Canada supports this year’s forum as its health insurance programme will also attract representatives from government bodies, health insurance and responsibility to become more proactive, instead of reactive, gives patients the opportunity to receive a new IT system, over £5 billion more was achieved. Formerly, an end the so-called ‘patient bondage’ was recently adopted, bringing to discussion the necessary transformation of healthcare systems to guarantee efficient and affordable 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 person-centred healthcare.

The initiators of the Global E-Health Forum – the Hamburg Chamber of Commerce, IBM and ICE – have developed this platform to discuss e-health strategies, best practices and new services/person-centric approaches in a global context. While the main target groups consist of GPs and healthcare professionals, the forum attracts participants from government bodies, health insurance organisations, service providers, influence 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 NPIT, including plans for EPRs, to be dropped and, backed vociferously by Members of Parliament, criticised IT suppliers – HIT 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 advanced payment. There is a provision that the firm, which is responsible for the implementation of i60’s Lorenzo software.

The DoH is looking for fewer systems than planned despite the Department paying contractors almost the same amount of money. This is yet another example of a department fundamentally under-estimating 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, will help to prevent further loss of public funds. It is an advanced payment. There is a prescription for the NHS itself. According to a DoH statement, continued on page 3.

The NHS now has matured applications for patient consent. The parliamentary working group, debating the bill, have many issues to consider. The working group is expected to meet daily. The NHS now has accumulated an inordinate amount of software, largely purchased between 1993 and 1998. The 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.

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 ‘opportunistic diseases’. Furthermore, the law will contain a provision on organ donation, which in Russia is very limited. The new legislation also aims to remedies 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 ‘opportunistic diseases’. Furthermore, the law will contain a provision on organ donation, which in Russia is very limited.

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European hospitals, with the increasing importance of EU policies and the related regulatory challenges, find themselves at a crossroads. One of the key challenges is the need to harmonise healthcare systems across Europe, which often operate under very different structures and conditions. The goal is to ensure that patients receive high-quality care regardless of where they are located.

The healthcare systems in Europe are diverse, with different levels of development and funding. Some countries have well-established systems with a strong focus on primary care, while others rely more on hospital-based care. The diversity in healthcare systems also reflects differences in socioeconomic status and cultural norms.

One of the main issues is the lack of harmonisation in medical education and training. This is a significant barrier to the free movement of doctors within the EU. The lack of recognition of medical qualifications can lead to unnecessary delays and additional costs for patients.

Another challenge is the lack of standardisation in medical equipment and technology. This can lead to inefficiencies and increased costs for patients. It is crucial that European hospitals work together to develop common standards and guidelines to improve patient outcomes.

The European Union has taken several steps to address these challenges. The directive on services in the internal market, for example, aims to remove barriers to the provision of healthcare services across borders. The aim is to ensure that patients have access to high-quality care, regardless of their location.

In conclusion, while European hospitals face a number of challenges, there are also many opportunities to improve patient outcomes and enhance the quality of healthcare across the continent. By working together, European hospitals can achieve significant improvements in patient care and outcomes, and contribute to the development of a more integrated and efficient healthcare system.

**References:**
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 thereby 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 guarantees 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 emphasizes: ‘Product-based environmental protection on the part of the EU must start during the product development phase. All diagnostic and imaging equipment is modified 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 Industrial Association of Radiological Systems), MSSG (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

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Refrerral management and referral cooperation

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-cutting labour divisions as well as cooperation and parallel players in healthcare providers. Wilfried von Eiff (right). From the Center for Hospital Management, University of Munster, Germany, outlines approaches to cope with these demands.

Successful referral management rests on the careful assessment and cooperation of diagnostic and therapeutic possibilities. The referring GP should always be aware of the specific requests of his/her patient and the referring department.

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 (97% frequently, 57% occasionally), 86% ask their specialists (19% frequently, 66% occasionally).

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

Referral management represents a 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 classified as ‘successful referees’ (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 factors interacts any strategy of direct referral care. But in any case, the referring GP’s letter does not make up for unfriendly care or the need for surgical revision (graph 2).

Referral management and referral matching are part of the market 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 the confidence of doctors.

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Successful referral management rests on the confidence of doctors.
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.

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 labor 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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Siemens Healthcare Diagnostics
**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 US’s Food and Drug Administration (FDA) and is designed for routine clinical chemistry applications that include nucleic acid 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 VersaTOF 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 XP1 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 Chemistry (AACC) as a joint project with the Ortho Clinical Diagnostics Solutions for mid & high range laboratories.

