VOL 21 ISSUE 4/12 • AUGUST/SEPTEMBER 2012

EUROPEAN HOSPITAL

EUROPEAN FORUM FOR THOSE IN THE BUSINESS OF MAKING HEALTHCARE WORK

8-pages of ESC 2012 highlights!

LAB & PHARMA 8-10

Molecular and genetic sequencing diagnostics are moving on

ORGAN TRANSPLANTS 29

Global shortages – then what makes Spain so different?

Organ donation
A business based on good faith?

Rumour had it for a while, and many found out when the bomb was finally dropped at, of all places, the Congress of the International Transplantation Society, held in Berlin this July – the waiting list for donor organs in the database of the Eurotransplant Foundation had been manipulated.

Report: Anja Behringer

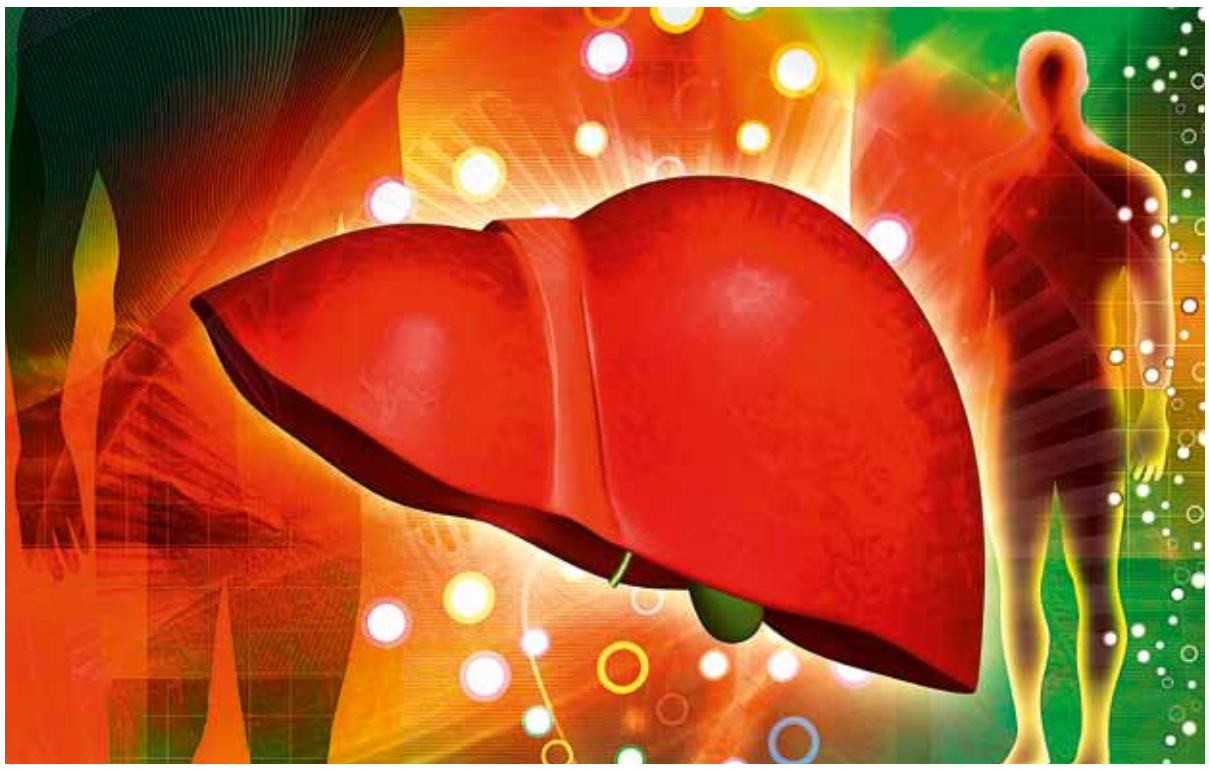
A transplant surgeon at the University Hospital Göttingen in Germany had forged dialysis and examination results to give a number of his patients – currently around 25 – improved slots on the waiting list and thus increase the number of his operations. Why? Transplant surgeons' salaries were then volume based, which in future will not be the case. However, in the country's largest transplant clinic at Hanover Medical School (MHH), a press officer stated that such performance-related contracts for doctors never existed at their clinic. So was this a systems error only in Göttingen; an individual single case in Europe? All hospitals have their own safeguards against manipulations, but when it comes to the assessment of patients to determine the urgency of transplantations, many doctors still advocate a 'Four Eyes Principle', i.e. diagnosis made by two doctors – which obviously requires more resources.

So far, there has been no proof of any financial damage or kickbacks; however, the Public Prosecutor's Office is investigating whether charges can be brought for involuntary manslaughter and also whether other doctors were involved in manipulation. Could this, therefore, be just the tip of the iceberg? Notwithstanding, the breach of trust, particularly among the most severely ill patients, will be almost impossible to atone for – and this also goes for the millions of potential organ donors whose ethical and psychological concerns about the donation of their own body parts the Government had been trying to allay with an amendment to the law.

In June, the majority in the Federal German Council (Bundesrat) decided that, in future, from the age of 16 everyone with medical insurance should be regularly consulted as to whether they would donate their organs after their death. This solution is to be part of the new transplant law.

Different rules apply in other European countries, and the advantages and disadvantages of various solutions and models remain controversial. However, across the board

continued on page 3



France: Almost 30% of medical acts are unjustified

A recent poll of more than 800 hospital and private doctors reveals that only 72% of medical acts are fully justified.

Report: Annick Chapoy

Conclusions from a new poll that indicates almost 30% of medical acts in France are unjustified, also shows that most of the practitioners are willing to open a debate on this matter. The survey, carried out be the FHF (Fédération Hospitalière de France) – which regroups the vast majority of public hospitals – also shows that those interviewed largely agree that the high proportion of pointless medical acts can be linked to doctor-patient relationships, with patients tending to interact significantly in the prescription of medical treatments.

79% of doctors think that patients' expectations have increased, especially in terms of information. Moreover, 53% of them reported that the potential risk of legal action has led them to modify their practice, driving them to prescribe superfluous tests. That's a positive reason to make patients actors in the health system instead of just healthcare consumers. An effort is needed to educate patients and inform them on their duties as well as their rights, the FHF explains, pointing to the example of a very successful media campaign launched a few years ago: 'les antibiotiques, c'est pas automatique!' (Antibiotics, it's not automatic).

The FHF also advocates the idea of publishing frames of reference: scientific authorities would publish the list of tests that are strictly necessary for such and such cases. Additional tests would not qualify for reimbursement by the social security system, and their absence could not be considered a deciding argument against the practitioner in the case of a legal action. The low number of existing frames of reference is actually mentioned by medical practitioners to explain the fact that they sometimes prescribe unnecessary tests.

The FHF has already suggested the setting-up of a 'patient's institute', which would provide a sort of continuing education. One concern of the FHF has been the avoidance of unaffordable waste. After a long study, in 2010 the FHF published the number of questionable medical acts performed each year that cost millions of euros: biological tests, X-rays, unjustified caesareans, screening elderly patients for prostate cancers, etc. Changing habits will take time, but the FHF is confident it will win that fight. The organisation is proud of some initial achievements: the number of caesareans greatly diminished after it publicised the gap between the number of caesareans performed without apparent need in public hospitals and private clinics, with comparative figures from region to region. The number of head X- rays, unnecessary in the case of a simple trauma for which a clinical examination is considered sufficient according to scientific consensus, dropped 9% in the months following FHF's explanations in the media.

According to Frédéric Valletoux, President of the FHF, public hospitals hold a real legitimacy in the matter: some subjects are to be faced head on, such as the closing down of small hospitals where safety is not guaranteed – because the FHF does not have an approach based on commercialism. Hospital doctors are not paid according to the number of their medical acts, even if public hospital budgets are based on the volume of medical acts performed.

Between the lines, the FHF appears to be blaming the Health Insurance (Assurance Maladie) that holds the record of acts performed by every physician, keeping them to itself in order to avoid a possible wind of protest among private practitioners. Yet, the FHF would not favour disciplinary actions against doctors who prescribe unnecessary acts. It claims that the priority is to continue to promote information and make that public. According to Frédéric Valletout, we cannot imagine that the 28% of acts that doctors themselves consider pointless could all disappear. Medical practice should in no way become cold and mechanical; it must remain basically humane. To reach an adequate relevance of medical acts will be a long process and will need strong political impetus – in fact, the FHF has already appealed to the new Health Minister, Marisol Touraine. Notwithstanding, the system of

continued on page 3

CONTENTS

EUROPEAN HOSPITAL Reader Survey

YOU may qualify for a FREE subscription to EUROPEAN HOSPITAL, the bi-monthly journal serving hospitals throughout the EU.

*If selected, you will be sent a copy of EUROPEAN HOSPITAL every two months, as well as the EH electronic newsletter

To participate, simply fill in this coupon and fax to: +49 201 87 126 864

Or post to: European Hospital Publisher Theodor-Althoff-Str. 45, 45133 Essen, Germany

DO YOU WISH TO RECEIVE EUROPEAN HOSPITAL AND THE EH ONLINE NEWSLETTER? ☐ Yes ☐ No

Signature | Date

Reader Number

Name

Job title

Hospital/Clinic

Address

Town/City | Country

Phone number | Fax

E-mail address

For new EH registrations, tell us more about your work, so that we can plan future publications with your needs in mind. Please put a cross [X] in the relevant boxes.

1. SPECIFY THE TYPE OF INSTITUTION IN WHICH YOU WORK

☐ General hospital ☐ Outpatient clinic ☐ University hospital

Specialised hospital/type

Other institution (eg medical school)

2.YOUR JOB

☐ Director of administration ☐ Chief medical director ☐ Technical director

Chief of medical department/type

Medical practitioner/type

Other/department

3. HOW MANY BEDS DOES YOUR HOSPITAL PROVIDE

☐ Up to 150 ☐ 151-500 ☐ 501-1000 ☐ more than 1000

☐ None, (not a hospital/clinic)

4 . WHAT SUBJECTS INTEREST YOU IN YOUR WORK?

☐ Surgical innovations/surgical equipment
☐ Clinical research/treatments/equipment
☐ Ambulance and rescue equipment
☐ Physiotherapy updates/equipment
☐ Nursing: new aids/techniques
☐ Hospital furnishings: beds, lights, etc.
☐ Hygiene & sterilisation
☐ Linens & laundry
☐ Information technology & digital communications
☐ Personnel/hospital administration/management
☐ Material Management
☐ EU political updates
☐ Radiology, imaging/high tech advances
☐ Intensive Care Units/ management/equipment
☐ Pharmaceutical news
☐ Speech therapy/aids
☐ Laboratory equipment, refrigeration, etc.
☐ Hospital clothing and protective wear
☐ Nutrition and kitchen supplies
☐ Waste management
☐ Hospital planning/logistics
☐ Hospital Purchasing
☐ Medical conferences/seminars

Other information requirements - please list

ESPECIALLY FOR DOCTORS:
Please complete the above questions and we would like you to answer the following additional questions by ticking yes or no or filling in the lines as appropriate.

What is your speciality?

In which department do you work?

Are you head of the department? ☐ Yes ☐ No

Are you in charge of your department's budget? ☐ Yes ☐ No

How much influence do you have on purchasing decisions?

I can only present an opinion ☐ Yes ☐ No

I tell the purchasing department what we need ☐ Yes ☐ No

I can purchase from manufacturers directly ☐ Yes ☐ No

Do you consider that your equipment is

out-dated ☐ Yes ☐ No

relatively modern ☐ Yes ☐ No

state-of-the-art ☐ Yes ☐ No

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

If so, what do you use of this kind?

Is your department linked to an internal computer network? ☐ Yes ☐ No

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

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

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

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

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

This information will be used only in an analysis for European Hospital,Theodor-Althoff-Str. 45, 45133 Essen, Germany, and for the mailing out of future issues and the EH electronic newsletter.

EH 4/12

Dear Readers,

European Hospital has a new look. Those of you who have known our publication since its first issue 21 years ago may recall that the design has changed only once in its lifetime, and that was many years ago. Why change now?

There is no such thing as a typical European layout. The idea strikes us as absurd. Too diverse are the backgrounds, design preferences and customs in the EU's 27 countries as indeed they are in all of Europe's estimated 50 countries.

So, why change a winning concept? Our readers tell us they like certain things but not so much others. For example, many want to know more about the authors or interviewees. Thus, from now on we will present their brief profiles. Moreover, our European authors are our most important sources of information, our most important assets. We would like to recognise this by giving them a personal space – a simple token of our appreciation of the fruitful exchange we have enjoyed for years.

European Hospital will continue to be colourful, but simpler in design, thus making it easier for you, the readers, to spot what's important and relevant for you.

Our advertising partners will also welcome the lesser competition between their advertisements and editorials, so they will be more eye-catching. We want to recognise the many medical technology and healthcare enterprises that have accompanied us for the past 21 years and we want their innovations and solutions to be clearly recognised. They have shaped the healthcare world – can you imagine one without a PET-CT or PET-MRI, without molecular tracers and markers, or endoscopy, modern labs, hybrid operating theatres, mobile devices, IT and the myriad other remarkable innovations?

For two decades we have presented these developments – whether in praise or criticism – within the European context. So stay with us, as we continue to give a voice to those innumerable people who make healthcare work for us all.

Enjoy your 'new' European Hospital.

Sincerely,
Daniela Zimmermann
Publisher
EUROPEAN HOSPITAL

75 biomedical firms resume production

Earthquake recovery

Italy's Emilia Romana, a core area for the biomedical devices industry, has reportedly suffered 40 earthquakes in the past year, the biggest and most recent of about 6-magnitude, *Brigitte Dinkloh* reports.

When the earth shook repeatedly and severely in the area between Modena, Bologna and Ferrara in the Italian region of Emilia Romagna at the end of May, many buildings collapsed and 24 people lost their lives. The effects of the quake also hit local industry hard. Since the 1960s, the centre of the Italian biomedical devices production, the Italian Medical Valley, has been located near the small town of Mirandola. Companies based here are amongst the largest producers of devices for heart-lung and dialysis machines worldwide. Almost all of the 75 companies with a total of more than 5,000 employees were affected by the earthquake and had to interrupt work as a result, moving production to temporary, alternative locations or even containers.

The fact that there was no resulting need across Europe to cancel important heart operations or to stop dialysis patients from having their blood washed is due to the effective crisis management of the affected companies, enabling them to resume production as quickly as possible, and also to the flexibility of the medical facilities.

It is still impossible to put the damage caused by the earthquake into exact figures. B. Braun, one of the manufacturers with affected Mirandola production, produces tube systems for dialysis, dialysis kits and concentrates, bags for enteral and parenteral feeding as well as application systems for enteral feeding. The authorities did not allow the removal of goods already produced and of safety stock in the warehouse in Mirandola. The production unit for dialysis concentrates was hardest hit and will have to be completely rebuilt.

B. Braun was able to compensate for the loss of production and delivery in Mirandola by shifting production to some of their other locations in Europe. At the same time they set up alternative warehouse and production facilities in the affected region. Production by the company's own employees resumed at the alternative location at the beginning of June. 'We were able to resume full delivery from calendar week 28, the only exception being bags of dialysis concentrates. However, we can deliver concentrates in canisters from our production site in Glandorf as an alternative,' explained Simone Ries, Head of Marketing Communications at subsidiary B. Braun Avitum AG.

Despite all efforts it was not possible to produce the disposable tube systems for a period of about four weeks. This mainly affected customers in Germany in Italy who had to be supplied with competitors' products. 'We personally and regularly updated our customers by letter and telephone about the delivery situation and about the current situation in Mirandola via our website. Because of the longstanding customer relationships and the quality of our products we are convinced that customers will continue to put their trust in our products,' the marketing head explained. The company hoped to take up production in their original facility in Mirandola at the beginning of August. The overall shortfall in revenue and the amount of damage currently cannot be put into exact figures, but luckily none of the 200 employees in Mirandola came to any harm.

Safe stock

Eurosets Srl in Medolla also experienced a loss of production for a whole month. However, the company could fulfil 80-90% of demand because the warehouse stocked supplies of two months' worth of production. After consultation with the fire brigade, the Medolla warehouse was cleared and the safe stocks were moved to a temporary, hired warehouse near Verona. 'Initially we resumed production of our tubing sets at the beginning of July, which we hope will run at 100% in August. A few days later we resumed the production of orthopaedic drainage and after a further ten days the production of thoracic drainage. However, the most important thing is to resume production of oxygenator membranes, which is due to be restored at the beginning of August,' explained Alberto Fiorani, International Sales Manager at Eurosets. For this firm, the earthquake was completely unexpected, as the Po Valley had then not been considered at risks of quakes. 'In the future, building will be much more earthquake-proof, just like in Japan,' he pointed out, as he also expressed gratitude to his customers for their understanding and sympathy in this difficult situation.

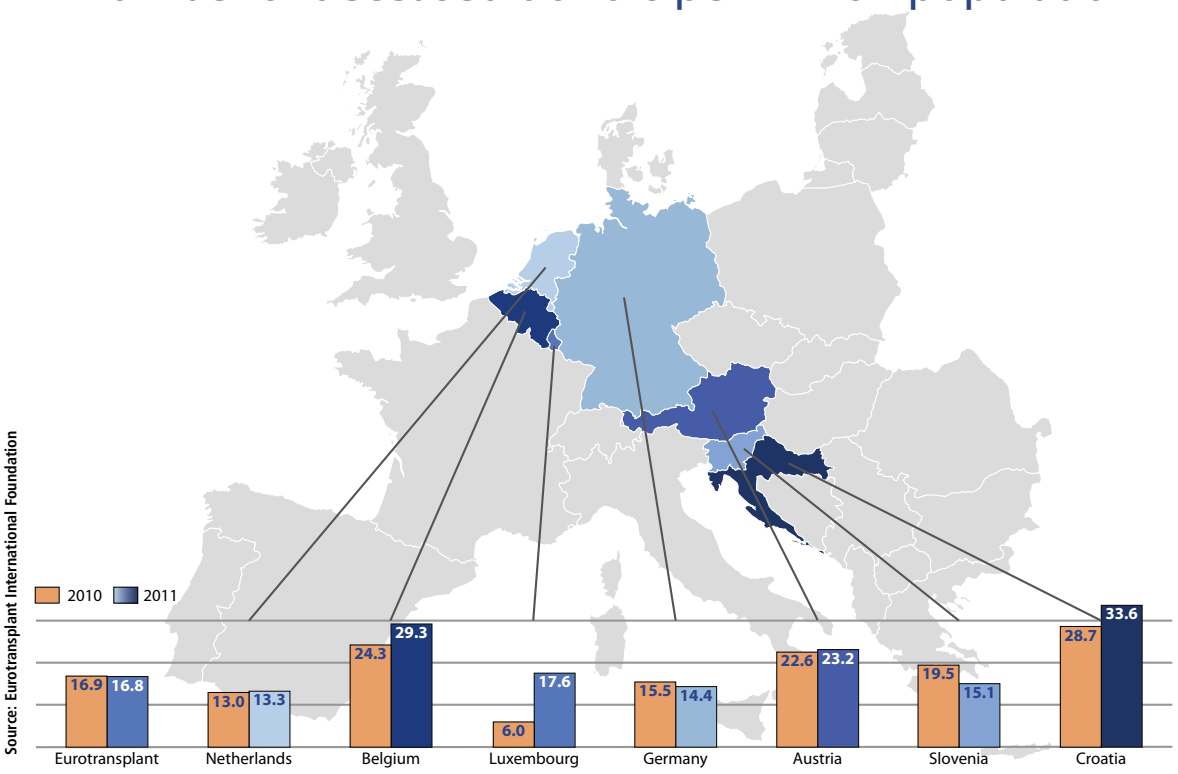
At Bellco, by the company's own account among the five biggest manufacturers for extracorporeal blood cleansing systems worldwide, one production hall almost collapsed completely. However, the company also hoped to restore full operations by the 1st August and 1st September respectively.

At the Sorin Group, the cardiopulmonary division was hardest hit. Production of their autotransfusion kits was gradually restored and has been fully operational since the beginning of August. Production of oxygenator membranes will be fully restored by 1st September.

Despite the large extent of damage, all companies remain committed to the region as the existing know-how and the tight network of suppliers and producers won't be easy to find elsewhere. Nobody in the German Heart Centres has officially admitted to any difficulties in obtaining supplies, although insiders confirm these do exist. The German Heart Institute Berlin reported certain shortages in the supply of membranes for heart-lung machines, and so did the German Heart Centre in Munich. 'Due to the multitude of equipment from different manufacturers, however, we always had enough heart-lung machines at our disposal, explained Dr Barbara Nickolaus, press officer for the German Heart Institute Berlin.

With more than 200 kidney centres across Germany and over 18,000 patients, the Curatorium for Dialysis and Kidney Transplantation e.V. (KfH) is Germany's largest blood cleansing supplier. According to officials, the Italian earthquake caused no problems with supplies. 'We have a multiple sourcing strategy, i.e. we have many different suppliers. This prudent supply strategy and the close exchange with all suppliers affected by the earthquake meant that we had no shortcomings supplying our patients,' confirmed Ilja Stracke, press officer at the KfH.

Number of deceased donors per million population



Source: Eurotransplant International Foundation

Organ donation

continued from page 1

the demand for donor organs is significantly higher than the supply. In many western and central European countries, including Spain, Austria and Portugal, organs are removed from all suitable bodies unless a person had specifically objected to this before their death. These countries have an average of 21 donors per one million inhabitants. In countries with less pressure the rate is around 15 donors per million inhabitants.

To remove the finality from this presumed consent solution it has been modified in some countries, where relatives can now veto organ removal after a person's death. This ruling applies in several European countries, including Italy and France. The Eurotransplant Foundation is responsible for the allocation of donor organs in its member states, Belgium, Germany, Croatia, Luxembourg, The Netherlands, Austria and Slovenia. It cooperates closely with the organ donor organisations, transplant centres, laboratories and hospitals. Foreigners not from one of those countries generally have no entitlement to the donor organs. However, recently this provision has also been undermined by doctors – in the shape of a kidney in a suitcase on its way to Saudi Arabia. The allocation of organs is based exclusively on medical and ethical criteria. Four general principles are important for allocation: The success predicted after transplantation, the urgency as determined by experts, the waiting time and the national organ exchange balance. The result to be expected after transplantation is, among others, predicted based on the donor's and recipient's individual characteristics after computer comparison. After the staff runs a computer comparison with the match list, the central Eurotransplant office offers donor organs to the transplant centre with the patient highest up the waiting list. To play side, the transplant centre with the patient ranked second highest on the list is also made a non-committal offer. After acceptance of the organ by the responsible doctor, the organ removal and transport is organised. There are around 16,000 patients on the central waitlist. This large number of patients makes it possible to allocate almost all donor organs to a suitable recipient – around 7,000 a year.

Thanks to international cooperation the chances for patients with the most urgent needs are increasing. Solidarity among the member countries, with their c. 125,000 million inhabitants, additionally makes it possible to help specific groups of patients such as children or patients with rare blood groups or tissue types.

The 72 transplant centres in the member states of the organisation input all important characteristics of patients waiting for an organ transplantation into the database of the central office, which is staffed 24/7. As soon as a donor has been found their characteristics are also included in the central database. Then the race against time begins. After removal, donor organs need to be transplanted within several hours, making the seamless organisation and allocation of the organ and the transport to its destination essential. This responsibility is increasingly being transferred to transplant coordinators in hospitals. The ETCO (European Transplant Coordinators Organisation) offers the necessary training for the CETC qualification (Certificate of European Transplant Coordination) at a cost of €400. Eurotransplant is ISO 9001 certified and is audited by independent organisations on an annual basis.

Medical acts

continued from page 1

financial remuneration of medical practitioners, in public as well as private sectors, in Frédéric Valletout's view, should be modified and be less dependant on the volume of activity. This is slowly being introduced to general practitioners and pharmacists. In the case of hospitals, a number of options are possible: for instance a regressive fee after a certain number of interventions by one given medical team, or a lump sum allowance for small hospitals, so that they would not be tempted to inflate medical acts in order to balance their budget.

A former journalist and politician, **Frédéric Valletoux**, 46, has been Mayor of the city of Fontainebleau since 2005. He is also a member of the Council of the Région Ile de France (greater Paris area) and President of the Conseil de Surveillance of Fontainebleau Hospital. In 2011, he became Président of the Fédération Hospitalière de France. Headed by a board of doctors, hospital directors and local politicians, the FHF regroups some 1,000 public hospitals.

Finding the right strategies for change

Team unification and good timing to improve hospital processes

Hospitals are complex systems and optimising processes in such systems is a truly challenging task. However, according to Professor Hans-Peter Busch, Director of the Department of Radiology, Ultrasound and Nuclear Medicine at the Barmherzige Brüder hospital in Trier, Germany, it can be done.

Report: Michael Reiter

The author of a number of books on hospital management and process optimisation in healthcare, Professor H-P Busch advises: 'In my experience, optimisation does not begin with inviting a consultant or forming a committee. Rather, it begins by creating an atmosphere that makes change possible.' This, he emphasises, not only includes management but also all members of staff.

'First of all, what you need is a clear idea why change is necessary. People also need to understand what is in it for them. Communication, face time with the staff, is crucial.' The past and present of hospital structures are dominated by the paradigm of optimised individual treatments and services; financial incentives are skewed that way, too. According the professor, all proposals for optimisation will be unsuccessful if staff and management don't learn to think and act in terms of overall processes. 'What we need are new incentives, new ways to motivate,' he insists. The success of the overall treatment process needs to become the focus, not individual performance and treatment.

A comprehensive strategy

Ideally, this discussion should start while the hospital is doing well, because it can take up two years until new, optimised processes really take hold and start showing an effect. When the hospital is already losing money it becomes a lot more difficult because optimisation in many cases means investment, too. A forward-looking answer for modern hospitals changing conditions, for example the introduction of fixed compensation (DRG), lies in a process- oriented realignment of structures and organisation forms. Based on the previous improvement of individual treatment steps, the optimisation of the overall treatment and value chain along the DRG is required. In the past, a process was considered optimised if individual steps were optimised. In the future, the quality of partial processes will be determined through their contribution to the overall result.

It is very important to plant and implement process optimisation steps as part of a strategic whole. Instead, things are often done piecemeal and in response to a pressing need. What is necessary is a comprehensive concept where every individual measure constitutes an important part of the puzzle. In many cases what we see are quick fixes for urgent problems. From a bird's eye perspective, hospitals suffer from a problem that most organisations know all too well: the difficult balance of dividing the management's energy and attention between operative and strategic tasks.

Measure and optimise

The lack of time and resources often leads to situations where a committee is created; the committee comes up with an ambitious plan on how to improve things and sees its mission as accomplished. Everybody returns to his or her regular job and the ambitious plan is forgotten the day after. 'What is lacking is a systematic approach to monitoring and controlling,' the professor points out. Monitoring and controlling don't come for free, the hospital needs to devote resources and manpower to make sure it happens. Process excellence costs money and many hospitals are reluctant to include those costs in their already strained budgets. One of the key areas of investment is the IT infrastructure. 'What you can't measure, you can't optimise. Insufficient or faulty IT equipment in the hospital can be a problem,' Prof. Busch explains.

Another crucial component he mentions is an element of top down control: process optimisation, monitoring and controlling needs to become a priority for top-management. 'In hospitals, that often means a different role profile for executive positions, like Medical Director and Head Physician,' he explains. 'Traditionally, there has been strong emphasis on medical qualifications alone and often a financial incentive to have the Head Physician treat as many private patients as possible, for example.' Top medical executives in hospitals need to shift and broaden their scope; they need to realise that optimised processes and good management can also add important contributions to medical excellence.

Today a lecturer at the University of Heidelberg and Mainz, **Professor Hans-Peter Busch** studied medicine and physics and initially became a resident at Manheim hospital. In 1993, he joined Barmherzige Brüder Trier, where he now heads the Radiology, Sonography and Nuclear Medicine department (Imaging Centre). His main focus lies on digital radiography, MRI, and management, and his research is on optimisation and radiation protection in digital radiography, MRI-angiography, workflow-management, process optimisation and clinical management.

