are therefore to make early diagnosis and to screen for adequate treatment.

Multiple sclerosis (MS) serves as kind of a role model for the diagnostic opportunities that neurological biomarkers can deliver. This inflammatory disease affects about 600,000 Europeans and 2.8 million people worldwide. It causes damage to the myelin sheaths, which results in axonal loss in the brain and neuronal loss in the brain and the spinal cord, leading to irreversible locomotor and cognitive disability. 'The huge variability of symptoms, caused by the fact that MS can affect any part of the CNS, along with a lack of meaningful laboratory and paraclinical tests, in the past led to delayed or uncertain diagnoses,' Prof. Filippi pointed out. 'Therefore, we are much happier that, in recent years, we could trace a remarkable number of biomarkers, allowing for an improved and quickened assessment of the disease and its progression.'

Many of the clinical questions posed in neurological diseases such as MS are answered today by magnetic resonance imaging (MRI).

The use of MRI in the field can be classified in three historical steps. Initially, it allowed the detection of lesions, which improved the diagnostic work up of patients suspected of having MS. Later on, with the advancements in MR technology, the path led to a better understanding of the factors associated with the development of physical and mental disability in MS, the professor continued: 'Among these new methods ranges diffusion tensor imaging (tractography), which allows the reconstruction of the white matter tracks of the human brain to show in exactly which part of the brain the disease hits.'

Besides the utility of MRI to define typical pictures of different neurological conditions and to understand the regional topography of damage, the introduction of another modern technique, functional MRI (fMRI), later helped to define the stand of functional changes associated to

NEW BIOMARKERS

Ushering a new era in clinical neurology

different neurological conditions, including MS.

By showing how the brain is activated to perform cognitive, motor or sensitive tasks in normal and pathological states, fMRI now enables an understanding of how the brain reacts to the presence of structural damage, in an attempt to limit its clinical consequences.

In MS, because many new

therapeutic options have been made available in recent years, it is even more relevant to have tools to define objectively whether a specific patient responds to a specific treatment. 'So instead of being in the dark for months and years, or dependent on very expensive and burdening diagnostic tools,' Prof Filippi added, 'we increasingly

understand an easier-to-read bio-language of the body. This is leading us on relatively simple paths to the right diagnosis and letting us watch the development of disease and/or treatment.'

'We expect this shift in diagnostic paradigms to continue and to yield even more exciting possibilities within the next few years.'

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Fuji's 3-D Mammography

When your eye works faster than computers

Fujifilm Corporation is taking an elegantly simple approach to mammography reading in three dimensions. Instead of relying on complex image processing with computers, Fuji 3-D Mammography exploits a human phenomenon called parallax vision, which those who remember the View Master stereoscope binoculars, or more recently watched the film Avatar

wearing special glasses, will understand.

Using a pair of polarised glasses the radiologist reads stereoscopic acquisitions on 5M pixel 3-D monitors that display an in-depth and intuitive image of the entire breast at 50-micron resolution.

It is the radiologist's natural 'visual system' that fuses the two images into a single 3-D image.

The Fuji stereoscopic approach marks an innovative departure from in-depth imaging of the breast using the tomosynthesis technique where up to 15 consecutive images are taken from different angles along an arc, creating approximately 120 - 240 slices per 2-view bilateral examination.

To read a tomosynthesis imaging exam, the radiologist scrolls through a series of 2-D image slices to detect suspicious structures at different depths in the breast. With Fuji's 3-D digital mammography, the radiologist views the breast directly in three dimensions and can see behind overlapping structures.

Studies have shown the Fuji technology results in faster reading times, significantly fewer false positives and lower radiation dose. The patient file is also 10 times smaller than the storage requirements for a tomosynthesis exam.

The Fuji 3-D mammography screening exam is comprised of the two traditional mediolateral oblique and cranial-caudal views of each breast. Two sequential X-ray images make up each view with one taken at an angle of 0 degrees and a second taken at about four degrees.

The 0-degree image matches specifications required for a 2-D Full Field Digital Mammography (FFDM) exam, and the radiologist can toggle between the traditional 2-D mode and the in-depth 3-D mode.

A phantom study evaluating the Fuji system, presented in March 2011 to the Society of Photographic Instrumentation Engineers (SPIE), concluded, 'There was a significant decrease in reading time for masses, calcifications and normals in 3-D compared to 2-D, as well as more favourable confidence levels in reading normal cases.'

A five-year clinical trial enrolling 1,458 patients at Emory University Hospital in Atlanta, Georgia found that compared to standard digital mammography the Fuji stereo mammography technology significantly reduced false positive lesion detections by 46% and significantly increased true positive lesion detections by 23%.

Reducing false positives results in fewer patient call-backs for supplemental exams and is expected to help reduce the number of biopsies required.

Five university medical centres in Europe will conduct studies to validate the diagnostic capabilities of the new system against conventional 2-D mammography.

These centres will utilise the next-generation X-ray detector with the Amulet FFDM system featuring dual layers of amorphous selenium that require only 1.2 to 1.3 milligray (mGy), or half the dose required in Emory University study, in which a different detector was used.

Amulet is the first digital mammography system equipped with a direct conversion flat panel detector that provides a small pixel size of 50µm, yet produces both high-resolution and low-noise images, greatly enhancing image quality at lower radiation levels.

Beyond breast cancer screening, Fuji expects the 3-D capability to have value in diagnostic mammography, especially for dense breasts and patients with prior interventions. The company is also investigating for potential applications for the 3-D mammography system in surgery.

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A revolution in diabetes care

Interventional Radiology maintains quality of life and reduces costs

Interventional radiology can effectively treat. This has been recognised by the *International Working group on the Diabetic Foot (IWGDF)*, which, in its protocol, has placed IR-interventions as a first-line therapy.

Avoiding amputations, lowering costs

Diabetic foot is the chronic deterioration of the leg vessels, which can lead to complete occlusion of the

foot. IR methods can avoid or delay limb amputation – the traditional treatment for this condition. The affected artery can be re-opened by inflating a tiny balloon, delivered by catheter (balloon angioplasty), allowing sufficient blood through and saving the foot tissue from necrosis. In this way, surgical intervention and amputation can often be avoided.

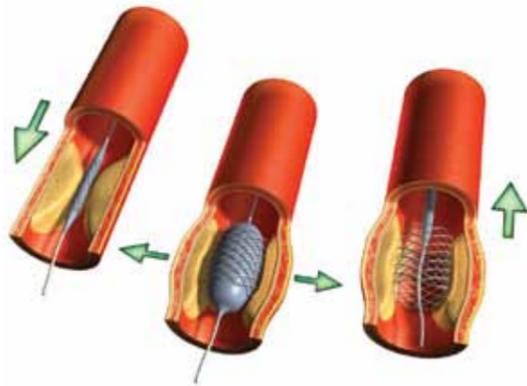
As this is performed under image-guidance (digital angiography), the intervention is very precise, and causes only a small skin puncture through which the catheter is introduced to the artery. The patient can usually leave the hospital on the same or the following day. As well as maintaining a good quality of life, and even the patient's ability to earn a living, IR can also reduce the enormous costs that an amputation entails.

For further details e-mail Daniela Jäger, Cardiovascular and Interventional Radiological Society of Europe - d.jaeger@diejaeger.at
Website: www.cirse.org

Interventional radiologists (IRs) throughout Europe are in a position to treat the consequences of diabetes in its different stages by means of minimally invasive, image-guided interventions. When performed in a timely manner, interventions, such as percutaneous recanalisation (the reopening of occluded vessels via image-guided microcatheters), can prevent significant disabilities, improve quality of life and help reduce associated treatment costs.

Rethinking diabetes care

Through early and minimally invasive interventions, interventional radiology is ready to redefine diabetes care. For the almost six million diabetics in Germany, for example, annual care costs fall in the region of 6.5 billion euros (Source: Robert Koch Institute: GBE Kompakt, Diabetes Mellitus in Deutschland, Issue 3/2011), most of which is spent on managing diabetic complications: coronary heart disease, stroke, diabetic foot and occluded vessels. Luckily, it is exactly these complications that



The artificial pancreas

Advancing methods to cope with a damaged organ

With a prevalence of 8.4%, Europe has the second large rate of Type 2 diabetes. Less frequent is Type 1 or juvenile diabetes, which is predominant in people <25 years and requires lifelong insulin therapy, either by daily injections or via continuous infusion pump, because the pancreas does not produce insulin. Their life could be simplified significantly by an artificial pancreas (AP) that will replace the damaged organ.

Current devices link an insulin pump with an implantable glucose sensor, thus insulin is delivered under continuous glucose monitoring (CGM). Also called as 'closed loop', they act more accurately than patient's self-measurement and injection.

Rese arches at Medical University Graz have developed such a device and brought it into the *AP@home* project, funded by the European Commission with €10.5 million.

In the first phase of this four-year project, currently available AP algorithms will be tested with CGM systems and insulin pumps already on the market, using a 'two-port' approach that requires two skin punctures to attach the glucose monitor and the insulin pump. In this stage, the aim will be to improve the accuracy of the glucose sensors and the safety and effectiveness of the algorithms that relate insulin delivery to blood glucose levels.

In parallel, innovative AP systems will be developed that combine an insulin pump and a CGM system into a single device that uses only one access point through the skin.

In the final phase, the performance of the newly created AP system, including remote monitoring facilities, will be compared with standard intensive insulin therapy in daily life in a multinational controlled trial.

'The aim of this project is to let Europe lead in the

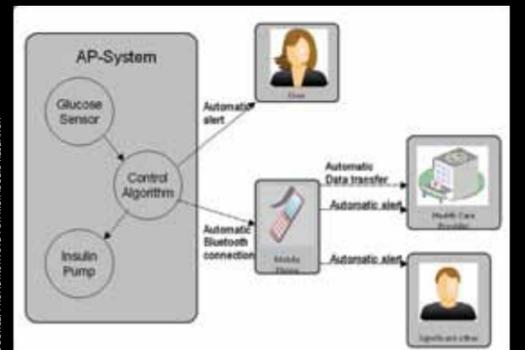
development of AP systems,' said project coordinator Lutz Heinemann of the Profil Institute for Metabolic Research, Neuss. 'Simplified care and improved quality of life for patients with diabetes will diminish related complications and health costs in the long run'.

A similar concept has been presented by El-Khatib and colleagues at Harvard Medical School. They use a triple chamber pump and include glucagon, the antagonist of insulin, into therapy because they do not believe that insulin alone can avoid hypoglycaemia at any time [Source: *Sci Transl Med* 14 April 2010 2:27ra27]. This is not only a question of software algorithm adjustment, as El-Khatib reported further: 'Improvements [...] could be achieved if ultrarapid-acting insulin formulations could be developed with faster absorption and less intra- and inter-subject variability than the current insulin analogs available today' [Source: *J Diabetes Sci Technol* 2010;4:1288-304].

On 11 June, the USA's Food and Drug Administration issued draft guidance that will help advance the development and approval of an artificial pancreas system to treat Type 1 diabetes in the United States: 'Our goal is to provide a clear pathway for artificial pancreas development so that people with diabetes can benefit from innovative medical devices,' said Jeffrey Shuren MD JD, director of the FDA's Centre for Devices and Radiological Health. 'Getting a safe and effective artificial pancreas system to Americans with Type 1 diabetes,' he added, 'is an FDA priority.'

Source: Lilly Pharma

Current concept of an artificial pancreas. The closed loop (left side) also sends alerts and may provide remote medicine



A date for the diary... 12-16 September

The 47th European Association for the Study of Diabetes (EASD) annual meeting

This September the attention of the medical world will be focused on the EASD Annual Meeting in Lisbon and the presentation of new insights into the pathogenesis, treatment and prevention of Type 1 and Type 2 diabetes.