**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 modular unit 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 added.

**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, 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 Vitrum 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, trending tools, and remote services.

**An award winning system**

Luminex Corporation, recently named Most Innovative Company of the Year by the National Business Awards, and winner of Business Innovation of the Year for its MagPix system, presented the Luminex xTAG G200 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.

The mobile app that answers patients’ medical test questions.

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. 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. It will debut next month at the AACC Annual Meeting and Clinical Lab Expo. The website already provides two million visitors a month with information 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

Covering even more exhibition space than in 2010, the Annual Meeting of the American Association of Clinical Chemistry (AACC) in Atlanta, Georgia, provided companies an even greater chance to show and demonstrate their latest diagnostic technologies – and our European Hospital team were there to gather up some of those striking laboratory developments and bring them to readers.
Early stage HIV infection test

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

Abbott 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 immunoassay 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, Intelliecheck and e-Connectivity Interactive System Management, which offers real-time access.

Additionally, the company introduced a new immunodiagnostic 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 ECU/ECi/Q and 3600 Immunodiagnostic Systems and can also run on the Vitros 5600 Integrated System. Equivalent analytical results are generated across all systems.

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

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 computer system, WebHIS, and is available free to its medical staff for 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 the patient’s 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 if 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 Micho
Trends and technology at the AACC 2011

Freezing point osmometry

Advanced Instruments was showing its new fully-automated, multi-sample A2O Advanced Automated Osmometer, which incorporates over 50 years of applied technology experience in the field of freezing point osmometry, the company points out. The A2O 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 A2O has been intelligently engineered to automate osmolality testing fully – and with ease and simplicity. For today’s busy laboratories, being asked to achieve more results faster, yet with fewer resources, this could prove a desirable choice.

The company reports these A2O features:
- Touch-screen user interface: With a menu driven operating system, intuitive software control, and multi-language capability, operating the A2O is simple.
- Automated sample cleaning: 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 sensors (no flash 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 that facilitates protocol 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 exudates (wound, skin, urine, etc.) and has built-in quality controls on every test strip.

RADIOLOGY

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.

A new MRSA test

The DRX-1 system, allow the market to serve the value-tier market by providing a digital DR solution that is easier to use, more affordable, and offers a lower total cost of ownership. The DRX-1 system is designed for the small to mid-size hospital and is available in three configurations: open-system, limited feature (LF), and full feature (FF). The DRX-1 system is priced at a lower total cost of ownership than a traditional CR system, making it an ideal solution for the value-tier market.

The DRX-1 system is designed to be user-friendly and intuitive, allowing for easy and efficient operation. The system is equipped with a user-friendly touch-screen interface that provides access to all system functions and menu-driven software, making it easy for operators to perform tasks ranging from patient identification to image acquisition.

The DRX-1 system is designed to be efficient and effective, providing high-quality digital images with excellent contrast resolution and low noise levels. The system is equipped with advanced image processing algorithms that optimize image quality, resulting in clear and detailed images that are easy to interpret.

The DRX-1 system is designed to be reliable and durable, featuring a rugged and robust design that can withstand the rigors of daily use. The system is designed to withstand harsh operating conditions, ensuring reliable performance and minimal maintenance requirements.

The DRX-1 system is designed to be versatile and adaptable, allowing for easy integration with existing hospital information systems and workflow processes. The system is designed to be compatible with a wide range of hospital information systems, allowing for seamless integration and efficient workflow.

The DRX-1 system is designed to be cost-effective and affordable, providing a digital DR solution that is easier to use, more affordable, and offers a lower total cost of ownership. The DRX-1 system is priced at a lower total cost of ownership than a traditional CR system, making it an ideal solution for the value-tier market.
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. Bertra Dieteren reports.

Multi-channel 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 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. Kamil Ugurbil, from the Centre for Magnetic Resonance Research (CMRR), University of Minnesota.

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 independent 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.
A 10-year-old patient is undergoing surgery for a primary tumour. The operating team prepares everything for the arrival of the mobile MRI scanner to assist in the image-guided therapy. The mobile MRI scanner is developed in the 1990s by Dr Garnette Sutherland at the Foothills Hospital in Calgary, together with Dr John Sanders at the Canadian National Research Council (NRC) Institute of Biodiagnostics in Winnipeg.

The mobile MRI scanner technology has been adopted into the patient’s cranium with the system’s pointer before the cranium has even been opened to determine the safest surgical access. Important functional data acquired pre-operatively, such as information on arterial structures related 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 neurological structures 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 pathways originating in these functions 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 beginning of our scope of experience with the new system,’ said the professor, adding: ‘We’re really just getting started.’