Espen

The 34th Congress of the European Society of Clinical Nutrition and Metabolism 8-11 September, Barcelona, Spain

Report: Michael Reiter

The Spanish Society of Parenteral and Enteral Nutrition (SENPE) has developed an attractive educational and scientific programme for ESPEN 2012. Broadly covering nutrition and metabolism, and dubbed 'Achieving goals in nutrition', the congress will address practicalities of nutritional treatment and disease prevention, defining goals in nutrition care and presenting recent advances. Target groups particularly include physicians in disciplines where nutrition and metabolism play a major role in clinical routine, e.g. oncology, intensive care and care for the chronically ill and obese. Nurses and dieticians who play an important role in hospital routine will also be part of the audience. Quality and costs – Sessions will highlight the fight against malnutrition, the quality of care and its cost to hospitals. Back in 2007, Munich-based Cepton analysts calculated an annual care cost of €9 billion due to malnutrition, with €5 bn borne by hospitals.

Nutrition and Health — Sponsored by seca Precision for health

THE SECA MBCA SYMPOSIUM AT ESPEN

The 34th Congress of the European Society of Clinical Nutrition and Metabolism (ESPEN) will take place from 8-11 September 2012 in Barcelona, Spain. On the opening day, seca will host a BIA symposium entitled Bioelectrical Impedance Analysis – Breakthrough in clinical practice? (8 September. 12-1.30 p.m.).

For of all body composition measurement devices, only the medical Body Composition Analyzer seca mBCA 515 works at a medically acceptable level, as validated against medical gold standards in international studies. Because the medical and scientific precision of the seca mBCA remains unmatched in the history of bio-impedance measurement, seca is in a position to make the innovative diagnostic device the topic of symposiums at international medical congresses.

Chairpersons for the BIA symposium are Professor Manfred J Mueller (Institute of Human Nutrition and Food Science, Christian-Albrechts-University Kiel, Germany) and Professor Marinos Elia (Institute of Human Nutrition and Faculty of Medicine, University of Southampton, Southampton General Hospital, United Kingdom).

Renowned scientists and medical specialists will present the subjects BIA in malnutrition; How to validate BIA?; Clinical applicability of BIA and BIVA; Use and limits of BIA for dialysis patients, and Ethnic differences in body composition.

One of the lecturers, Professor Dympna Gallagher from the Human Body Composition Core, New York Obesity Nutrition Center, St Luke's-Roosevelt Hospital and Columbia University, NY, USA, will travel specially to Barcelona to participate in the seca symposium.

seca's next symposium: 4 October. Venue: German Obesity Society (DAG) annual congress, Stuttgart. In each trade event the seca mBCA will be on show at seca's stand.

Details: mbca.seca.com

seca mBCA 515

MBAs versus M

Are physicians poor managers? Do trained managers kill humanity? *Michael Krassnitzer* sought answers from *Dr Markus Schwarz* from the international executive search consultancy Egon Zehnder.

The hospital is a theatre of operations where physicians battle managers – this rather martial metaphor of today's hospital reality seemed indeed very apt at a recent symposium in Vienna where physicians and business administrators engaged in a ferocious verbal fight. Physicians are very poor managers who are clueless about business and economics, the business side declared. Humbug, the medical staff countered – physicians with clinical experience are the ideal hospital managers and it is MBAs that kill humanity in the hospital. The combatants took no prisoners.

Markus H Schwarz PhD MBA, heads the Vienna office of the personnel consulting agency Egon Zehnder International. He gained a doctorate in immunology at the University of Vienna and an MBA at the IESE Business School, Barcelona. After his role as manager at Medtronic he directed the hospitals in Salzburg county for eight years. He is still on the Board of Directors there. The headhunter also belongs to the extended Board of the European Health Forum Gastein.

While such fights may have a certain entertainment value for the detached onlooker, Dr Markus Schwarz, himself a physician with MBA training and head of the Vienna office of the international executive search consultancy Egon Zehnder, has little patience with such professional skirmishes. Whether a physician or an MBA leads a hospital, he says, is not at all the issue. The crucial factor that determines a hospital's success is the skills of the people at the helm. 'It's not about basic training, but about the qualifications and leadership skills one acquires in the course of one's professional life,' he explained in our European Hospital interview. 'The person who understands the hospital as well as the necessity of long-term commercial success,' he emphasises, 'is the better manager.' To understand the hospital means to acknowledge that a hospital is an organisation of experts – and experts, Dr Schwarz points out, need room – space in which to move, act and decide. Many managers with a business training, he concedes though, tend to set tight rules. In an organisation of experts, he is convinced this is not the adequate mode of operation. An MBA, he underlines, does not necessarily mean a good manager.

On the other hand, physicians who become managers have to develop an understanding of the overarching relationships and necessities in a hospital. They need to learn to look at medicine not from a demand point of view but from a resource angle. 'A hospital manager has to weigh the interests of the individual patient and of all patients and the interest of the enterprise respectively,' he says. There are indeed, he adds, examples of physicians who did not manage this change of perspective and are thus not good managers.

Because hospital physicians are basically forced to assume management tasks, offering them the chance to acquire the necessary qualifications is of paramount importance – and those qualifications refer less to business issues than to personal and personnel development and

2012

Prolonged stays and therapy complications are also caused by malnourishment. Suppressed immune response in surgical patients is part of the problem. Malnutrition is manifest in up to 75% of patients initially diagnosed with cancer, as it is among geriatrics and abdominal surgery patients. Only a third of hospital patients receive dedicated nutrition plans, explained senior study researcher Klaus W Uedelhofen. Also in relation to the study, Dr Jürgen Bauer, Head Physician for Geriatrics, at Oldenburg pointed out that demographic changes will lead to even bleaker figures – the annual cost will probably reach €11 bn by 2020. The Council of Europe resolution suggests similar situations in other countries. Numerous studies show the negative medical effects of malnutrition. Conversely, obesity is a major issue. Science-based guidelines and standards for nutritional intervention have emerged and are available in multi-module therapies to help meet challenges. Modulation of fats, for example, can help fight inflammation, and increased protein intake will build muscle tissue, supporting muscle function.

Nutrition in diagnosis and therapy

In very many relevant cases, physicians invest their efforts in the primary symptom, said Professor Johann Ockenga MD, Secretary of the German Society of Nutritional Medicine DGEM and head of Gastroenterology and Hepatology, Klinikum Bremen Mitte. They tend to disregard the nutrition issues associated with diseases, which might have to do with Germany's DRG reimbursing scheme, he suggested. To optimise patient outcome, nutrition must become integral to diagnosis and therapy. In the Netherlands and Sweden, where in- and out-patient sectors are more closely interwoven, this is easier to achieve, Prof. Ockenga said. Cross-care chain patient management and compliance checks could be the way to go for better results.

The Barcelona congress also offers a host of sessions on nutritional support for the critically ill and a large number of conditions. Will the audience include representatives from policymaking and from payer organisations? They are the actors who may be able to bring about the structural change needed to put nutrition in the focus of care providers.

Professor Johann Ockenga MD is Secretary of the German Society of Nutritional Medicine DGEM, head of Gastroenterology and Hepatology at Klinikum Bremen Mitte, and a specialist in internal medicine and gastroenterology, with additional involvements in proctology, nutritional medicine and quality management. He is also involved in numerous projects to help develop nutritional medicine guidelines.

Correction

The article Upgrading 'Big Iron' for the digital century (European Hospital June/July 2012) incorrectly identified the Chief Technology Officer for the IVD Industry Connectivity Consortium (IICC). Edwin O Heierman PhD, Informatics Software Architect for Abbott Diagnostics Division serves in this capacity, not Eric Olson, Vice President, Automation & IT, Siemens Healthcare Diagnostics, who is the President of IICC.

IDs

leadership skills. 'Seminars are only one component. The most important things happen on the job,' he confirms. Projects, process optimisation but also participation in professional associations – these are all good preparations for management functions.

'Since healthcare systems differ enormously from country to country, different management skills are needed in different countries,' Dr Schwarz points out. For example, in Austria, where hospital management is above all about managing existing resources, different skills are required than in Germany, for example, where managers have to explore and exploit new ways of healthcare provision as a business, or in Great Britain where efforts are underway to make the provision of healthcare more efficient using private business mechanisms.

No matter whether a hospital manager is a physician or an MBA by training – what is really important, Dr Schwarz concludes, is the personality: 'The patient as a human being, and his or her health, must be close to the heart of any hospital manager. The manager has to be able to deal with a wide variety of employees and has to show a certain humility – to know that he is not omniscient.'

* Konfliktherd Krankenhaus: Ärzte versus Manager, 24 May 2012, Allgemeine Unfallversicherungsanstalt, Vienna

The European Health Forum Gastein (EHFG) – 3-6 October 2012. Bad Hofgastein, Salzburg, Austria

Crisis as an opportunity

Rarely have the topics at the EHFG been so relevant to the current international economic crisis – reason enough for EH correspondent *Christian Pruszinsky* to interview the Forum's founder and outgoing President Professor Günther Leiner.

In times of crisis, governments often cut healthcare budgets – particularly for hospitals. Are cuts in services therefore pre-programmed?

Prof. Leiner: 'Unfortunately, it's a common misbelief that hospital costs can be tackled through cuts in services. Demographic developments alone tell a different story. Clever rationalisation means: Making more with less, better utilisation of existing resources, shaping instead of administrating, rethinking structures, making systems more efficient. The potential is there – it just needs to be made use of.

This sounds simple – why isn't it happening?

'It does happen, but not always and not everywhere and not with the same intensity. Take hospital density, for instance. In many countries – not least in Austria and Germany – there are too many hospitals, some are too small, have too many beds, too many admissions. Everyone with an insight into this knows the figures. However, there are also countries, such as in Scandinavia or the Netherlands, where the structures are already more streamlined, and that, I must emphasise, whilst maintaining the same level of care for patients. The Netherlands was the trailblazer in reducing hospital numbers and is considered an example for many quality indicators – for example in the fight against multi-resistant hospital bugs.'

This means hospital closures, longer distances for patients to travel, difficulties in obtaining necessary care.

'I beg to differ. A hospital's economic problems cannot be solved by preventing sick people from access to necessary treatment, or by making it more difficult, but we can make sustainable changes to the structures. Not every smaller hospital should offer all services. We need specialisation and a division of labour. This means better utilisation of existing savings potentials, more efficiency in care and improved treatment quality.'

In the early 1990s **Günther Leiner MD**, currently President and Founder of the European Health Forum Gastein, also founded the International Forum Gastein. A former medical director of Badehospiz, Bad Gastein, he also served several terms in Austria's Parliament, where he was Deputy Chair of the Health Committee. As an MP he also represented the government in the Roundtable on Human Genetics of the European Parliament. Dr Leiner also presided over the Salzburger Hilfswerk, which he established in the late 1980s. With around 800 employees, this non-profit group delivers home health services, domestic aid, support for the elderly and related services.

Cutting costs with simultaneous improvements in treatment quality sounds like squaring the circle.

'No, it's just a logical consequence from numerous international studies. Would you like some examples? Johns Hopkins University found that in hospitals with fewer than six heart transplant operations per year the mortality risk for risk patients is 67% higher than in centres that carry out more than 15 such operations a year.

'A new study at Stanford University has shown that, with such diverse interventions as aortic aneurysm, bypass or gastric band operations the frequency with which a hospital carries out these interventions is in a clear, inverse relationship to the rate of complications. The mortality risk in specialist centres with high case numbers is 11% lower than in smaller hospitals for heart attacks, 9% for cardiac insufficiency and 5% for pneumonia. Generally speaking: the more interventions the lower the number of mortalities and complications and vice versa. The EHFG communicates all these aspects to decision makers in the worlds of politics, economy, science and specialist associations during its varied programme of events.'

The EHFG is celebrating a small anniversary. Taking stock, what stands out for you?

'We've managed to establish the forum as an international meeting place for experts and decision makers from all parts of the healthcare system and as a central discussion forum on health related policies in Europe. With the EHFG we have developed a network where the different, relevant forces – politics, the economy, science and non-governmental organisations - meet at the highest European level. This platform allows us to work through and discuss important health-related proposals from the EU and the WHO. The results of our forums are generally considered valuable and help many with further work in their national committees.'

Helmut Brand MD is Professor of European Public Health and heads the Department of International Health at Maastricht University. He studied medicine in Düsseldorf and Zürich and gained a Master in Community Medicine from London School of Hygiene and Tropical Medicine and the London School of Economics. He specialises in Public Health Medicine in Germany and the UK and he has worked in several health authorities and health ministries, and was Director of the Public Health Institute of North Rhine Westphalia for 13 years. European Integration in Health is now a main focus, with research on European cross border health, comparative studies, policy advice and surveillance systems.

What makes you particularly proud?

'The composition of the more than 600 participants has clearly developed and changed over the years. Not only that the degree of internationalisation – key word Eastern European expansion – has strongly increased, but also that the interests of the participating officials have multiplied. EU commissioners, ministers, health politicians, representatives from the WHO and World Bank, decision makers from large medical devices and pharmacological companies, participants from statutory and private insurers, numerous NGOs, patient associations, representatives of the media, decision makers in medical, nursing and administrative occupations, representatives of public institutions and from private hospitals meet in Gastein nowadays and enjoy the unique atmosphere.

'I'm really proud that the forum's work is increasingly delivering profound, thought-provoking impulses for day-to-day political life and that we can have a direct impact on health-related political decisions in Brussels and/or national bodies. I'm also proud of the introduction of the European Health Award, for which high quality, practice-oriented projects are submitted year after year. I'm also particularly proud of all my wonderful colleagues who have contributed to our successful groundwork right from the beginning.'

We understand that wish for the 15th EHFG to be the last under your leadership. What are your hopes for the future?

'Obviously I hope for health and for a little more time for my private life. I will always be involved with the forum in the future and obviously still at hand. After all, it is like my "baby". I would like to see it being carried on in the spirit of the four pillars, i.e. integration into politics, the economy, science and NGOs, because this makes it unique. I am happy to have found the perfect successor in the shape of Professor Helmut Brand and to hand over an organisation to him in a good state. After all, a lot remains to be done – particularly in these turbulent times. The crisis is an opportunity for us to prove ourselves.'

Successful strategies

Battling against hospital acquired infections

Hospital acquired infections (HAIs) are among the most common complications during a hospital and care home stay in the West (although they also occur in developing countries, with even an assumed higher incidence), causing enormous strain for those affected as well as high follow-on costs for healthcare systems.

Many of these infections were/are caused by multi-resistant bacteria. Therefore adherence to hospital hygiene standards has a key function in the avoidance of hospital-acquired infections. Although this has been known for many years, effective infection protection is often made difficult through lack of staff, funding and information. In the US the Centre for Disease Control and Prevention has recently presented measures from individual hospitals that were particularly successful in fighting these HAIs. One of these measures is the linking of bonus payments to managers to a hospital's compliance rate for hand disinfection. EH reporter Brigitte Dinkloh looked into whether this incentive could also be conceivable in Europe.

For the seven hospitals run by Novant Health in Winston-Salem, North Carolina, USA, the death of a 28-year-old parachutist who died not from his injuries but an MRSA infection, was the trigger for an aggressive hand hygiene campaign. Earlier campaigns had failed in the long term. The new campaign was based on the principle of liability by making bonus payments to managers, due in three years' time, dependent on whether a compliance rate of 90% for hand disinfection was achieved. The hospital group invested around US$325,000 in monitoring, training and documentation for adherence to the hand disinfection guidelines. At the start of the campaign the MRSA infection rate stood at between 0.8 and 1.0% per 1,000 patient days; after the campaign the rate of infections was lowered by 60-70% to 0.15 infections per 1,000 patient days.

Gertie van Knippenberg-Gordebeke, an experienced hygiene expert from Venlo, the Netherlands, who now advises hospitals worldwide on hygiene issues, and lectures at many international congresses, deems the campaign carried out in the USA to be effective, albeit unpopular. 'Control and punishment, or reward respectively, are the only measures that really work,' she explains. However, keeping the rate of HAIs at a constant low also depends on other factors – the sparing use of antibiotics, good training of hygiene specialists and correct cleaning procedures (Keep it clean, keep it dry), as well as the correct emptying and decontamination of bedpans. 'The Netherlands, along with the Scandinavian countries, has the lowest rate of MRSA worldwide – 1.2% (2010 - http://www.ecdc.europa.eu/en/activities/surveillance/EARS-Net/database/Pages/table_reports.aspx). The reason why is one of the most sparing uses of antibiotics for humans worldwide. Moreover, hygiene standards in hospitals are higher than the European average: Dutch Hygiene specialists must be certified every five years. This along with consistent screening of MRSA risk patients contributes significantly to the low incidence of MRSA. We don't regularly screen for other pathogens but, due to the low use of antibiotics, there are fewer multi-resistant bacteria than in other countries anyway.'

However, even in the Netherlands there are problems with compliance with hand hygiene. For her doctoral thesis, Vicki Erasmus, researcher at the Erasmus Medical Centre, in Rotterdam, carried out an exemplary investigation into the hand disinfection practices among doctors and nurses. She found that the rate of adherence to the guidelines on hand hygiene was only 20% i.e. only every fifth pair of hands was being disinfected according to the guidelines.

The large German hospital group Helios has a different approach to the fight against HAIs: 'We don't link the bonus payments to hand disinfection but to medical objectives,' explains Prof. Henning Rüden, Consultant Hospital Hygiene Specialist at Helios. The hygienists of the hospital group are paid a bonus once the prevalence of a pathogen has fallen below a certain level. The hospital hygiene specialists are therefore very motivated to prevent nosocomial infections with multi-resistant bacteria.

'Hand disinfection is such a big matter of course for us that I'm not sure why we'd want to make bonus payments depend on it. I think we should concentrate on containing infections, because what really counts are fewer multi-resistant bacteria and fewer infections,' Prof. Rüden added.

He sees the key to success in awareness. The Helios group are therefore taking part in the Hospital Infection Surveillance System (KISS) at the National Reference Centre for Surveillance of Nosocomial Infections. Patients with an increased risk of being MRSA carriers, such as residents in residential homes for the elderly, and farmers, as well as patients on ICUs, are screened on days 1, 2 or 3 of their hospital stay. Since 2010, the incidence of nosocomial MRSA cases at Helios has fallen significantly and is currently at 0.05 per 1,000 patient days. According to Prof. Rüden, MRSA is not the real problem nowadays, the real problem are the gram-negative bacteria that only

DIARY DATES

10-13 October 2012.
Zagreb, Croatia. 12th International Federation of Infection Control Congress.
Details: www.ific2012.com

19-21 November 2012.
Liverpool, UK. 8th International Healthcare Infection Society (HIS) Conference and Federation of Infection Societies (FIS) annual conference. Accreditations: ACCME and the Royal College of Pathologists.
Details: www.hisconference.org.uk

Professor Henning Rüden MD, specialist and consultant in hospital hygiene at the Helios Hospital Group (since 2007) and head of the Central Hospital Hygiene Department, studied Actuarial Science and then medicine at the Universities of Hamburg and Marburg/Lahn. His doctorate (Bonn University) had a pathology focus. From 1972-77 he was a scientific assistant at the University's Institute for Hygiene. Following his habilitation he moved to the Technical University of Berlin (Environmental, Construction and Hospital Hygiene, to date) and, in 1982, also held a position at the Free University of Berlin (Hygiene). Until September 2007 he was Hospital Hygiene Specialist at Charité University Hospital, Berlin.

respond to two to three antibiotics.The hospital group is currently trialling an intranet-based documentation system for the use of antibiotics, whereby the daily doses per 1,000 patient days in the whole hospital are reduced so that bacteria that have become pan resistant through certain antibiotics are not selected.

In July the Robert-Koch Institute introduced the data from Germany in the context of the first European Prevalence Survey by the ECDC – the survey is still being carried out in other European countries. It shows that, compared to the first German prevalence study in 1994, the prevalence of nosocomial infections has not changed significantly but that there has been a defined increase in the administration of antibiotics (RKI: Epidemiological Bulletin No. 26). Even though the exact analysis of data is still outstanding there will be a continued need for extraordinary measures to contain the spread of HAIs.

An infection control nurse for 38 years, **Gertie van Knippenberg-Gordebeke** RN CCIP became owner/director of the international KNIP Consultancy in Nijmegen, the Netherlands, focusing on infection prevention and covering hand hygiene, safe bedpan management, cleaning and disinfection of the environment and equipment, washer-disinfectors, MRSA prevention and coaching.
A member of the Dutch Hand Hygiene Working Group Take 5, she has served as a Board Member of the International Federation of Infection Control (IFIC) for eight years, and is co-chair of its Hand Hygiene Special Interest Group. She co-chairs the International Section of the Association for Professionals in Infection Control and Epidemiology.

Round-up on IT trends at Medica 2012

A new name and new focus

Medica Media has done a good job. For years, the section in the world's largest international medical trade fair has provided a meeting place for representatives from medical care, research and manufacturing organisations. Now, however, the name and format is changing. *Michael Reiter* asked *Dr Volker Hempel*, the section's organiser, about the implications of change.

'Medical information and communication technology has been part and parcel of MEDICA for many years. Of the 4,571 exhibitors in 2011, 400 were from the health IT sector,' explained Dr Volker Hempel. Medica was quick to pick up on the globalisation of medicine, emerging in the mid-1990s through the first telemedicine projects. From 1998, the fair offered the trade symposium and exhibition, called Medica Media, Medical Information Systems and Telemedicine, following on from a preceding exhibition on IT practice.

'We address decision-makers and IT specialists from care provider, payer, academic, research, and vendor organisations. Our programme gives prominence to market trends from both the medicinal and assistive perspectives as well as from an economic point of view.'

Asked to describe the formats and key topics, Dr Hempel said, 'Most of our programme, now on two forums, is made up of one-hour interdisciplinary panel discussions featuring prominent guests.The exhibition involves leading research and academic institutes. We'll be organising networking activities to help researchers find business partners; our continuing education programme combines face-to-face and virtual events in a brand new format.

'R&D Talent Awards are presented to up-and-coming researchers. This year we will run a major event on developments in mobile health (m-health) in cooperation with dotopen. The AppCircus is a platform for young developers to show their apps in a competition. Medica Health IT – Medica Media is also linked to the 'Future Care' event organised in cooperation with BITKOM and focusing on Germany's health ID.

Cross-disciplinary panels on current challenges in care and how to meet them are a key element of the Medica Health IT Forum.

Another important partner will be the American association CTIA – The Wireless Association.

'The telematics infrastructure, networked healthcare, and telemedicine applications have been key topics through the years. Last year, presentations at the European level finally started to draw a significant response. With mobile health attracting growing attention in care, our aim is to cover the entire innovative spectrum, particularly regarding points of contact with medical technology, mobile services and devices and emerging personalised medicine. Our focus is on e-health, m-health and p-health; we also take into account international developments and markets. Last year, more than 20% of our attendees came from abroad. We aim to make our forum even more international to encourage the best in their fields to discuss and present their results and products at Medica.

'The name change is to underline the fact that our forum is becoming a platform for all health IT. We'd like to provide a clear indicator of what we represent. As well as the shift in content, which began last year, we'll also be offering new formats and adding new sections to our programme, as described.'

2012 highlights

'We'll again be putting on a top-class show that really hits the spot – thanks to our advisory board, the Expert Circle, and their associated members. Our industry partners, such as BITKOM, CTIA, and HIMSS, will focus on new developments from an industrial point of view. The worldwide AppCircus show will add to our big event. Young developers, who register on the network and go through a pre-selection process, will present their health-related apps – live. The organisers have received more than 1,600 registrations from over 30 countries.

We'll begin on the Wednesday with topics revolving around e-health – e.g. the use of telemedicine with critically ill patients, assessment of national and international telemedicine centres, EMRs and nursing records. Then, on Thursday, we'll discuss links to medical technology, e.g. in-vehicle medical technology, IT in the operating theatre, assistive technologies and best practice when it comes to technology transfer. The clear centrepiece on Friday will be mobile health, with applications in hospitals and practices at a national and international level. On Saturday we'll be presenting the R&D Talent Award.

The exhibition accompanying the forum includes leading research and academic institutes.

Dr Volker Hempel comes from an academic background in geological science, with years of experience in managing knowledge transfer processes in biotechnology, medicine and telemedicine. He has headed the Medica Media Forum since 1998 and is founder and CEO of Science Service – Dr. Hempel GmbH, in Düsseldorf, Germany, a consulting and event organiser focusing on telemedicine.

The 2012 American Association of Clinical Chemists convention

Did the giants bring in anything really new to this year's meeting?

During the annual American Association of Clinical Chemists (AAMC) convention and meeting held in July, the giants in the field of medical chemistry, including Siemens, Roche, IL/Werfen, Beckman Coulter, and Abbott, had a huge presence at the trade show, which filled two halls and packed in a hefty crowd. *Jacquie Michels* reports from Los Angeles, California.

Source: Jacquie Michels

Founded in 1948, the international scientific medical society AACC has 8,000 members: clinical lab professionals, physicians, research scientists and others involved in clinical laboratory medicine

Probably the biggest introduction at the AAMC was Siemens' Aptio platform, which the manufacturer calls the next generation of lab automation. The system, filling nearly half of Siemens' booth, starts with an automated tube collection bin that saves the operator from racking samples. Each tube is bar-coded, telling the machine where along the automated track to send it and which of hundreds of possible tests to run. Each tube can be tracked automatically and sent back for re-testing if required, without ever touching human hands. STAT cases can be sent to the head of the line for priority treatment. A refrigerator unit stores the tubes for a specified period of time, automatically recalling them if additional tests are required.

The Aptio unit is just being introduced in the U.S.; a prototype is up and running in Northern Scotland. Siemens also showed a full line of training, software, point-of-care testing equipment, and scalable lab equipment to handle any workflow.

Robotics is the word at Abbott Technologies. Recognising the upcoming shift in the lab technology labour force, with up to a third reaching retirement age in the coming five years, the company is focusing on making the best possible use of trained personnel.

Abbott's 'OneLab' web-based, integrated lab informatics system, can be connected to work with additional modules including sorting, centrifuge, and assays, and is designed to manage information flowing through the lab and improve efficiency. The new system is available in select European markets, and will be forthcoming to the US soon. Abbott also announced it has received FDA clearance for a new assay to detect vitamin D levels in the blood. Instrumentation Laboratory, one of the largest manufacturers of in vitro diagnostic instruments, announced at the show that they have severed a twenty-year strategic alliance with Beckman Coulter and will now handle sales, service and support functions directly with customers.

The company focuses on two areas of testing: critical care and haemostasis. They have approximately fifty years of experience in these fields, and have done their own manufacturing and development throughout this time.

In order to accommodate the change, IL has doubled its sales and support staff, and foresees a smooth transition. The company also announced that its fully automated Hemosil Acustar HIT assay panel is now being offered in Europe and other international markets.

Beckman Coulter, a 75-year veteran in the field of biomedical automation, introduced the AU5800 chemistry series at the show. This platform is designed to be one of the fastest and most reliable of its kind available today. Also at its display were the company's newest high-throughput chemistry analysers, clinical information solutions, lab automation technology, and cellular analysis systems, all displayed to replicate a core lab, reference lab, and regional and community hospital lab. The in-booth Innovation Station gave attendees the chance to meet industry experts and discuss how today's labs are using robotics and online advances to increase productivity and maximise staff capabilities.

Interesting about Roche Diagnostic's new RALS-Plus system is its compatibility with dozens of POC (point of care) devices and testing equipment, eliminating the need for additional interface equipment. This integrated data manager uses one reporting source, one format, and there is only one programme that members of staff need to learn. Overall, the company claims it minimises the need for extra hardware. RALS-Plus also offers a single solution for managing multiple POC devices, consolidating POC results through a single browser-based data management system.

According to Siemens executive Dr David Stein, the wave of new laboratory automation and robotics clears the way for enhancements in POC technology. 'When test results are available during a patient-physician interaction, rather than weeks later, there is an opportunity for faster segue to treatment,' he said. 'This can make all the difference in overall patient outcomes.

'I believe POC testing will support the trend we're seeing in personalised healthcare, and overall enhance the laboratory's role in improving healthcare outcomes.'

Step-by-step automation

Optimising productivity is now a top priority for today's clinical laboratories

The ever-increasing demand for analysis, combined with an unrelenting pressure to control costs, is pushing every laboratory to find ways of better managing the chain of tasks for sorting blood and tissue samples from patients, dispatching them to the right instruments and preparing a report for clinicians.

Typically, only high volume centres handling upwards of seven million samples per year could install the highly complex aas well as high-cost equipment.

Yet, the challenge to efficiently deliver diagnostic results for patient care decisions are just as great for hospital labs, blood banks and local processing centres that do not have the volume of samples to justify the expense.

At the 2012 AACC Annual Meeting, Ortho Clinical Diagnostics (OCD) demonstrated a fresh approach that opens a step-by-step path to clinical lab automation, creating a way forward for every operation. 'Over the past 18 months we have gone back and reassessed what automation truly means to laboratories,' explained Colin Hill, the firm's international marketing director. 'We sit down with customers in partnership, working along the continuum of needs to understand their goals and outlining ideas for process improvement.'