The Local Organising Committee, chaired by Professor Luís M R Gardete-Correia, has organised prestigious international award lectures that include: The Claude Bernard Lecture, the Minkowski Lecture, the Castelli Pedrolini Lecture and the Albert Renold Lecture.

The 43rd Claude Bernard Lecture Diabetes: A brief history of conspiracy
Speaker: E Ferrannini, Italy

Ele Ferrannini obtained his medical degree and specialty certification in Nuclear Medicine from the University of Pisa, and his specialty certification in Diabetes and Metabolic Diseases from the University of Turin. He spent a year as a visiting scientist at the Department of Clinical Physiology of the Karolinska Institute in Stockholm and three years as a Fogarty International Research Fellow at Yale University, Connecticut. Back in Italy he has worked both at the National Research Council (CNR) Institute of Clinical Physiology, where he currently heads the Metabolism Unit, and at the University of Pisa School of Medicine where he is Professor of Internal Medicine.

46th Minkowski Lecture Exploiting biomarkers and large datasets for insights into diabetes and cardiovascular disease
Speaker: N Sattar, United Kingdom

Naveed Sattar graduated in medicine from the University of Glasgow in 1990 and was appointed Professor of Metabolic Medicine in 2005. He was trained at an internationally renowned

lipid centre, responsible for the West of Scotland Coronary Prevention Study (WOSCOPS), and his initial research was in the lipid arena. However, he quickly ventured into clinical diabetes and related research, which remains his prime focus. That noted, his exposure to other disease areas such as obesity, cardiovascular disease and autoimmune conditions, and his insight into mechanisms, potentially underpinning and/or linking these diseases, has enabled him to make novel observations relevant to diabetes pathogenesis and prediction and its associated vascular and non-vascular risks.

Dr Sattar heads an expanding biomarker group in Glasgow, with multiple collaborations worldwide. He has also extended his epidemiological contributions (including inputs to the Emerging Risk Factor Collaboration and Scottish Diabetes Research Network Epidemiology Group) and is involved in several clinical trials relevant to diabetes.

He chaired the Diabetes UK 2010 conference committee, has given numerous invited international talks and contributed to several clinical guidelines.

He is also an associate editor for *Diabetologia*, has published over 300 papers and his several national awards for research include the RD Lawrence Lecture by Diabetes UK.

The 26th Camillo Golgi Lecture The failure of glucose lowering in clinical trials: The way to novel biochemical concepts explaining diabetic late complications
Speaker: A Bierhaus, Germany

Born in 1962, in Bremen, in 1982 Angelika Bierhaus began studying Biology/Molecular Biology at the University of Heidelberg. After gaining her diploma at the Centre for Molecular Biology, Heidelberg (ZMBH) in 1988, she began her PhD studies in the Department of

Medicine I, University of Heidelberg.

As a Post-Doc, Dr Bierhaus worked at the Institute of Pathology at the University of Dresden and the Department of Medicine IV, University of Tübingen.

Returning to Heidelberg in 2001, she has since been Senior Scientist and head of the Research Laboratory at the Department of Medicine I and Clinical Chemistry.

Her Higher Doctorate (Habilitation) in Experimental Medicine was awarded in 2006, and she has served as Associate Professor at the University of Heidelberg since 2010.

Her scientific work focuses on the molecular mechanisms underlying late diabetic complications, in particular diabetic neuropathy, with special emphasis on the receptor RAGE and the transcription factor NF-κB.

Since 2008, she has also served as an Associate Editor of *Diabetologia*.

5th Albert Renold Lecture Tricycling along the beta cell and its coupling mechanisms for fuel induced insulin secretion
Speaker: M Prentki, Canada

Marc Prentki studied biochemistry at the University of Geneva, gaining his PhD under Bernard Jeanrenaud. Subsequently he joined the Albert Renold laboratory to work on intracellular Ca²⁺ homeostasis and insulin secretion. Later, as a Research Assistant Professor in the Department of Biochemistry and Biophysics at the University of Pennsylvania, he studied the coupling mechanisms of fuel-induced insulin secretion, which has remained his main area of research.

After a seven-year period at the Institut de Biochimie Clinique, Geneva, in 1994, Dr Prentki joined the Departments of Nutrition and Biochemistry at the University of Montreal, where he is now a Professor.

Founded in 1965, The European Association for the Study of Diabetes (EASD) aims to encourage and support diabetes research, rapidly diffuse acquired knowledge and facilitate its application. With 8,000 members, the Association is headed by an Executive Committee and a Council.

The Association's annual meetings, which attract some 17,000 participants from more than 100 countries, are the most important international events in diabetes research. Submitted abstracts are anonymously reviewed by a programme committee to guarantee independent evaluation and the high quality of presented scientific work. Travel Grants assist young researchers to attend these events. This year, 2,145 abstracts received by the Association and 1,294 were accepted for inclusion in the annual meeting. Considered anonymously, the abstracts were scored by 40 referees. The Programme Committee Members designed the programme and created Oral and Poster Sessions based upon the abstracts, which were reviewed and scored without any information on authors or places of work.

The Rising Star Symposium

Aiming to identify promising and innovative young researchers who are developing their research activities in Europe, at this multidisciplinary research symposium the selected candidates will present an overview of their past and ongoing research activities.

Four candidates are selected and invited annually by EASD to give a lecture, for which they receive a commemorative certificate. They are:

- Inga Prokopenko (UK): Insights into the pathogenesis of diabetes from studies of genetic variation in healthy individuals
- Magalie A Ravier (France): Regulatory mechanisms of insulin secretion: role of metabolism and Ca²⁺
- Andreas L Birkenfeld (Germany): The role of the mammalian INDY homologue in lipid and glucose metabolism
- Agbor Ndip Ebok Ako (UK): Vascular calcification, dialysis, foot ulcers and amputations: from bench to bedside; does RANK matter?

Among numerous highlights this year, of particular interest for those in medical practice are topics such as *Diabetes in young people*, focusing on Type 1 diabetes and also looking at the question of diagnosis of young diabetics and the management of Type 2 diabetes for

younger patients.

The stimulating *Controversies in gestational diabetes*, to include input from P Damm, R B Fraser and D Simmons, will examine the proposed IADPSG diagnostic criteria, the difficulty in identifying those at risk of poor foetal outcomes caused by gestational diabetes and also question whether we should treat mild gestational diabetes.

There will also be presentations on the most basic – though some might say most important – topics, such as *Exercise in Type 2 diabetes* and the effects of Type 2 on the physical body. The session on *Diabetes and the lung*, on the last day (16 September), will focus on very new ideas about diabetes, such as the link between air pollution and Type 2 diabetes and ask: *Can impaired lung function be considered a complication of diabetes?*

An iPhone app

This year, EASD will also present its new iPhone app, for virtual access to the meeting, including presentations, abstracts, e-posters and a community forum to discuss presentations and topics.

Details, and for scientific programme and abstracts, plus webcasts of major presentations after the meeting: www.easd.org



Russia's healthcare system is still in the midst of serious reforms and one of the important tasks is the proper establishment of infection control in its medical centres and hospitals. For example, every year about 2.5 million patients contract infections during hospital treatments. 21.9% of young patients in the children's surgical units and about 15% of patients in adult surgical units have suffered post-operative purulent septic complications.

The urgency of this problem for Russia is confirmed by the flashes of outbreaks constantly reported by the hospitals.

Ancient buildings defeat hygiene measures

Containing nosocomial infections is a serious problem for Russia's hospital staff, EH correspondent *Olga Ostrovskaya* reports



Alex Yakovlev

Although infection control systems have proved themselves around the world, this focus is rather new for Russian hospitals – having a hospital epidemiologist was only ruled by the Ministry of Health 1993. A considerable achievement since 1990 has been the introduction of nosocomial infection registration within state statistical reporting parameters, enabling analysis of this data to estimate the disease level and structure. However, at the same time, the reporting level of nosocomial infections in this country far from completely reflects its true level. Why?

'One reason for the incomplete account is the absence of accurate definitions and criteria for revealing these infections in standard documents,' explained Professor

Alex Yakovlev, lead physician at Botkinskaja, the St. Petersburg infections hospital. He considers that a complexity of factors influence the development of nosocomial infections, and the hygienic condition of equipment, including ventilation efficiency, are uppermost. However, the considerable majority of Russian hospitals are housed in old buildings, with structural deterioration of these and laboratories sometimes up to almost 70%.

For example, the Botkinskaja, the largest hospital in the millions-strong city, was built in 1880 with

the outstanding Russian doctor Sergey Botkin the trustee of this 'Aleksandrovsy barracks-type hospital'. The expression "Botkinsy barracks" lives on to this day. Many achievements in the development of this service are connected with his name: the first disinfection chambers, the first sanitary carriages, a special system of sewage treatment system, and many other achievements. But time marched on and the triumphs of the 19th Century became the hospital's shame at the start of our new millennia. Approaches to a method for the safety of patients and medical employees, as well as medical technologies, had cardinaly changed.

The last time this hospital was reconstructed was in the 1970s and some years ago this fact became obvious: St Petersburg needs a new hospital with advanced technologies.

The building is expected to be completed by the end of this year, 'Then,' Prof. Yakovlev said, 'St Petersburg will have two new infections hospitals.'

The City's Health Care Committee has now developed a model infection control plan to introduce to the large city hospitals to improve standards of patient care.

Systematic infection control in a Maltese hospital



Microbes have been around longer than humans and yet we had to wait till the 19th century for Pasteur and Lister to elucidate their equally beneficial and destructive properties and ways to control their activity and spread.

In a hospital, four types of infection transmission can occur: patient to patient, staff to patient, environment to patient and patient to staff in order of incidence.

In an interview with *Moirá Mizzi*, **Dr Michael Borg**, head of the Infection Control Unit at Mater Dei Hospital in Malta, described the ideal infection prevention set-up in a standard hospital.

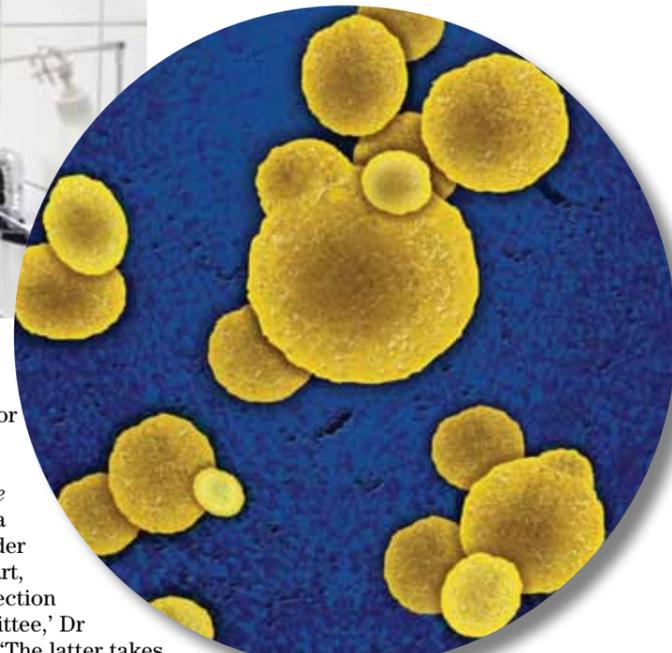
'An infection control unit should have an *executive arm* made up of one infection control

nurse per 150-300 hospital beds; one doctor per 700-1,000 beds and an *administrative arm*, which is a multi-stakeholder consultative part, namely the Infection Control Committee,' Dr Borg explains. 'The latter takes care of setting up policies and getting consensus. At Mater Dei we have four nurses in an 800-bed hospital and an Infection Control Committee, chaired by myself, which makes us quite up to scratch.'