The mobile MRI scanner is currently unique in Europe.

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 formula – it takes time and staff resources.

The determination of the rest energy requirement for both options, based on the site of operation.

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

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

After the operation, we perform 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 image 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 theatre via a switch, the team carries out a standard safety check, for which they received special training.

The implant of barb expand soft copy checklists they ensure that all ferromagnetic instruments and equipment have been placed outside the five Gauss line. Three 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 IMRIS unit in Tubingen has a special volumetric neuronavigation system 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 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 amount of time used.

For Germany, Austria and Switzerland the calculation is preset based on the formulas of Schellek 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 overweight children.

The operating team prepare everything for the arrival of the mobile MRI scanner to monitor the tumour resection results and, prior to that, remove all intra-operative instruments from the safety zone.
NEW BIOMARKERS
Ushering a new era in clinical neurology

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, pathogenetic 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 MRI 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 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.”

Who is Carestream?
We are a global company of passionate professionals dedicated to the cause of healthcare. We use our extensive experience, insights and innovative medical imaging and healthcare IT solutions and services to improve outcomes, lower costs, simplify the work for healthcare professionals, and give you exactly what you need...a smarter way forward.

OPEN.
Healthcare IT is rapidly evolving around Electronic Medical Records and integrated community-wide systems. Done right it will accelerate the sharing of vital information and drive better outcomes. There is no acceptable alternative. So how do you do it right? Start with a partner who can put it all together for you. When you sit at a CARESTREAM RIS+PACS workstation, you know right away that we get it. After all, for more than 100 years we've been helping radiologists spend significantly less time on the technology and considerably more time on the critical tasks of capturing, reading and reporting. When it comes to integration, we go beyond open and DICOM. We are vendor- format- and source-neutral, for easy connectivity. We have successfully transformed some of the world's largest multi-site, multi-vendor PACS environments into a single-view global workflow. Want to leave the IT to us? Carestream e-Health Services puts your IT in our secure cloud. No matter where you are today, when you look at it from our perspective, it's easy to see your next move.

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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 callbacks 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.
A revolution is exactly these complications that foot and occluded vessels. Luckily, it coronary heart disease, stroke, diabetic on managing diabetic complications: the region of 6.5 billion euros (Source: ready to redefine diabetes care. For the Through early and minimally invasive interventions, such as percutaneous interventions, such as percutaneous lesion of the leg, which can lead to complete occlusion of the foot. IR methods can avoid or delay limb amputation and salvage the foot. This condition is treated surgically or invasively: foot ulcers, diabetic foot and occluded vessels. Luckily, it is exactly these complications that interventional radiology can effectively treat. This has been demonstrated by the international working group of the International Working Group of Interventional Radiology (IWGIR), which, in its protocol, has placed IR interventions as a first-line treatment.

Avoiding amputations, lowering costs DIABETES AND METABOLIC DISEASES

As this is performed under image-guidance (digital angiography), the intervention is the shortest, safest, and causes only a small skin puncture through which the catheter is advanced to the artery. The patient can usually leave the hospital on the same day or the following day. As a result, 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 Giger, Cardiovascular and Interventional Radiological Society of Europe - d.giger@biergiger.at Website: www.cire.org

Interventional Radiology maintains quality of life and reduces costs

Interventional radiologists (IRs) throughout the world 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 Bosch Stiftung). The cost of treating diabetic complications: coronary heart disease, stroke, diabetic foot and occluded vessels. Luckily, it is exactly these complications that interventional radiology can effectively treat. This has been demonstrated by the international working group of the International Working Group of Interventional Radiology (IWGIR), which, in its protocol, has placed IR interventions as a first-line treatment.

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Russia’s healthcare system is still in the midst of serious change and one of the important tasks is the proper establishment of infection control in medical institutions. For example, every year about 2.5 million patients contract infections during hospital treatments. A large number of young patients in the children’s hospitals and elderly patients in adult surgical units have suffered post-operative purulent complications.

The urgency of this problem for Russia is confirmed by the flashes of an infectious disease report from the hospitals.

Ancient buildings defeat hygiene measures

Containing nosocomial infections is a serious problem for Russia’s hospital staff, DH correspondent Olga Ostrovskaya reports

The outstanding Russian doctor Sergey Botkin the trustee of this Aleksandrovsky barrack type hospital ‘Infectious patients live on to this day. Many achieve a second life after a second infection. This service is connected with the name: the first disinfection chambers, the first antiseptic of every type, the first system of sewage treatment system, and many other achievements. But time passes on and the boundaries of the 19th Century became the start of our new millennia. Approaches to a method for the safety of patients in the medical centers, with medical technologies, had radically changed.