The result is enGen CoreCell, a flexible solution applied across the full range of OCD's Vitros systems, allows customers access to the advantages of automation in stages covering every variant imaginable from haematology to molecular diagnostics, he said. 'CoreCell allows laboratories to only automate specific processes where there is a clear need and an immediate cost-effective result. We can start small and only automate the area a laboratory truly needs for process improvement. After that the track can expand.'

Recognising a need for better managing informatics and the tremendous data generated by lab instruments, brought OCD into a partnership with Data Innovations, a market leader for middleware solutions – the layer of software between the instruments and the information networks.

The partnership enabled OCD to take the built-in intelligence of Vitros instruments to the next level, rewriting rules and algorithms to coordinate how samples are assessed, dispatched and reported, Colin Hill explained. At this year's AACC, his company also introduced the Vitros Immunodiagnostic Products 25-OH Vitamin D Total Assay, which recently received European CE Marking.

More than one billion people globally are thought to have an insufficiency or deficiency of vitamin D, a pre-hormone essential in the maintenance of kidney, bone and intestinal health. Increasing concern about vitamin D levels is driving a need for fast and reliable laboratory testing – the only way to definitively determine if an individual suffers from, or moving towards, a vitamin D deficiency.

OCD also introduced the Vitros Immunodiagnostic Products Total PSA II Assay and the Vitros Immunodiagnostic Products Free PSA Assay, which also were recently approved for commercialisation in Europe. These new assays round out OCD's state-of-the-art oncology portfolio for the early detection of prostate cancer.

Ortho-Clinical Diagnostics products enable gradual progress towards laboratory automation

With a BSc in Immunology, MSc in Molecular Pathology & Toxicology and a Post-Doctoral Fellowship in Rheumatology, **Colin Hill** worked in the in vitro diagnostics industry for over 15 years, gaining experience at firms such as Siemens Healthcare Diagnostics, Bayer Healthcare Diagnostics (France) and Bayer Diagnostics, Miltenyi Biotech and BioGene, (both UK). In 2010 he became global marketing director for Ortho-Clinical Diagnostics, Inc. (OCD), part of Johnson & Johnson, a role in which he developed global marketing strategies and planning for the firm's clinical lab instrument, software and services portfolio. He also developed the collection and utilisation of market research data and customer evaluations to give strategic direction for customer-dependent product development.

Checking the biological clock

'The egg timer test' is widely used to help determine how long a woman can expect to remain fertile. Lately it has shown even greater potential for clinical use as a biomarker for ovarian viability.

Every woman hears her biological clock ticking, marking the time in her life when she can fulfil a hope of becoming pregnant. The sound can echo powerfully among professional women who, arriving at a more stable period in life, wonder if there is still time to begin a family. For these women, the universal question is: 'How much time do I have?' For their doctors, it is a question of her 'ovarian reserve.'

From the moment a woman is born, the number of eggs that she will produce in her lifetime is already determined by both the quantity and quality of her ovarian pool, which diminishes with each passing year.

Today both the woman's question of time, and the clinician's question about the ovarian reserve can be answered thanks to the anti-Mullerian hormone (AMH) test, more commonly called the 'egg timer test'.

'Many women are waiting later and later to become pregnant,' says Sherry Faye, the Director for Global Scientific Affairs with Beckman Coulter, citing as an example a healthcare professional who she said, 'studies and trains for so many years, and then at the age of 33 finds her first opportunity to consider having a baby.'

Cost and emotions

Not all women will be successful, she adds, arriving at an in vitro fertilisation (IVF) specialist to explain this unexpected infertility. Here the AMH test can help provide some explanation.* 'AMH is a measure, a true biomarker of fertility that can provide a woman with compelling, even riveting, information to assess her current condition. There is growing evidence to suggest that AMH can also predict the age when the woman will begin menopause.'

Beyond the dilemma faced by professional women, there is the straightforward fact that infertility affects approximately 15-20% of reproductive aged couples.

In addition, with an increasing incidence of cancer among young women of child-bearing age, many have undergone radio- or chemotherapy, which are highly toxic and directly affect the ovaries.

Here, AMH becomes a powerful tool to assess the likely success of assisted reproductive techniques. 'IVF is very costly,' Dr Faye points out. 'Yet the drive to become pregnant can feel quite strong as well. A couple will want to keep on trying, though it takes a great toll on the woman's body and on her psyche as well.

'It is a complex area emotionally, morally, socially and, in this context, the AMH test helps to ground a couple's decision in something more solid. It is true that family planning based on information can make a difference in a woman's life.' She goes on to underline that assisted reproduction often requires the use of powerful drugs for ovarian stimulation, some of which can be harmful to some women. There is a risk of developing ovarian hyper-stimulation syndrome, which could require hospitalisation.

Physicians use the anti-Mullerian hormone test to help indicate how a treatment can be tailored to an individual to avoid toxic effects, to make the procedure safer. 'On one hand it can help assure the best outcome, the best result for a pregnancy,' Dr Faye points out. 'On the other, the test may help the physician counsel the woman that assisted reproduction procedures may not work for her.'

Currently AMH is gaining wide adoption in the fertility clinic, yet the ability to determine the number of ovarian follicles for a woman indicates the test may serve as a robust biomarker for other conditions, especially polycystic ovarian syndrome (PCOS), one of the most common female endocrine disorders.

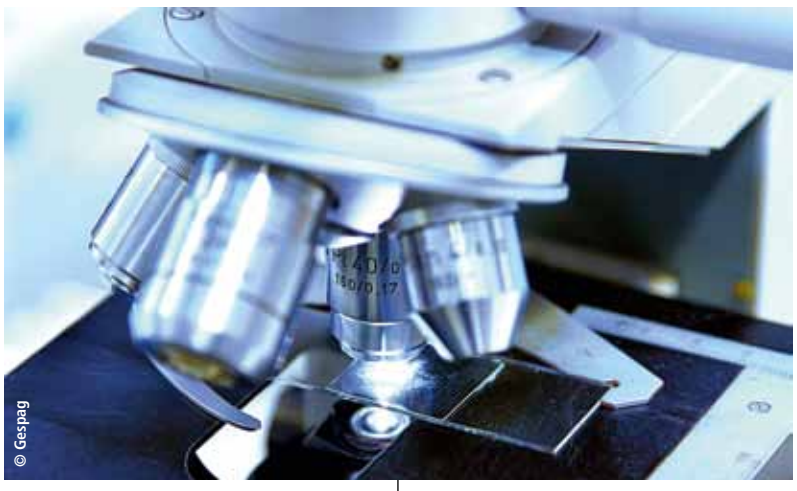
* Beckman Coulter is not promoting any of its products for any purpose other than those specifically approved in the product's labelling and instructions for use.

A Royal College of Pathologists Fellow, **Sherry Faye** has contributed to advancing the diagnostics industry for 20 years. With Pharmacology and Clinical Biochemistry degrees, she earned her doctorate from Leeds University, UK. Her research has focused on engineering, conducting clinical trials of new instrumentation and product development for thermal cyclers and robotic sample processors. Recently she was invited to present and contribute to the UK's National Institute for Clinical Excellence (NICE) Pathway Programme for Medical Technologies.

Molecular diagnostics

Research in the field is booming thanks to newly arriving methods to identify gene sequences. Scientists are interested in a wide range of issues from disease-relevant variations of human genetic information to the detection of viral genetic material that supports therapies. Several highlights of current research were presented this spring at the 9th International Symposium on Molecular Diagnostics (ISMD 2012) held in Graz, Austria.

Michael Krassnitzer reports


© Gespag

Individualised treatment of viral hepatitides was a major topic during the recent ISMD 2012 gathering. Liver inflammation is usually treated with antiviral substances that aim to decrease the viral count in blood. 'Today, specific diagnostic methods allow us to assess very early in the therapy whether, and to what extent, a patient will respond to a certain treatment,' explains Professor Peter Ferenci MD, from the University Clinic for Internal Medicine III at the Allgemeines Krankenhaus in Vienna, Austria.

With hepatitis C, he adds, a crucial objective is to adapt the therapy duration to the course of the disease. For example if, in patients with a certain virus genotype, the virus is no longer present after four weeks, the subsequent standard therapy with pegylated interferon and ribavirin will be applied for only 24 instead of 48 weeks. In patients with a different genotype the therapy might even be reduced to 12 weeks. In hepatitis B, however, the issue is not to shorten the therapy but to evaluate the effectiveness of the treatment. Here, reducing the virus load is a precondition for therapy to begin.

Another important topic at the molecular symposium was the prevention of cervical cancer caused by an infection with human papilloma virus (HPV). The conventional Pap smear, used for decades to detect HPV infections, has a sensitivity of only 60-75%. 'New molecular methods allow us to increase sensitivity in early detection to more than 95%,' says Dr Hans Georg Mustafa, who directs a medical chemical laboratory in Salzburg.

In other words, the new test has a high negative predictive value. If the result is 'HPV negative' the woman's cancer risk is close to nil. In biology 'dark matter' refers to the many genes that are not encoded for proteins but remain so-called non-coding RNA (ncRNA). Researchers hope to decipher the role of ncRNA in the prevention and treatment of widespread diseases. Today, 20,500 protein-coding genes are known but they form but 1.5% of the genome that is continuously coded. The working group RNA biology, led by Dr Marcel Scheideler, at the Institute of Genomics and Bio-Informatics, Technical University Graz, tries to use this 'dark matter' to fight adiposity and obesity. The microRNAs miR-27b and miR-30c are two recently discovered 'switches' whose influence on the development and function of fat cells may well support adiposity, as well as diabetes therapy.

Gene sequence identification is leading to earlier disease discovery as well as greater understanding of drug efficacy and therefore correct dosage for individualised medical treatment.

There is also news on statins that are used to lower lipid levels. A genetic variant of the transporter SLCO1B1 is considered to be the most important risk factor of statin-induced myopathies. The molecular genetics lab team at the Medical University Graz has developed a test to determine the SLCO1B1 genotype and thus the individual risk of statin intolerance prior to the start of therapy. This test can avoid severe side effects and sequelae.


© private

HANS GEORG MUSTAFA


© Gespag

Connectivity and interoperability

Roche's new information system aims to tackle the complexity and variability of clinical processes within and beyond laboratories.

'One of Roche's missions is to improve services to clinicians and patients by reducing the complexity and variability of clinical processes inside and outside laboratories,' the firm states. To this end, and following participation in the IHE Connectathon 2012, the firm has introduced cobas omega4, its latest laboratory information system for integral interoperability testing.

Remote access

This system is designed for the integral management of analysers, specimen flow, data flow and laboratory control and, the firm adds, it represents a radical change in the way clinical laboratory processes are managed.

'The web-based architecture used in cobas omega4 enables laboratories to access the system from anywhere, a feature that ensures functionality even over a lower-bandwidth network infrastructure. The solution not only ensures seamless data management between LIS and analysers by complying with the IHE LAW profile,' Roche notes, 'it also enables laboratory managers to expand data management processes to a variety of HIS and LIS solutions by also fully complying with the IHE LAW (Laboratory Integration Profile).

Modular and scaleable

'Our stakeholders request highly interoperable platforms in a multivendor environment that supports the new IHE LAW profile,' said Georgios Spitadakis, Head of the company's Workflow & IT Product Lifecycle division. 'At Roche we are committed to reducing the variability and complexity of information exchange between IVD analysers and healthcare IT systems. cobas omega4 fully conforms to today's standards.

'The idea underlying Roche's new solution is derived from over 25 years of experience and more than 600 systems installed in 17 countries, including all types of hospital and commercial laboratories, Roche reports. 'The new generation of cobas omega4 labware is based on a modular and scalable concept incorporating substantial functional improvements that offer laboratories organisational flexibility and regulatory compliance.'

In the firm's WAM middleware solution, cobas IT middleware is designed to increase workflow efficiency and usability by supporting automated laboratory processes and reducing non value added steps in the laboratory. 'This middleware continuously monitors laboratory sample workflows and manages data from different workplaces and sites so as to ensure optimal information exchange between analysers, a variety of LIS and HIS.'

Georgios Spitadakis holds three master's degrees – in Business Administration (University of Chicago), Applied Economics, Accountancy, and Finance (University of Hasselt/Belgium) and International Relations and European Politics (University of Liège/Belgium). Following his role as Head of Marketing in Europe Healthcare IT, at Agfa in Belgium, he now Heads the Workflow & IT Product Lifecycle at Roche Professional Diagnostics in Rotkreuz, Switzerland.

'For multisite labs with a wide array of workplaces and a throughput of up to 15,000 samples a day, further optimising workflows and continuously enhancing efficiency is something that really carries a lot of weight with clinicians, end-users, laboratory managers, and patients,' Georgios Spitadakis pointed out. 'For them, cobas IT middleware, which supports more than 170 Roche and third-party instrument and device connections, is nothing less than a core component of their total lab solution. The intuitive user interface of our middleware is the result of involving our customers in the early phase of the development process.'

'Our workflow and IT specialist has an in-depth knowledge of daily lab routines combined with expertise in software and instrument development, so we got him/her together with representative customers from the segments we target to serve at an early stage. This helped to ensure that our solution was jointly developed with key end-users.'

Lab managers can expand data management processes to a variety of HIS and LIS solutions by complying with IHE LAW.

New planning software for orthopaedic and trauma surgeons

Although mandatory for joint replacement surgery, precise surgical planning and documentation is arriving only now for trauma surgery.
Siemens Healthcare has developed the software package PreOPlan with Synthes (Soloturn, Switzerland) and reports that the programme enables the virtual, precise planning of routine operations for new fractures and deformity corrections.

For 18 months, Dr Steffen Schröter, orthopaedics and trauma surgery specialist at the BG Accident and Emergency Hospital, Tübingen, Germany, has been one of the system's first regular European users. Prior to PreOPlan, he used X-ray images 'in his head' to plan routine operations for fractures of the extremities, or he manually marked the planned procedure to correct deformities on the images. 'Sometimes there were moments of surprise in the course of operations when the nails or plates chosen to fix a fracture didn't actually fit,' he recalled.

Using the PreOPLan software he can measure and choose on the monitor the exact implant for the patient. The PreOPlan trauma module enables very careful planning of the repositioning of the actual bone continuity by segmenting the fragments of the fracture, measuring them and reassembling them anatomically correctly. A database containing osteosynthesis material automatically suggests suitable implants for the respective body region. 'There are bones that, by nature, have a strong curve, which makes it very problematic to place a normal nail. In such cases there's a chance you might have to deviate from the planned procedure and if you only realise this during the course of the operation you have to solve the problem very spontaneously,' Dr Schröter explains. 'However, if you can virtually plan the surgical procedure beforehand – which can be done very quickly – and you find a problem is likely, you can adjust your approach accordingly and this also allows the operating theatre staff to prepare properly for the intervention.'

Since all implants are not always available in a hospital, pre-surgical planning can ensure the right one is. However, the trauma surgeon must make decide on the dcorrect implant – the length, for example, from a list suggested.

Dr Schröter says the software also enables young doctors to feel what the fracture is like, i.e. what the shift is and which implants are possible.

Varus deformity and simulation of a double osteotomy for deformity in distal femur and proximal tibia.

With its osteotomy module, PreOPlan also supports surgeons in deformity corrections – through prior measuring and with all joint angles shown in a table, PreOPlan has the European CE mark and is already in use in many countries here, with all Finnish trauma centres using this system.

Light that throws no shadows

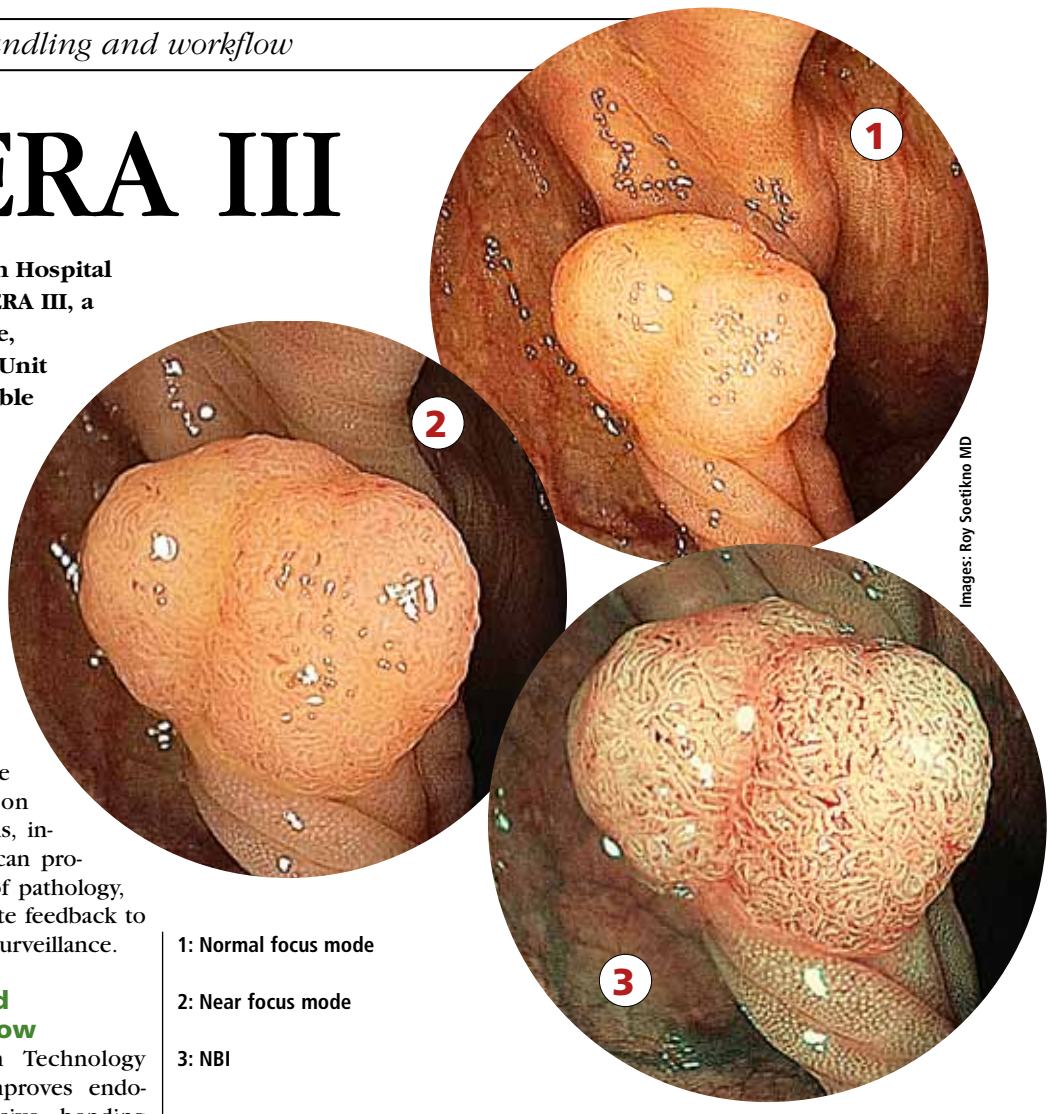
Designed for diagnostics, minor surgery and universal applications, the Soled LED examination light is a helpful tool for use in intensive care units, the recovery room, for first aid and more.

The model supplements the Starled Series range of lamps manufactured by ACEM Medical Company.
The firm explains that this flexible product assures 'excellent light intensity, IR-free light beam, colour temperature (CCT) of 4.900°K, colour rendering index (CRI) of 95, long life and low power consumption. 'The high technological level combined with the use of high-powered LEDs allow it to have a very linear yield and a negligible performance decay for its entire life duration,' ACEM points out.
The Soled LED has a light intensity of 65.000 lux and a low power consumption (35W). The easy-grip removable and handle can be sterilised, so is suitable for critical sanitary applications, the firm notes. The lighting is available for ceiling, wall or trolley mounting.
Details: www.acem.it

Olympus advances endoscopic visualisation, handling and workflow

The new EVIS EXERA III

Major developments in endoscope technology were at the top of the agenda when European Hospital editors visited the European headquarters of Olympus in Hamburg, Germany. The EVIS EXERA III, a recent portfolio addition, makes significant contributions to quality and productivity in care, explained Olympus representatives *John Cobain*, Group Leader Gastroenterology, Business Unit Gastroenterology and Respiratory Endoscopy, and Mirko Feuring, Product Manager of Flexible Endoscopy for Germany, Austria and Switzerland.



Images: Roy Soetikno MD

1: Normal focus mode

2: Near focus mode

3: NBI

Image quality obviously plays a vital role in endoscopy. Thus, according to John Cobain, the new features developed for the EVIS EXERA III open up opportunities in diagnosis and treatment. Clearly detection is a key area, with the discovery of even the smallest lesions optimising patient care, and increased detection rates leading to reduced time spent on procedures.

Characterisation is another important area. Supporting the physician in determining a diagnosis and treatment cuts the cost for pathology. Better images positively affect quality control and accelerated digitisation facilitates documentation.

It's all about the image

New image-related developments built into the EVIS EXERA III are dual focus, brighter Narrow Band Imaging (NBI), and pre-freeze. Dual focus is a two-stage optical technology that allows the user to select the position of the focal lens. The physician optimises the required depth of field to normal mode (5-100 mm / 170°) or near mode (2-6 mm, 160°). In normal mode, the highest resolution, wide field of view and the depth of field support detection, whereas in near mode the increased resolving power enhances in-situ characterisation. The depths of field of these modes overlap, facilitating their use. This, John Cobain emphasised, presents major advantages over zoom endoscopes. With the latter in tele mode, the depth of field is very limited and the field of view is also very narrow; wide and tele modes do not overlap and leave a wide area out of focus. EVIS EXERA III offers 1.5 brighter NBI – enabling twice the viewable distance when observing in NBI mode. The higher brightness of NBI will reduce the need to switch off NBI, and is bound to 'unleash the true potential of NBI for detection', Mirko Feuring pointed out. The pre-freeze function continuously stores acquired video footage; the least blurred frame is selected on demand.

Imaging is fundamental to characterisation

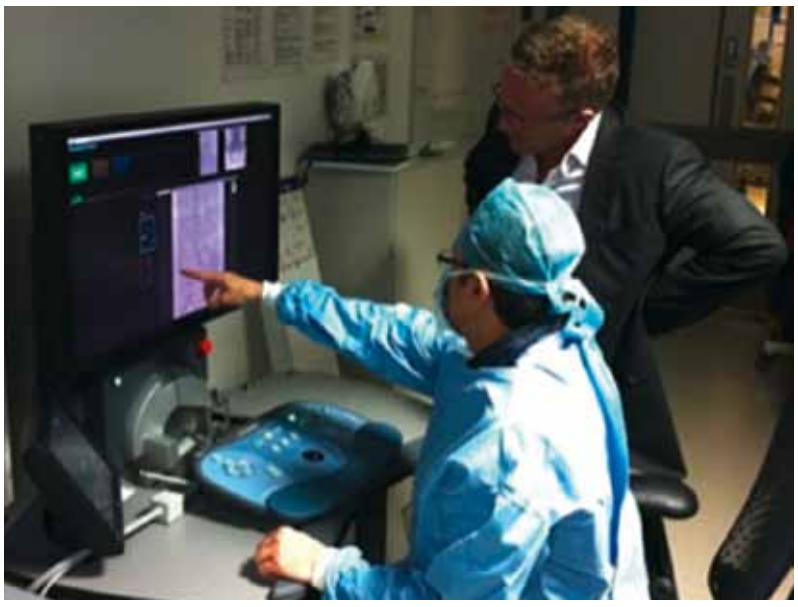
A number of attributes are crucial to optimal characterisation: high resolution near focus; high magnification levels without image deterioration; high contrast, enabling effective enhancement of vessels and pits. Key features of the EVIS EXERA III fulfil these requirements. Essential prerequisites for in-vivo characterisation are precise classification schemes; on this basis, in-vivo characterisation can provide faster diagnosis of pathology, and provides immediate feedback to the patient regarding surveillance.

Better control and optimised workflow

Responsive Insertion Technology (RIT) significantly improves endoscope handling. Passive bending integrates a passive, non-controllable bending section proximal to the active, controllable, distal bending section on PCF and CF scopes. This allows smooth passage through acute flexures or difficult anatomy. In contrast to standard scopes, High Force Transmission (HFT) efficiently transfers torque and lateral forces along the insertion tube, even when angulated. The endoscope comes with a new data management platform that supports staff in their work. Pictures in JPEG or TIFF format can be stored on USB media, allowing for review and comments. 'Thanks also to IT connectivity for data sharing with clinical and administrative departments,' added Mirko Feuring, 'EVIS EXERA III is an interoperable, future-proof investment.'

Magellan is quick and good for complex ops

Surgeons at a leading UK hospital are pioneering robotic endovascular surgery to treat patients with complex conditions.



NICK CHESHIRE

Mark Nicholls reports

Earlier this year, in a world first, a team at St Mary's Hospital in London – which is part of the Imperial College Healthcare NHS Trust - used Hansen Medical Inc's Magellan (TM) Robotic System to treat a patient with a complex abdominal aortic aneurysm. Now, vascular surgeons are using the system for other procedures in trials to assess the full potential of the equipment. Professor Nick Cheshire, consultant vascular surgeon and head of circulation and renal sciences at Imperial College Healthcare, said the new robotic system used for endovascular surgery is a smaller version of those initially designed for heart surgery.

The Magellan robotic system is controlled from a workstation outside the operating theatre and displays the patient's blood vessels on a screen, allowing the clinician to navigate through them with a flexible robotic catheter. The clinician can steer the catheter and position its moveable tip and joints to access the patient's peripheral anatomy. Professor Cheshire explained: 'You can flex the tip almost to 360 degrees, which means you have the ability to put the catheter where you want it and then push a wire into the right place. It is so much easier than with a standard shaped catheter.'

The Hansen system being used by the Imperial team is still the only one in use in the world at present and while its full potential for vascular surgery is still being assessed, a number of early advantages have already been identified. The Imperial team has worked closely with Hansen Medical to develop the endovascular robot system and Prof. Cheshire said the operation to treat a patient with a complex abdominal aortic aneurysm (conducted in January) was a significant step forward and one where the system showed a clear advantage. He explained that such cases often required a tailor-made graft for the individual with a complex series of movements to successfully fix it in place, which can often take several hours using manual techniques with a risk of potentially damaging the wall of patient's blood vessels. However, Professor Cheshire said: 'We found the robot was significantly quicker and more accurate and we see its biggest advantage is in treating very complex cases where there is a complex series of movements. The easier steer-ability through the vascular tree will also allow many more surgeons to be able to do these complex techniques. As a result more patients will be able to have these complex procedures because there will be more people able to do them with this robot assistance.'

The reduced time it will take for such procedures – compared with often more than six hours using ordinary techniques - means the surgical team is in front of the radiation source for less time, cutting radiation exposure. In the January operation, from which the patient made a good recovery, Professor Cheshire said it took one and a half hours to cannulate the vessels on the right side using traditional manual techniques and only 15 minutes to do the left with the robot. Since then, the team has regularly used the Magellan robot system to further discover its potential in lower limb ischaemic cases, embolisation of uterine fibroids and renal artery angioplasty, and is now looking at the potential for carotid artery work to prevent stroke.

The equipment costs USD 1.2-1.5 million, plus the cost of single use steerable catheters, but the team believes quicker procedures with the robot, meaning reduced lab time, may ultimately offer cost savings to hospitals, as well as less radiation exposure for clinicians. Formal trials are being conducted with the Hansen Medical Inc's Magellan (TM) Robotic System, particularly with complex aneurysms, where the team will use the standard technique on one side and the robot on the other and will accurately measure time and radiation exposure. Professor Cheshire also points out that patients who undergo an endovascular procedure typically have a shorter hospital stay – with an average recovery time of five days compared with 10 or longer for open surgery.

'The robot is one piece in a much bigger picture of the promotion of endovascular surgery,' he said, 'and we believe there is plenty of evidence to support the statement that endovascular surgery is better for everybody - surgeon, patient and health system.'

Bruce Barclay, president and CEO of Hansen Medical added: 'Hansen Medical's new Magellan robotic system is the first such system specifically designed for peripheral endovascular interventions. It is designed to be flexible and versatile, allowing physicians to use it for complex catheter procedures.'