Prevention at Mater Dei Hospital follows a PDSA, i.e. a Plan, Do, Study, Action cycle. 'Planning involves setting up the policies,' Dr Borg explains. 'This is then acted upon by relevant staff training and

the provision of consumables and equipment necessary to "do" the "plan". Regular surveillance is then carried out to ensure that the outcomes of both are satisfactory and the data acquired is used to check out the policies and alter them accordingly.'

This cycle of prevention aims at containing both



Following the first publication of a scientific paper introducing W.A.R. in *Skin Pharmacology and Physiology Journal* (Vol. 24, No. 5, 2011), in May the new wound at risk scoring system was presented at the Annual Conference of the European Wound Management Association, in Brussels. It drew considerable attention.

Headed by lead author Dr Joachim Dissemond, Department of Dermatology, University Clinic Essen, its initiators consist of wound care specialists from Germany, the UK, Austria, Switzerland, Italy and the Kingdom of Bahrain.

Based on expert discussions and current knowledge, they developed the W.A.R. score, using a simple points scoring system, co-author Andrew Kingsley MSc, Clinical Manager for Infection Control and Tissue Viability, at the UK's Northern Devon Healthcare Trust, explained during our interview.

'The W.A.R. score is composed of three classes of risk point levels. They are oriented on concrete patient circumstances. So, for example, if a patient suffers from an immunosuppressive disease, such as diabetes, and if he or she is aged over 80 years, this falls under class category I and means 1 point is scored for every indication identified on the list of risk definitions in that risk class. Risk factors included in class II are scored at two points each and,

W.A.R. against wound infections

Prevention is better than a fight against an infected wound – but, to avoid a battle you must know your enemy – and the wound's infection risk level. Unfortunately, there are no generally accepted definitions for those risk levels. Now, the introduction of a new clinical assessment score – named W.A.R. (wound at risk) – which makes standardised classification of 'risky' wounds possible, could bring welcome changes to wound infection prevention and healing. *Karoline Laarmann* reports

among other things, these are bite wounds, gun or stab wounds penetrating up to 3.5cm.

'In the same way, risk factors of category III score three points – for example, severe burn wounds of >15% body surface area, and wounds with a direct connection to an organ or functional structure. All applicable points are added up. If a total of three points or more is reached, the wound is considered to be at risk and 'W.A.R.' is declared.'

Parallel with the point scoring method, W.A.R. is also declared for any wound known to contain a multi-resistant organism, as specified by the Robert Koch Institute, such as MRSA, or it is considered to be critically colonised. In this case, the W.A.R.

score gives recommendations for the use of antiseptics on the basis of polihexanide, which is characterised by a broad antimicrobial spectrum, excellent cell and tissue tolerability, a capacity to bind to an organic matrix, low risk of contact sensitisation and positive adjuvant effects to wound healing.

'In contrast to silver or iodine, polihexanide is more compatible with human tissue,' he pointed out. 'Although silver is highly accepted in Europe, and shows good clinical results when used as indicated by the manufacturers, there is a concern that it might penetrate into and persist in the body with the potential for as yet unidentified effects sometime in the future. So



Andrew Kingsley was awarded a BSc in nursing and MSc in wound healing

polihexanide might have the better safety profile both in the short term and in the long-run.'

Despite a clinical need for antiseptic dressings in controlled release formulations to be available for the prevention and control of infection, they are commonly either not included or placed on restricted access in local wound dressing formularies because they are more expensive than non-antiseptic versions. This is another reason why, according to Andrew Kingsley, it is important to have a systematic way of appraising the wound infection risk so that healthcare funds can be spent effectively. Achieving consistency in product selection between clinicians by enabling an evidence-based decision to be made using a risk calculator will ensure that those holding the purse-strings in European healthcare systems will become more confident in providing funds for more expensive

antiseptic dressing products.

Now that the concept has been made public, he emphasises that the W.A.R. score has nowhere near reached its final stage. 'We're really more at a starting point in terms of calculating risk factors. As it will reveal, over time through wider debate, certainly other risk features will be included.'

An additional part of that work will be to transfer the W.A.R. score into clinical practice where it has yet to prove its uses.

Another future step will be to combine the W.A.R. score with the Sign Checker, a checklist, developed by Andrew Kingsley, for the early identification of mild to more severe infection in open wounds. Normal inflammatory processes of healing and the abnormal states of wound infection share many similarities that can confuse clinicians and lead to inappropriate therapy choices. The Sign Checker uses signs and symptoms to help clinicians to understand whether the wound is progressing normally or is in need of anti-infective interventions.

So either way, in prevention as well as management of wound infection, with these two new instruments, clinicians in the future will be well kitted out for battle.

individual infections acquired during a hospital stay and outbreaks, which can be more problematic as they can cause more morbidity and mortality if uncontrolled. 'Infections can be acquired either exogenous, that is those occurring outside the body and endogenous infections where bacterial flora could be transmitted from wounds, or the gut, or through the blood stream,' explains, adding that there are three main ways to prevent the transmission of infection.

'The best way to avoid contamination is by eliminating the organism at source – that is, ensuring that patients are not exposed in any way. This we do by using sterile techniques for all interventions, major and minor and strictly advocating regular hand washing and disinfection. If infection does occur then hand hygiene measures are stepped up and, if necessary, the patient is isolated.'

He also points to a third way of preventing infection: increasing the host resistance by using antibiotic prophylaxis. 'It's still a standard procedure here to give a single intravenous shot of antibiotic post-op, because it has consistently shown to be a very cost-effective way of reducing the onset and subsequently the transmission of infections in the surgical arena.'

Despite its comparatively small size, Mater Dei is still proud of its cohesive infection control system, set up by transposing standards of knowledge and practices from leading expert bodies and institutions, such as the European Centre of Disease Control and adapting these to our local needs. The data from continuous surveillance systems is the living proof of its efficacy. As Louis Pasteur said: 'In the field of observation, chance favours only the prepared mind.'

Don't be complacent about TB

With few experts, we need to raise awareness among physicians and undertake research to upgrade our knowledge of this disease



TB expert Klaus Magdorf is a physician in the Paediatrics Clinic in the Department of Pneumology and Immunology at Charité, University Medicine Berlin

Although the incidence of tuberculosis (TB) in Germany is low, considering a slight rise of childhood TB since 2009, and facing the still high, partly increasing TB incidence in Eastern Europe, the rise of multi-resistant TB worldwide, and migration augmented by globalisation, TB expertise remains very important for all countries.

Seeking an insight into the TB situation in Germany, Bettina Döbereiner interviewed paediatrician Klaus Magdorf MD, among the few TB specialists in that country. He is positive that we need to again raise awareness about TB and, equally important, undertake more research to advance our knowledge of this disease.

Nonetheless, when asked whether we could face an epidemic of childhood TB, the expert was reassuring: 'No, not yet. With about 160 cases of childhood

TB in Germany in 2010, the disease is definitely under control and also the number of TB in adults is low – around 4,000 in 2010 – although childhood TB cases increased from 1.2 per 100,000 in 2008 to 1.3 in 2009, a rise seemingly continuing in 2010. I assume that every statistician would negate the impact of this increase, but we notice it – without panicking,' Dr Magdorf pointed out.

'Nevertheless,' he added, 'we face the problem that, from my experience, only a few clinicians know about TB; the majority of paediatricians is no longer aware of this "forgotten" disease. This is also an educational problem. So, to educate our future paediatricians about TB, we engage in scientific collaborations with South African universities.'

Are there multi-resistant childhood TB strains in Germany?

'Cases of multi- or extremely resistant TB are still rare in

Germany. More than 86 percent (including adult patients) of the Mycobacterium tuberculosis strains are fully sensitive to first line anti-tuberculosis drugs, about 11 percent are resistant to at least a single drug and only about two percent are multi- or extensively resistant (MDR, XDR).'

Are there fatalities among TB infected children here?

'It's extremely seldom – about one child per year – which is nearly always linked with a delayed diagnosis of the disease.'

How could our TB diagnostic quality and accuracy be improved?

'First, we must raise awareness of TB infection and we must include TB in the differential diagnosis of unclear pulmonary and extra-pulmonary diseases. Secondly, we should implement subsequent contact tracing to identify and screen all close contacts of each infectious patient, to prevent possible transmission to children. Finally, we must upgrade our knowledge about the disease and improve pre-screening of risk groups, for example immigrants from high-incidence countries.'

'The impact of immigration is the subject of an on-going study here in Berlin. We still have no reliable epidemiological data of the relevance of migration for the incidence of TB in this country. The study, launched in 2009, is being conducted by the Charité, University Medicine, the Robert Koch Institute and the Centre for Patients with Tuberculosis and People at Risk. I

would say that TB is by no means only "imported"; our preliminary data indicate that the effect is even smaller than expected.'

Do we have adequate drugs and regimens in Germany to prevent and treat TB in children?

'Yes. Presently we do, but studies on pharmacokinetics and side-effects of anti-tuberculosis drugs in children are scarce,' said Dr Magdorf, adding: 'Therefore, two years ago we started studies in South Africa to increase our knowledge.'

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Subscription rate
6 issues: 42 Euro, Single copy: 7 Euro. Send order and cheque to: European Hospital Subscription Dept

Printed by Dierichs Druck + Media GmbH & Co. KG, Kassel, Germany

Publication frequency bi-monthly
European Hospital ISSN 0942-9085

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Global registry will track wound care treatment

Wound care remains a sore point in healthcare. To identify optimal wound healing, 10 hospitals are creating the first real-world registry that will compare different approaches to treatment, John Brosky reports

Up to a fourth of the acute beds in a hospital are filled by patients with a wound received while in the hospital, typically a pressure ulcer, according to the *Journal of Wound Care*.

Outside the hospital, one in every 100 people suffers a non-healing wound, accounting for a significant cost to national healthcare budgets, according to Finn Gottrup MD, speaking at the recent Expert Conference of the Academy of Wound Technology in Paris.

As scrutiny of healthcare spending increases, he said, there is an increasing interest in the quality of available evidence for the effectiveness of specific wound care interventions, technologies and dressing materials.

There is no lack of clinical trials for new treatments. In fact, the avalanche of specialised studies is part of the problem for clinicians

trying to compare different techniques for the same wound, or the same treatment across different types of wounds. The paradox, said Dr Gottrup in his recent article 'The challenge of using randomised trials in wound healing', is that the higher the clinical quality of a narrow study, the lower its relevance for generalised analysis.

The head of the Copenhagen Wound Healing Centre, Dr Gottrup announced at the Paris expert meeting the launch of the Transcontinental Wound Registry (TWR) the first worldwide registry designed to cover a range of wound types and real-world treatment using wound care technologies.

TWR will begin as a minimum dataset, he said, in order to validate the structure and the data gathering practices. Ultimately, he added, '... with a database we will be able to compare treatment strategies by countries, to calculate outcomes

and improve treatment'.

The first phase of the registry project is a feasibility test that will run for 12 months among 10 enrolled centres.

The proof-of-concept from this pilot phase will be presented at the Congress of the World Union of Wound Healing Societies in Yokohama, Japan in September, 2012.

In a second phase, running through 2014, TWR will be used to identify predictive factors that lead to optimal wound healing and, in a third phase, the data will be analysed to evaluate the economic impact of treatment approaches.