The last time this hospital was reconstructed was in the 1970s and categorizes this fact becomes obvious: St Petersburg now has a new hospital with advanced technologies. The building is expected to be completed by the end of this year. Its construction by the end of 2011, St Petersburg will have two new infectious 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.

The urgency of this problem for Russia is confirmed by the flashes of an infectious disease report from the hospitals.

The growing infection control systems have proved themselves around the world. This focus is rather new for Russian hospitals. The Russian epidemiologist was only ruled by the Ministry of Health 1993. A considerable amount of work has been done by the introduction of nosocomial infection registration and reporting systems, the reporting parameters, enabling analysis of this data to estimate the disease incidence. At the same time, the reporting forms have been developed in the country far from completely reflects its true level.

Why, the score for the incomplete account is the absence of accurate definitions and criteria for revealing the infections in the medical documents,” explained Professor Alex Yakovlev, lead physician at Botkin’s hospital, the St. Petersburg infection control committee, which prescribes that a complexity of factors influence the transmission of nosocomial infections, and the hygienic condition of equipment, including ventilation with ultra-violet equipment. Fitness, the considerable majority of Russian hospitals are located in old buildings, with structural deterioration of these and laboratories sometimes up to 50%.

For example, the Botkin’s hospital, the largest hospital in the millions city, was built in 1818 with a multi-resistant organism, as discovered by Dr. Michael Borg.

The W.A.R. score is composed of three classes of risk point levels. They are oriented on concrete patients. For example, if a patient suffers from an immunosuppressive disease, such as diabetes, 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, among other things, those are severe wounds with wounds penetrating up to 3.5cm.

In the same way, risk factors of category III have more 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 are 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 polymyxin, which is characterised by a broad antimicrobial spectrum, excellent cell and tissue tolerability, a capacity to fund to an organic matrix, low risk of contact sensitisation and positive adverse effects to wound healing.

In contrast to silver or iodine, polymyxin 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 undefined effects sometime in the future. So polymyxin 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 formulations 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.
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

Wound registry will track wound care treatment

U p to a fourth of the acute beds in a hospital are filled by patients with a wound. The cost - $30 billion in the hospital, typically a pressure ulcer, according to the Journal of Wound Ostomy and Continence Nursing.

Outside the hospital, one in every 100 people suffers a non-healing wound. The cost to healthcare, including long-term care, is substantial.

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, Dr. Brosky said. Dr. Gottrupp announced at the recent Expert Conference of the Academy of Wound Technology in Paris.

Any study of all aspects of wound care spending increases, he said, there is an increasing interest in the question of evidence - for the effectiveness of specific wound care interventions, technologies and treatments.

With few exceptions, there are three main ways to prevent the transmission of infections.

The best way to avoid contamination is by eliminating the organism and breaking the chain of transmission. With few exceptions, that is ensuring that patients are not exposed in any way. This we do by employing infection control 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 drugs or physiotherapy. It's still a standard procedure here to give a single intravenous shot of antibiotics, he said. This is, he thought, not consistently shown to be a very cost-effective way of reducing the transmission of infections in the surgical arena.

As the comparatively small size, Mater Dei is still proud of the fact that the infection control system is set up by transposing the standards of knowledge and practice from leading expert bodies and institutions, such as the European Centre of Disease Control and adapting this to the local level of the hospital. The data from continuous surveillance systems in the living proof of its efficacy.

In a field of observation, chance favours only the prepared mind.

A lthough the incidence of tuberculosis (TB) in Germany is low, considering a slight rise of childhood TB since 2000 and facing the still high, partly increasing TB incidence in Eastern Europe, the role of a 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 Doberer was interviewed paedriatian Klaus Magdorff 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 in Germany, 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 can be ramping from 1.2 per 100,000 in 2008 to 1.3 in 2009, a rise seemingly continuing in 2010, assumes that every statistician would negate the impact of this increase, but we notice it - without panicking,' Dr. Magdorff pointed out.

'Nevertheless,' he added, 'we face the problem that we have, for example, only a few clinicians know about TB, the majority of parents are unaware of this "forgotten" disease. This is also an educational problem. So, to educate our future paediatricians about TB, we engage in scientific discussion with South African universities.'

Are there multi-resistant childhood TB strains in Germany?