EUROPEAN HOSPITAL @

WWW.EUROPEAN-HOSPITAL.COM

ESC CONGRESS 2012

NEWS AND TECHNOLOGY UPDATES FOR CARDIAC CARE

MUNICH • GERMANY 25-29 AUGUST 2012

Teamwork works well in Hamburg

One heart – One Team, the motto for this year's German Society for Thoracic and Cardiovascular Surgery Congress emphasises that cardiac surgeons and cardiologists must now work more in tandem for their mutual patients. This is not just a short-lived three-day slogan, but a daily reality at the University Heart Centre Hamburg, as EH correspondent *Holger Zorn* reports

PD Dr Hendrik Treede is a cardiac surgeon, senior consultant and Director of the Minimally Invasive Surgery Programme and Surgical Director of the Interventional Valve Programme at the University Heart Centre Hamburg. Beyond his clinical work he is a Principle Investigator for several studies to evaluate new devices and techniques for the interventional treatment of structural heart disease. He has published more than 70 peer-reviewed articles and is regularly invited to join the faculty of international cardiac surgery and cardiology conferences.

At the University Heart Centre Hamburg (UHZ), an enterprise of the University Hospital Eppendorf (UKE) led by heart surgeon Professor Hermann Reichenspurner and cardiologist Professor Stephan Blankenberg, it is particularly touching to observe this. 'When the UHZ was founded in January 2005,' consultant Dr Hendrik Treede says, 'we wanted to care for and treat all patients with heart problems under one roof – from infants to the aged, out- and in- patients.'

New therapies, nowadays almost forcing cardiologists and cardiac surgeons to work together, were not even established then. For instance, the first transapical aortic valve replacement (TAVI; see EH 2/11 p. 8 and EH 2/12 p 8) received CE certification in 2007 (SAPIEN, Edwards) and the first transcatheter mitral valve intervention (TRAMI, see this issue) in 2008 (MitraClip, Abbott).

Meanwhile, the UHZ is now not only among the pacemakers in the introduction of interventional procedures to treat diseased heart valves, but also in the development of hybrid interventions, i.e. simultaneous interventional and open heart surgery, or minimally invasive treatment of heart and cardiovascular diseases. Two things make this success: the people who work here and the technology they utilise.

The people

'But we are a team' is heard repeatedly across the UHZ premises – not only in the treatment rooms but also in the pre-operative areas, the staff break rooms or even in the goods in area. It is a statement not only heard by patients when they attend the joint admission interview but also used amongst colleagues in the same way that people elsewhere might say 'nothing to do with me'.

It is a statement that stakes a claim, an expectation of the standards for day-to-day work. Ultimately, it is a statement that must be lived on a daily basis if it is not to turn into an empty phrase. 'We surgeons cooperate with interventional procedures, the cardiologists cooperate with surgery – and this has not even been considered as the breaking of a taboo for quite some time now,' Dr Treede, says, pointing out the statement's benefit also in training future generations of doctors. In times to come, will probably have 'cardiac interventionalists' who specialise in the treatment of heart valve and coronary disease, or dysrhythmia.

Interventional aortic valve replacement in the hybrid operating theatre at the University Heart Centre Hamburg. The centrepiece of the Hybrid-OT is a Monoplane-DSA (a). The heart surgeon crimps the new heart valve (b). The cardiologists deposit it in the aortic valve position (c). The patient tolerates the procedure well (d).

The technology

The structural basis for these capabilities is the hybrid operating theatre. It combines the classic operating table and high quality anaesthesia workstation with a digital Monoplane X-ray system. Interventions on heart valves are not the only procedures jointly carried out by cardiologists and cardiac surgeons there. Vascular interventions on the aorta, such as endovascular aneurysm repair (EVAR), thoracic endovascular aneurysm repair (TEVAR), or fenestrated endovascular aneurysm repair (FEVAR), are also carried out in the hybrid operating theatre. 'Everything that can be imaged by the Monoplane DSA system is done better than in a conventional operating theatre,' Dr Treede explains, adding his regrets that the German medical reimbursement system is not keeping up with these new capabilities.

Multi-vessel coronary artery disease for instance could be operated on very elegantly in the hybrid set-up. The left main stem would be anastomosed with an artery extracted from the chest wall with its quality immediately being radiologically assessed. The stenosis in the other coronary vessels could be dilated interventionally and stented during the same procedure – however, such an interdisciplinary treatment concept – requiring the patient to attend hospital only once – is not yet part of the German DRG-System.

Could bone marrow cells prolong life? BAMI intends to find out

Acute myocardial infarction

Report: Mark Nicholls

Recruitment of 3,000 patients will begin across the EU later this year for the BAMI (Bone Marrow Cells in Acute Myocardial Infarction) study, which will test whether stem cells taken from bone marrow and administered after a heart attack will prolong life. Although earlier trials showed positive indications for stem cell therapy in this area, the new study aims to provide a definitive answer as to whether the cells will work specifically in this treatment.

Funded by €5.9 million from the European Union Seventh Framework Programme for Research and Innovation (FP7), the trial is led by Professor Anthony Mathur and colleagues from Barts Health NHS Trust in London and Queen Mary, University of London NIHR Cardiovascular Biomedical Research Unit.

Eighteen partners across eleven EU countries are also participating in this the biggest and most comprehensive five-year trial of its kind in the world. Centres taking part include those in Frankfurt, Hannover, Rome, Copenhagen, Oslo, Rostock, Katowice, Leuven and King's College Hospital in London and University College London (UCL). It is also hoped that more centres across Europe will join. Professor Mathur, confirmed that the trial is 'still in the planning stage', adding: 'Our studies will tell us if adult stem cells in bone marrow can repair damaged hearts and, if so, how these cells should be administered to patients.' He also added that more clinical centres are needed for the trial as it works to recruit the 3,000 patients, researchers are keen to hear from clinical centres interested in

continued on page 2

Interview: Professor Rafaelle Bugiardini, University of Bologna

A woman's heart too often kills her

The biggest cause of death for most adult women in industrialised nations is coronary heart disease (CHD). Why the disease affects the genders differently is still not fully understood. European Hospital Editor *Brigitte Dinkloh* asked Professor Rafaelle Bugiardini MD FESC, from the Department of Internal Medicine Department, University of Bologna, whether he could explain the reasons and what can be done to improve women's chances to live

What impedes greater understanding of the variations in coronary artery diseases in males and females?

Prof. Bugiardini: For statistical purposes, clinical presentation is of special importance. The pain that women develop is often atypical, which frequently leads to misdiagnosis. It could be the tendency towards over interpreting the relevance of the typical case. It's the kind of phenomenon that the psychologist Daniel Kahnemann discusses in his bestseller 'Thinking Fast and Slow'. It's often difficult to keep in mind the statistical reality behind the vivid, salient impression of the individual case. A strong, immediate impression – or lack of it, in this instance – can be very deceptive.

In a survey conducted by the American Heart Association, just half of the women interviewed knew that coronary heart disease is the leading cause of death in their sex. Other survey data suggest that, on a day-to-day basis, women still worry more about getting breast cancer, even though coronary heart disease kills six times as many women every year.

In addition, doctors only occasionally talk to women about coronary risk and they sometimes don't even recognise the symptoms, mistaking them instead for signs of panic disorder, stress and even hypochondria. Accordingly, the clinical reality is often like this: you see the female patient, you are uncertain about the disease because it doesn't correspond to what you expect of coronary problems, you place the patient in a hospital, but without prescribing the most beneficial medications. After a few days, the clinical picture becomes clear and you make the correct diagnosis. You realise that a female patient is very often falsely diagnosed at the beginning of their treatment.

Therefore, when you look at the statistics, you see that women are much more likely than men to die within a few weeks of having a heart attack, but you have to remind yourself that women are given less medication than men because the diagnosis is often made at discharge rather than admission to the hospital.

Could that situation be improved?

We'll reach the critical point when men and women receive more equal, i.e. more accurate treatment. Beyond that critical point we'll begin to gain a clear understanding of whether the physiological differences between the genders are really responsible for the statistical gap. When preparing the statistics researchers often don't take into account that female patients aren't treated with the right medication at the right time.

Statistics can be deceptive. The outcomes of studies may be partially influenced by the fact that there is still a gap when it comes to prescribing the appropriate medication. Women also don't seem to fare as well as men after taking antiplatelet or anticoagulant drugs, or undergoing certain heart-related medical procedures.

Research is only now beginning to uncover the biological, medical and social bases of these and other differences between men and women. We need a huge campaign by the European Society of Cardiology – a huge effort supporting further studies. It's crucial to provide training for physicians to employ a more severe, aggressive approach towards women who present themselves to a hospital admission system.

What are the differences that trigger such misunderstandings?

Generally people may be confused because women are more affected when they are older. It would be extremely naïve to think that differences in outcomes could be simply due to an older age. In reality, there are many biological and pathophysiological factors that are not the same in the two genders. Low HDL and high triglycerides appear to be the only factors that increase the risk of death from heart disease in women over 65 years old. Women who smoke are twice as likely to have a heart attack as male smokers. Women have smaller and lighter coronary arteries than men, which makes angiography, angioplasty, and coronary bypass surgery more difficult. The atherosclerosis progresses more toward the adventitia than the lumen. Consequently, women suffer from non-obstructive coronary disease more than men. Women are also more likely to contract endothelial dysfunction, which makes them more susceptible to a lot of triggering vasoconstrictor factors. It should be noted that to suffer from non-obstructive coronary disease does not, however, mean the patient suffers from benign disease. You can still develop thrombosis and myocardial infarction.

In conclusion, most of our ideas about cardiac disease in women used to come from studying it in men. However, there are many reasons to think that it's different in women. This is a vexing problem and I truly hope we'll be able answer the questions satisfactorily in the near future.

The potent cardiac depressant in our own homes

Scientists state concern for both human and environmental health from a very commonly used antibacterial/antifungal age

Brenda Marsh reports

Triclosan, an antibacterial, antifungal agent, arrived in our homes and general environment 40 years ago. It is an additive in innumerable personal hygiene products – toothpastes, deodorants, soaps, shaving creams, detergents, cosmetics, toys, fabrics, bedding, plastics – the list is endless. The agent is also used by hospitals as to combat MRSA infections – a recommended addition of 2% triclosan to showers and baths for affected patients.

Recently the chemical, regulated by the USA's FDA, the Environmental Protection Agency and the EU, has been under review by the FDA and Health Canada. Now researchers in California have found that triclosan (TCS), a high-production-volume chemical, is a priority pollutant of growing concern to human and environmental health. According to their findings, published online in Proceedings of the National Academy of Sciences of the USA (PNAS August 13, 2012, doi: 10.1073/pnas.1211314109) the chemical was found to hamper muscle function in animals and fish. The study results have strong implications – particularly for cardiac care. 'We report that TCS impairs ECC of both cardiac and skeletal muscle in vitro and in vivo,' the authors write in the study abstract. 'TCS acutely depresses haemodynamics and grip strength in mice at doses ≥12.5 mg/kg i.p., and a concentration ≥0.52 μM in water compromises swimming performance in larval fathead minnow. In isolated ventricular cardiomyocytes, skeletal myotubes, and adult flexor digitorum brevis fibres TCS depresses electrically evoked ECC within ~10–20 min. 'In myotubes, nanomolar to low micromolar TCS initially potentiates electrically evoked Ca2+ transients followed by complete failure of ECC, independent of Ca2+ store depletion or block of RyR1 channels. 'TCS also completely blocks excitation-coupled Ca2+ entry. Voltage clamp experiments showed that TCS partially inhibits L-type Ca2+ currents of cardiac and skeletal muscle, and [3H] PN200 binding to skeletal membranes is noncompetitively inhibited by TCS in the same concentration range that enhances [3H]ryanodine binding. 'TCS potently impairs orthograde and retrograde signalling between L-type Ca2+ and RyR channels in skeletal muscle, and L-type Ca2+ entry in cardiac muscle, revealing a mechanism by which TCS weakens cardiac and skeletal muscle contractility in a manner that may negatively impact muscle health, especially in susceptible populations.'

If that sounds too scientific, comments among the study's 13 co-authors are more straightforward in their message. For example, Professor Bruce D Hammock, at the Department of Entomology, University of California Davis, said: 'We were surprised by the large degree to which muscle activity was impaired in very different organisms and in both cardiac and skeletal muscle. At the very least, our finding call for a dramatic reduction in its [TCS] use.' Cardiovascular specialist Professor Nipavan Chiamvimonvat, also at UC Davis, and another co-author, said: 'The effects of triclosan on cardiac function were really quite dramatic. Although triclosan is not regulated as a drug, it acts like a potent cardiac depressant in our models.'

Principal investigator Professor Isaac N Pessah, at the Department of Molecular Biosciences, UC Davis School of Berinary Medicine, said: 'Triclosan is found in virtually everyone's home and is pervasive in the environment. 'These findings provide strong evidence that the chemical is of concern to both human and environmental health,' he concludes.

Acute myocardial infarction

continued from page 1

contributing patients and researchers are keen to hear from clinical centres interested in contributing patients.

Initially half of the 3,000 patients will have their own stem cells taken from their bone marrow and injected into their heart within five days of suffering a heart attack. The remainder will undergo conventional therapy.

'This study is designed to see whether we can achieve a 25% reduction in mortality at two years,' Prof. Mathur explained. Other associated studies will look at mechanistic explanations of what is happening, but the fundamental study is designed to demonstrate this mortality reduction. 'What we want to do is find out whether cell therapy will make people live longer and with a better quality of life; we want to address whether, in its very early and easiest form, the use of adult stem cells has a mortality benefit. 'It is an ambitious study, but one that will really answer the question about the role of stem cell therapy in its current form.' Professor Mathur's team has been conducting stem cell trials since 2005 in various groups of patients who have had heart attacks, those with established heart failure and those with dilated cardiomyopathy. But the BAMI trial, one of the first of its kind in translational medicine of this size, follows on from positive indications from similar smaller studies elsewhere – success that was significant in attracting EU funding. Professor John Martin from UCL pointed out that the powerful partnership of European doctors and scientists could solve a fundamental problem of importance to everyone. 'It will answer whether adult multipotential stem cells in their natural environment can treat human disease.'

After a two-year follow-up, participants' data will be analysed to see how many are alive after being in the trial. The trial comes as researchers at the University of Louisville, USA (recently reported in The Lancet) showed that stems cells taken from a patient's heart could be used to repair damaged heart tissue. The team said results from the preliminary trial indicated that cardiac stem cells could 'markedly improve contractile function of the heart'.

* Centres interested in contributing patients to the BAMI study can contact Prof. Mathur at anthony.mathur@bartshealth.nhs.uk

An academic at Queen Mary's Hospital, and Honorary Consultant Cardiologist at Bart and the London NHS Trust, **Professor Anthony Mathur** divides his time between clinical work and basic science aimed at conducting translational research. His PhD focused on platelet and stem cell biology as well as cellular bioenergetics, interests that consolidate his current study of the mechanisms by which stem cells may improve cardiac function. He is Secretary of the ESC Task force on stem cells in cardiovascular disease and chairs the clinical group of the British Cardiac stem cells collaborative by Professor John Martin.

The low-impact alternative to cardiac catheter lab examinations

CT coronary angiography

Cardiovascular diseases, the most common cause of death in the West, includes diseases for which early detection is an important objective in cardiac imaging – particularly for coronary artery stenosis

Diagnosis is often made in the cardiac catheter laboratory. Now, however, CT scanning advances provide a lower impact alternative to that invasive exam. PD Dr Thomas Schlosser, Consultant at the Institute for Diagnostic and Interventional Radiology and Neuroradiology at Essen University Hospital, has shown that the less invasive CT coronary angiography (cTCA) is as good as the cardiac catheter for many indications.

For his cumulative habilitation, Dr Schlosser investigated several problems, including the impact factors for the assessment of coronary stents in CT scanning and analysis of left- and right ventricular functionality from cTCA datasets. Quantification of coronary calcifications via CT also makes conclusions about a patient's risk of a heart attack possible. 'With a technically adequate examination and no pathological findings any narrowing relevant to circulation as well as arteriosclerotic changes in the coronary arterial walls can be safely ruled out, which minimises the probability of a myocardial infarction,' Dr Schlosser points out.

The coronaries can be directly shown during a CT examination – something usually done with invasive coronary diagnostics in the cath lab. During a comparison of both procedures it was possible to show that narrowing of the coronary arteries, leading to reduced mycardial perfusion, can be excluded or detected with high precision via CT.

Most commonly, he says, cardiac cath lab exams find no abnormalities, ruling out coronary disease. 'It's those patients we'd like to examine via CT because we can achieve the same result with high diagnostic precision. As an examination without any abnormal findings remains without consequences in the cardiac cath lab, patients could be spared this exam, which is not without risks,' he explains.

Dr Schlosser's work therefore delivers a further contribution towards establishing CT for cardiac examinations, as defined in the joint guidelines of the German Radiological Society and the German Cardiac Society this year.CT technology advances have mainly contributed to the establishment of CT for cardiac examinations. Apart from the improved spatial and temporal resolution, fewer artefacts and sharper contrast, dose reduction has significantly contributed towards CTA establishment.'Around ten years ago, radiation exposure during CT angiography was around 15 mSv; 5-6 years ago it was still around 7 mSv. With the latest scanners, the dose can be only 1 mSv and below, without any impact on image quality. Radiation exposure is therefore clearly below that of a cath exam, with around 3-5 mSv, and also below the level of annual, natural exposure of around 3 mSv,'

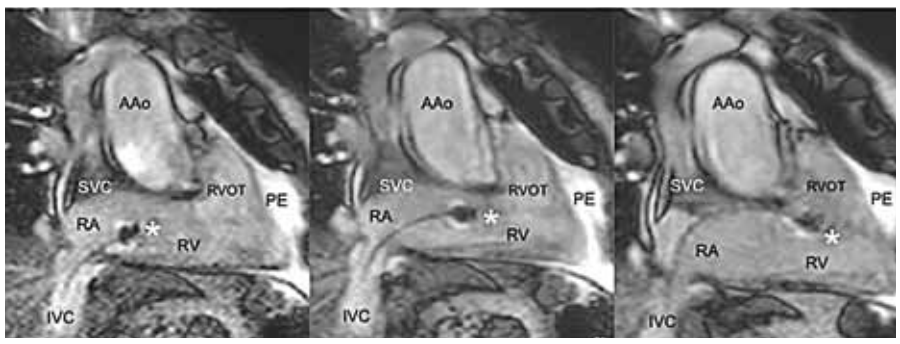
Modern scanners scan in seconds. Dr Schlosser uses a Somatom Definition Flash, Siemens latest high-end scanner with dual source technology (2 x 128 slices).

Dose reduction drives CTCA

Today, initially sceptical cardiologists accept the undeniable advantages of cTCA as an unrivalled, good, non-invasive procedure to assess coronary arteries. Although MRI could image them, 'the procedure is not as robust as with CT,' he says.'MRI is very suitable for imaging anomalies in the vessels, but to detect obstructions of the coronary arteries it is not yet sufficiently refined,' he explains. 'MRI strengths are clearly in the functional analysis of the left and right ventricle and in the imaging of the myocardium, to make smaller scars from myocardial infarctions visible and to determine the perfusion of the heart muscle.'

CT coronary angiography now achieves the same precision in ruling out significant stenosis as the cardiac catheter – both methods are completely comparable. Moreover, the CT can show the very smallest changes in the coronary vessels, i.e. the very beginning of arteriosclerosis. For the last two years or so it has also been possible to show cardiac function and coronary bypasses – with a very low dose of 1 mSv or below.

PD Dr Thomas W Schlosser graduated in medicine from Rheinische Friedrichs Wilhelm University, Bonn, where his focus on radiology rose during his practice year. From 1996-2002 he was one of the working group on experimental and clinical echocardiography at Bonn's University Hospital. He became a resident at the Institute for Diagnostic and Interventional Radiology and Neuroradiology, Essen University Hospital, where he is now Senior Consultant. At the German radiology congress 2012 he received the Wilhelm-Röntgen Prize.



MRI post inferior isthmus ablation: the catheter tip, much of the shaft and curve are visible on the way from the inferior isthmus to the right ventricular outflow tract (RVOT) (from: Eitel C at al. Eur Heart J 2011)

MRI brings a new beat to rhythmology

More anatomy details, real-time visualisation of catheter movement, and reduced exposure – MRI has promising potential in rhythmology, explain Professor Matthias Gutberlet and PD Dr Christopher Piorkowski, at the Heart Centre, University Hospital Leipzig, Germany

Matthias Gutberlet (left) and Christopher Piorkowski

What are the key trends in rhythmology?

CP: Interventional electrophysiology is one of the fastest growing fields in cardiology. Our specialty has evolved from the treatment of rather rare and mostly inborn specific electrical disorders of the heart (such as AV nodal re-entrant tachycardia or WPW syndrome). For these, catheter interventional treatment has been developed as a first line therapy and today can already provide a high cure rate with low complication risks, only little radiation exposure and short procedure times.

During the past decade, however, the face of our specialty has changed. Beyond the treatment of such simple arrhythmias, we have entered the field of routine catheter interventional treatment of endemic arrhythmias such as atrial fibrillation and ventricular tachycardia.

Atrial fibrillation is currently diagnosed in approximately two million patients in Germany. Beyond deterioration in well-being and life quality, the arrhythmia is associated with significant impact on morbidity and mortality. Catheter interventional treatment concepts of atrial fibrillation are rather new and still developing. Currently in Germany, less than 1% of affected patients receive such treatment. In our institution we perform about a thousand of these ablation procedures per year.

The second rapidly growing indication for catheter ablation is the treatment of ventricular tachycardia. The affected patients are mostly patients suffering from heart failure – one of the leading causes of death in western nations. These patients develop life threatening ventricular arrhythmia subsequent to their underlying cardiac disease. Successful treatment of such arrhythmias may have an impact on the survival prognosis of these patients.

Nowadays, the treatment of these endemic arrhythmias accounts for more than 60% of the cases in high-volume centres of interventional electrophysiology.

What are the current challenges in rhythmological therapy?

CP: Interventional therapy of atrial fibrillation and ventricular tachycardia follows novel, complex, and extensive ablation approaches which were developed during the past 10 to 15 years and are still subject to further improvement. The advanced focus on procedural aspects of therapy delivery and the pathophysiological understanding of the underlying electrical abnormality.

One should bear in mind that even today, the respective procedures are still time consuming, radiation intense and manually difficult to perform. The challenges relate to aspects of 3-D and 4-D catheter visualisation in a moving target organ, variations in individual patient anatomy, and uncertainties of successful and uncomplicated delivery of ablation energy into the target tissue. These difficulties clearly have impact on treatment success and recurrence rates.

On top of that we are still learning new aspects of the pathophysiology. According to our current understanding, both these endemic diseases are largely caused and influenced by cellular and sub-cellular myocardial tissue changes, which represent a morphological substrate of the electrical disease. As an illustration, currently we focus on the detection of scar and fibrosis constituting the ground for areas of slow conduction that have the potential for electrical re-entrant formation (tachycardia development) in the atrium as well as in the ventricle. Better appreciation of such disease processes could give us the possibility to tailor our extensive ablation approaches to the actual needs of the individual patient.

How can MRI help?

MG: Interventional procedures in rhythmology, such as EP and ablation, can be rather time-consuming also due to corresponding long fluoroscopy times, and can involve high radiation exposure for the patient and the interventionist. MRI helps reduce exposure for patients and staff – at least in the present transition period in which a fluoroscopy or X-ray backup is necessary. Furthermore, besides a fluoroscopy-free working environment, interventional procedures guided by real-time MRI may have benefits in providing more detailed insights into the target anatomy, and tissue properties relevant for pathomorphology as well as for therapy. This can have a major impact on patient outcome.

With MR imaging techniques already in routine use for the visualisation of acute infarction or inflammation, e.g. oedema and scar imaging, it may also be possible to assess atrial tissue properties prior to, during, and after RF ablation. This can be of significant relevance to the electrophysiologist when treating patients with, in particular, complex arrhythmias, and may constitute a further step towards a more 'personalised' treatment in rhythmology over all.

We are not sure as yet about the added value MRI-guided ablations will provide in the end. Our first experiences with MR-guided EP-procedures and published data from other groups in the area of image guided therapy lead to the following hypothesis: being able to see the catheter within the real cardiac anatomy – instead of merely a 'grey fluoroscopy shadow', as described once by Dr Piorkowski – may indeed facilitate interventional procedures.

Please demonstrate.

MG: In the case of a 70-year old male after successful inferior isthmus ablation, the catheter tip, much of the shaft, and also the curve are visible on the way from the inferior isthmus to the right ventricular outflow tract (RVOT). We used a real-time CINE MRI sequence (commercially available) in a standard right anterior oblique (RAO) orientation.

How can MRI be integrated into the workflow of planning and carrying out the therapy?

MG: An MRI, or more frequently, a CT scan used to visualise atrial anatomy is already a standard procedure, and therefore already integrated in the workflow of therapy planning in rhythmology usually performed in the radiology department. The acquired images are transmitted to the EP navigation system, e.g. Carto, and merged with imaging data from the ablation system during the EP study or ablation therapy. This is done by the electrophysiologist in the rhythmology department.

If it was possible to perform a complete ablation procedure – from access site puncture to complete catheter navigation, ablation monitoring, and assessment of the primary success – in the MR environment, this would definitely ease the workflow and bring the two disciplines radiology and rhythmology closer together.

FAME 2 rates F a new gold sta

John Brosky **reports on a ground-breaking trial and how CT-FFR may change the practice of invasive cardiology and cardiac surgery**

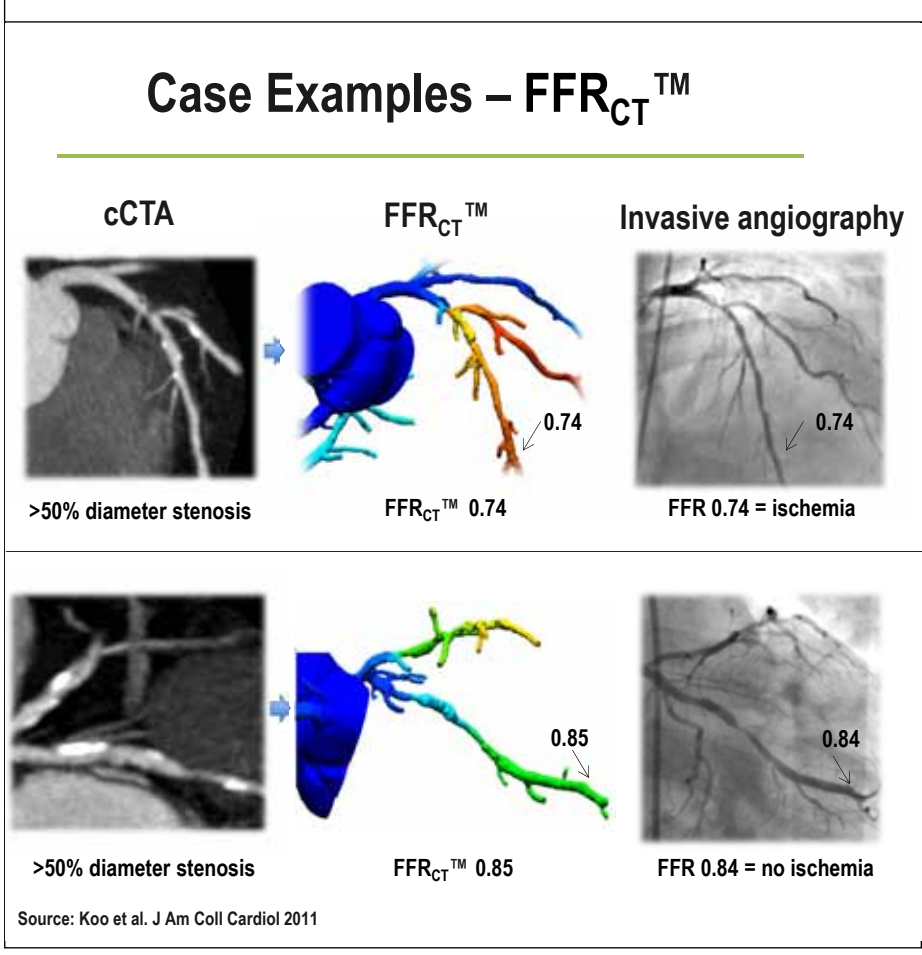
Watching the grey angiography images of a beating heart, it is often clear where arteries are pinched or blocked. The temptation is to re-open each lesion with angioplasty and then place a stent to be sure the artery stays open. This seemingly safe-sounding approach turns out to be excessive, leading to unnecessary stenting. First, cost to the healthcare system for the procedure is high. Then there is risk for patients, as cardiologists agree implanting a stent to fix coronary artery disease is equivalent to implanting a new disease with the risk of in-stent thrombosis. Now, however, thanks to a technique called fractional flow reserve (FFR), each artery can be evaluated to determine which of the pinch points is actually the 'culprit lesion' causing the patient's distress. Using a pressure-sensitive tip on a guide wire, the cardiologist can measure blood flow on either side of the lesion. In January 2009 the New England Journal of Medicine published results from the clinical trial, Fractional Flow Reserve versus Angiography for Guiding PCI in Patients with Multivessel Coronary Artery Disease (FAME), showing that the FFR measure significantly improves clinical outcomes. Put into practice, FFR also reduced the excessive stenting of patients.