Luc Téot MD, with the Hôpital Lapeyronie, (Montpellier, France) and the President of the Academy of Wound Technology, told *European Hospital* that the first phase of the registry project will cost €500,000 for the initial data collection from participating centres. National centres will be established for Korea, Singapore, Japan, and France. Denmark and Sweden will report as a single centre, while a centre in Hamburg, Germany, will jointly report data with a hospital in Salzburg, Austria.

WOUND MANAGEMENT

Three participating centres in the USA will be located in Miami, Chicago and New York.

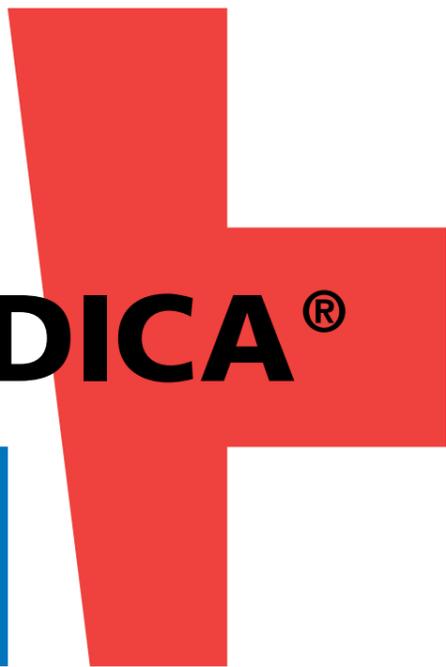
Funding for the TWR is provided by Kinetic Concepts, Inc. of San Antonio, Texas, in an effort to create what the company said will be a more complete picture of wound healing options. 'The reason a database is so strongly supported by industry is simply economics,' according to Kathy Sherwood, with KCI in Europe, in her presentation at the Academy of Wound Technology conference.

A significant barrier for clinical evidence in the fragmented landscape of Europe is that each country seeks different data for its regulatory approval process. 'The challenge is how to present the results from a randomised clinical trial from France in Germany,' she explained. 'Germany will tell you they want German data.'

'Randomised controlled trials are breaking our back,' she added. 'The multi-million cost of each study means we cannot afford to go to every country, into each care setting and assess every wound type and treatment algorithm.'

A second issue with clinical trials is that the data does not reflect the real world. 'We are required to prove clinical effectiveness in trials that are always done under ideal conditions and rarely represent the regimes actually being practiced on patients,' she said. 'Wound care is complex, and a registry will provide the real world data that is needed.'

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AUGUST 2011

A time to tackle controversies face-to-face

'The annual meeting of the ESC is the largest cardiovascular conference in the world – we're expecting up to 35,000 attendees in Paris,' Prof Komajda pointed out, adding that the event also will draw in cardiac specialists from far beyond Europe. 'About 30 percent of the delegates will come from outside Europe – for example from the Asia/Pacific region, Africa or Australia. We're looking forward a very interesting mix that for sure will provide interesting insights in treatment habits all over the world.'

Almost 400 sessions will cover the interests of hospital and private practice cardiologists as well as nurses and associated professionals.

'This year, what is very striking

A hefty debate on controversial issues in cardiology is the definite intent of Congress President Professor Michel Komajda and the ESC Congress 2011 organisers. To that end, he plans to open the event with a focus on disagreements among cardiologists over treatment methods. This is not the only promise of a lively meeting for congress participants, as Prof Komajda explained in conversation with Meike Lerner

is the number of submitted registries, meaning the evaluation of treatment of patients with one given disease in real life,' he said. 'Those registries provide us with detailed insights into how patients with cardiovascular disorders are managed in real life practice, which obviously provides a lot of new and useful information about the status-quo and the differences

in treatment across Europe.'

In particular, several registries that deal with atrial fibrillation, and one that focuses on the management of cardiovascular diseases during pregnancy, will provide new perspectives for clinical cardiology. Additionally, Prof Komajda said, 'the results of several huge clinical trials will be under the spotlight. In particular,



Michel Komajda

the Aristotle trial, testing a new anticoagulant in patients with atrial fibrillation, will gain a lot of attention.'

The results from *France II*, a huge French registry offering information about the follow-up of more than 1,000 patients with TAVI, are also anticipated.

'Of course, a lot of sessions are devoted to the diagnosis of

cardiovascular diseases; for example the *Meet the Expert* sessions should increase awareness among cardiologists of the bouquet of opportunities new imaging modalities and techniques are offering,' he added, foreseeing the near future of cardiology for which that awareness is as vital as the increase in cardiological interventions as an alternative to conventional surgery.

Finally, he concluded, 'one challenge will be post-graduate medical education, which needs to be in the hands of professional organisations such as ours to provide balanced and neutral information with the aim of homogenising procedures and treatment of patients across Europe'.

Congress details:
www.escardio.org

Cardiac biomarkers: What's real, what is hype?

'We have shown benefit from patient management with the natriuretic peptides. The question is whether there are other biomarkers we can obtain from the same blood sample that can tell us things the peptides can not. This brings us to the next class of markers, the pipeline markers. I titled one of my lectures 'Pipeline or pipe dream?' because we do not know whether these novel markers are necessarily going to add to our everyday management of patients. Several appear quite promising.

'Highly sensitive troponin are markers of heart injury. While the mechanism may differ as to why the level elevates, it is a very high risk finding. It identifies a patient who, independent of the value of the peptide findings, is at higher risk for heart failure, hospitalisation, or death. The problem right now is we don't know if managing patients according to their elevated troponin level will make any difference in outcome. Knowing that a patient is at high risk for heart failure does not mean you can do anything about it.

'ST2 is a really fascinating marker. Biologically, it is a measure of heart fibrosis, or scarring. When the heart is injured, it goes through a process called remodelling. While remodelling is a good thing for our homes, when the heart remodels it is a bad thing. It can result in enlargement of the heart chamber size and a weakening of the heart muscle. ST2 is remarkably prognostic, predictive of progressive heart failure, hospitalisation and death, above and beyond any other measure of tropins or natriuretic peptides.

Cardiac biomarkers PIPELINE OR PIPEDREAM?

A drop of blood can unlock secrets of the heart. By analysing the biological elements present in a blood, a physician can better understand the extent of damage or disease for patients with heart failure and more confidently prescribe a course of treatment.

At this year's European Society of Cardiology meeting, Harvard University Professor James Januzzi, (right) who leads the Cardiac Intensive Care Unit at the Massachusetts General Hospital in Boston, will update colleagues and challenge them with emerging evidence that supports biomarker-guided therapy. In this interview with *European Hospital* he also promises to deliver some 'eye-popping

news' about the benefits of this approach to patient care.

An active researcher with more than 150 publications, the focus of Prof Januzzi's work is with natriuretic peptides, protein-based hormones released by the heart when it is stressed. High levels of these peptides describe specific biological conditions of heart muscles. The studies, he said, 'are extremely encouraging and imply that biomarker-guided care using this class of blood tests will be important and useful in a large percentage of patients with heart failure'



Preliminary data suggests that specific therapies have favourable effects on heart remodelling and particularly benefit patients with an elevated ST2 value. This is very encouraging for biomarker guided management.

'Also in the pipeline there are metabolomic markers and genomic markers like microRNA, but these are far in the future and very far behind the protein markers now available or soon to be available.'

Many cardiologists are not convinced about the benefits of biomarkers ...

'Biomarker-guided care fits very well with other approaches, typically as a first step. We have proven two markers, BNP and NT-proBNP, are effective for the diagnosis of patients with heart failure, as well as establishing

the prognosis of patients. It turns out the higher the level of these peptides, the higher the risk for hospitalisation and death from HF. The One Million Euro Question is whether these blood tests can be used as a guide to patient care.

'There is positive data from other centres that is encouraging, notably the work of Richard Pacher at the Medical University of Vienna. It's important to acknowledge that other studies, including one in Basel, Switzerland, have been negative, showing there is not a benefit in biomarker-guided management. The benefits of biomarker guidance have not been disproven and there are many questions as to why different trials have produced different results. Next year we'll be examining the effectiveness of biomarker guidance in a larger international trial.'

How do biomarkers help guide treatment?

'Typically a cardiologist spends 15 minutes with a patient measuring blood pressure and hoping that the doses prescribed for a medication actually will achieve a benefit. If instead we use a reproducible, non-invasive, biologically relevant measure that not only tells you how well the blood is flowing but also tells you, at the biological level, that there's something wrong with the heart that can be addressed with an adjustment to medication, you can understand why biomarker-guided care can have a huge advantage.

'How we define optimal medical treatment for patients with heart failure can vary. Yet there is a clearly defined path for care with patients with weakened heart muscles. The guidelines are unequivocal. We know which

drugs to use and we know how to use them. For patients with heart failure and preserved heart function there is not yet a clearly defined management strategy. It stands to reason that a biomarker approach to heart failure care will not work for patients where the therapeutic strategy is not established. How can a compass guide you if you do not know where you are going?'

Your recent work suggests further benefits for biomarker guided care

'You want to know what the eye popping moment in my ESC presentation is? We have a very big finding that we are in the process of writing up for publication. Using echocardiography at baseline and then at 10 months of follow-up, we showed people with robust reductions in their NT-proBNP values had greater improvement in their ejection fraction and greater reduction in their ventricular volumes. In other words, these patients had a greater improvement in heart remodelling metrics than patients who did not have a big reduction in their NT-proBNP values.

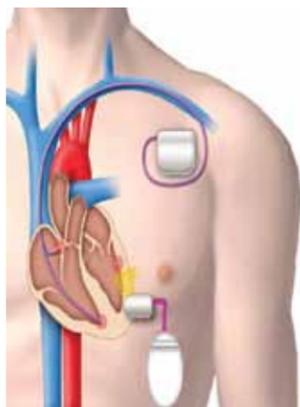
'What this says is that, besides leading to better management from a medication perspective and leading to more attentive medical care, these patients felt better – they had better quality of life scores, and they had considerably fewer cardiovascular events. But, importantly, even on the biological level we can see the benefit. This lends biological reasons for utilising natriuretic peptide reduction as part of an overall care strategy for chronic heart failure.'

The cardiac pacemaker of the future will be wireless and monitored by the physician via satellite, says EH writer *Holger Zorn*



Trends in cardiac pacing

'Sacriligious meddling with divine providence' was the charge brought against New York cardiologist Alfred Hyman in the 1930s when, after successful animal experiments, he applied the first cardiac pacemaker – then still a cumbersome external device – in human patients. A quarter of a century later the first cardiac pacemaker, mounted in a shoe polish tin and covered by epoxy resin, was implanted. However, Swedish heart surgeon Ake Senning, of the Karolinska Institute, and engineer Rune Elmqist of Siemens-Elma, were not confident that their development, which had worked for a mere three hours, would become a medical success. Unlike the inventors, the patient, Arne Larsson, believed in the new device and underwent more than two dozen implantations.



The wireless generator senses the signals transmitted by the pacing device implanted below the collar bone and, via ultrasound, stimulates the wireless receiver/transducer in the left ventricle

Small device, big business

In 2008, the year that marked the 50th anniversary of the first pacemaker implant, Sreevidhya Praveen, analyst for consultants Frost & Sullivan, determined a market volume for pacers of €2.68 billion in Western Europe alone. For 2015, Praveen predicts the business will reach €5.76 billion. Three drives currently propel pacing technology: cardiac resynchronisation therapy (CRT), telemonitoring and – newest of all – wireless pacing.