'Cases of multi- or extensively resistant TB are still rare in Germany. More than 86 percent (including adult patients) of the Mycobacterium tuberculosis strains fully sensitive to first line anti-tuberculosis drugs, about 11 percent are resistant to at least a single drug and only 0.2 percent are multi- or more extensively resistant (MDR, XDRC).'

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 routine contact tracing to identify and screen all close contacts of each infections patient, to prevent possible transmission to children. Finally, we must upgrade our knowledge of antibiotic resistance and improve pre-screening of risk groups, for example immigrants from high-risk countries.'

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

Three participating centres in the USA, one in Miami and one in Chicago.

Wound Healing Centre, Dr. John Brosky

EUROPEAN HOSPITAL Publisher, Tel-Aviv-Alluf-Str. 45, 41133 Essen, Germany

Three participating centres in the USA, the one in Miami and one in Chicago.

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 economics,' according to Willem de Vries, PhD, the Hôpital Lapeyronie, (Montpellier, France) project director.

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) project director. 'The proof-of-concept from this phase is that the data does not reflect the impact of treatment approaches. 'The challenge of using randomised controlled trials is to assess the structure and the data gathering process,' he said. "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 options.'

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 apply to the actual setting in which it is actually being practiced on patients, she said. 'Wound care is complex and a registry will provide the real world data that is needed.'
Be part of it!

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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 cardiac troponins. 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 heart failure. Seven years ago I argued that this would be promising.

Highly sensitive troponin are markers of heart injury. While the mechanism may differ as to why the levels elevate, 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 a remarkably prognostic, predictive of progressive heart failure, hospitalisation and death, above and beyond any other measure of troponins or natriuretic peptides.

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 metabolic markers and genome markers like miRNA, 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 heart is functioning but also tells you, at the biological level, that there is 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 evidence-based. However, it can provide 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 was? 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 an individualistic level, we can use this 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 Dr. Horger Zorn

Sacrilegious meddling with the delicate rhythm that brings new life to the heart, forewarned New York cardiologist Alfred Hyman in the 1930s with his implantation of the first cardiac pacemaker. Despite successful animal experiments, he applied the first cardiac pacemaker – then a cumbersome external device – to a human patient, but it failed after only a few days. A quarter of a century later the first cardiac pacemaker was implanted in a 45-year-old Swedish heart surgeon Ake Senning, of the Karolinska Institute, and engineer Rune Elmqvist. Both were convinced, but the patient, Arne Larsson, believed in the new procedure and underwent more than two dozen implantations.

Small device, big business

In 2008, the year that marked the 50th anniversary of the first pacemaker implant, SteevenTydra Praven, analyst for consultants Frost & Sullivan, quoted sales figures of about US$2.6 billion in Western Europe alone. For 2013, Praven predicts the business will reach €5.76 billion. Three drivers currently propel pacing technology: cardiomyopathy, 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 a device that improves the heart’s pump function in patients with congestive heart failure (CHF). The progressive congestive heart failure (CHF) disease, which in advanced stages may require major interventions, such as heart transplantation, actually entails a gradual loss of heart muscle. The remaining tissue cannot transport the electrical impulses. The CRT device contains three rather than the usual two leads, which are fastened directly onto the ventricle wall in the right atrium and the left and right ventricle. By pacing both chambers the heart beat is coordinated – resynchronised.

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.

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: Europ. Heart J. 2006;27:452]. This has a significant impact not only on patients’ quality of life but also on healthcare costs: with a prevalence of 2–5%, around 15 million people in Europe suffer from CHF. About 600,000 new cases will be recorded every year.

Frieder Breuenschweig of the Heinrich-Heine University of Düsseldorf analysed the data of 253 days in the year before the CRT device had been implanted and 43 days in the year after the implantation (p<0.01). Average total costs of in-patient care per patient were €31,901 per pre-implant year and €1,654 in the following year. With average implant-related costs of €8,019 per patient, CRT had paid off in the second year. Since then, Christian Butter, head of Cardiology at the Heart Centre Rechberg in Berlin, Germany, recently implanted three of the currently six sites in six patients.