The follow up clinical trial FAME 2, which compared use of FFR against managing patients with medications, proved to be so good that it had to be stopped. Enrolment in the trial was halted as the independent data safety monitoring board concluded it was unethical to randomise patients away from the arm of the study offering fractional flow reserve (FFR). The board found a highly statistically significant reduction in the need for unplanned hospital readmission and urgent revascularisation when FFR-guided assessment was used to direct treatment in patients with coronary artery disease. David Holmes MD, the recent president of the American College of Cardiology (ACC), commented, 'FAME 2 tells us to treat ischaemia and not lesions. It is a ground-breaking trial that changes clinical practice.' Endorsed with the highest recommendation in the European Society of Cardiology guidelines, FFR is now the gold standard for a clinical decision to treat coronary lesions with stents.

Drug-Free FFR

Although the high profile success of FAME has greatly boosted sales of FFR systems, despite its effectiveness FFR is not widely used. In the USA, for example, its use is estimated to be less than 10% of stenting decision-making. A key reason is that as a patient is at rest during the procedure, the physician needs to inject the pharmaceutical stress-maker adenosine to simulate heart function and simulate chemically the pressure levels detected by FFR. The drug is contra-indicated for a significant number of conditions and, for acute patients, the ones where a decision on multiple stenting needs to be made quickly. In November 2011, a team from Imperial College, led by Justin Davies MD and Sayan Sen MD, presented an alternative technique for measuring the severity of a coronary stenosis, which is similar to FFR. Called Instant Wave-Free Ratio (iFR) it does not require a pharmaceutical boost for a pressure-derived index scoring system. The multi-centre ADVISE study assessed 157 stenoses in 131 patients, demonstrating an overall diagnostic accuracy of 88%.

In May 2012, at EuroPCR in Paris, Dr Davies presented a registry of 339 patients from the ADVISE study where he claimed a 94% diagnostic accuracy for the new technique, iFR. He concluded that adenosine does not add



FFR as ndard

any incremental benefit to the diagnosis. He said that iFR is easier to use, can be indicated for far more patients, and makes the procedure faster. 'The work on FFR has been fantastic,' he said. 'But today we are in a different era with computational power that did not exist when the FFR calculations were developed.'

Making a quantum leap in processing power to the level of a super-computer brings a new method of 'virtual FFR' for measuring the severity of coronary lesions Software developed by a team from Stanford University (Palo Alto, California) has demonstrated that a haemodynamic modelling of the heart created on a supercomputer using digital data from a common CT scan can accurately identify vulnerable plaque formations.

Virtual FFR with any CT

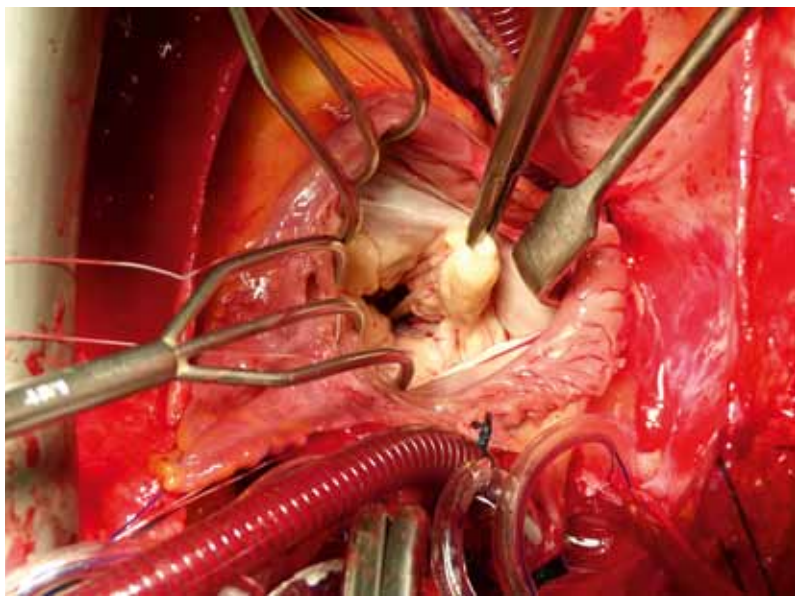
The virtual CT-FFR technique being brought to market by the start-up firm HeartFlow (Redwood City, California) presents a non-invasive, desktop alternative with a point-and-click capability to read FFR for a specific patient in any coronary artery on a 3-D map of the heart, rather than one-by-one while the patient is lying on the cath lab table. HeartFlow won the Innovation Award from the Board of EuroPCR in 2011, which found CT-FFR to be 'potentially disruptive to the diagnosis and treatment of patients with stable ischaemic heart disease . . . [and] it may change the practice of invasive cardiology and cardiac surgery.'

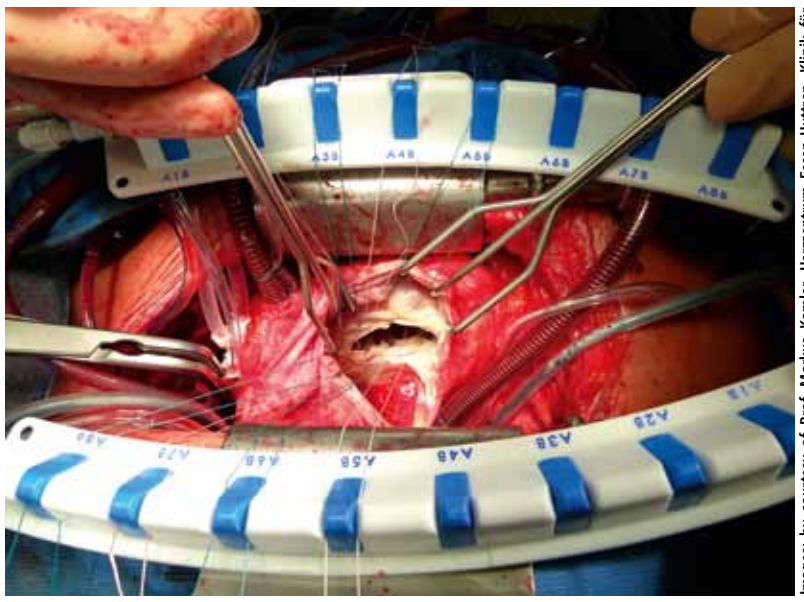
To obtain a virtual FFR exam, a radiologist uploads a 20 megabytes file with the raw DICOM data from any CT coronary exam. There is no need to run an additional exam, any recent data set will do. Five hours later the radiologist receives from HeartFlow a 3-D dynamic flow map of the patient's heart generated by the super computer. According to HeartFlow CEO John Stevens, 40 million coronary diagnostic tests are ordered annually worldwide, 24 million in the USA alone. The cost for the service 'will be vastly less expensive than going to a cath lab and measuring FFR,' he said. Yet, the target for virtual FFR is not necessarily FFR. He pointed out that a pre-operative CT-FFR assessment might prove an alternative to other non-invasive tests for assessing coronary artery disease – such as stress echo or nuclear medicine. 'Stress echo, SPECT and CTA,' he said, 'are suboptimal examinations compared to FFR, which has proven to be so precise and today is so valued as a tool.

'We need to do a lot better with the number of coronary studies and the accuracy of these exams.'

Two case examples of patients with >50% coronary artery stenosis on cCTA but in one case with ischemia (top) and in the other without ischemia (bottom). Note the close correspondence between FFR_{CT}™ and invasively-measured FFR. Non-invasive FFR_{CT}™ is computed from conventional cardiac CT angiography images and can be determined throughout the coronary tree.

Images by courtesy of HeartFlow, U.S.A





Images: by courtesy of Prof. Markus Kamler, Herzzentrum Essen-Huttrop, Klinik für Herzchirurgie, Essen, Germany

Advances in mitral valve replacement

Initially limited to the aortic valve, interventions are becoming routine for the mitral valve. Thus the only available product has enjoyed huge commercial success – until now.

Report: Holger Zorn

In May 1925, at The London Hospital, when British surgeon Henry Souttar attempted surgery and used his finger to open a patient's severely blocked mitral valve he was able to refute the then popular view that no disease affected heart valves. Nonetheless, for several decades referring cardiac specialists has been ignoring him and his epoch-making intervention, letting rapid developments in heart surgery take their course for the rest of the century.

Unintentionally, therefore, Henry Souttar probably has the honour of being the only cardiac surgeon ever to have achieved a 100% success rate.

Cardiologists are now recapturing that ground. Holes in the cardiac septum are closed and thrombosis in the atrial auricles is occluded with interventional procedures. Surgeons open blocked valves, fit new ones in the aortic position (TAVI) and increasingly venture towards treating mitral valve insufficiency (image).

Sowmya Rajagopalan, Programme Manager for Medical Devices at the markets consultancy Frost & Sullivan, remembers: 'Ironically, in 2000 it was predicted that interventional mitral valve therapy would grow more rapidly than interventional aortic valve therapy, but it proved otherwise.'

With hindsight this appears to be logical because mitral valve insufficiency (MI) – the inability of both leaflets to close properly – is not noticed by patients over a period of several years and only leads to severe cardiac insufficiency at a very late stage.

Treated with drugs, the disease has a ten-year survival rate of 60% whilst symptomatic, high grade aortic valve stenosis – the main indication for catheter-guided implantation of an aortic valve (TAVI) – has a ten year survival rate of only 10% with conventional treatment. Therefore, the pressure to do something, along with the clinicians' interest as well as the medical devices industry, was obviously more pronounced here

However, interventional mitral valve repair still has a future, although it is very unlikely to replace the conventional surgical procedures in the next 5 years at least. 'It is important to understand that specific types of patients who will most benefit from these interventional mitral valve therapies have to be established,' Sowmya Rajagopalan explains.

Currently only one product that is supported by data from clinical studies is accepted by interventionists – the MitraClip from Abbott Vascular, using sutures to mimic edge-to-edge clipping of mitral leaflets.

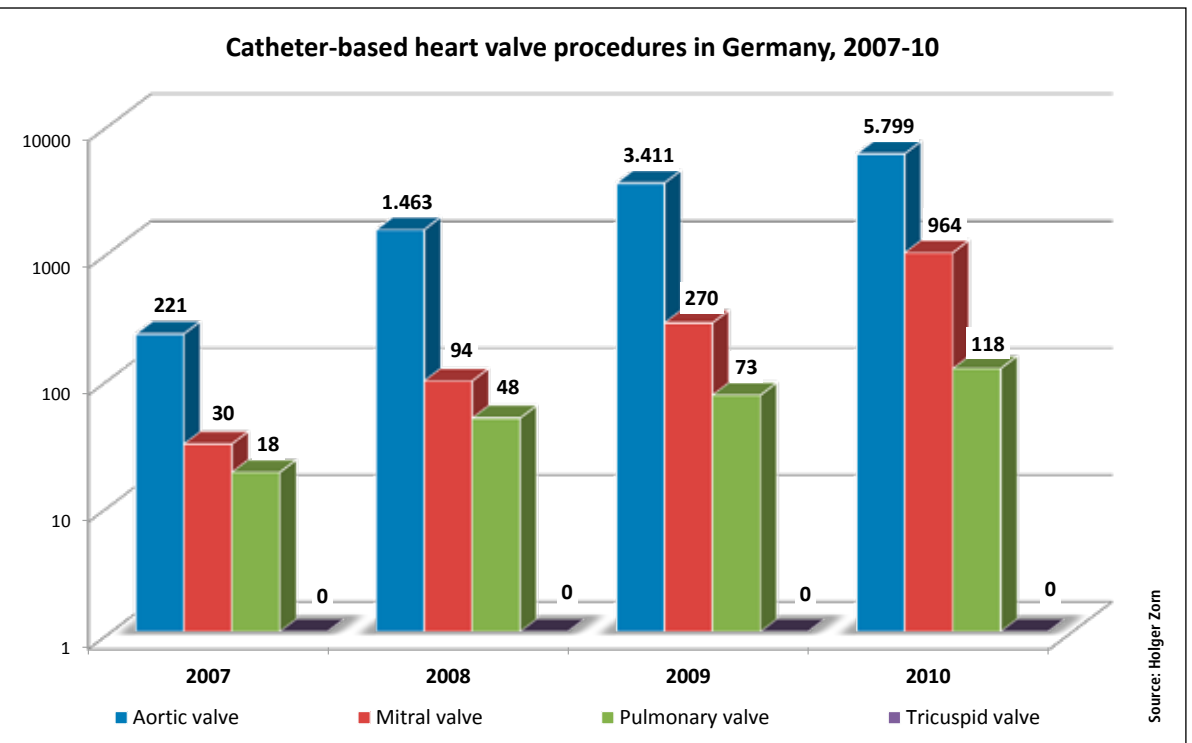
A significant success

Professor Stephan Baldus, cardiologist at the University Heart Centre Hamburg, recently reported clinical results from 486 patients with a median age of 75, two hundred of female (41%), between January 2009 and August 2011. At baseline, 93% of patients were in the New York Heart Association (NYHA) functional class III or IV and 71% of patients had a left ventricular ejection fraction (LVEF) ≤50%. Two-thirds of patients presented with functional MR. 99% of patients were treated with MitraClip, procedural success was achieved in 94% of patients. The periprocedural complication rate was low, with only minor bleedings as the most significant event. In-hospital and post-discharge mortality was 2.5% and 12.5%, respectively [Source: Eur J Heart Fail. 2012 Jun 8. Epub ahead of print]. Presenting these data from the German transcatheter mitral valve interventions (TRAMI) registry, Prof. Baldus believes '…that MitraClip therapy is a viable treatment option in daily clinical routine for high surgical risk patients with significant mitral regurgitation'.

Naturally no long-term data is yet available, but such success does not remain undetected. In 2011, sales reached €26 million in Germany, which in turn encourages competition: Whilst Edwards (Edwards Lifesciences) had to abort the clinical studies on their MONARC device, and St. Jude (St. Jude Medical), on the takeover of AGA Medical, no longer found the then promising company Ample Medical, with its PS3 mitral valve repair system in their portfolio, Sorin (Sorin Group) recently invested in a start-up company that so far has only been able to show the proof of concept in porcine and human models: Cardiosolutions is developing the Mitra Spacer, which is inserted interventionally (transvenously and transseptally) or surgically (transapically) into the mitral valve position and then forms a plug-like closure of the orifice in between the mitral leaflets.

An ambitious time plan is to be implemented with the US$8 million invested by Sorin. In the second half of 2013 the EU safety study will begin with the aim of achieving CE certification for surgical access in 2014 and interventional access in 2015.

Ronald Murphy, Vice President of Investor Relations, is convinced about his concept's advantages. 'Currently, there are several different technologies in development to address mitral regurgitation. Of course all of these technologies attempt to replicate open surgical procedures and involve modifying the native valve structure,' he said, adding: 'The PercuPro System is unique in that it does not alter the structure of the mitral valve, but simply provides a sealing surface for leaflet coaptation. The system provides an adjustable, reversible solution that does not need adjunctive therapy nor does it modify the native valve or burn any therapeutic bridges.'



Catheter-based heart valve procedures in Germany. All interventions show a tremendous increase (logarithmic y-scale). Aortic valve procedures (TAVI) still hold the top spot in absolute numbers. However, mitral valve procedures (TRAMI) hold the top spot in percentage growth. About half of these operations worldwide were made in Germany. Leading hospitals are the Hamburg University Heart Centre with more than 200 and St Georg Hospital Hamburg, Goettingen University Hospital, Brandenburg the Heart Centre and Munich German Heart Centre with more than 100 TRAMI. A personal compilation based on data from the German Federal Statistical Office, the National TAVI registry of the German Society for Thoracic and Cardiovascular Surgery, the National TRAMI registry of the German Cardiac Society, and from Abbott Vascular, Inc. Changes in coding may have caused minor inaccuracies.

Interview: Professor W R Bauer, University Hospital Würzburg

CIED patients can have MRI examinations

A new generation of cardiovascular implantable electronic devices (CIEDs) includes the Implantable Cardioverter Defibrillator (ICD), Cardiac Resynchronisation Therapy Defibrillator (CRT-Ds) and Cardiac Resynchronisation Therapy Pacemakers (CRT-Ps). Professor W R Bauer at University Hospital Würzburg has been significantly involved in their development, EH Editor *Ralf Mateblowski* to ask him about their value in terms of MRI use


Source: Biotronik

The high frequency fields of the MRI scanner are the biggest problem, explained Professor Bauer. 'The electrodes act like antennae, receiving the ultra-short waves and transmitting them to the cardiac tissue. This can lead to overheating and dysrhythmia, and the equipment can also become damaged.

'In our hospital we've been looking into this problem and into further developments of this technology since 2003. However – and this is important to me – we've carried out fundamental research rather than industrial research. For instance, we spent a lot of time and did an endless series of measurements trying to identify the centres in the MRI scanner that are dangerous for patients with pacemakers. We worked out solutions that have been integrated into the configuration of the new electrodes and equipment.'

What prospects does that present?

'The indications for MRI examinations are becoming dramatically more important: MRI scanning is now the imaging procedure with the best soft tissue contrast. It allows functional examinations, is unsurpassed for neurological examinations and for heart and abdominal examinations. Add to this the fact that patients are living longer and longer, which increases the probability of them needing an MRI examination at some stage. This affects around three quarters of patients with these devices who, due to the problems mentioned, were previously excluded from MRI examinations.'

Will some patients still be excluded from MRI exams and are there limitations when dealing with the new CIEDs?

'No, there are no differences to previous solutions regarding handling and features. No adjustments are needed for the implantation, and diagnosis and therapy are not limited – to the contrary.

'There are a few unspectacular exclusion criteria – patients with MRI compatible systems need to be of a certain height and must not be suffering a high fever. The implant should have been in place for six weeks before the first examination, the field strength should be 1.5 Tesla.'

Conversely, would it make sense to exchange CIEDs that are not compatible with MRI before their expected life span ends?

'No. If somebody has a system implanted that works well, I would definitely not exchange it. Taking a new aggregate and connecting it to the old electrodes is not enough because the system as a whole would still not be MRI compatible. The only alternative would be to exchange the electrodes and aggregate before time, but I would advise against this.'

What else is important regarding, for instance, cooperation with radiologists?

'The most important basis for good cooperation is to work as a well-rehearsed team. When radiologists carry out MRI examinations a cardiology team should always be involved in the process, also for the pre-selection of patients. Moreover, cardiologists have the competency when it comes to pacemakers and defibrillators and last, but not least, patients should obviously be looked after by a cardiologist during the examination.'

What is your conclusion regarding the future management of dysrhythmias with MRI compatible CIEDs?

'The new devices are definitely a milestone for cardiology. They link the best, most modern imaging procedure with a growing group of people in need of this technology: The number of patients wearing an ICD or CRT is strongly on the increase. Now we can also help these patients thanks to innovative technology.'

With doctorates in medicine and physics, **Professor Wolfgang Rudolf Bauer** is a consultant at the Centre for Internal Medicine, Medical Clinic I, University Hospital Würzburg, where heads the MRI and Clinical Electrophysiology Department. Beyond patient care, the cardiologist's interests lie in fundamental research into MRI imaging, as seen in the Collaborative Research Centre 688 'Mechanisms and imaging of cardiovascular cell-cell-interactions', as well as in his work as head of the Cardiac MRI and Biophysics research group and the working group with the same name based at the Comprehensive Heart Failure Centre.

Unnerved by denervation

Cardiologists are increasingly concerned about patients with persistent hypertension demanding a new technique, in the absence of clinical proof of its long-term benefit. As more related devices are launched, *John Brosky* reports on the procedure, drawbacks, and a potential €2 billion market

If you are one of the six million people in Europe who suffers from persistent hypertension, a new miracle cure will be hard to resist. The minimally invasive procedure called renal denervation seems relatively safe and promises immediate relief from high blood pressure that is resistant to treatment with medications.

But, you are going to trouble your cardiologist who is still waiting for the clinical proof that in the long term this procedure is actually good for your health. The current treatment for hypertension is first to curb unhealthy lifestyle choices. The second, and equally unpleasant step, is to prescribe as many as three different pills, all of which have disagreeable side effects. If, after all this, your systolic blood pressure does not stay below 160 millimetres of mercury you have resistant hypertension and will want to consider this new approach. Simply put, a physician runs a wire from the groin through the femoral artery placing the tip in the main artery of your kidney. Turning on a heating device destroys jumpy nerve endings that are continuously sending signals to the brain to increase the blood pressure. This method of heating tissue inside the body is frequently used in many outpatient surgeries, such as burning away tumours. So, the effects are controllable and safe. Which is one reason why so many medical technology companies have re-engineered existing equipment and are filling the pipeline with new renal denervation devices. The other reason is that there are, potentially, 12 million patients to be treated in Europe and North America.

Three new devices were approved for sale in Europe in February 2012, another was approved in May and many more are on the way. Companies with devices already on the market include three major players in cardiology Medtronic, St Jude, and Covidien Vascular as well as two specialists ReCor Medical and Vessix Vascular. Optimistic Wall Street analysts are already estimating a market potential for these companies of almost €2 billion by 2020.

This commercial pressure is moving faster than clinical evidence that the procedure has real benefits, like a tidal wave. Fewer than 300 patients undergoing the procedure have been studied, and all of them in clinical trials paid for by manufacturers. Fewer than 10% of these patients have been followed for three years or longer.

Long-term effects on the kidney, the damage to the renal artery, and the potential for re-nervation, or nerves recovering and creating new problems, are all unknown. 'Patients are driving the delivery of this procedure and these patients will be knocking on your door,' warned William Wijns MD, former president the European Association of Percutaneous Cardiovascular Interventions (EAPCI) leading a panel discussion on renal denervation in May 2012 at EuroPCR, his society's annual meeting. Jean Renkin MD, a cardiologist at UCL St Luc University Hospital (Brussels, Belgium) was also cautious. 'We are told this procedure drops blood pressure to a better level, yet these patients do not drop out of the hypertension category,' he said. 'We are told we will see a 10mm or 20mm drop in blood pressure. Is this clinically relevant?' 'What we do not want to see is patient auto-prescription, and then a cardiologist who agrees to do the procedure two days later,' Dr Renkin said. 'We are inducing an irreversible effect on the kidney,' said Pierre François Poulin MD, Professor of Medicine and Hypertension at Hôpital Européen Georges Pompidou (Paris). 'We do not even know if the denervation we performed was partial or complete.' 'What is the durability of the effect?' he asked. For cardiologists, renal denervation is again pushing the fine line between an evidence-based approach to medicine and a willingness to experiment with innovative new treatments.

In 20 years the practice of interventional cardiology, where procedures can be performed without invasive surgery thanks to a guide wire, has exploded moving rapidly from opening blocked arteries with angioplasty to reinforcing artery walls with metal stents, and now to replacing aortic valves. The European Association for Percutaneous Cardiovascular Interventions (EAPCI) has grown 10 times to 4,000 members in just the past six years. New technology from industry has been the driver of this growth with clinical evidence trailing slowly behind.

In January 2012 the UK's National Institute for Clinical Excellence (NICE), Europe's most credible health technology assessment panel, issued cautious guidelines for renal denervation, encouraging the procedure be performed primarily in the interest of building clinical evidence. 'The limited evidence suggests a low incidence of serious periprocedural complications, but there is inadequate evidence on long-term safety,' said NICE, adding that patients should be forewarned. Isabelle Durand-Zaleski MD, the director for clinical research and health economics with the French Public Health Service, weighed in for the debate among cardiologists at EuroPCR, saying the issue for renal denervation is not one of patient choice but a public health issue. While patients expect to drop medications after the painful intervention, the medications need to continue because their blood pressure is not restored to normal levels. Adoption of renal denervation runs a risk of adding the high cost of the intervention to the on-going burden of medications for these patients, she said.

Professor William Wijns MD, Dean-emeritus of cardiac intervention, is an esteemed advocate for minimally invasive heart procedures. The Past-President of the European Association for Percutaneous Cardiovascular Interventions, he served as Chair of the prestigious Task Force that issued the Guidelines on Myocardial Revascularisation in 2010. The author of over 200 publications in peer review journals, Prof. Wijns also co-directs the Cardiovascular Centre, Onze-Lieve-Vrouw Ziekenhuis in Aalst, Belgium.

Nanotechnology

Over the last five years the tiniest particles have attracted large attention in relation to the diagnosis and treatment of cardiovascular disease. Indeed, as in other medical disciplines, nanotechnology is advancing in cardiology despite as yet insufficient research on the extent of its effect and double blind studies to confirm findings

In cardiology, nanotechnology has two foci: Nanoparticles improve the early detection of arteriosclerosis in diagnostic imaging and are also used to deliver stem cells and medication to specific body areas with pinpoint accuracy. With standardised imaging, an arteriosclerotic vessel can only be detected once a morphological – i.e. structural change, generally a narrowing (stenosis) of the lumen – is already present. With conventional contrast media an infection of the arterial walls, which occurs in the early stage of arteriosclerosis, cannot be diagnosed. 'Therefore we are looking for procedures that can make contrasts in these regions visible very specifically and at an early stage. Nanoparticles coated with receptors can accumulate where early arteriosclerotic changes occur so that they make these clearly visible on an overview image,' explains Professor Axel R Pries, Managing Director of the Institute for Physiology at the Charité Clinic in Berlin.

Working with microparticles

The administration and effect of nanoparticles in diagnostic imaging is comparable with that of standard contrast media; however, they do not show the entire vessel but only the area where they have accumulated. This means the particles need to be functionalised, i.e. they have to be coated with a surface that contains certain receptors or chemical groups, which in turn interact with the structures they should make visible within certain areas.

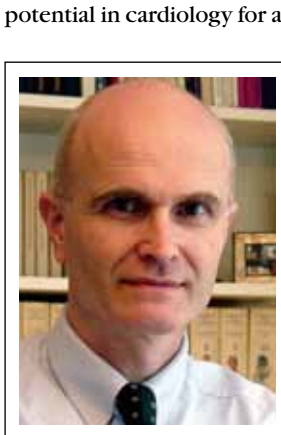
Semi-circular or discus-shaped silicone particles are one such tested substance. These so-called nanovectors act as means of transport, which must not damage the cells. 'The description 'nano' is often used rather liberally; frequently the vectors are actually microparticles; they are still, however, a lot smaller than blood or tissue cells,' Prof. Pries explains.

Nanotechnology has therapeutic potential in cardiology for arteriosclerosis as well as for hypoxic regions in the case of tissue ischaemia. The principle is the same as in imaging: 'You need a suitable vector of nanoparticles, which must be coated in such a way (for instance with a receptor) that it reaches the desired target. The vector can also be equipped with drugs for drug delivery, or with stem cells for stem cell delivery,' Prof. Pries points out.

Functional processes made visible

Through precise targeting of the stem cells the affected tissue regenerates far better after a heart attack compared to their injection into the bloodstream. In this case, the stem cells would travel to where it is attractive for them, rather than where they are actually needed. 'Especially in cardiology, where the boundaries of myocardial tissue need to be reached, targeting is extremely important. This can, for instance, be achieved through anchorage to a changed endothelium. The vascular system is the best means of reaching all cells.' Even though nanotechnology in medicine is still experimental rather than an everyday procedure in many areas and the effectiveness can only be ascertained at the end of the process, Prof. Pries sees considerable potential in this field, which requires further research. 'Nano-imaging, as yet making up only a small part of functional imaging, has advanced into clinical practice the most, as functional contrast media make processes visible which previously were not visible at all or only visible via PET-CT.

This delivers an entirely new quality of diagnosis,' the professor points out, although also warning: 'Nanotechnology has so far been viewed very positively. However, through uncontrolled use in everyday objects nanoparticles can also be detrimental to health. Although dosing for medicinal purposes has so far been considered safe.'