CRT

In 1994, Serge Cazeau of the Institut Parisien de Rythmologie et de Stimulation Cardiaque (InParys) presented CRT, a device that improves the heart's pump function in patients with congestive heart failure (CHF). This progressive cardiac disease, which in advanced stages may require major interventions such as a heart transplant, usually entails a gradual loss of heart muscle. The remaining tissue cannot transmit the electrical impulses. The CRT device contains three rather than the usual two leads, which are fastened to the wall of the heart – in the right atrium and the left and the right ventricle. By pacing both chambers the heart beat is coordinated – resynchronised.

Several studies indicate dramatic benefits of CRT. According to the Multisite Stimulation in Cardiomyopathies (MUSTIC) trial, CRT reduced the number of hospitalisations by two thirds [Source: *Europace* 2004;5:42-8]. This has a significant impact not only on patients' quality of life but also on healthcare costs: With a prevalence of 2–2.5%, around 15 million people in Europe suffer from CHF; about 400,000 new cases per year will be recorded.

Frieder Braunschweig of Karolinska Hospital analysed 16 patients who received CRT. He found that the number of hospital days decreased from 253 days in the year before the CRT device had been implanted to 43 days in the year after the implant ($p < 0.01$). Average total costs of in-patient care per patient were €9,301 per pre-implant year and €1,654 in the year following the implant. With average implant-related costs of €8,019 per patient, CRT had paid off in the second year [Source: *Eur J Heart Fail* 2000;2:399-406].

Wireless pacing

Frequently, the usual access route to place the third lead – the coronary sinus – is blocked. WiCS, wireless cardiac stimulation technology developed by EBR Systems Inc., Sunnyvale, California, offers a way out. The

device is co-implanted with a conventional CRT system since 'the leads have always been the weakest link in any cardiac pacing system,' explains Dr Debra Echt, co-founder of EBR Systems. Dislodgement and failure due to fatigue occur in about every fifth lead.

In the course of a feasibility and safety trial Dr Christian Butter,



The next generation pacing device will be fastened directly onto the ventricle wall

Head of Cardiology at the Heart Centre Brandenburg in Bernau, Germany, recently implanted three of the currently six devices in use worldwide.

He inserted a wireless receiver/transducer via catheter through the femoral artery, the aorta and the aortic valve in the left ventricle and fastened it to the posterolateral ventricle wall. The generator is implanted on the left side below the sixth rib, about eight centimetres away from the lead. Upon sensing the stimulation of the right ventricle by the CRT device, the generator transmits its own pacing impulse using a frequency of 800 kHz to the receiver in the left ventricle (Fig. 1).

If the device were implanted at the usual location below the sternum, the lungs would absorb and the ribs would curve and break the sound waves. With the new device, Butter explains, 'different sites in the left ventricle can be stimulated independently of the venous anatomy. Implantation of a wireless lead makes CRT an option for many more patients.'

The technology allows access to further pacing sites in the right ventricle or the right atrium and it can replace all pacing leads – maybe

even all sensor leads. Continuing along these lines, Butter is convinced, will one day provide a device in which the entire technology is set in a single housing and uses several frequencies. This will be the advent of fully wireless cardiac pacing.

Fully wireless pacing is by no means science fiction, as N Oesterle MD, Vice President for Medicine and Technology at Medtronic, showed at TEDMED, held last October in San Diego: The next generation cardiac pacemaker will be inserted via catheter through the blood vessels, the right ventricle and the septum into the left chamber. There, right at the pacing site, the device will be fastened to the ventricle wall with four hooks. These hooks – and this is the most amazing idea behind the technology – serve as leads (Fig. 2). Oesterle expects this technology to reach marketability in three to four years.

Telemonitoring

Technology can indeed develop from science fiction to clinical reality in just a few years – as telemonitoring shows. Today, data are transmitted from a pacemaker, implantable cardioverter/defibrillator (ICD), or CRT device to an internet-based platform from where they can be retrieved by the physician.

Biotronik Home Monitoring by Biotronik SE & Co. KG Berlin handles this communication

wireless, automatically and safely via the frequency range reserved for medical implants (403 MHz) and the mobile phone network. Technical and clinical data are regularly coded and transmitted to the Biotronik computer centre where they are decoded, analysed and summarised in reports that the physician in charge can access via internet (Fig. 3). Clinically relevant data are transmitted instantaneously and the physician is alerted via text message, e-mail or fax. This not only improves early detection and allows timely intervention by the physician but also reduces the number of visits at the physician's office.

In the TRUST Landmark study Niraj Varma et al. of Cleveland Clinic, Ohio, compared 473 ICD patients who received conventional follow-up – out-patient presentation after 3, 6, 9, 12 and 15 months – with 977 patients who presented only twice – after three and 15 months – for follow-up and underwent Biotronik Home Monitoring (and were called in as required). This procedure decreased the number of hospitalisations by 45% within one year – while maintaining utmost patient safety.

Furthermore, the study showed that arrhythmias are detected much earlier: The time between a recorded event and its analysis by a physician occurred on average in less than two days compared to 36 days in the control group [Source: *Circulation* 2010;122:325-32].

Cardiac contractility modulation (CCM) is an upcoming method to treat cardiac insufficiency of those patients who do not or no longer benefit from cardiac resynchronisation therapy – which applies to at least 30% of them [Source: *Eur J Heart Fail* 2007;9:955-8].

In contrast to conventional cardiac pacing, CCM signals do not initiate a heartbeat. In contrast to cardiac resynchronisation therapy, CCM do not alter the activation sequence. Instead, CCM signals are delivered after a preset delay following detection of muscle activation. This augments the calcium influx into the heart muscle cell – and calcium is essential for cardiac contractility. The effect is an improved ejection fraction, thus an improved exercise capacity, measured by peak oxygen consumption, and a better quality of life.

Moreover, Christian Butter, head of cardiology at Brandenburg Heart Centre and one of the pioneering investigators of CCM, confirms 'there is no adverse effect on long-term survival'.

He recently reported 59 consecutive patients who underwent CCM therapy [Source: *Europace* 2011 Jun 28; Epub ahead of print] with implantation of an *Optimiser* system from Impulse Dynamics, presently the only manufacturer of such a device (pic. 1).

Since its clinical introduction, there are more than 750 patients treated with CCM in Europe. Germany, often berated for restrictive reimbursement of innovative therapies, has included this therapy in its DRG system: With a cost weight of 9.018, and depending on their base rate, hospitals earn about €27,000.

The leap from the 157 TAVI procedures carried out in 2007 to the 3,629 undertaken in 2010 is impressive. Was it solely the German reimbursement policy – almost €35,000 per procedure – that boosted the use of this novel treatment for severe aortic valve stenosis?

Prof Strauch: 'Definitely not! Taking the results of the Helsinki Ageing Study, 2.9% of 75-86-year-olds suffer from this disease. In relation to the German population, this means 160,000 potential patients. A high proportion of these patients are too frail for conventional surgical valve replacement – and conservative treatment is of limited success. They were underserved, if not un-served. With minimally-invasive, catheter-based aortic valve replacement we can prolong their life expectancy and improve their life quality.'

Is there evidence of that?

'Yes. The PARTNER trial – with 358 patients at 21 centres the largest multicentre study on transcatheter aortic valve implantation for aortic stenosis in patients who cannot undergo surgery – has shown a significantly reduced rate of death from any cause after one year. These data are confirmed by my own

Transcatheter aortic valve implants

The slow emergence of second generation options

Although transcatheter aortic valve implantation (TAVI) is increasingly the most used surgical procedure in Germany, only two products have been approved for routine use. Although this has prompted other medical device manufacturers to go into action, according to Professor Justus Strauch, head of cardiac surgery at the Klinikum Bergmannsheil, Bochum, no one has yet taken the lead in this technology. Interview: *Holger Zorn*



Justus Strauch

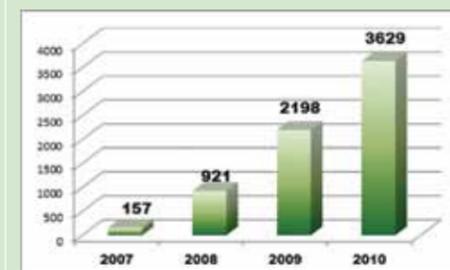
experience over the last four years.' Those results were achieved with Edward's Sapien valve, so far one of the two approved products. Meanwhile, other global players, as well as start-up companies, have announced a couple of new developments. Which one might win the race? 'It's really too early to say. One device, for example, from an Israeli start-up that

was acquired two years ago by Medtronic, was completely withdrawn from all clinical evaluation. Some other companies – even global players such as St. Jude Medical – have only reported the first human implant. Others are still undergoing feasibility trials and the most advanced start-ups, JenaValve Technology in Munich, or Symetis in Lausanne, have reported only series of less than 100 patients with short-term outcome data. So far, the

Sapien valve with its transapical approach has a technological edge of two to three years with proven results.'

What do you expect from a next generation valve?

'From a next generation valve I'd want the property of re-positioning within the procedure, a reduced rate of paravalvular leakage and a smaller dimensioned introducer sheath.'



TAVI procedures 2007-2010



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Keeping donor organs 'alive' in transit

Although donor organ management is improving, the number of heart transplants is decreasing. According to Eurotransplant, 115 heart transplants were performed in the first quarter of 2011 compared to 149 of such interventions in the same period last year.

A new, portable, warm blood perfusion system now promises to enable living organ transplants. Using novel technologies Transmedics Inc. has produced the *Organ Care System (OCS)* to maintain human donor organs in a warm, functioning state outside of the body during transport, thus optimising their health and allowing continuous clinical evaluation.

The system integrates a compact wireless monitor, an organ specific perfusion module, and proprietary solutions for organ maintenance, the manufacturer explains, adding: 'Hearts beat, lungs breathe, kidneys produce urine, livers produce bile.' In transit, a donor heart, for example, can be connected to the pulsatile pumping system and perfused with warm, oxygenated donor blood and nutrients, thus reducing time dependent ischemic injury.

This not only lengthens the transportation time, potentially expanding the catchment area of a transplant centre, but also enables fully functional, biochemical and metabolic assessment of the organ by the receiving physician and potentially enabling the transplant surgeon time to resuscitate the organ *ex vivo* to build up its energy stores, optimise its function and perform full viability assessment prior to transplantation.



The OCS may also enable the utilisation of organs currently not used due to the limitation of the existing preservation method.

The device was first used for a beating heart transplant in February 2006 in Bad Oeynhausen, Germany – where it became available at selected heart centres in 2007.

Meanwhile, the OCS has received CE approval and the series recently expanded to include the *OCS Lung* transportation device.

In view of discussions regarding the amendment of the organ donor law, this May members of the German parliamentary committee on healthcare, led by Dr Carola Reimann and supported by Professor Martin Strüber of the Medical University Hannover, Germany, visited TransMedics in Andover, Massachusetts, for a first-hand presentation of the Organ Care System.

MRI and plaque imaging

A research 'toy' or clinically relevant tool?

Cardiovascular disease is the leading cause of death in industrial nations. More than 50 percent of those deaths are associated with pathologies of the coronary arteries, despite the fact that luminal obstructions that lead to myocardial infarction or ischemia do not occur out of the blue. The initial symptoms are preceded by a whole slew of arteriosclerosis stages and the early detection of these could prompt treatment to slow, stabilise or even reduce the disease.