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 posterior-lateral ventricular wall. The generator is implanted on the left side below the sixth rib, about eight centimetres away from the lead. Under ultrasound, the stimulation of the right ventricle by the CRT device 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 patients who need to replace all pacing leads – maybe even all sensor leads. Continuing along these lines, Butter is convinced, will one day provide a device that includes wireless 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 a fantasy, as N. Oesterle MD, Vice President for Medicine and Technology at the Medtronic subsidiary, TandemR, held last October in San Diego: The next generation cardiac pacemaker will be inserted via catheter through the blood vessels, the right vertebrum 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 reality in just a few years – as tele-monitoring shows. Here, patient data are transmitted from a pacemaker, implantable cardioverter/defibrillator (ICD), CRT device or CRT device to an internet-based platform from where they can be retrieved by the physician. The PARTNER trial – with 358 patients – of the University Hospital of Heidelberg has shown a significantly lower number of hospitalisations by two thirds – as tele-monitoring shows. Here, patient data are transmitted from a pacemaker, implantable cardioverter/defibrillator (ICD), CRT device or CRT device to an internet-based platform from where they can be retrieved by the physician. The PARTNER trial – with 358 patients – of the University Hospital of Heidelberg has shown a significantly lower number of hospitalisations by two thirds and improves the heart’s pump function. According to the data, the physician is alerted to any arrhythmia and can react fast.

Cardiac contractility modulation (CCM) is a new method for adjusting the electrical charge of the heart muscle and, therefore, the heart’s contractility to the patient’s individual needs. While pacing, CCM does not affect the activation sequence. Instead, CCM signals are delivered after a preset delay following detection of the myocardial activation. This augments the calcium influx into the heart muscle cell and calcium is essential to the heart muscle cells to generate heart muscle contractions. The effect is an improved ejection fraction – the heart muscle’s capability – and improved oxygen consumption, and a better quality of life.

The leap from the 157 TA procedures carried out in 2007 to the 3,629 undertaken in 2010 is impressive. Was it solely the German reimbursement policy – almost €3,000 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 75-84-year-olds suffer from this disease. In relation to the cardiac population, this means 160,000 potential patients. A high proportion of these patients are too frail for conventional valve replacement – and conservative treatment is of limited success. They were undereasured, if not untreated. With minimally invasive, catheter-based aortic valve replacement we can prolong their life expectancy and improve their life quality.

But the technology...? ‘Yes. The PARTNER trial – with 358 patients – of the University Hospital of Heidelberg has shown that 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 experience over the last four years.’

These results were achieved with Edward’s Sapien valve, so far one of the two approved valve products. Mihai Costea, 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 are working on innovative therapies, has included the module phone network leakage and a smaller dimensioned introducer sheath.

Sapien valve with its transapical approach has a technological edge of two to three years with product availability.

What do you expect from a next generation valve?

‘From a next generation valve I’d want the property of re-positioning within the patient, and that arrhythmias are detected over less than two days compared to 36 days in the control group [Source: Circulation 2010;122:325-32].

Moreover, Christian Butler, head of Cardiology at the Heart Centre and one of the pioneering investigators of CCM therapy, confirms ‘there’s an enormous difference on long-term survival.’

He recently reported 59 consecutive patients who underwent CCM therapy [Source: Europ. Heart J. 2011;32:955-963]. In contrast to conventional cardiac pacing, CCM signals do not initiate a heartbeat. In contrast to cardiac resynchronisation therapy (CRT), CCM do not alter the activation sequence. Instead, CCM signals are delivered after a preset delay, following detection of myocardial activation. The device is an improved ejection fraction – the heart muscle’s capability – and improved oxygen consumption, and a better quality of life.

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

Transcatheter aortic valve implants

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Are you ready for the long-run?
Sustainable Cardiovascular Care

Cardiovascular care is in motion. On the one hand, healthcare systems hold increasing economical challenges. On the other hand, you want to safeguard your position as a leading cardiovascular care provider, both today and in the years to come. How to solve this issue?

With a partnership that lasts. At Siemens, we accompany you. We provide solutions that are sustainable and affordable, again and again. This is the long-run. And to navigate it, we provide you with technology that can support your ability to make sounder decisions, perform safer procedures, operate with better efficiency, and invest resources wisely. In short, we help you establish a sound basis for the future – so you are perfectly prepared for the long-run.
Keeping donor organs ‘alive’ in transit

Although donor organ management is improving, the number of heart transplants is decreasing. According to Eurotransplant, 135 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 propitiatory 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 portable, pumping system and perfused with warm, oxygenated donor blood and nutrients. It then retains its beating time dependent ischemic injury.

This not only lengthens the time during which the organ can be transported, but also enables fully functional, biochemical and metabolic assessment of the organ by the receiving physician and potentially enabling the transplant surgeon to reestablish 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 laminar 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 arteriosclerotic 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 BioMedical – 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 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 up for what MRI loses in that 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 perfect 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 transparent animals to human path (‘From mouse to man’) and foster multi-disciplinary collaboration between basic sciences, biomedical science and clinical applications.