Professor Axel R Pries studied medicine at the University of Cologne and was habilitated by the Free University of Berlin (FU), where he began work as a research assistant in its Physiology Department in 1985. Ten years later he was an Associate Professor. In 1997, he became Senior Consultant at the Institute of Anaesthesiology, at the German Heart Centre in Berlin. Since 2001 he has headed the Physiology-CBF Department at Charité-Berlin, where he is also a Board Member of the Medical Faculty and Vice-Director of the Centre for Preclinical Medicine and the Centre for Cardiovascular Research at Charité.

Interview: Dr Rafael Vidal Perez, Hospital Clínico Universitario de Santiago de Compostela

Learning from the deceased

The case-based approach holds considerable promise for medical science. In a way, it's a return to the roots, since this approach was common at the dawn of modern medicine. A case serves as a narrative that can be explored interactively in order to draw a conclusion, determine a course of action, or debate issues in a realistic context. Spanish cardiac imaging consultant Dr Rafael Vidal Perez, will guide 'cardiologists of tomorrow' through a case-based session during this year's ESC. *Daniela Zimmermann* asked the specialist about the striking title of his session: What can death teach us?

Rafael Vidal Perez MD is Consultant in Cardiac Imaging at the Cardiology Department, Hospital Clínico Universitario de Santiago de Compostela in Spain. During the course of his education in medicine and surgery,) he received several awards, as well as a Master's degree in Management Tools and Health Research and a Master's in Clinical Management. A new Fellow of the European Society of Cardiology in 2011, he is among seven professionals in the society's 'ESC Cardiologists of Tomorrow' initiative, as well as an EAE Club 35 Committee Member and a member of the ESC Working Group on Acute Cardiac Care.

What can death teach the cardiologists of tomorrow?

Rafael Vidal Perez: That the clinical investigation doesn't end with death of the patient. Some of the cases I'll be discussing were resolved in the autopsy or by finding an indication of hereditary diseases in the deceased patient's family. Obviously, every cardiologist tries to get to an accurate diagnosis before the patient dies; but, unfortunately, this isn't always possible. In those cases, it's important to continue on the path of clinical investigation beyond the patient's death. This way, you might be able to save his relatives at a later point in time. In some cases of sudden death the clinician needs to look beyond the common aetiologies. We will be looking at cases where the patient died and others where the patient recovered from a near terminal condition.

Where do the main benefits of the case-based approach lie?

Unusual clinical cases are an excellent way of developing the skills of young cardiologists. In the session we'll introduce rare, strange cases that you don't often encounter in everyday clinical practice. Young cardiologists are normally familiar with the typical cases, which might lead them to forget the more unusual clinical presentations and symptoms.

It's important to think outside of the box. In general, young cardiologists are familiar with current clinical trials and standard cardiology curriculum, but the more unusual cases are not included in those studies.

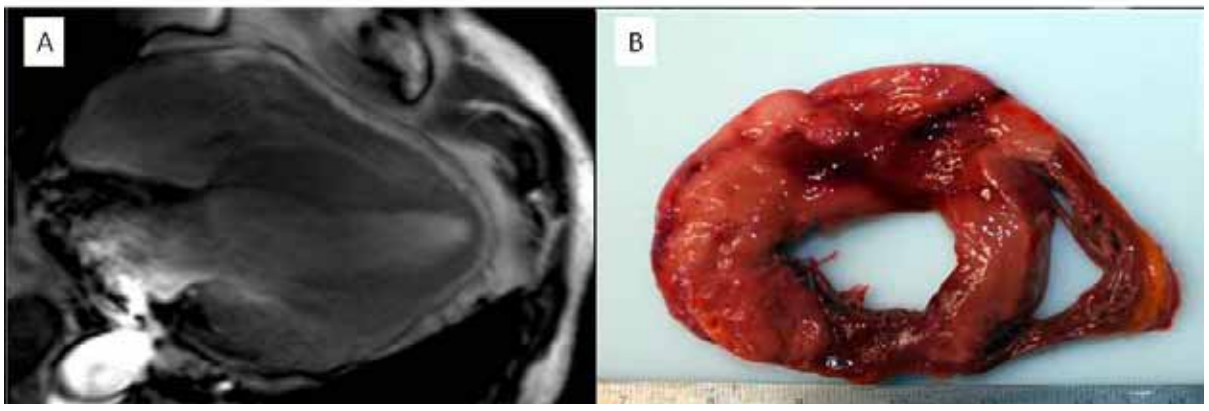
What shape will the session take?

The idea is that we'll choose the most appropriate cases during the pre-selection. Our focus will be on cases that render the most important insights, of course. The presenter will provide an overview of the case evolution, followed by the differential diagnosis and an explanation of the most important factors to keep in mind when faced with such a case.

In the discussion part of the session we'll try for look for mistakes during the case management and analyse why they were made.

To achieve this, will it be necessary to look beyond the heart?

Exactly. Some cases, especially the ones during my session, are those of systemic disease. Sometimes you have symptoms outside the heart and you find the problem inside the heart. Then sometimes it's a systemic disease that also affects the heart. Those are the two sides of the problem: a systemic disease that includes all the body's organs or the heart disease is the first symptom and then proceeds to affect other parts of the body. In some of these cases, you have to broaden scope and look beyond heart diseases. A detective story is a good analogy of how you need to proceed: you look for a clue, it raises a suspicion and you explore the possibilities.



Cardiac magnetic resonance imaging revealed an infiltrative mass in the pericardium and myocardium (A). Macroscopic examination revealed diffuse myocardial infiltration (B)

Fatty Blood

Michael Rühl from the University of Greifswald, Working Group on Immunoadsorption and Cardiovascular Technology, describes therapies to tackle familial hypercholesterolemia

Myocardiac infarctions are almost always blamed on our Western lifestyle. 'It's too many calories, not enough exercise, too much stress'. Such trite declarations could lead to a fatal outcome for some younger patients. Chest, shoulder and jaw pains when walking, and you're in your mid-twenties? 'You are not exercising correctly' or: 'Running marathons is not healthy, anyway' are other common observations. At worst, patients are referred to orthopaedic specialists – and suffer a second heart attack while awaiting the appointment.

Good laboratory diagnostics can deliver the correct diagnosis in those cases: familial hypercholesterolemia (FH), which, with an incidence of 1:500 is among the most common monogenic diseases. The classic form of FH results from an autosomal dominant inheritance and is characterised by an increase of LDL cholesterol in the serum. Patients with the homozygous form of the disease often develop severe arteriosclerosis in childhood and suffer heart attacks before the age of 30.

Extracorporeal blood cleansing procedures, used in dialysis to remove urophanic substances from the blood of kidney disease patients, are also suitable for the elimination of lipids from the blood of FH patients. Developed in 1969, LDL apheresis treatment was first used by internist Dr Helmut Borberg in 1981 (Source: Lancet 1981;8254:1005-7). At the same time, Wieland and Seidel, in partnership with healthcare company B. Braun, Melsungen, developed their procedure for Heparin induced LDL precipitation (Source: Klin Wochenschr 1987;65:161-8).

Every year in Germany 1,300 patients benefit from lipid apheresis – mainly those with homozygous familial hypercholesterolemia whose LDL levels are often over 600mg/dl. Patients with heterozygous familial hypercholesterolemia can also be considered for apheresis if, after an arteriosclerotic event has already occurred, LDL cholesterol could not be sufficiently lowered after 12 months of documented, maximum dietary and medicinal therapy. The isolated increase of Lipoprotein(a) (LP(a)) with levels over 60mg/dl combined with progressive cardiovascular disease is a further indication for the treatment.

The state of technology

A range of systems has become established that can basically be divided into two groups: plasma and haemo therapies. There are three different types of plasma therapy: Filtration, adsorption and precipitation. In the case of filtration, plasma is guided through a plastic filter that retains particles above a certain size. This procedure facilitates the elimination of all blood lipids at a high level, with fibrinogen also intensively lowered, bringing a very positive effect on microcirculation in the short term but limiting treatment intensity.

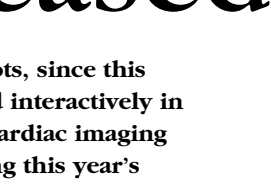
In the case of adsorption the components to be eliminated are removed through binding to an agent. This can be a specific antibody that is highly selective and only binds LDL, or a negatively charged surface such as dextran sulphate, which adsorbs positively charged plasma components from the blood.

In the case of precipitation, with the HELP procedure offered by Braun, lipoproteins as well as fibrinogens are precipitated through the use of Heparin, and by lowering of the pH level, and then removed from the plasma. There are two systems available for haemotherapy, the treatment of whole blood. They use a negatively charged surface that binds positively charged particles. Polyacrylate is the adsorber for the DALI system and dextran sulphate cellulose for the Liposorber D system.

In the future

Although apheresis is combined with statins this method now has competition – Mipomersen. From the end of 2012 Mipomersen, the first representative of a new substance class, will be marketed.

In relevant studies Mipomersen reduced LDL cholesterol by 25% in patients with homozygous FH and by a further 36% in severely heterozygous FH patients. For the latter, whether this means invasive therapy will no longer be a needed, or not, remains to be seen. This year also sees the start of the 'German Lipid Apheresis Registry', supported by the Foundation for Nephrology initially with four-year funding. The background for this initiative is a Federal Joint Committee request for a systematic study of lipid apheresis therapy. This aims to see lipid apheresis accepted into the range of established forms of therapies. Perhaps it will also lead to improved intelligence on heart attacks in the young, with the events no longer dismissed, but being proactively avoided.



Michael Rühl is a therapy specialist in extracorporal applications at the Department of Internal Medicine B (led by Professor Stephan Felix), at Ernst-Moritz-Arndt University in Greifswald, Germany. His special interests include cardio-technical applications and the immuno-adsorption for patients with dilated cardiomyopathy. He also advises other universities on extracorporal procedures in the context of clinical studies. In 2011, during the EHEC outbreak in Germany, he performed the first immunoadsorption procedures on patients with haemolytic uraemic syndrome.

The 36th Austrian, German and Swiss Sonography Societies meeting

26-29 September. Davos, Switzerland

Davos has strong ties with medicine. At the end of the 19th century this mountain village was a treasured resort for TB patients and Belle Epoque hospitals, such as the Schatzalp, endure as a period reminder. Following the arrival of antibiotics, while still maintaining some medical services based on climate and air quality, Davos managed to attract a rather more chic clientele - winter tourists. For the remaining year, the town retains a cultured, laid-back atmosphere – thus a perfect setting for the three-country event, the 2012 Dreiländertreffen.

Along with masses of topics of 'practical value for daily routine,' explained André Dietschi, the 2012 Congress President, there will be courses on gastrointestinal and contrast ultrasound, and a focus on prenatal diagnostics. The Dreiländertreffen Academy distinguishes those practice-oriented elements from the scientific programme, providing brief presentations of new findings with follow-up discussions.

Key developments

'High resolution for probes has helped optimise image quality and diagnostic precision,' Dr Dietschi says. Convenient 3-D imaging of tendon lesions in, e.g., the shoulder would be a technological achievement surgeons could appreciate in planning and conducting interventions.

'Whereas more recent technical developments have been rather non-revolutionary, with the practical benefits of fusion imaging waiting to be defined, there are exciting new trends in the field of contrast agents.' Emerging expertise about their effects and potential areas of application have attracted significant attention, he added. 'Based on current contrast agents, symptoms can now be differentiated more easily, with fewer additional exams required to achieve diagnostic precision. Conditions of the liver, kidneys, and pancreas provide a very good example of these improvements. There are basically no restrictions to experimenting for new areas of application because this will cause no harm, and potential benefits are significant.'

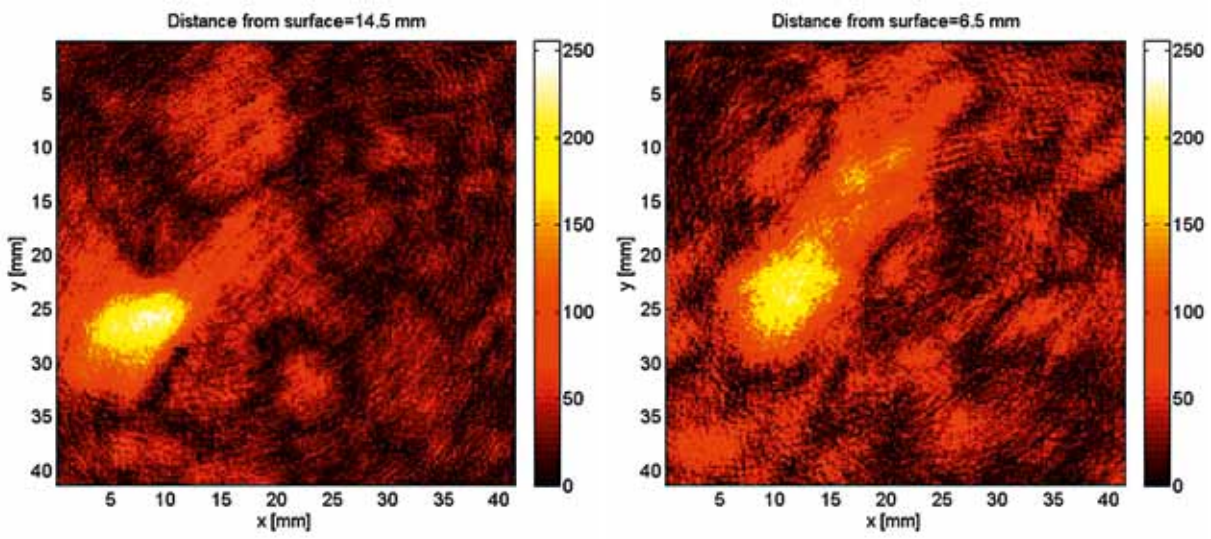
Anyone involved in ultrasound will be welcomed in the Swiss Alps to expand skills and know-how, and exchange ideas, the President adds.

André Dietschi MD, Congress President of the Ultraschall-Dreiländertreffen 2012, gained his doctorate at Basle University, Switzerland, and then specialised in internal and sports medicine, ultrasound and traumatology. In 1996 he joined the Board of the Musculoskeletal System Section of the Swiss Society for Ultrasound in Medicine (SGUM), became a Member of the SGUM Board (2006) and is now its President. Dr Dietschi also heads Santémed Gesundheitszentrums in Diepoldsau, serving on the company's Management Board .

Interview: Professor Wiendelt Steenbergen, University of Twente, Enschede

Boosting the potential of ultrasound

Photoacoustics offers an additional contrast mechanism that makes the technology far more sensitive for the presence of blood



Two images acquired with the photoacoustic mammoscope developed by the Steenbergen team. These show an infiltrating ductal carcinoma with two hot spots at a depth of 14.5 (image 1) and 6.5 mm (image 2) of the illuminated breast surface.
(Images of the tumour depicted in fig. 3, Optics Express art. no. 11582, vol. 20, no. 11)

Interview: Michael Reiter

Absorption of pulsed light produces ultrasound signals. This photoacoustic approach to ultrasound imaging could help diagnose tumour growth and its suppression by therapy. An expert in Biomedical Photonic Imaging, Professor Wiendelt Steenbergen outlined the highly promising potentials of the technology during our European Hospital interview.

Asked what the technical-medical principle is behind photoacoustic imaging, he explained: 'Photoacoustic imaging is an ultrasound imaging modality where the ultrasound is generated by the absorption of short light pulses in the tissue. Absorption of pulsed light by e.g. haemoglobin and melanin causes a slight but rapid heating of the absorbing structures, leading to the emission of ultrasound. These waves are measured at the tissue surface and allow for constructing the 3-D distribution of optical absorption inside the tissue. The images therefore reveal blood vessels, enhanced blood concentration, but also optical contrast agents.'

How does this expand the horizons of imaging?

'For ultrasound imaging, photoacoustics offers an additional contrast mechanism that makes the technology much more sensitive for the presence of blood. In addition, being based on ultrasound, photoacoustics enables imaging of optical absorption at a resolution and depth that would not be possible by optics alone due to optical scattering. Therefore, photoacoustics forms a natural expansion of the ultrasound imaging modality. Compared to angiography techniques based on MRI and X-ray, and nuclear imaging techniques PET and SPECT, photoacoustics has the advantage of not requiring contrast agents, while light is a safe form of radiation. On the other hand, MRI and X-ray have a superior penetration depth, so it is not to be expected that photoacoustics will completely replace any of these modalities.'

For which diagnostic applications could this be useful?

'Photoacoustics can visualise angiogenic processes associated to tumour growth and its suppression by therapy. For instance, we focus on photoacoustic mammography for early detection and improved diagnosis. If tumours are to be followed during therapy, photoacoustics is attractive in terms of radiation load and probably also in terms of costs. A further sophistication of photoacoustics is spectroscopy, which may enable further diagnosis of tumours by their oxygen saturation. An interesting development is the possibility to provide anti-tumour drugs with an optical label. While this labelling is done with the purpose of fluorescent imaging, these labels can be visualised with photoacoustics too. This would turn photoacoustics into a tool for targeted therapy management.

'A much less investigated application field of high relevance is rheumatology. Diseases such as osteoarthritis and rheumatoid arthritis affect a large number of people, and diagnosing these diseases at an early stage is difficult. In a recently granted European project, a range of partners including Osram, ESAOTE Europe, Quantel, and University of Twente, team up to realise a compact ultrasound-photoacoustic device for this purpose.

'While (Doppler) ultrasound imaging can visualise synovial inflammation through the presence of big vessels, photoacoustics also targets the smaller vessels, potentially giving higher sensitivity for earlier signs of inflammation. A device like this will also be applicable for skin, such as skin cancer and 'port wine' stains.'

What will need to change in hospitals when photoacoustic imaging is embraced?

'How easily photoacoustics is introduced into the existing workflow depends on the application. A compact hybrid photoacoustic-ultrasound imager is basically an ultrasound imager with a photoacoustic option. It may be a portable or bedside device that will be easily accepted and integrated in existing procedures. The position of photoacoustic mammography in the entire diagnostic chain may vary from completely replacing X-ray in screening, or being an additional tool in the complete chain, to a tool for monitoring breast-conserving therapies. It would be great if photoacoustics could lead to a reduction in unnecessary hospitalisations or if we could screen younger women than is currently the case with X-ray mammography.'

What will the cost be?

'This is very difficult to predict. In addition to the purchase price of the device, logistics costs should be taken into account. In the end, what counts is the total healthcare benefit, to be determined by health technology assessment methods. As for the device price: for devices based on normal ultrasound scanners, the photoacoustic option will lead to a moderate cost increase if diode laser technology can be used. This is the aim of our new European project. However, for the optical mammoscope the device price will be higher, because a more powerful laser is needed and a specific tomographic detector arrangement has to be developed.'

When might photoacoustics become part of routine work?

'For the introduction of photoacoustics as an integrated part of a normal scanner, I expect an introduction time of about five years. In addition to developing the device, clinical research must be performed aiming at developing medical applications. For mammography it's rather a ten year period before the technology will have secured a position within breast cancer care.'

Professor Wiendelt Steenbergen holds a Master of Aerospace Engineering degree (Delft University of Technology) and a PhD in fluid dynamics (Eindhoven University of Technology). In 1995 he joined the University of Twente, Enschede (the Netherlands) where he became full professor of the Biomedical Photonic Imaging group in 2010.
Specific to his research on optical techniques for quantifying and imaging vasculature and blood flow are photoacoustic and acousto-optic imaging, fast laser Doppler perfusion imaging and low coherence approaches to quantify tissue perfusion. He is also involved with a spin-off company developing photoacoustic mammography.

Too old for technological innovation? Never!

Modern transducers enhance ductal echography

After medical school in Basle, **PD Dr Rosanna Zanetti-Dällenbach** trained in gynaecology and obstetrics in Switzerland and South Africa. Following a period at the Charité Berlin she joined the Women's Hospital at University Hospital, Basle, where she now heads the out-patient mammography service and places a high value on interdisciplinary cooperation in diagnostics and breast tumour surgery. Dr Zanetti-Dällenbach is President of the Mamma Section of the Swiss Society for Ultrasound in Medicine (SGUM).

Ductal echography, meaning imaging the ducts of the female breast, is an established ultrasound procedure that may offer unexpected new insights due to technological innovations, explains Deputy Senior Consultant Dr Zanetti-Dällenbach, who is convinced that radial ductal echography – or radial ultrasound – can provide relevant information in breast assessment.

'During a conventional ultrasound scan the investigator examines the breast in a meandering movement, which means the section is coincidental rather than anatomy specific. The new and large transducers Hitachi developed for Real-time Tissue Elastography, HI-RTE for short, in radial ultrasound, allow the examination of the breast with a circular movement. 'In a small breast, one circle is sufficient, larger breasts require two circles.'

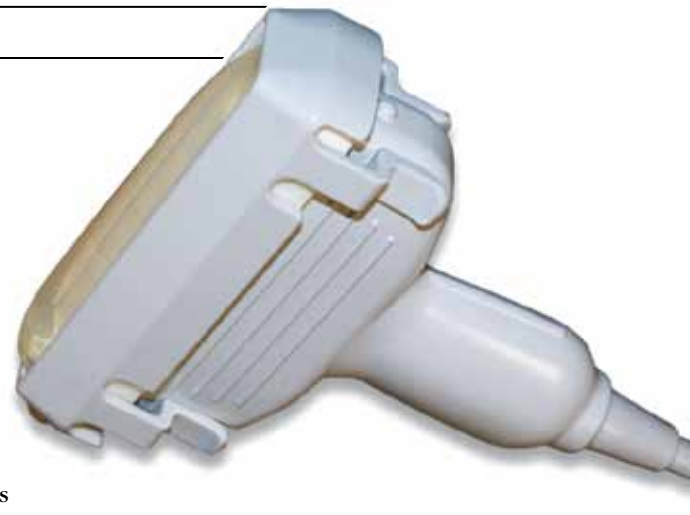
The major advantage of radial ultrasound is the fact that not only breast tissue but also breast anatomy is well visualised. The duct and the lobules can be assessed in longitudinal sections, which offers additional diagnostic information. Dr Zanetti-Dällenbach: 'The visualisation of the anatomy is really superb and some experts maintain that radial ultrasound is the better method to detect small tumours. However, more importantly, it enables the investigator to evaluate better whether a detected lesion is relevant or not. Do I see a cyst protruding from the duct or is it rather a thickened cyst that is not yet anatomically suspicious? This is the type of question radial ultrasound can answer with the help of the large transducers.'

Thus the newly developed large transducers cast an entirely new light on the tried and true method of ductal echography. This may well lead to a re-assessment of the method's usability and value. It remains to be seen whether and what advantages the new approach offers because further research is needed.

However, she is excited about the new possibilities this procedure opens up and uses it regularly as a supplementary examination and as a comparison to conventional ultrasound. Nonetheless, she cautions: 'Radial ultrasound does require experience. Moving the transducer smoothly around the nipple while looking at the monitor is not so easy.' For patients, HI-RTE for ductal echography is far more comfortable, because the water bag softens the pressure applied to the breast. Despite the pouch, high quality images are acquired.

The large transducers used for ductal echography were especially developed by Hitachi for its Real-time Tissue Elastography application.

*Hitachi Real-time Tissue Elastography (HI-RTE) is an innovative modality to assess tissue elasticity. The system has a complementary diagnostic role in B-mode imaging, providing further criteria for the characterisation of lesions. Second generation HI-RTE includes the Strain Ratio, a quantitative method for analysing the elastography score.



The new Acuson P300 compact portable ultrasound system

Announcing the addition of the Acuson P300 to its ultrasound portfolio, Siemens Healthcare reports that this is a compact portable device designed to meet the imaging needs for a wide spectrum of patients, body types and clinical disciplines – from radiology and general imaging to cardiovascular imaging, as well as obstetrics and gynaecology (OB/GYN) to specialty imaging such as musculoskeletal, breast and small parts. 'The new system integrates high-performance hardware and software and offers 13 multi-frequency transducers for high clinical versatility,' the company explains. 'It also features advanced image optimisation technologies to support both routine and specialty application needs. Dr Jeffrey Bundy, CEO for Ultrasound at Siemens Healthcare, adds: 'The Acuson P300 is ideal when a physician needs to obtain a fast diagnosis under difficult conditions – for instance, where space is limited or a mobile solution is needed.' The firm outlines other attributes: 'The new system includes advanced image optimisation tools, such as panoramic imaging, speckle reduction and spatial compounding, which optimise the imaging data automatically, thus improving diagnostic confidence and supporting efficient clinical workflow. The system comes with 13 transducers, including specialty laparoscopic and intra-operative probes for interventional procedures. With a frequency range of up to 18 MHz, these multi-frequency transducers allow a selection of several imaging frequencies to meet different scan depth requirements without having to change transducers. The system enables linear, convex, phased array and endocavity transducers to provide scanning solutions for a wide range of clinical cases.'

The Acuson P300 also comes with a 15-inch XVGA LCD display, integrated power supply and two transducer ports for maximum ease of use.


The Acuson P300

Edan's newest release

From China: The U50 portable colour imaging system

Launched in spring 2012, the U 50 the newest portable colour imaging diagnostic ultrasound system from medical equipment manufacturer Edan Instruments, Inc. offers colour flow, pulse wave, and power Doppler.

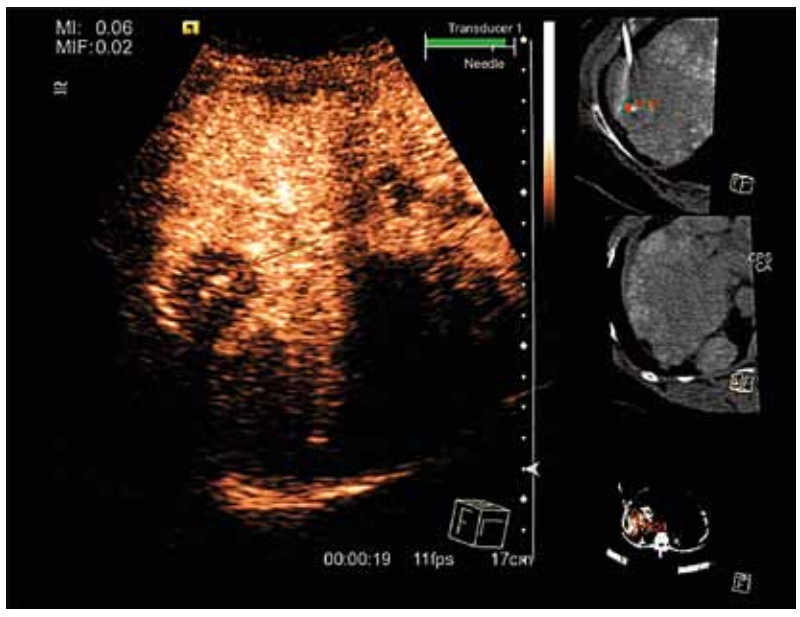
'U50 has been well-designed based on sophisticated survey of the real needs from specific target group,' Edan reports. 'The accurate product orientation and optimised technological integration ensure U50 exert authentic accounts to pioneer the popularisation.'

U50 is a new landmark during the development course of ultrasound, the firm adds. It marked Edan as having achieved a technology breakthrough and progress in ultrasonic research.

'After years of accumulation, Edan has become one of the very few manufactures who grasp self-owned and core imaging technologies in China,' the company points out.

The neat, robust U50 is CE certified

About the company: Based in Nanshan Shenzhen, China, Edan manufactures products (over 80) for five medical areas – obstetric & gynaecology, patient monitoring, diagnostic electrocardiographs, ultrasonic imaging and in-vitro diagnostics. 'We master the core technologies in various domains, such as physiological signal detection, medical transducer, main-control platform,' the firm explains. 'Other than that, the company has around 300 patents, software copyrights, core confidential technology, confidential technics.'



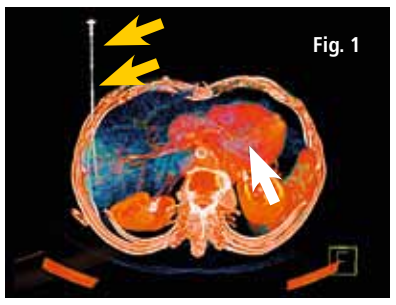


Fig. 1

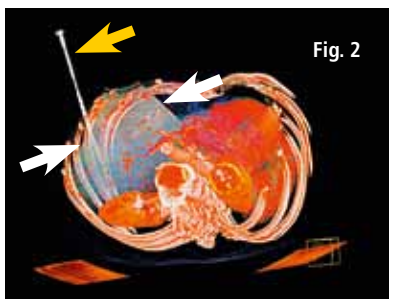


Fig. 2

Post-interventional control of the successful ablation of the HCC (red arrow) in image fusion, with simultaneous display of CT in two plans and contrast enhanced ultrasound (CEUS) information.