However, such early detection would involve diagnostic examinations of healthy and thus far asymptomatic people – which therefore precludes invasive procedures and those that entail ionised radiation. MRI might offer a feasible alternative, according to **Professor Matthias Stuber**, Director of the Centre for Biomedical Imaging (Centre d'Imagerie BioMédical – CIBM*), in Lausanne, Switzerland. Interviewed by *Meike Lerner*, he addressed the question of whether MRI in plaque imaging is a clinically relevant tool or just a toy for the research community

'Today, arteriosclerosis assessment via MRI is mainly limited to research. However, there are initial studies evaluating the benefits of the method to quantify plaque and its progression in animal models and human patients. Moreover, we try to analyse the composition of the plaque, which is an important issue with regard to establishing risk profiles, since many of the stenoses that rupture are in regions that don't



PHOTOGRAPHE RAINER SCHLEIBER

Professor Matthias Stuber received his doctorate in engineering at the Institute for Biomedical Engineering at the Eidgenössische Technische Hochschule – ETHZ in Zurich, Switzerland. Following professional roles at Harvard Medical School in Boston and Johns Hopkins University in Baltimore, Maryland, for the past two years he has directed CIBM, a division of Centre Hospitalier Universitaire Vaudois (CHUV). Thus he is not only the interface between research and clinic but also one of very few non-physicians in Europe to hold a chair at a university hospital. While such interdisciplinary cooperation is well established in the USA, the European medical community has only recently realised the necessity of this approach

show significant disease in heart catheter images' Professor Stuber explained.

Today, such MRI applications are technically rather demanding in terms of the technology, particularly in terms of system operation and thus the training for radiographers. There is also another obstacle to surmount, he said. While manufacturers can produce contrast media that may show different plaque components, due to regulatory issues their research and

development efforts have cooled down considerably. Nevertheless, according to this expert, MRI in plaque imaging may well make it into clinical practice: 'Technology will make use of MRI so that the early detection of arteriosclerosis is possible, although it remains to be seen who will pay for such a procedure and for which patient groups the procedure should be indicated.'

No matter how these decisions are to be made in the future, today the method has already demonstrated its value. 'Non-invasive and radiation-free diagnostics provided us with many insights into arteriosclerosis, particularly in its early stages. Today, we can also examine younger individuals and not have to wait until the patient presents with symptoms in the cath lab.'

As to whether MRI for plaque imaging is a tool or a toy, Professor Stuber said: 'It depends... There is a clear difference between applications that are already being used, and thus will become clinical tools shortly, and research projects experimenting with contrast media that are perfectly suited for visualisation purposes but which are clearly toxic and thus will probably remain as mere research toys.'

* *The CIBM aims to advance our understanding of biomedical processes in health and disease, focusing on mechanisms of normal functioning, pathogenic mechanisms, characterisation of disease onset prior to structural damage, metabolic and functional consequences of gene expression, and non-invasive insights into disease processes under treatment. The research will use model systems ranging from transgenic animals to human patients ('from mouse to man') and foster multi-disciplinary collaboration between basic science, biomedical science and clinical applications.*



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Building human hearts on an assembly line

An artificial heart will be implanted in a patient before the end of 2011, marking a milestone in medicine. The developers are now accelerating plans to manufacture thousands of these mechanical hearts for patients worldwide, reports *John Brosky*

The International Standards Organisation (ISO) gave the green light this summer to the design and quality processes for manufacturing a fully implantable mechanical human heart.

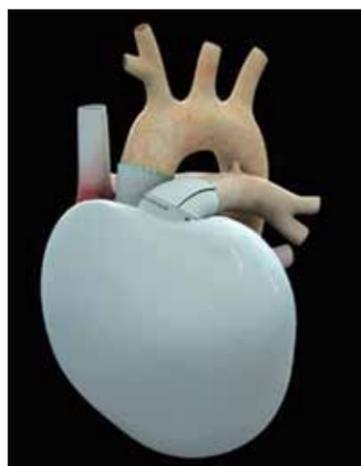


Marcello Conviti



Alain Carpentier

The financial world is fully behind this bold venture. In one year the share price of Carmat, the Paris-based company that is bringing the artificial heart to market, soared to 10 times its value when introduced in July 2010. The capitalisation for the company on the NYSE-Euronext is currently estimated at €712 million.



The Carmat artificial heart

Marcello Conviti, CEO of Carmat, said the final step to bring the heart into the operating theatre is the approval of the both the French authority Agence Française de Sécurité Sanitaire des Produits Santé (AFSSAPS) and patient protection committees.

Under AFSSAPS rules, Carmat qualifies for a fast-track approval process because it is bringing forward a new technology. 'Given the progress made in our project, we are confident we will meet the goal of a first implant of the heart before the end of 2011,' said Carmat's CEO.

The firm is expected to receive a further €25 million in August from investors to power its accelerated drive for a commercial launch in 2013.

There is a vast unmet medical need for a mechanical heart. Each year, 100,000 people are diagnosed with severe heart failure and learn they have about 12 months to live as their heart loses its ability to pump blood. Only one in 10 can hope to receive a transplanted human heart.

Frustrated that he could not offer any hope to patients, the world renowned heart surgeon **Dr Alain Carpentier** spent 15 years developing the Carmat heart (European Hospital, 08/31/2010). 'The aim of this heart is to allow patients to go from an impossible life – where they can do just a few

steps from bed to armchair – to a normal social life,' he said. (EH, 04/26/2011)

Meeting this clinical ambition to help thousands of patients presents a formidable industrial challenge for Carmat and its CEO. The first 20 patients

will provide the technical and clinical data required for CE marking and the beginning of commercialisation,' Marcello Conviti pointed out. Then will come what he called 'a solid and efficient industrial structure with a second source of supply for all

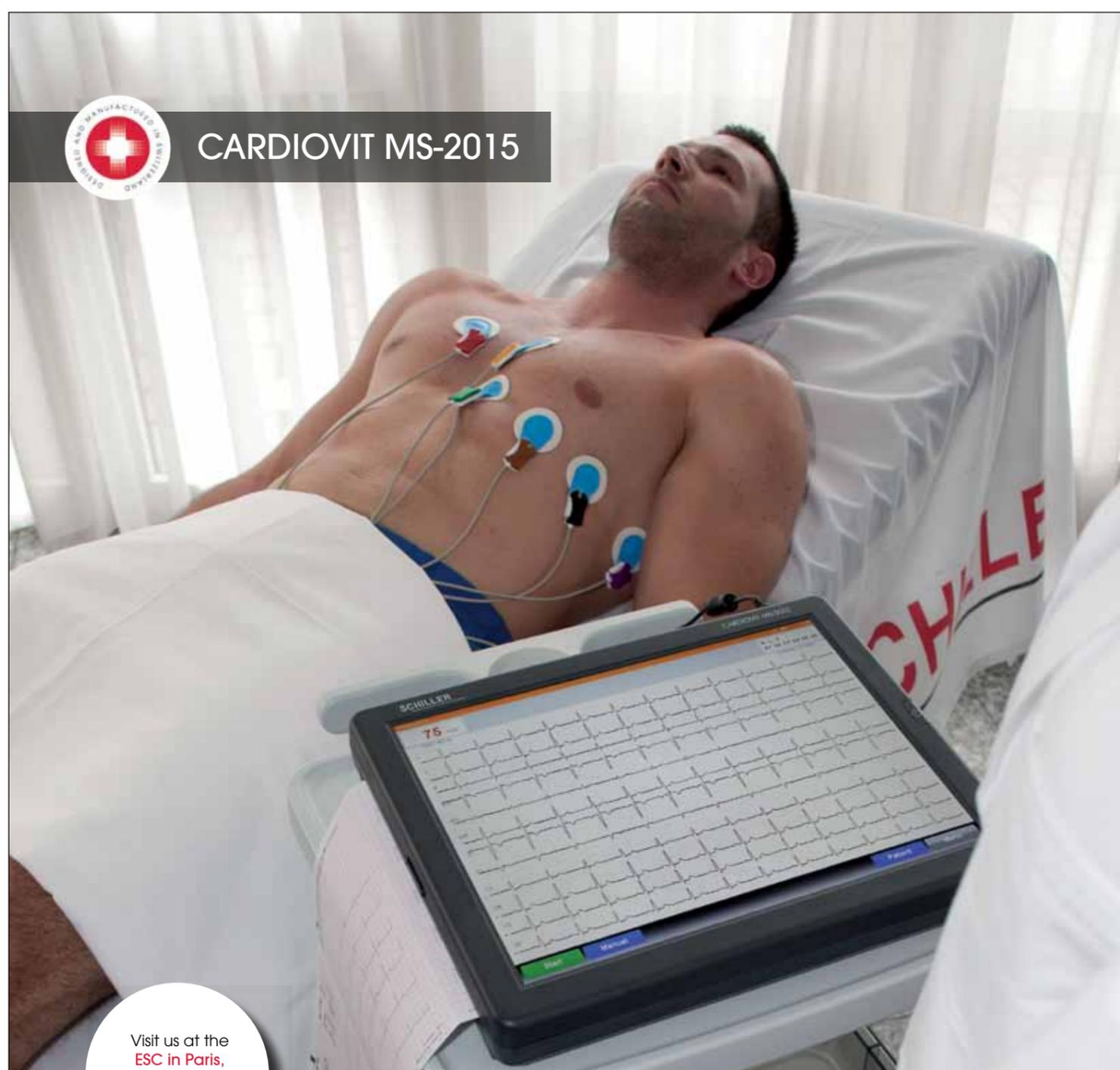
critical components, optimisation of production processes and costs, manufacturing qualification of suppliers, and automation of certain fabrication processes to meet the requirements of commercialisation.'

Finally, the company is accelerating development of the portable peripherals required for patients to move about, which include next-generation, body-worn batteries to extend the autonomy and external consoles

to monitor the device's operation either in the hospital or at home.

The peripheral system will be available by early 2012 – in time for the hospital-to-home discharge of the first recipients of the Carmat heart.

Once implanted, the only external sign that a patient has an artificial sign that a patient has an artificial sign that a patient has a wire extending from behind the ear to a harness holding the battery, system monitors and wireless connectivity transmitters.



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A modern-day childhood totally differs from what was common just a few decades ago. It is mostly spent sitting – at school desks, in front of TV screens or before computer monitors – all combined with the sweet temptations of the kid's food industry. According to a WHO worldwide estimate, an estimated 10% of school-age children between five and 17 years old are overweight or obese. The consequences of abnormal or excessive fat accumulation are insulin resistance, high blood pressure and lipid metabolic disorder, which are all part of the same health-threatening clique: cardiometabolic syndrome. Childhood obesity is also associated with a higher chance of developing cardiovascular disease in adulthood.

positivity and weight patterns during early childhood, or even *in utero*, may programme people to develop more cardiovascular problems in adulthood. In addition, longitudinal studies that have followed kids through to adulthood have clearly shown that three-quarters of overweight children become obese adults, and that this sets them up to be in the highest risk category in terms of cardiometabolic risk factors and vascular changes.'

Does cardiometabolic syndrome management differ between children and adults? 'Yes. The roots of disordered and emotional eating often have their origins mainly in the paediatric age groups, but the reasons that are driving kids to become overweight and obese are different than in adults.

also developmental considerations, particularly regarding behavioural management strategies, because kids span a wide range of ages and abilities to comprehend what lifestyle changes might be necessary.'

So, what kind of management produces the best effects? 'An ongoing issue in the field is that no single level intervention is going to have a significant benefit. In order to achieve a positive effect, interventions must be designed to be adaptive to the patient's individual circumstances and also address environmental factors.