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 clinical practice but also a rare example 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.
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.

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.

Marcello Conviti, CEO of Carmat, said the final step to bring the heart into the operating theatre is the approval of 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 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 heart will be a wire extending from behind the ear to a harness holding the battery, system monitors and wireless connectivity transmitters.

The Carmat artificial heart

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When overweight kids become heart condition adults

The bad child of metabolic obesity and cardiometabolic disease

During this year’s ESCP* Dr Brian McCrindle will lecture during Childhood Obesity. The well-known Canadian cardiologist and his PhD students have for years been dedicated to studying the consequences 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 syndromes in children and its long-term effects on cardiac health in later life.

‘There are no evidences,’ 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 certain is already present in the paediatric age group is cardiometa-
boletic syndrome, which is not much different than in adults. These kids can suffer from the typical pattern of lipid abnormalities, high blood pressure, and diabetes.’

‘There is also evidence that the pathophysiologic process of adult obesity is also associated with a diometabolic syndrome. Childhood obesity is also associated with a higher chance of developing cardiovascular disease in adulthood. 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 extra- curricular activities such as video games are easily available within their home and school, makes it difficult to address the problem with a straightforward behav-
ioral solution. So, actually, changing the environment by working within the school system may have higher chances 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 children may be overweight, the parents tend to bring up some negative push back. So, there’s a lot of opportunities for education-based education to get people to think of this as a problem and then also to equip health professionals with the appropriate counselling skills.

‘In comparison to adults there are also developmental considerations, particularly regarding behavioural management strategies, because kids have a different age and abilities to comprehend what lifestyle changes might be necessary.’

‘So, what kind of management produces the best effects?’ An ongoing issue is whether it is that no single level intervention is going to have a significant benefit. In order for this, correct management interventions must be designed to be adaptive to the patient’s individual circumstances and also address environmental factors.

‘One of the most important aspects that needs improvement is probably the role of motivational interviewing as a counselling strat-
egy to cope with the behavioural changes around lifestyle. This means aban-
doing prescriptive and didactic forms of communication and adopt-
ing a more client-focused counselling form where the doctor deter-
mines the agenda and the inter-
viewer is helping the patient to tap into their own intrinsic motivations for making behavioural changes.’

‘I also do believe that the most effective strategy is to develop a population-based screening pro-
geram. For pre-schoolers, it can be integrated within routine prima-
ry 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 strat-
egeny 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 sup-
port are really necessary and require a great deal of consistency that cardiometa-
bologic syndrome is a crucial and fundamental health burden.’

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

Nothing beats a heart attack to motivate someone to exercise regularly, stop smoking, and lose weight. Yet, for many of us, these are the few weeks cardiovascular patients return to the clinic after a heart attack in the first stage – and, sooner or later they find themselves back in a heart attack ward.

To break this cycle and help keep patients out of the hospital, along with medications a cardiologist should prescribe a nurse to help keep them on track,” according to Ron Peters MD, pro-

The role of the physician is to establish protocols to be followed in 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 protect-
ed from the risk of liability, he pointed out.

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

A nurse-led programme improves outcomes for cardiovascular patients

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 Brophy.

RESPONSE trial results

A nurse-led programme improves outcomes for cardiovascular patients

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

‘The study confirms what can be expected in practice guidelines and outcomes, in that driving risk factors for high blood pressure, smoking, and high cholesterol can greatly improve cardiovascular risk,’ he said.

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

Instead, REPSONSE is important for providing clinical proof to over-
publishers the benefits of nurse-led care in the prevention of cardiovascular disease in community settings.

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

Ron Peters

Ron Peters MD, PhD. Director of Zena and Michael Wiener at the Cardiovascular Institute for Children and the Mount Sinai Children’s Research Institute, New York City, spoke at ESC.

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One of the most important aspects that needs improvement is probably the role of motivational interviewing as a counselling strategy to cope with the behavioural changes around lifestyle. This means abando
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 [Burr Heart J 1997;18:502-3]. 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, tautnahm 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 25% diabetic patients,’ Dr Hamon commented. ‘They do their job and disappear’

They do their job and disappear’

HOLGER ZORN
BIOTRONIK

...at 19 European sites.

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Meanwhile, Michael Hausle 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.

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$9,065 million for all coronary stents, US$84,375 million was spent for DES and US$2,560 million for BMS [Source: MedMarket Diligence Report #C245 ‘Worldwide Market for Drug-Eluting, Bare and Other Coronary Stents, 2006-2017,’ 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 29.0% for bio-absorbable stents (BAS), the next innovation in intrahumal stent technology. Made from biodegradable polymers (e.g. poly-caprolactone) or biocomprable 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].