Fig. 1: Intra-interventional percutaneous microwave ablation. A single 16 gauge microwave applicator (yellow arrow) is inserted into the lesion under CT-guidance.

Fig. 2: Intra-interventional percutaneous microwave ablation using the overlay technique, with simultaneous display of CT and ultrasound information (white arrows). The microwave applicator (yellow arrow) is placed in the centre of the HCC lesion

Imaging liver lesions

CT-ultrasound fusion optimises planning and monitoring of ablations

The fusion of contrast-enhanced ultrasound (CEUS) and CT supports the pre-, intra- and post- interventional management of liver lesions by providing additional clinical and spatial information. Applied in the context of percutaneous thermal ablation, combining the advantages of both modalities can increase operator confidence, the accuracy of the procedure and technical success in real time, according to Dr Dirk-André Clevert, Institute for Clinical Radiology, Ludwig Maximilians University Hospital Munich. It can also speed up the process and help reduce cost.

The evolution of CT-ultrasound fusion

Fusing CT and ultrasound is a major step forward compared with previous approaches, Dr Clevert explains. 'Left to right and vice versa – that's how we used to compare images from two modalities. Then came experimental software aimed at fusing those images.' Today, the most recent version 3.1 of the eSie fusion imaging software of the Siemens Acuson S3000 ultrasound device, with a single click, enables the automatic fusion of real-time ultrasound with 3-D CT volumes. Whereas previous approaches needed time-consuming manual registration, automatic, one-click advanced registration capabilities now reduce CT image registration to mere seconds.

The study

For a recent study, a team headed by Dr Clevert enrolled 15 patients with a single liver carcinoma of up to 3 cm in diameter. For each patient, the physician first carried out an ultrasound exam to find out whether lesions could be detected. Then, a CT scan was done; a CD with the CT images was inserted in the ultrasound device. As soon as this material was presented onscreen, the ultrasound image stream was fed into the system in real time, available for fusion with the CT images. The combination helps to clearly verify the location, dimensions, and margins of the lesion, as well as of the position of the needle and the suitability of its size, Dr Clevert says. Subsequently, the intervention was carried out and fused CT and ultrasound were used to monitor puncturing and ablation in real time. Eight patients underwent radiofrequency ablation and seven patients underwent microwave ablation.

Positive results

'The results show that the fusion-based procedure is easy and convenient to perform, as well as efficient,' he concludes. The study suggests that the use of image fusion with CT and contrast-enhanced ultrasound can improve diagnostic precision in the peri-interventional management of malignant liver lesions during thermal ablation.

Fusion imaging provides real-time information on the effect of the ablation. The physician can be certain that the lesion is completely necrotised, eliminating the need for follow-ups done with CT on the day following the procedure and minimising re-interventions. This helps cut time and cost significantly, for example by reducing the use of additional expensive needles and further examinations to control therapy results. The use of fusion provides improved clinical information without requiring additional radiation; both patients and staff will benefit from this.

Today a senior physician who also organises national and international ultrasound classes, as well as Vice President of the European and German Society for Clinical Haemorheology and Microcirculation, **PD Dr Dirk-André Clevert** began his career at the MRT Diagnostics Institute Westend in Berlin and at Waldkrankenhaus Gransee before becoming an assistant physician at the Clinical Department of Radiology in Passau. In 2004, after transferring to the Clinical Radiology Department, Munich University Clinic Grosshadern, he developed and managed its Interdisciplinary Ultrasound Centre.

Entering t Champion

Accuvix A30 produces impressive results in the prenatal diagnostics arena

With the Accuvix A30 Samsung could become a serious contender in the ultrasound champions' league. Dr Rainer Bald, head of prenatal medicine at Leverkusen Hospital, is one of the few chosen for the chance to test the new system. His verdict is unambiguous: 'I cannot imagine working without the A30 anymore.'

Of all the enhancements developed for the current model, Dr Bald is particularly impressed by the B-mode image, used for about 95% of diagnoses: 'The resolution of both the conventional 2-D image and 3-D image has remarkably increased, which surely is the result of improved noise suppression. It provides excellent detail.'

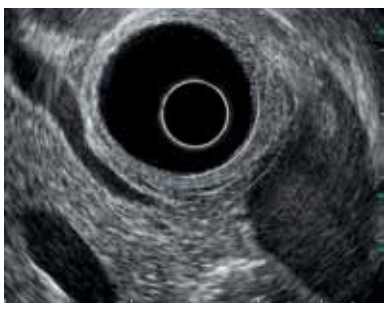
Another convincing development Dr Bald points to is the sensitivity of the colour Doppler. With new functions the system achieves very good spatial resolution that allows detailed assessment of minute vessels. 'Unlike systems by other manufacturers, the A30 offers Alpha Blending, which means the colours can be set to transparent; the structures in the background remain visible and can be identified in terms of anatomy.'

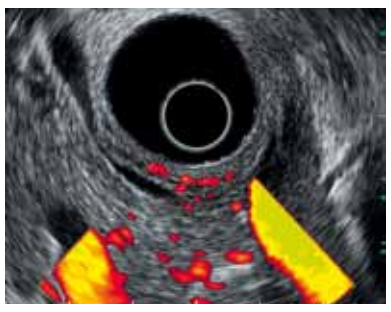
This function offers major advantages in cardiac diagnostics because the valve in the background is visible while the inflow into the heart is being assessed. The exam method is highly sensitive and allows evaluation of detailed structures. 'However,' he adds, 'the bi-directional power Doppler does not replace the conventional B-mode image because the latter is the only one capable of showing turbulences that indicate, for example, a narrow valve.'

As far as ergonomics and workflow are concerned Dr Bald is also full of praise. Examination steps that are frequently performed, for

Now fully integrated

An endoscopic ultrasound processor





The compact endoscopic ultrasound (EUS) processor EU-ME1 from Olympus is completely integrated. Designed for diagnostic, therapeutic, and interventional applications in EUS and endobronchial ultrasound (EBUS), advanced technology drives mechanical scanning endoscopes and probes as well as electronic scanning endoscopes.

The manufacturer also explains that the system is suitable for GI endoscopists performing EUS, and pulmonologists and thoracic surgeons performing EBUS. The EU-ME1 brings together endoscopic imaging, ultrasound scanning, and interventional capability compatible with Olympus EUS and EBUS products.

Olympus highlights the system's assets:

- Support for both EBUS-TBNA and EBUS guide sheath technique.
- EUS-guided FNA and interventional EUS procedures can be performed.
- Backward compatibility with most Olympus ultrasound endoscopes and miniature probes.
- Available frequencies vary from 5 to 30 MHz.

The compact size allows for configuration on the same endoscopy cart as the video endoscopy system centre. With picture-in-picture function, the monitor can display the endoscopic and/or ultrasound image.
www.olympus.com

the ns' League

example, can be pre-programmed and automated: 'In prenatal diagnostics certain parameters are routinely measured in a certain sequence. I programmed these sequences in the Accuvix A30 and now when I press the Next button the system automatically moves, let's say from measuring the biparietal diameter to the ellipsis for measuring the head circumference, and so on.'

However, he says that the Accuvix A30's ultimate highlight is the vaginal transducer; it far outsmarts the competition. Particularly notable is cervix elastography that enables the gynaecologist to assess not only the length of the cervix but also tissue stiffness, a feature set to improve the predictability of premature births over coming years. Beyond the technological innovations, Dr Bald is impressed by Samsung's corporate philosophy of 'listening' – in his experience an art not every manufacturer easily masters. 'When developing the A30, Samsung went out of its way to incorporate user input. Not every company is prepared to do that – despite the fact that real enhancements can only be realised jointly by the manufacturer and the users, as the A30 so nicely proves.'

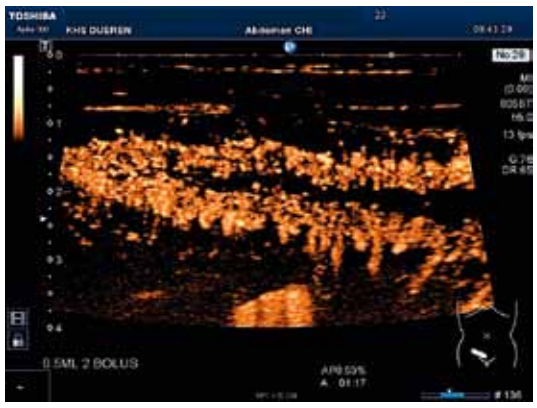
Head of Prenatal Diagnostics at Klinikum Leverkusen, a DEGUM III certified centre for advanced ultrasound training, **Dr Rainer Bald** is one of Germany's most experienced sonographers in prenatal diagnostics , and a sought-after expert speaker.

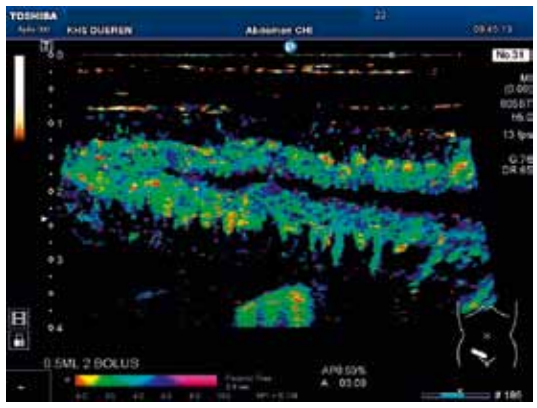
Manufacturer's notes:

The Accuvix A30 offers world's first 21.5-inch LED monitor enriched 3-D performance, increased detection rates, advanced automation, customisable interface and forward-looking ergonomic design.These are the most striking features, Samsung points out:
Hybrid Beamforming Engine - With enhanced H/W and newly added S/W engines, users can process data more accurately through optimised processing.This Hybrid Beamforming Engine enables a more in-depth, more detailed scanning with a higher energy output.
The DMR plus - This is a completely new engine that integrates Samsung software and enhances image quality, DMR plus has a noise reduction processor that increases edge enhancement and minimise noises.
ElastoScan - Helping to identify early detection of malignant tumours and various other diseases, ElastoScan provides clinical information that conventional studies typically cannot detect.
Cervix ElastoScan - Highly sensitive, Cervix ElastoScan easily reveals changes in the uterine cervix often missed by palpation, enabling more accurate assessment.
ADVR - Integrated real-time DVD recording, ADVR permits simultaneous scanning and recording, creating an environment that allows users to choose desired recording areas.
Colour Opt Flow - The technology supports quick colour image representations of blood flow. Upgraded capabilities include changing slow, moderate or fast colour speeds. The pre-set ranges allow for faster evaluation of optimised blood flow images, depending on the application.
New 3-D imaging tools have resulted in more realistic images, and more accurate scans and diagnoses.

- *Face Auto Detection:* The tool removes unwanted volume data that can obscure foetal face details.
- *Smart Filter Volume Imaging:* Touch-activated, it provides sophisticated tools to optimise 3-D imaging and eliminate noise.
- *Volume Shade Imaging:* This displays 3-D images of skin tones and shading and improves visualisation.
- *SmoothCut:* User-controlled, it erases objects hiding desired 3-D images, reducing unnecessary exams.

Contrast enhancement: CEUS proves to be a boon for abdominal diagnostics





From left:
Crohn's disease - ADF image showing minute flow

Crohn's disease - CEUS image showing perfusion

Crohn's disease - MicroFlow image showing arrival time of contrast

The use of contrast agents in ultrasound imaging of the gastrointestinal tract is no longer limited to the liver, although the clinical results of hepatic applications continue to be those that are most comprehensively confirmed. Today, about ten percent of all diagnostic ultrasound investigations of the gastrointestinal tract are performed with contrast agents in order to visualise specific structures and processes. However, gastroenterology patients are not the only ones to benefit from contrast enhanced ultrasound (CEUS); the procedure is increasing applied in paediatrics, surgery and oncology – and, in trauma medicine, it is used to exclude organ injuries. 'Basically, we turn to contrast agents when conventional abdominal ultrasound has reached its limits,' explains Dr Horst Kinkel, Head of Ultrasound at the Academic Teaching Hospital in Düren, Germany.

Consequently, the guidelines of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) were recently amended to include a significantly wider range of CEUS indications. Contrast agents are used in many diagnostic applications when neither the conventional B-mode image nor Doppler ultrasound yields satisfactory results. This might be the case in spleen imaging as well as in studies of the kidney or the pancreas.

CEUS supports tumour differentiation because it shows vascularisation. Moreover, the procedure visualises chronic inflammatory bowel diseases very well, both in terms of contrasting the bowels themselves and surrounding tissue, such as abscesses and fistulas.

CEUS – versatile and well tolerated

From left:
Ileum Wall - ADF image showing enhanced flow

Oedematous jejunitis with small bowel torsion

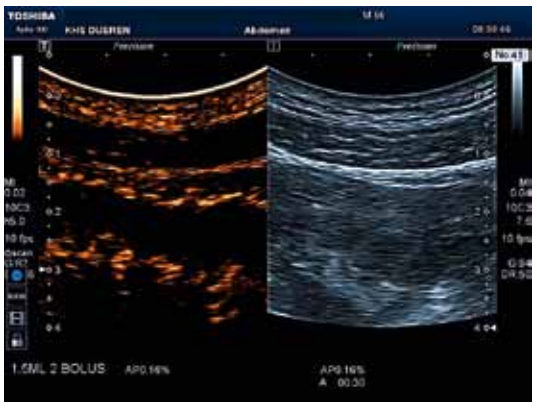
Oedematous jejunitis - CEUS image showing perfusion

'In general, vascular architecture and kinetics, which are more easily visualised with contrast agents than without, provide valuable information on the perfusion patterns of a lesion,' Dr Kinkel explains. A renal tumour, for example, which, can be hard to differentiate from a cystic mass in conventional ultrasound, is evident in contrast agent imaging since minute perfusions are displayed. The same holds true for pancreatic lesions. Here, vascular kinetics provides even more information: the difference between the wash-in of the contrast agent in the tumour and in the adjacent tissue tells the ultrasound expert whether the mass under investigation is a neuroendocrine tumour or a pancreatic carcinoma. Abdominal ultrasound of the intestines – which are next to the parenchymatous organs, a particular region of interest in gastroenterology – focuses on inflammatory processes, not only with regard to inflammatory diseases such as Crohn's or ulcerative colitis. With the transducer even enterocutaneous fistulas can be detected and the contrast agent can confirm, for example, diverticulitis-related abscesses. 'Moreover, CEUS is helpful when you want to assess the severity or course of an inflammation, or when you need to check whether avital, that is necrotic, tissue is present. Moreover, CEUS is well suited to differentiate a tumour from normal parenchyma based on vascular architecture or to clarify the tumour entity,' he points out.

Contrast agent intolerance, a problem frequently encountered in other modalities, is not an issue in CEUS because the agents used usually do not contain iodine. They do not interact with the thyroid gland and are not eliminated by the kidneys. The incidence of allergic reactions to a contrast agent in ultrasound is one in 15,000, which is significantly less than in CT and MRI.

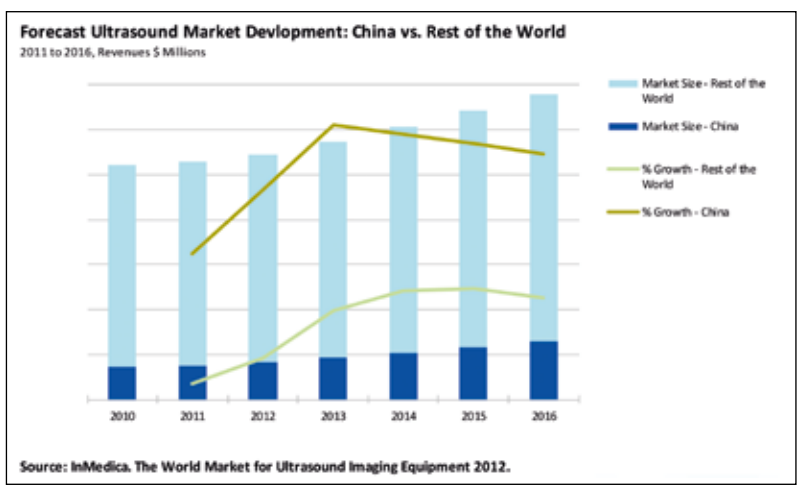
Easy handling and good contrast sensitivity

No doubt the quality of the CEUS results is directly related to the quality of the system being used. Dr Kinkel works with the Toshiba Aplio 500, a system, he says, that 'is fun. It is comfortable and easy to handle. More importantly, however, the Aplio offers crucial qualities in terms of image technology. When you perform about 10,000 examinations per year, of which roughly 1,000 are with contrast agent and 9,000 are without contrast agent, the B-mode image quality is decisive. In CEUS, as in conventional ultrasound, high B-mode image quality is indispensable.'



China may scoop a fifth of global ultrasound revenue by 2016

Market experience is likely to sharpen between local Chinese suppliers and multinational suppliers.



Source: InMedica. The World Market for Ultrasound Imaging Equipment 2012.

Following a period of vast investment in healthcare, the outlook for China's ultrasound imaging equipment market remains very positive, according to a new report from InMedica, part of IHS Inc.

The Chinese Ultrasound Equipment Market – 2012 cites recent public health investment from 2009 to 2011 as merely a stepping stone in China's healthcare revolution. Consequently, revenues generated from Chinese sales of ultrasound are forecast to represent close to 20% of global revenues by 2016. The report points out that the three-year Chinese government healthcare reform drove rapid growth in unit shipments of ultrasound between 2009 and 2011. 'Growth was most evident in simple value and low-end ultrasound systems (average selling price less than $30,000), a combination of government targets to provide low-cost healthcare for rural regions, and increasing competition and influence of local Chinese suppliers. Combined with further growth in premium and high-end equipment in the top Tier 3 hospitals, China experienced revenue growth of 8-10% annually.'

There appeared to be little evidence this year of a saturated market. 'In fact,' InMedica continues, 'revenue growth is forecast to increase to a compound annual growth rate (CAGR) of 11% over the next five years.'

Stephen Holloway, senior analyst at InMedica, further explained: 'While the volume of lower-value ultrasound equipment is forecast to decline significantly, a dramatic shift in demand for higher value colour equipment in Tier One and Tier Two hospitals will drive strong revenue growth. Public investment in Tier two county-based hospitals, to produce regional centres of excellence, will also increase demand for mid-range ultrasound equipment.

Intriguingly, this market should experience stiff competition between local Chinese suppliers now producing higher specification systems, and multinational suppliers looking to expand into new markets.' Conversely, ultrasound market growth in the rest of the world is forecast to remain below 5% over the next five years. One key factor curbing this growth is the on-going financial crisis in the Eurozone, the InMedica analysts explain.

'This is particularly evident in Southern European countries such as Italy, Greece, Spain and Portugal, where the ultrasound market has been heavily impacted. 'As economic instability continues and tight public austerity measures are implemented,

EUROPEAN HOSPITAL

EUROPEAN HOSPITAL Publisher, Theodor-Althoff-Str. 45, 45133 Essen, Germany
Phone: +49 (0)201 87 126 850
Fax: +49 (0)201 87 126 864
E-mail: info@european-hospital.com

www.european-hospital.com

Editor-in-Chief Brenda Marsh
Art Director Olaf Skrober
Managing Editor Brigitte Dinkloh
Senior Writers John Bosky, Michael Reiter
Executive Director Daniela Zimmermann

Correspondents
Austria: Michael Kraßnitzer, Christian Pruszinsky.
France: Annick Chapoy, Jane MacDougall.
Germany: Anja Behringer, Annette Bus, Bettina Döbereiner, Karl Eberius, Guido Gebhardt, Walter Schäfer, Susanne Werner, Holger Zorn.
Great Britain: Brenda Marsh, Mark Nicholls.
Malta: Moira Mizzi.
Poland: Pjotr Szoblik.
Russia: Olga Ostrovskaya, Alla Astachova.
Spain: Eduardo de la Sota.
Switzerland: Babara Steinberg, Dr. André Weissen.
USA: Kerry Heacox, i.t. Communications.
UK editorial address
55 Wey Meadows, Weybridge, Surrey KT13 8XY
Subscriptions
Janka Hoppe, European Hospital, Theodor-Althoff-Str. 45, 45133 Essen, Germany
Subscription rate
6 issues: 42 Euro, Single copy: 7 Euro.
Send order and cheque to:
European Hospital Subscription Dept
Printed by Frotscher Druck, Darmstadt, Germany
Publication frequency: bi-monthly
European Hospital ISSN 0942-9085

Representatives
China & Hongkong: Gavin Hua, Sun China Media Co, Ltd, Room 802, 15th Building, BinJiang Residential Quarter, Dongyuan Road, Futian District, Shenzhen, Guangdong, China, Code: 518031
Phone: +86-0755-81 324 036
E-Mail: gh@european-hospital.com
Germany, Austria, Switzerland:
Ralf Mateblowski, Hintergasse 1, 55234 Hangen-Weisheim, Germany
Phone: +49 6735 912 993
E-Mail: rm@european-hospital.com
France, Italy, Spain: Eric Jund, 2264 Chemin de Sainte Colombe, 06140 Vence, France
Phone: +33 493 58 77 43
E-Mail: ej@european-hospital.com
GB, Scandinavia, BeNeLux: Simon Kramer, Willem Alexander Plantsoen 25, 2991 NA Barendrecht, The Netherlands
Phone/Fax: +31 180 6200 20
E-Mail: sk@european-hospital.com
Israel: Hannah Wizer, International Media Dep. of El-Ron Adv. & PR Co., Ltd., 7, Leteris street, Tel-Aviv 64166, Israel
Phone: +972-3-6 955 367
E-Mail: hw@european-hospital.com
South Korea: CH Park, MCI, Room 103-1011, Brown Stone, 1330, Baekseok-dong, Ilsan-Ku, Goyang-si, Gyunggi-do, Korea 410-360
Phone: +82 2 730 1234
E-Mail: chp@european-hospital.com
USA & Canada:
Hanna Politis, Media International, 8508 Plum Creek Drive, Gaitherburg, MD 20882, USA
Tel: +1 301 869 66 10
E-Mail: hp@european-hospital.com

Asked why he would opt for the Aplio again, Dr Kinkel lists several reasons: First, the user interface is comfortable in terms of ergonomics and ease of use. Then, the system can easily be adapted to the individual user's preferences and needs. Finally, the Aplio offers very good contrast sensitivity. 'I can achieve a very good image both in detail resolution and in the evaluation of deeper lesions, since I'm familiar with the system and can work with different frequencies. This will yield good results for the patient, which is, after all, what's most important.' This patient-friendly approach of man and machine is appreciated both inside and beyond his hospital. So, if you'd like Dr Kinkel and the Aplio take a look at you, prepare yourself for a bit of wait.

Horst Kinkel MD received his medical training and doctorate at the University of Cologne, Germany. In 1994 he joined Düren Hospital and following specialist training in internal medicine in 2001, he further pursued his ultrasound interests, three years later being certified a trainer by the German Society of Ultrasound in Medicine. He has been Deputy Senior Consultant of Medical Department II at the Düren Hospital since 2008, focusing on contrast enhanced ultrasound, interventional sonography, interventional endoscopy, hepatology and chronic inflammatory bowel diseases.
A member of several pro-fessional associations, he is co-author of medical textbooks and an interactive ultrasound teaching CD, and expert speaker at international congresses.

the replacement of ultrasound equipment is being cancelled or postponed,' added InMedica analyst Carly Reed.

New emerging ultrasound markets are counteracting European low growth. India, Thailand and Indonesia are demanding increased access to healthcare services, thus driving strong growth in low-cost ultrasound equipment. Long-term, those emerging markets are predicted to experience similar development as China, albeit at a slower rate, the report foresees.

As Carly Reed points out, many newer emerging markets remain in infancy. 'These regions have huge potential for further growth, yet currently don't have the economic or public firepower to implement wide-ranging healthcare initiatives in the short-term.'

In the next five years, the analysts predict that China will emerge as a dominant and insatiable consumer of ultrasound equipment, driving rapid growth. 'The value of future market growth here is best reflected in the movements of the global market-leading suppliers; almost all have invested heavily in specific Chinese centres for research, manufacturing and sales,' Stephen Holloway concludes. 'The future of the ultrasound in China looks to be very assured.'

Mindray's DC-8

Indicating the way to the next step in your examination and inserting comments automatically.

The DC-8 '…performs well across a wide range of physical examinations, from deep abdominal to superficial small parts, or from minute vessels to big muscular structures,' the manufacturer Mindray reports.

Using iZoom, the 19" high-resolution LCD monitor gives a bigger clinical image area, enabling better assessment of more detailed structures, the firm adds. 3T New Transducer Technology, unique to Mindray, the company points out, increases bandwidth and transmission efficiency, thus offering better SNR and improved resolution. 'It allows you to scan with higher frequency, even focusing on in deep structures, to acquire images easier and faster of different body types, and to obtain better image clarity when scanning the most challenging patients.' iFlow provides better visualisation of tiny vessels and complex flow patterns. 'Based on our exclusive processing algorithm, the system can detect very weak colour Doppler signals with an optimal S/N ratio, and provide extraordinary spatial resolution without compromising penetration or sensitivity.'

The new platform also enables an optimum flexibility for post processing and analysis of the Raw Data image. Mindray also adds that, due to iWorks, the DC-8 can indicate the next step of an exam and automatically inserts comments, initiates the required measurements – and more.

'All this is enabled by the powerful iWorks, by which you can have standard scan protocols or you can easily customise a user-defined protocol'.

New technology prevents scarring from artificial skin grafts

Sprayed on skin

Although scientists and medics have sought ways to grow artificial skin in laboratories since the 1970s, only now has it become possible to reproduce the top layer of skin, thanks to work at the Trauma Surgery and Orthopaedics Clinic in Berlin (ukb).

Report: Susanne Werner

The young woman had been holding a bottle of barbecue lighter fuel in her hand when it suddenly burst into flames. With large-scale burns to the face and hands, she needed skin grafts. The patient was admitted to the ukb Burns Unit – one of the largest and most modern facilities of its kind in Europe.

There she is to benefit from results of the work of doctors at the Trauma Surgery and Orthopaedics Clinic in Berlin (ukb), a team that is also involved in the EuroSkinGraft project with researchers from Switzerland and the Netherlands.

Their joint efforts aims to recreate multi-layer skin to improve grafts. For a decade, consultant Dr Bernd Hartmann and team at the Severe Burns and Plastic Surgery Centre (BVZ) have worked on artificial skin graft development, finally arriving at a spray-on skin that promises to heal second-degree burns without scarring. This product is now ready for mass production.

One step removal and re-spraying

The human skin, our largest organ, protects against cold, heat and even viruses. Many small skin injuries heal by themselves. However, the destruction of large areas and several layers of skin is critical.

All procedures for growing artificial skin utilise the patient's remaining, healthy skin. Initially an area of skin the size of a postage stamp is removed from an affected patient and these cells are usually cultivated in laboratories and grown for a few days. The new spray-on skin from Berlin shortens that process:

From the patch of healthy skin, cells are extracted enzymatically, put in an electrolyte solution and then re-sprayed an hour or two later, in a sterile operating theatre. Dr Hartmann: 'We call this a "one-time" procedure because the skin cells are removed and replaced within the same operation. We basically intensify the healing process. The important cell growth occurs directly in the wound.'

Utilising the wound healing mechanism

The ukb procedure – from removal to application via spray can – has not only been largely standardised but also, adds Dr Hartmann of its particular success '… our spraying of skin cells almost always ensures wounds heal well or very well whilst avoiding scarring.' The specialists utilise the body's natural mechanisms and literally trick them. 'The body's additional skin cells speed up the wound healing. This in turns stops the process of scarring.'

When the barbecue victim underwent the procedure about ten days after the accident, her skin cells were removed, cultivated in a suspension and transplanted as a solution via the spray gun a few hours later.

Led by Professor Axel Ekkernkamp, Medical Director of the ukb, the supra-regional Trauma Centre, is currently planning to equip other large German Burns Units with the necessary technology and training for skin cell spray transplants.

Image: ukb

Following medical studies at the Johann-Gutenberg-University, **Dr Bernd Hartman** focused on plastic and hand surgery at the BG-Trauma-Centre in Ludwigshafen and University Hospital Giessen and Mannheim. From 2000, he has headed head the Severe Burns and Plastic Surgery Centre (BVZ) at ukb, Berlin's Trauma Surgery and Orthopaedics hospital. The specialist is also involved in several studies on pain management and treatments for burns patients. He has published more than 50 articles in international medical journals.

In partnership is the German Institute for Cell and Tissue Replacement (DIZG) in Berlin, the country's only organisation licensed to grow artificial skin from the body's own tissue.