'One of the most important aspects emerging in intervention is probably the role of motivational interviewing as a counselling strategy to achieve behavioural changes around lifestyle. This means aban-

When overweight kids become heart condition adults

The bad company of childhood obesity and cardiometabolic disease

During this year's ECR* **Dr Brian McCrindle**, Professor of Paediatrics and Nutritional Sciences at the University of Toronto and Section Head of Clinical Epidemiology in the cardiology division at the Hospital for Sick Children, Toronto, Canada, will speak about the management of metabolic syndrome in children and its long-term effects on cardiac health in later life

There are, said Professor McCrindle, when asked whether cardiovascular diseases associated with overweight and obesity are already manifest in childhood, 'early markers for increased risk of future cardiac events in obese kids, such as hypertension and increases in the left ventricular mass. What certainly is already present in the paediatric age group is cardiometabolic syndrome, which is not much different than in adults. These kids suffer from the typical pattern of lipid abnormalities, high blood pressure and Type 2 diabetes.

'There is also evidence that the pathophysiologic process of adi-

'In kids, the problem is more driven by environmental factors. Direct marketing to kids of energy-dense food and sugary drinks, as well as the fact that certain extracurricular activities such as video games and computers are readily available within their home and school, makes it difficult to address the problem with a strictly behavioural solution. So, actually, changing the environment by working with the family and restricting the accessibility to these things within the school system may have higher chance of success.

Another problem is that a lot of families don't recognise the issue of overweight and obesity. In addition, if a healthcare practitioner brings up the concept that their child might be overweight, the parents tend to bring up some negative push back. So, there's a lot of opportunity for population-based education to get people to think of this as a problem and then also to equip healthcare professionals with the appropriate counselling skills.

'In comparison to adults there are

doing prescriptive and didactic forms of communication and adopting a more client-based counselling form, whereby the patient determines the agenda and the interviewer is helping the patient to tap into their own intrinsic motivations for making behaviour changes.

'I also do believe that the most effective strategy is to develop a population-based screening programme. For pre-schoolers, it can be integrated within routine primary healthcare. Once they are school-aged, the main environment where they can be screened is within the school system. However, this has to be backed up with a referral strategy so that if a child turns out to be obese and have cardiometabolic risk factors they get further assessment and management through the healthcare system. But, to realise this, governmental and public support are required to create a consciousness that cardiometabolic syndrome is a serious and fundamental health burden.'

*** At ESC 2011 on 28 August, Prof McCrindle will lecture during the session *Childhood Obesity and Cardiometabolic disease: Prevention and management*, running from 4.30 to 6 p.m. in the Lisbon Room – Zone D**



Brian McCrindle

A date for the diary... 4-5 November – Barcelona

The New York Academy of Sciences Conference

Promoting cardiovascular health through molecular biology, clinical pathophysiology and population research

This two-day international scientific symposium follows two previously successful conferences held by the New York Academy of Sciences (NYAS), 'la Caixa' Welfare Projects, and the International Centre for Scientific Debate (ICSD) for researchers, physicians, scientists and representatives of the related industries, working in cardiology, vascular disease, inflammation, regenerative medicine, metabolic disorders, haematology and nutrition.

'The meeting in Barcelona is a challenge because we are going to touch on two transitions: how we go from disease to promoting health in the next 20 years, and how we move from the heart to the brain,' explained **Valentin Fuster MD PhD**, Director of Zena and **Michael A Wiener** from the Cardiovascular Institute and the Marie-Josée and Henry R Kravis Centre for Cardiovascular Health at Mount Sinai Medical Centre, New York and also Director of Fundacion Centro Nacional de Investigaciones Cardiovasculares Carlos III (CNIC) in Madrid. 'Therefore it will be a very interesting meeting with a tremendous sense of the future, putting together all sorts of people in the health system and in science. It's really exciting, because what we are really talking about is the next two decades.'

The symposium will present an impressive roster of 23 keynote and plenary speakers and panel discussions, posters – outstanding poster presenters may be selected to give brief oral presentations in the Data Blitz session – along with the usual panoply of networking breaks, a conference reception, and a career development workshop. Along with fostering



multidisciplinary dialogue among those working in this field, the programme aims to disseminate the symposium's proceedings to a wider public by producing high-quality materials and gaining press coverage.

In addition, on 3 November the scientific programme will be paired with an evening satellite lecture on this topic, by Dr Valentin Fuster, to target the general public.

Details: www.nyas.org/cardiovascular

Nothing beats a heart attack to motivate someone to exercise regularly, stop smoking and lose weight.

Yet, left to themselves, after a few weeks cardiovascular patients return to the bad habits that brought on the crisis in the first place – and, sooner or later they find themselves back in a hospital bed.

To break this cycle and help keep patients out of the hospital, along with medications a cardiologist should prescribe a nurse to help improve a patient's prognosis, according to **Ron Peters MD**, professor of cardiology at the Academic Medical Centre in Amsterdam.

At the Paris meeting of the European Society of Cardiology (ESC) Professor Peters will present the results of the RESPONSE clinical trial, which demonstrates the effectiveness of a nurse-coordinated programme for follow-up care of cardiovascular patients.

Conducted at 11 medical centres in the Netherlands, the Randomised Evaluation of Secondary Prevention by Outpatient Nurse Specialists showed that 40% of patients increased their control of risk factors

RESPONSE trial results

A nurse-led programme improves outcomes for cardiovascular patients

Studies show that when a nurse follows patients after a cardiovascular crisis those patients stay healthier, live longer and reduce the risk of returning to hospital. Now the challenge is how to convince insurers to pay for this care, reports **John Brosky**

for a repeat cardiovascular event and reduced the risk of dying in the next 10 years by almost 17%.

The study confirms what cardiologists know so well that it is enshrined in practice guidelines worldwide: reducing risk factors for high blood pressure, smoking, and high cholesterol can greatly improve a patient's outcome.

It is also not news to say that the personal attention and follow up with a nurse can help put these practical steps for prevention into practice.

Instead, RESPONSE is important

for providing clinical proof to overcome the barriers that prevent this approach from being put into widespread practice.

'The short answer for why nurse-led prevention is it not widely practiced in Europe is that there is no funding,' Prof Peters told *European Hospital*. Lacking a separate billing system for the services of nurses, he said, the cost of the follow up visits must come from the fees paid to the physician.

RESPONSE was designed to convince Dutch insurers to create reimbursement for nursing services to



Ron Peters

heart patients, he said. 'We needed outcome data and it is now under review with one of the world's leading medical journals. Once the article is published, we can approach the insurance companies and say, 'Here's the evidence, let's talk about reimbursement.'

At ESC in Paris, Prof Peters will seek to convince fellow cardiologists to support nurse-led preventative care because, even with reimbursement, such a programme cannot be implemented unless it is prescribed by a physician.

Some cardiologists do not see secondary prevention as part of their specialty, he said.

After treating the complications that put the patient in hospital, cardiologists tend to send patients home without addressing the underlying disease that is most often the cause of the complications.

'The changes needed in a patient's

lifestyle become the most difficult part of follow up treatment,' he said. 'If you want to coach people to stop smoking, or change their eating habits, you need to build a basis of trust in one-to-one relationship and regular visits.'

The role of the physician is to establish protocols to be followed for an individual's programme of follow up care. The role of the nurse, who is recognised as an allied professional, is to stay within these protocols. The nurse is doing exactly what we have prescribed and, by staying within these protocols, the nurse is protected under the doctor's responsibility,' he pointed out.

Key to wider adoption of nurse-led prevention programmes in Europe will be to establish a successful programme that can serve as an example for other countries and professional societies to follow.

'There is no way we are going to coordinate this in a uniform way across Europe,' he said. 'The best we can hope for is that examples are set in some progressive countries, perhaps like my own, that will encourage adoption because it is successful.'

Trends in stents and balloon angioplasty

When, 25 years ago, Ulrich Sigwart, from Lausanne University Hospital, began to implant the first 24 stents in coronary arteries of 19 patients, he hoped 'that this vascular endoprosthesis may offer a useful way to prevent occlusion and re-stenosis after transluminal angioplasty' [N Engl J Med 1987;316:701-6]. Sigwart had vision. Just a decade on, 'stent fever' had spread among his colleagues [Eur Heart J 1997;18:552-3].

At that time, balloon-expandable **bare metal stents (BMS)** were the gold standard. These were mesh-like tubes of thin wire made from stainless steel, tantalum or, more recently, from a cobalt chromium alloy, like the PRO-Kinetic stent.

Biotronik, the leading German manufacturer, uses this as a platform technology to design the today's gold standard, **drug-eluting stents (DES)**, where the mesh tube is coated with a drug releasing biopolymer to limit the growth of neointima, thus preventing stent restenosis.

This May at the EuroPCR congress, Martial Hamon MD (Caen University Hospital), presented the final first-in-man (FIM) *Orsiro Hybrid DES* trial results: In-stent late lumen loss at nine months, the primary endpoint, was of 0.05 ± 0.22 mm. 'The results are especially encouraging considering the challenging patient characteristics, atypical for a FIM trial - a medical history including 73% previous MI and 23% diabetic patients,' Dr Hamon commented. 'The exceptional deliverability of Orsiro is a necessity with the degree of complex stenting that is performed in current cath lab practice.' His colleagues appear to agree.

Meanwhile, Michael Haude at Neuss Luke Hospital, enrolled the first patient in a prospective international trial that will randomise around 440 patients with Biotronik's *Orsiro* or Abbott's *Xience Prime* at 19 European sites.

However, Patrick Driscoll no longer believes the 29.4% CAGR is likely for those products. 'The strength and priorities of the market have shifted, as evidenced in the least by J&J's decision to exit the market'.

A more recent analysis, fully focused on Europe, confirms the market momentum, but requires a different focus. Based on 2010 data, with more than 880,000 angioplasties performed, the coronary stent market was valued at over €870,000,000 [iData Research Inc., Report EUIC11. 'European Markets for interventional cardiology devices', pub: 3-2011].

The analysts also found that, '70% of PTCA balloon catheters sold in Europe were not used for stent placement, but for pre-dilating the vessel before placing a stent'.

This number is also known to the founders of Avidal Vascular, a Halle based start-up that won the federal *German Founders Champion 2010* prize in the category *Economically Successful in the High Tech Sector* category. Their wraps over medical balloon technology (Wombat) is designed to treat de novo or in-stent stenosis and more efficient than any other drug eluting device. CEO Torsten Heilmann, one

of the founders, explains: 'Current state-of-the-art drug-eluting stents work with drug release sustained over months. Metal stent and carrier polymer remain in the body. This is of inadequate biocompatibility. Long and expensive oral follow-up medication is the consequence. Our **drug eluting balloon** allows higher drug release within one minute during dilatation'.

Stent fever, first diagnosed in 1997, has been spreading throughout the medical world – fuelled by new technologies, says *Holger Zorn*



The PRO-Kinetic stent combines super-alloy cobalt chromium (L-605) with an advanced thin-strut stent design and has exceptional stent flexibility and manoeuvrability in even highly challenging vessels

Studies have shown neither drug washout nor emboli – a new technology, expected to be marketed as of 2012. Then, the fever may rise again.

20%
REDUCTION IN ALL-CAUSE MORTALITY AT ONE YEAR*

STANDARD TREATMENT

BALLOON-EXPANDABLE TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

A new option for your high-risk patients with aortic stenosis

In the landmark clinical study—the PARTNER Trial—Edwards SAPIEN balloon-expandable transcatheter aortic valve implantation demonstrated a 20% absolute reduction in all-cause mortality versus standard treatment at one year.¹ Additionally, the reduction in mortality and rehospitalization versus standard treatment at one year was 40%.¹ For more information, visit edwards.com/EU.

Reference: 1. Leon MB, Smith CR, Mack M, et al; PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;363(17):1597-1607.