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 Atrial Vascular, a Hallie 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 ballahs 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’.

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.


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Edwards Lifesciences
Irvine, USA | Nyon, Switzerland | Tokyo, Japan | Singapore, Singapore | São Paulo, Brazil

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 [Burr Heart J 1997;18:502-3]. 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, tautnahm 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 25% 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.

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Investigating treatment options for atrial fibrillation
The International Landmark EAST Study

The first patient has been enrolled for the EAST (Early Comprehensive Atrial Fibrillation Stroke Prevention Trial) trial, which aims to determine whether an early, comprehensive, and standardized approach to atrial fibrillation (AF) management strategy has the potential to maintain the health and functional effectiveness of patients with AF-related complications, and disrupt the cycles that maintain AF and contribute to demographic and other health characteristics.

The EAST trial is a large, multicenter, randomized, controlled trial with a parallel control arm that includes the recommencement group of the current management guidelines and clinical practice in Europe. The primary purpose of the EAST trial is to compare the effects of early, comprehensive, and standardized intervention to maintain the health and functional effectiveness of patients with AF-related complications, and disrupt the cycles that maintain AF and contribute to demographic and other health characteristics.

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Cardiovascular disease prevention
Strategies to protect against heart disease

While depression and anxiety have long been recognised as risk factors for heart disease, there is increasing evidence that the psychological profile of patients with angina may also be associated with a higher risk of total coronary disease.

Such findings may be accounted for by the biological and psychological mechanisms that underlie depression and anxiety. Patients with depression and anxiety are more likely to have a genetic predisposition to heart disease and more likely to have a history of heart disease in their family. Moreover, these findings suggest that interventions to bolster positive psychological states - not just alleviate negative psychological states - may be effective in reducing the risk of heart disease.

For instance, a recent study found that patients with depression and anxiety were more likely to experience a higher risk of total coronary disease than patients without these conditions. This suggests that interventions to bolster positive psychological states - not just alleviate negative psychological states - may be effective in reducing the risk of heart disease.

Commenting on the results, Dr. Nashef said: "These are excellent results indeed, but we are not complacent and will continue to strive for even better outcomes."

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Commenting on the results, Dr. Nashef said: "These are excellent results indeed, but we are not complacent and will continue to strive for even better outcomes."

"We discussed with him the possibility of temporary cardiac assist (TCA) device. He agreed to undergo the TAH replacement in 2009, and the TAH was successfully implanted in 2010. The patient, a 40-year-old male, underwent a successful heart transplant.

The patient, 40-year-old Matthew Green, suffered Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC), a genetically inherited condition that can lead to sudden death. Despite the availability of heart transplants, many patients with ARVC are not eligible for transplant due to underlying medical conditions or poor organ function.

Matthew Green's case highlights the importance of developing new treatment options for patients with ARVC. He was able to continue with his career and enjoy a normal life thanks to the TAH device.

Commenting on the patient's story, Professor Paulus Kirchhof, co-chair of the CONSENSUS II trial, said: "This is a great example of how technology and medical advancements can improve the lives of patients with heart conditions."

Recent events have again underlined the reason why Papworth Hospital in Cambridge, England, maintains a renowned international reputation for cardiac and thoracic procedures. As Britain's largest specialist cardiothoracic hospital, over 2,000 major heart operations were performed there in 2010. In the year ending 1 April 2011, 842 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.’

Papworth Hospital

A constant and continuing success story

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Brenda Marsh reports

Papworth Hospital’s surgeons 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 Most Innovative Concept in the Cardiovascular category.

"We are delighted to have received this recognition, which reflects the commitment of clinicians at Papworth Hospital because all electronics are located outside it, in the pneumatic driver that powers the TAH and monitors blood flow. The Freedom portable driver has a Stroke volume of 70 ml.

Following six-hour surgery in June, at the beginning of August, the first of the UK’s end-stage biventricular failure heart failure patients to go home with his heart replaced with an implanted plastic Total Artificial Heart left Papworth with his son and wife carrying the Freedom portable driver that powers his TAH. This is the world’s first wearable portable driver designed to power SynCardia’s Total Artificial Heart both inside 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 TAH project team at Papworth Hospital, 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 Arnaoutoglou, an expert TAH 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 would have not survived the wait until a suitable donor heart could be found for him. His condition was worsening, and he would not 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 £200m (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 completed by 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 savers."