Although the skin cell spray solution is impressively simple, numerous problems associated with artificial skin replacements remain unresolved due to the skin's complex, three-layer structure. The lower layers are particularly important for the human organism; they contain the lymphatic and blood vessels as well as immunological cells. For very deep burns the skin cell spray application does not suffice.

EuroSkinGraft

Could a multi-layer skin replacement be developed quickly? Solving that need for the benefit of accident victims is the EuroSkinGraft project's objective and it is this on which Dr Hartmann and his Swiss and Dutch colleagues are focused.

Coordinating the project is PD Dr Ernst Reichmann, at the University of Zurich, who heads the Surgical Clinic research division and has been involved in developing and testing clinically usable, complete skin-replacement for years.

Within the project, Professor Esther Middelkoop MD, from the Medical Centre at the University of Amsterdam, is a skin wound healing expert.

Image: ukb

Bernd Hartmann (right) with an earlier model of the spray gun. Following years of R&D the procedure can now be used as a standardised method.

Dr Hartmann's ukb patients will be the first in Germany to benefit from these new procedures.

Expected to last five-years, the project is subsidised by just under €6 million from the EU.

Many regulatory obstacles must still be overcome. Legally in Europe artificial skin is classed as a pharmacological substance. Therefore, growing tissue outside the body under the terms of the Pharmaceuticals Act requires licensing.

The complex project management is overseen by Gabo:mi in Munich, which assists organisations with applications for and the execution of scientific projects, particularly in the healthcare sector.

A new POC test transforms non-healing wound care

The world's first point-of-care wound test, unveiled last November at the Wounds UK conference, is now used by the National Health Service (NHS) -- and internationally.

Report: Mark Nicholls

Devised by wound care specialists Systagenix, the Woundchek Protease Status is reported to rapidly identify whether a wound has elevated protease activity (EPA), enabling clinicians to deliver a quicker, more accurate response to patients with long-term wounds.

Jacqui Fletcher, a Senior Lecturer at the Wound Healing Research Unit at Cardiff University, Wales, explained that the test was developed with the aim of offering a range of diagnostic tests to target markers, which had been recommended by the 2008 World Union of Wound Healing Societies (WUWHS) consensus document, emphasising the importance of effective assessment and diagnosis in wound care.

Woundchek, she said, is simple and flexible enough for use anywhere and has the potential to save health systems millions of pounds or euros annually due to better medical decision-making among those dealing with a large range of wounds with delayed healing, possibly caused by infection, malignancy, EPA etc. 'To treat these non-healing wounds we have a range of more specialised interventions and dressing products that cost rather more than the normal range of moist wound healing dressings,' the wound healing specialist explained. Before the new test, she added, trying to work out what the problem was had been 'trial and error based on clinical experience'.

JACQUI FLETCHER

Estimates indicate EPA affects around 28% of non-healing wounds. 'If these can be identified quickly, treatment can be targeted to manage the EPA thus improving the healing rates. Equally, for wounds that don't have EPA, the range of potentially appropriate dressings that should be tried is reduced, giving a better chance of selecting the right one.'

Woundchek gives clinicians a clearer idea of what the underlying problem may be, she added. 'Identification of elevated protease activity would direct them to a specific group of dressings, enabling them to have confidence that they are either targeting a treatment appropriately or, as important, not using a more expensive product where it isn't required.'

The procedure

A swab taken from the wound is inserted into a card already primed with four drops of solution. The swab is rotated in the card and the card is then left for five minutes to develop the test. The entire procedure takes about 15 minutes, Jacqui Fletcher confirmed. Before the Systagenix test, no methods to test for EPA were used in routine clinical practice. Now, she said, other POC tests are in development to help identify or exclude other causes for delay or non-healing in chronic wounds.

Aiming to beat infectious diseases

Annick Chapoy **reports on plans to create a Centre of Excellence in Marseille, France.**

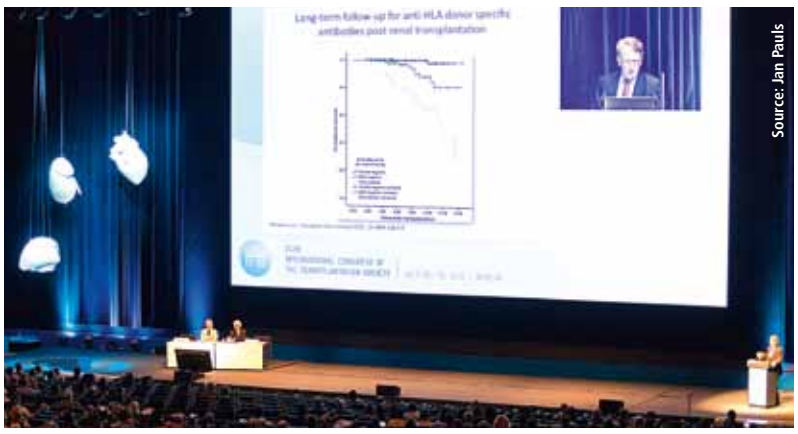
Marseille, a major harbour on the Mediterranean, has been naturally exposed to all kinds of epidemics. Natural enough then that the city now aims to become the world's best centre to specialise in infectious diseases. La Timone University Hospital, third in Europe for state-of-the-art equipment and human resources, is to house the new Fondation Méditerranée Infection (FMI). Created last November and led by Professor of Microbiology Didier Raoult, the foundation regroups the Institut Hospitalo-Universitaire (IHU) Méditerranée Infection and the research centre Infectiopôle Sud, which, since 2007, has recruited some 166 students from Asia, India, North Africa and Sub-Saharan Africa. From 2015, Infectiopôle Sud – now a Fondation department – will recruit around 150 foreign students from those countries. The FMI aims to create a centre of excellence to treat, teach and research infectious and tropical diseases by centralising patients, doctors, researchers and industrialists, explains Prof. Raoult, whose team already receives samples for analysis from all over the world.

Among infectious and tropical diseases research centres, the IHU ranks 9th in Europe, accounting for 550 of the 4,900 scientific publications released in Marseille in all specialities. In 1992, Prof. Raoult and team discovered the Mimivirus, the biggest ever, and later Spoutnik, which can duplicate itself by infecting another virus. In 2009, he discovered Marseillevirus, another giant. Since the '90s, the team has described some 96 new pathogenic bacteria, two named after the professor: Raoultella planticola and Rickettsia Raoultii.

PROF DIDIER RAOULT

The IHU is also developing projects such as 'diagnosis suitcases', with the shipping firm CMA-CGM for emergency diagnosis aboard cruise ships. High-tech mobile laboratories have also been developed to enable one non-trained person, in an 18 square metre set-up, to produce a diagnosis in four hours. The first is in the Hôpital Nord de Marseille. Two are in a Senegal village that lacks electricity. 'This has totally revolutionised paediatric emergencies,' the professor says, adding that France would need 200 units for hospitals lacking a paediatric emergency department.

By 2015 the foundation will occupy a new 25,000 square metre building on the La Timone campus. This €70 million site will employ 700 people. Over an area of 5,000 m³ there will be 75 in-patient beds, 24 ambulatory care beds, 600 sq. m of office space and 10,000 sq. m for diagnosis and research.



The chronic lack of donor organs

When some 4,500 scientists, transplant teams and related social groups from 94 countries gathered in Berlin for the International Congress of the Transplant Society, the event went without a hitch – apart from the news of an organ transplant scandal at Germany's Göttingen and Regensburg University Hospitals.

Bettina Döbereiner reports

During the 24th International Congress of the Transplant Society, Dr Beatriz Dominguez-Gil, from the Spanish Transplant Organisation emphasised (see interview) that early identification of potential organ donors is crucial for deceased organ donation rates. This argument was also supported by a small, non-representative study 'Detection of potential donors in hospitals without neurosurgery in Bavaria, Germany', from the German Organ Transplantation Foundation (DSO), presented at congress by Dr Angelika Eder. Fourteen hospitals without a neurosurgery department had an in-house coordinator established on a regular basis to detect and analyse potential donors. Preliminary results: the implementation of an in-house coordinator increases awareness of identifying potential donors, resulting in a moderate increase of potential.

Psychological training of ICU staff appears to be very important. In her thesis, German psychologist Annett Pöpplein analysed the training and education of staff on the donor-transplant coordination teams in Spanish ICUs. Presenting her results at the Congress she underlined that, in Spain, major emphasis is put on adequate staff training to identify stress reactions correctly and emotionally stabilise family members while interviewing on organ donation. In her lecture she also suggested that this may be a key to receiving a positive feed-back for an organ donation agreement - in Spain family members are always asked for permission for organ retrieval even though they have a presumed consent policy.

These arguments were also considered in the readjustment of the German transplant legislation adopted by the Bundestag in May 2012. The new legislation foresees inter alia that every German hospital with an ICU must have at least one in-house coordinator responsible for organ donation organisation. Professor Wolf Otto Bechstein, President of the German Transplantation Society and head of the Department of General and Visceral Surgery at the Johann Wolfgang Goethe University in Frankfurt am Main, also confirmed that special training on how to approach and care for the bereaved families is planned for organ donation coordinators. With the German medical association, the Transplantation Society has already developed a curriculum for organ donation coordinators. If the new German legislation and its measures can withstand the organ transplant scandal – and in the long run enhance the preparedness and raise agreements towards organ donation in this country – as observable in Spain during the past two decades – remains to be seen.

Dr Angelika Eder, Anett Pöpplein, Prof. Bechstein

Interview: Beatriz Dominguez-Gil, Spanish National Transplant Organisation

The Spanish Model

'Organ donation is normal when a person dies'

The worldwide scarcity of organ donations inevitably draws attention to the so-called Spanish model. From the end of the '90s Spain became a worldwide reference due to its high deceased organ donor rates. In 2011 Spain even had the highest after death organ donor rate in the world – 35.3 organ donors per million population (pmp). In recent years the rate has stabilised at about 33 to 35 organ donors pmp. However, the European average is almost half this – about 17 deceased organ donors pmp. During the 24th International Congress of the Transplantation Society Beatriz Dominguez-Gil MD, who works at the medical department of the National Transplant Organisation (ONT) in Spain, explained the Spanish model to EH-correspondent *Bettina Döbereiner.*

Dr Dominguez-Gil: Contrary to the common notion that you only have to convince the public to donate and you will have more organs available, which is of course true to some extent. I'd like to underline that it is even more important to identify early whether a person dies in conditions that allow the person to become an organ donor. If the healthcare system is not ready to identify such situations, donation will not happen, even if you have a very supporting society. Therefore, early identification of potential donors is crucial for our success.

So the presumed Spanish consent policy, that people are donors unless they opt out, is less important for high donor rates?

Even though we have a presumed consent policy, we don't apply it in practice. We always approach the relatives, we explain to them the patient's health conditions and we try to find out whether our patient wanted to be an organ donor or not. Anyway - if the relatives oppose to deceased organ donation, we don't go on with it. So, I think in practice that this is not very different from an explicit consent policy.

Some believe that organ availability in Spain is so high due to an assumed deficiency in intensive care, causing a higher rate of brain deaths. Is this true?

That is a myth. In Spain, the mortality relevant for organ donation, i.e. deaths due to cerebrovascular diseases or traffic accidents, is one of the lowest in the European ranking, something that has much to do with excellence in healthcare. Besides, there are countries in Europe with a quite higher mortality relevant to organ donation, but they do not have higher donation rates than Spain, so there is no strict relationship between mortality rates and the number of deceased organ donors you finally have.

Would you briefly describe the Spanish system?

In 1989, the Organisazión Nacional de Transplantes (ONT) was established as an agency dependent upon the ministry of health and in charge of overseeing donation and transplantation activities. By coincidence with this creation, a set of measures mainly of an organisational nature was created. One of the elements of the model is a donor transplant network structured at three levels: the national agency of the ONT coordinating all activities, the regional level and the network of organ procurement hospitals, actually 181 hospitals all over Spain.

These hospitals are specifically authorised for organ procurement and equipped with a specially trained donor-transplant coordination team on-site. The teams, usually only part-time dedicated to organ coordination, consist of physicians and nurses and are ideally lead by an intensive care doctor, something that facilitates the early identification of potential donors.

A respected German newspaper* objected in an article, covering the Spanish system, specifically that one person may hold this double function - identifying potential organ donors as well as determining death. It was also argued that the organ donor-transplant coordinator receives a bonus payment per identified organ donor. Is there a conflict of interests?

I don't see a conflict of interests. The whole idea of our system is that organ donation is the normal thing to occur

continued on page 30

After years working in a clinical setting and as a clinical researcher on nephrology and organ transplantation, in 2006 internist and nephrology specialist **Beatriz Domínguez-Gil MD PhD** joined the Spanish National Transplant Organisation (ONT). Today, within a team of professionals headed by Dr Rafael Matesanz, she works on international cooperation, for which ONT along with the Transplantation Society, received the Prince of Asturias Award. She is now also Chair of the European Transplant Coordinators Organisation – European Donation Committee.

A gem of transplantation medicine celebrates its 30th year

The Collaborative Transplant Study has evaluated data on approximately 500,000 transplantations worldwide, providing a scientific basis for organ allocation and transplant treatment.

The world's largest transplantation medicine study is turning 30. Since 1982, Professor Gerhard Opelz and team at the Department of Transplantation Immunology, at Heidelberg University Hospital's Institute for Immunology, have collected and evaluated data on more than 500,000 transplants in around 500 hospitals in 43 countries. The Collaborative Transplant Study (CTS) has demonstrated how important immunological characteristics – the HLA antigens – are for successful kidney transplantation and how effective – as well as how toxic – immunosuppressant drugs can be. The CTS data also serve as the scientific basis for allocating organs by Eurotransplant.

'Tens of thousands of patients all over the world have benefited from this study,' explained Professor Markus Büchler, head of the Transplant Centre at Heidelberg University Hospital. The wealth of data allows statistically reliable statements to be made that directly benefit proper organ allocation and scientifically based treatment of patients.

The Lancet and New England Journal of Medicine

'The study's significance is evidenced by the high number of journal articles, with 14 of them alone in the top clinical journals The New England Journal of Medicine and The Lancet,' Professor Stefan Meuer, Director of Heidelberg University Hospital's Institute for Immunology, pointed out.

The study's beginnings lay in the discovery that certain surface proteins on donor organs activate the recipient's immune defence, which can trigger the organ rejection. But which of these HLA antigens are key – and should the organs be allocated on this basis? 'We provide reagents to transplant centres, which they use to test organ recipients for their HLA antigens.' In return, the centres have provided the institute in Heidelberg with data on transplant results over a period of decades. This allows conclusions to be drawn about the significance of HLA antigen 'matching' and of the efficacy and side effects of drugs used for immunosuppression.

An immunological match is vital

Findings of the CTS include the following:

- The immunological match plays a key role in the success of kidney transplantation. For this reason, a great deal of attention is paid to this factor when the kidneys are assigned to a recipient. For liver and pancreas transplants, an exact match is less influential. While heart and lung patients would profit from matching as well, urgency is the major criterion for allocating these organs.
- Certain drugs, including cyclosporine and tacrolimus, can considerably boost the success rate of transplantation. However, depending on the dosage, the risk of developing cancer is significantly greater. Transplant patients with better HLA compatibility require lower doses of immunosuppressive medication. Better HLA matching therefore not only improves the graft survival rate but also reduces the side effects of immunosuppressive treatment, such as the development of certain tumours, the occurrence of life-threatening infections and cardiovascular complications, and the occurrence of post-transplant bone fractures.

The study has been financed by donors from the IT and transplant sectors and through the proceeds from the reagents sent to transplant centres for testing the HLA antigens. 'Scientific independence has been ensured at all times,' said Prof. Opelz. This gem of transplantation medicine will be continued after he retires in two years. Now, sponsors are being sought to contribute to preserving the world's largest transplant data registry, the Collaborative Transplant Study.

The shielded MRI compatible Hamilton-MR1

Ventilators for mobility and intensive care units

Conventional ventilation and monitoring systems demand constant operator attention. Hamilton Medical reports that its ventilation solutions are based on advanced Intelligent Ventilation technologies and patient-adaptive lung-support algorithms that 'deliver need fewer operator/ventilator interactions to decrease the chance of errors and offer new perspectives on traditional parameters'. The manufacturer also adds that it is among the top three global providers of ventilators and has the largest, most modern ventilator portfolio worldwide.

The Spanish Model

continued from page 29

when a person dies and we think that intensive care doctors are the perfect professionals for the job of donor-transplant coordinators because they may best identify situations in which donation is possible. Besides, data of our recently performed benchmarking study proved that the hospitals with the best results, in terms of deceased donation, had frequently developed policies targeted to optimise the treatment of neuro-critical patients. It seems that the better the care for neuro-critical patients the better your results are in terms of survival, but this also derives in better deceased donation rates.

Regarding reimbursement, costs related to donation are provided by the Spanish healthcare authorities. Every region and every hospital has different models of reimbursement, but whatever the model is about, the hospitals get payment for human and material resources needed to make donation effective, that is to say donation is financially covered exactly the same way as any other medical activity within a hospital.

*Further details: http://www.sueddeutsche.de/gesundheit/neues-transplantationsgesetz-wie-andere-laender-an-spenderorgane-kommen-1.1336448-5

The 3M Bair Paws Flex™ warming gown can be controlled by the patient and enables the body to be warmed partially or completely before, during and after surgery

Maintain perioperative normothermia

Warm every patient says 3M, on its Bair Hugger™ System's 25th Birthday.

Even mild perioperative hypothermia can have significant effects on rates of surgical site infections (SSIs), morbid myocardial outcomes, blood loss and transfusion requirements, altering the response to drugs, extending recovery rates, hospital stay and patient discomfort.

To raise awareness of this problem and the available solutions, 3M Healthcare hosted the symposium Can you afford to have hypothermic patients? during Euroanaesthesia 2012, the European Anaesthesiology Congress held in Paris this June.

As explained by Professor Andrea Kurz, Cleveland Clinic, Ohio, USA, in her opening presentation, hypothermia commonly develops in patients under anaesthesia because both general and epidural anaesthetics inhibit thermoregulation.

This, and the loss of the ability to shiver due to the muscle relaxants, means that in the cool operating theatre the patient's core temperature can fall rapidly (even 1.6°C in the first hour), due to the redistribution of heat from the core to the peripheral tissues.

Consequently, up to 70% of post-operative patients in the recovery room may be hypothermic i.e. core temperature <36°C. This common problem, although a contributory factor to poor outcomes, for example a threefold increase in postoperative surgical wound infections as well as lengthening hospital stay of up to 20% – is often accepted as an inevitable consequence of surgery.

Professor Daniel Sessler, Cleveland Clinic, Ohio, USA, demonstrated how keeping the patient warm, i.e. with core temperature at least 36°C throughout surgery is not hard and can have a significant positive effect on outcomes. He showed how temperature should be measured taking oesophageal, rectal or tympanic readings, which accurately record core temperature compared with measurements via axillary, nasal or oral routes that register values lower than the actual core temperature. To reduce the risk of hypothermia in surgical patients, perioperative temperature measurement should be carried out when any procedure is performed under anaesthesia or with regional anaesthesia close to the spinal marrow lasting over 30 minutes, anaesthesia in paediatric or geriatric patients, procedures with an increased heat loss, or perioperative techniques involving active warming or cooling of a patient, as well as when they are at risk from malignant hypothermia.

Dr Ratan Alexander, Birmingham, UK, continued the symposium flow by describing the creation of the first NICE guidelines in 2008, on the management of inadvertant perioperative hypothermia in adult patients (cg65).1 Although NICE is a UK institution and any economics presented are based on the NHS costs, Dr Alexander recognises the importance of these recommendations on the international stage as other European countries look to create their own guidelines.

Emerging from these guidelines are clear findings, such as the importance of patients being warm during the preoperative phase. If the core temperature is lower than 36°C an hour before surgery, NICE recommends that the procedure be postponed until the patient has regained acceptable warmth. The guidelines also provide practical advice on how to avoid hypothermia in terms of remembering to factor pre-med time into the calculation of overall anaesthesia time, increasing the ambient temperature of the operating theatre, warming fluids if transfusing more than 500 mls and ensuring that the patient does not move to the ward postoperatively until their temperature is at least 36°C. The NICE recommendation shows that the use of forced-air warming (FAW) is cost effective compared with usual care. Sarah Davis, Sheffield, UK, described how the calculation of QALYs is used to reach this finding.

Convective or forced-air warming is the application of heated air over a patient's body using sheets, under body blankets or heating devices developed for this purpose. Optimum heat distribution and the efficacy of forced-air warming systems is ensured by the use of warming blankets designed to adapt to different surgical procedures and creating a complete patient warming experience, such as that provided by the 3M Bair Hugger Warming System, the manufacturer points out. 'The Bair Hugger Warming System was the world's first forced-air warming system introduced in 1987 and over the past 25 years 3M has contributed to patient perioperative safety by continued innovation and improvements. Forced-air warming is considered as the gold standard for patient warming in 17 European countries and is used in 80% of cases where active warming is considered necessary.'

3M's latest innovation is the Bair Paws Flex warming gown. Wearing this, the patient can control several warming solutions and thus it covers virtually the full range of perioperative requirements for body warming.

Experts have unanimously endorsed forced-air warming as a safe and easy way to reduce inadvertent hypothermia in almost every surgical patient, whether paediatric or adult. However, they felt that in Europe and even in the UK where guidelines exist, greater auditing of the use of forced-air warming is needed to ensure compliance with maintaining normothermia in surgical patients and greater awareness in patients and medics as part of a drive to reduce infection rates and improve surgical productivity, as is the case in the USA, where Medicare reimbursement is reduced by 2% in hospitals do not comply with best practice guidelines.

Details: http://www.nice.org.uk/nice media/live/11962/40432/40432.pdf

A 'Sky(I)CU' for the world travel champions

In 2011, among Germany's 82 million people 69.5 million holiday trips were made, each lasting at least five days; 47.8 million (68.8%) of these were abroad. Inevitably this has an impact on the healthcare system: An increasing number of travellers need to be repatriated via air ambulance. The plane is no longer just a fast means of transport, but a flying intensive care unit.

Holger Zorn reports

The German Automobile Association (ADAC) alone looked after around 51,000 sick or injured travellers. For more than 14,300 of them the "best time of the year" ended with repatriation and hospitalisation back home. 4,500 of them were returned by air, with 1,700 transported via special air ambulance.

There were 620 flights from Spain, particularly from the coasts, the Balearic Islands and the Canary Islands. 580 flights also transported the wounded from Turkey, 400 from Italy, 300 from Greece and 270 from France.

The main reasons for these plane repatriations were, in 70% of cases, cardiovascular disease, strokes and cerebral haemorrhages. 15% were due to accidents, particularly road and sporting incidents. The fleet of ADAC air ambulances consists of two jets of the type DO 328, a Beechcraft turboprop and a Learjet 60. The largest plane, the DO 328, can transport up to 11 patients simultaneously.

The German Red Cross air rescue service also repatriates severely insured and sick patients, chartering planes on a case-by-case basis from the two airports in Cologne-Bonn and Munich. The Swiss Air Rescue REGA, with its three Challenger CL-604 (Bombardier) air ambulance jets, is active in and from Germany – particularly in special cases where patients need ventilation and extracorporeal circulation is required.

Mechanical ventilation under aircraft cabin pressure

A nine-year-old boy with a history of cardiac arrest of unclear origin, and therefore often needing resuscitation, developed an acute respiratory infection resulting in cardiac insufficiency, which was initially treated with an extracorporeal membrane oxygenation device (ECMO) as bridging therapy until a ventricular-assist device is implanted at the German Heart Centre Berlin.

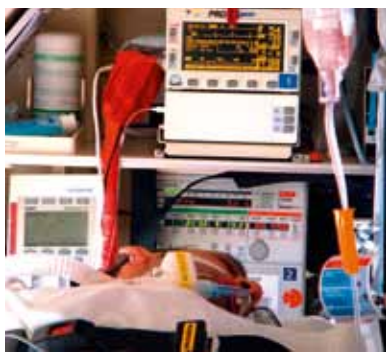
Thus, in October 2011, the boy was flown from Düsseldorf to Berlin. At the takeover, the REGA team was confronted with the boy's open chest connected to the ECMO. However, ventilation on a conventional ICU ventilator had been demanding. The patient was disconnected and reconnected to the inbuilt transport ventilator HAMILTON-T1 (Hamilton Medical, Bonaduz, Switzerland). The patient's height was entered as a basic setting and the mode Adaptive Support Ventilation (ASV) selected.

ASV relies on closed-loop regulation of settings in response to changes in respiratory mechanics and spontaneous breathing. Once a target minute volume is entered by the clinician using a percent Minute Volume setting, ASV automatically determines a target tidal volume (VT) and respiratory rate combination based on the minimum work of breathing principle. Within a minute, the patient was showing normal ventilation parameters for the circumstances. During the entire flight, this respirator especially developed for air transport adapted perfectly to the various changes in environmental and patient conditions and maintained a stable respiratory performance. Throughout the transfer, with on-going ECMO treatment the REGA team could care for the patient without the need to constantly check and adjust ventilator settings. Upon arrival Berlin, the patient was disconnected from the HAMILTON-T1 and reconnected to a conventional ICU ventilator. Mechanical ventilation under decreased ambient pressure is a challenge. Dependent on the speed of the pressure drop, the volumes which patients can be given with a ventilator increase by up to 30%.

The patient could therefore be forced into respiratory alkalosis. This is why the ventilation volume should be reduced according to the flight altitude. Modern transport ventilators, such as the HAMILTON-T1 by Hamilton Medical or the Oxylog 3000 plus by Dräger, automatically adapt to the respective cabin pressure. Thus for the mechanically ventilated patient who would previously have needed to be flown with a cabin pressure corresponding to 0m above sea level, the situation has changed: flight is fine at normal altitudes – significantly reducing transport time.

Photos: ADAC

Repatriation of a patient by air ambulance



An in flight intubated patient

Generally covered by DIN 13234, the plane's intensive care equipment is also governed by European Aeromedical Institute (EURAMI) equipment guidelines. Along with a complete monitoring system (e.g. non-invasive and invasive blood pressure, central venous pressure, pulse oximetry, capnometry, 12-channel ECG, etc.) it also includes an intensive care ventilator, 8 syringe pumps, mobile blood gas analysis machine, bronchoscopic intubation equipment with suction channel option and a complete mobile ICU.

Breathing new life into ventilators

The 2012 world market for ventilators and interfaces study identifies needs for interoperability and decision support tools.

The importance of to optimise workflow in clinical care is highlighted in from InMedica, a division of IMS Research (recently acquired by IHS Inc.). As cost-efficiency becomes an increasingly important factor when purchasing, the technology is being more closely scrutinised by manufacturers.

Traditionally, innovation in the ventilators market has been slow with the focus on the quality of ventilation provided. However, manufacturers are witnessing a strong drive for digitisation for hospitals, according to a new study, *The World Market for Ventilators and Interfaces – 2012,* from InMedica, a division of IMS Research (recently acquired by IHS Inc.).

As cost-efficiency is now more closely scrutinised by manufacturers, as is interoperability in an ICU ward. Ventilators need to work with other devices, e.g. patient monitors and infusion pumps. Buyers have shown preference has to firms offering this technology.

InMedica's research found ventilator digitisation reflected an increasing trend for medical devices to be networked to a clinical information system (CIS). 'Automated workflow within the hospital is becoming more important. Closed loop systems and Adapted Support Ventilation (ASV), minimising risk of over-oxygenation and reducing monitoring demand on the care-giver are becoming increasingly accepted,' said InMedica market analyst Nicola Goatman. 'Closed loop systems are particularly popular in the US and Europe, where healthcare services provide a high level of care to a large population. Within the ventilators market there is a need to improve integration with IT systems, allowing data from the ventilator to be stored digitally. Increased use of electronic patient records (EPRs) stored on the CIS is forecast, allowing more informed decision making and treatment planning within the hospital.'

Western Europe's critical care market is largely saturated, and unit shipment growth rates are reflective of a replacement market. InMedica forecasts a five-year compound-average annual growth rate (CAGR) of 1.2 percent for this area. Predictions are that future ventilator developments will be led by interoperability needs, with firms joining IT specialists to improve connectivity between medical devices and the HIS. Along with high spec clinical features firms should now produce lightweight, easy to use ventilators with decision support features at lower cost.

MEDICA®

Be part of the No. 1!

14 – 17 Nov 2012
Düsseldorf · Germany

www.medica.de

Basis for Business

Messe Düsseldorf