The Edwards SAPIEN transcatheter heart valve and delivery systems bearing the CE conformity marking comply with the requirements of the European Medical Device Directive 93/42/EEC. For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

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Torsten Heilmann, CEO of Avidal Vascular, shows the inside of a coronary vessel, taken by Optical Coherence Tomography (OCT). After Wombat dilatation, the lumen is completely free of emboli and not restricted

Such innovations increase the fever. MedMarket Diligence, LLC, the California-based publisher of medical technology market and assessment reports, analysed the worldwide coronary stent market. Based on 2008 data, of US\$6,965 million for all coronary stents, US\$4,375 million was spent for DES and US\$2,590 million for BMS [Source: MedMarket Diligence Report #C245 'Worldwide Market for Drug-Eluting, Bare and Other Coronary Stents, 2008-2017'. May 2009]. Patrick Driscoll, the firm's founder, predicts a compound annual growth rate (CAGR) of 4.3% for DES by 2017, of 1.6% for BMS.

He predicts a CAGR of 29.6%(!) for **bio-absorbable stents (BAS)**, the next innovation in intraluminal stent technology. Made from biodegradable polymers (e.g. polycaprolactone) or biocorrosible metals (e.g. magnesium alloy) they may allow local drug or gene delivery. Cardiologist Ron Waksman from Washington Hospital Centre, said: 'They do their job and disappear' [J Invasive Cardiol 2006;18:70-4].

Investigating treatment options for atrial fibrillation

The International Landmark EAST Study

The first patient has been enrolled for the largest pan-European study to determine whether an early comprehensive rhythm control strategy for the treatment of atrial fibrillation (AF) will benefit patients. Patients with recent-onset AF at risk for stroke or death are eligible for the trial. The researchers plan to enrol more than 3,000 patients from 200 centres in 11 European countries.

The European Heart Rhythm Association (EHRA), a registered branch of the European Society of Cardiology (ESC) together with the German Competence Network on Atrial Fibrillation (AFNET) and industry partners has joined forces to conduct the EAST (Early comprehensive Atrial fibrillation Stroke prevention Trial) clinical trial. This investigator-initiated study aims to determine whether an early, comprehensive, standardised rhythm control therapy, when included in a comprehensive AF management strategy, has the potential to maintain the heart's rhythm more effectively, prevent AF-related complications, and disrupt the cycles that maintain AF and cause complications.

Professor Paulus Kirchhof, coor-

dinating investigator of the trial, said: 'The trial is based on the observation that insufficient, non-structured and delayed therapy of the multiple factors that maintain AF and cause its complications has most likely contributed to the limited effectiveness of rhythm control interventions in past trials. This trial takes an important step forward to learn more about the value of rhythm control therapy to improve the lives of AF patients.'

Participants will be randomised to either an 'early, comprehensive, standardized' intervention to maintain sinus rhythm on top of usual care, or to 'usual care' alone.

Early intervention will include anti-arrhythmic drug therapy and/or pulmonary vein isolation (PVI) using catheter ablation as well as ECG monitoring of therapy. Usual care follows standardised therapy under the 2010 ESC guidelines for the treatment of AF.

The primary outcome of EAST is the composite of cardiovascular death, stroke and heart failure or acute coronary syndrome (hospitalisation).

There will be outpatient follow-up at 12, 24 and 36 months.

Details: <http://www.easttrial.org>

Cardiovascular disease prevention

Satisfaction in everyday life may protect against heart disease

While depression and anxiety have long been recognised as risk factors for heart disease, there is less certainty over the beneficial effects of a 'positive' psychological state. Now, according to results from a study of almost 8,000 British civil servants, published online by the *European Heart Journal*, researchers report that a satisfying life is indeed good for the heart.

The UK civil servants - all members of the Whitehall II study cohort* and with an average age of 49 years -- were questioned about seven specific areas of their everyday lives: love relationships, leisure activities, standard of living, job, family, sex, and oneself. They rated their satisfaction in each domain on a scale of one ('very dissatisfied') to seven ('very satisfied'). Ratings for each domain were also combined to provide an average satisfaction score for their overall lives.

The participants' health records were then examined for coronary related deaths, non-fatal heart attack, and clinically verified angina over a follow-up period of around six years.

Results of the investigation showed that higher levels of average life satisfaction were associated with a reduced (and statistically significant) risk of total coronary heart disease of 13% (HR 0.87; 95% CI: 0.78 - 0.98), after controlling for demographic and other health characteristics.

An approximate 13% reduced risk of heart disease was also associated with satisfaction in four of the specific life domains -- job, family, sex, and self (but not with love relationships, leisure activities, or standard of living). The reduced risk of total coronary heart disease was found in both men and women.

There was a 'dose response' in these associations, such that those reporting the greatest average life satisfaction

appeared to enjoy the greatest risk reduction in total coronary disease. However, when examining the association between average life satisfaction and fatal or non-fatal heart attack separately from angina, reduced risk was only evident with angina, which appeared to be driving the association between life satisfaction and total coronary heart disease.

Such findings may be accounted for by the relatively young age of the study participants or by the possibility that life satisfaction may relate to a general risk of atherosclerosis but not to factors predisposing individuals to heart attack. Nevertheless, the authors propose that understanding the psychological profile of patients with angina may add predictive value to an assessment of their subsequent heart disease risk.

'Taken together,' say the investigators, 'this research indicates that being satisfied with specific life domains -- in particular, one's job, family, sex life, and self - is a positive health asset associated with a reduction in incident coronary heart disease independently of traditional risk factors.'

Commenting on the results, investigator Dr Julia Boehm from the Department of Society, Human Development, and Health, at the Harvard School of Public Health, Boston, USA, said: 'Although conventional risk factors, such as health behaviours, blood pressure, lipids and body mass index -- did not explain the relationship between life satisfaction and total coronary heart disease, other behavioural or biological mechanisms that promote resilience cannot be ruled out. Moreover, these findings suggest that interventions to bolster positive psychological states - not just alleviate negative psychological states - may be relevant among high-risk individuals.'

Papworth Hospital's clinicians have taken innovative steps in heart and lung transplantation since carrying out the UK's first successful heart transplant in 1979, and also used mechanical devices to support patients with end-stage heart failure since the 1980s.

In June, at the national Medical Futures Awards Ceremony in London, consultant cardiac surgeons Sam Nashef and Stephen Large received the Overall Winner prize in the Cardiovascular Awards and first prize in the Best Innovative Concept in the Cardiovascular



Without his human heart but with the TAH in situ, patient Matthew Green leaves hospital with his son, wife and the Freedom portable driver

because all electronics are located outside it, in the pneumatic driver that powers the TAH and monitors blood flow. Weight: 160 grams Stroke volume: 70 ml.

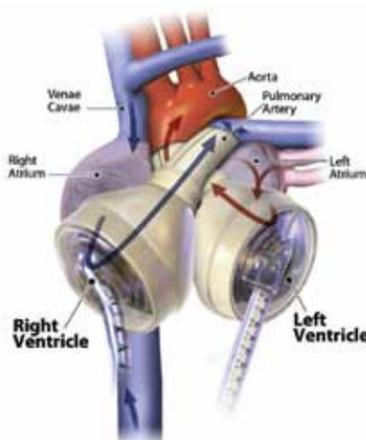
Following six-hour surgery in June, at the beginning of August the first of the UK's end-stage biventricular heart failure patients to go home with his heart replaced with an implanted plastic Total Artificial Heart left Papworth with his son and his wife carrying the Freedom portable driver that powers his TAF. This is the world's first wearable portable driver designed to power SynCardia's Total Artificial Heart both inside

often for as little as 30 minutes after heart surgery, the device provides instant access to that support - and at a far reduced cost to the NHS. 'We are very excited to have achieved national recognition for Temporary Cardiac Assist which reflects the commitment of clinicians at Papworth Hospital

Papworth Hospital

A constant and continuing success story

Recent events have again underlined the reason why Papworth Hospital in Cambridgeshire, England, maintains a renowned international reputation for cardiac and thoracic procedures. As Britain's largest specialist cardiothoracic hospitals, over 2,000 major heart operations were performed there in 2010. In the year ending 1 April 2011, 824 patients had coronary bypass operations, including urgent, emergency, salvage and repeat operations. Mortality for this year was 0.85%, the lowest the hospital has ever achieved. Commenting on the reported survival rates for coronary bypass surgery - better than 99% for first time in the hospital's history, consultant cardiac surgeon Sam Nashef commented: 'These are excellent results indeed, but we are not complacent and will continue to strive for even better outcomes.' Brenda Marsh reports



Total artificial heart

Innovation category for their Temporary Cardiac Assist (TCA) device. This aims to support the heart immediately after heart surgery. Connected to the bypass machine, the device works in a similar way to an aortic balloon pump but offers significant additional advantages:

- It is immediately available after surgery as the patient is already connected to the bypass machine.
- It is far cheaper per use than aortic balloon pumps, which cost around £1,500 each.
- Potentially, the TCA can reduce the amount of time patients spend in critical care.

The TCA allows the heart-lung machine, which is already connected to the patient, to operate in a similar manner to the balloon pump. It can provide immediate help at a crucial moment without the need for additional equipment, intervention and the risks and complications of using and placing the balloon pump. Mr Nashef confirmed that, because sometimes patients' hearts need a small amount of support,

to improve the quality of patient care,' he added. 'These awards give us an excellent platform from which to seek development funding.*'



Steven Tsui

Papworth Hospital is also the only centre in the UK currently certified to implant the Total Artificial Heart (TAH) developed by the Arizona-based firm Syncardia. This modern version of the Jarvik-7 Artificial Heart designed by Robert Jarvik in the very early 1980s, is a bridge-to-transplant device that received FDA, Health Canada and CE approvals in 2004 and 2005.

The TAH is reported to be the only device that eliminates the symptoms and source of end-stage biventricular failure. Similar to a heart transplant, the TAH replaces both failing heart ventricles and the four native heart valves. It is the world's first and Total Artificial Heart, and more than 900 implants have accounted for over 210 patient years of life on the device.

The TAH pumps up to 9.5 L/min through both ventricles, a high volume of safe blood flow that helps vital organs recover faster, thus helping to make patients better transplant candidates for a transplant.

The partial fill/full eject design allows the patient's body to determine blood flow based on activity level. In almost 30 years of use, the diaphragm failure rate has been less than 1% over 900 implantations.

There are no motors or electronics within the body

and outside the hospital. Weighing 13.5 pounds, it is designed to be worn by the patient in the Freedom Backpack or Shoulder Bag.

The transplant team at Papworth Hospital, was led by surgeon Steven Tsui, Consultant Cardiothoracic surgeon and Director of the Transplant Service. Papworth's transplant team had received rigorous training in Paris and was assisted by Dr Latif Arusoglu, an expert TAF surgeon from Bad Oeynhausen, Germany.

The patient, 40-year-old Matthew Green, suffered Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) and his health had declined to a point where his only option was having a heart transplant.

'We discussed with him the possibility of receiving this device, because without it he may not have survived the wait until a suitable donor heart could be found for him,' Steven Tsui explained, adding that his patient would now be able to do a lot more than before the operation with a vastly improved quality of life 'until we can find a suitable donor heart for him to have a heart transplant'.

The Papworth Hospital Board of Directors is planning for a new 300-bed (100% single rooms) purpose-built hospital and research and education institute, all located on an eight acre site in the Cambridge Biomedical Campus. The construction phase is expected to be complete by late 2015.

* Health Enterprise East, the National Health Service Innovation Hub for the East of England, helped with the development by supporting a patent for the device and funding prototypes for the inventors.