VOL 22 ISSUE 4/13 • AUGUST / SEPTEMBER 2013

EUROPEAN HOSPITAL

EUROPEAN FORUM FOR THOSE IN THE BUSINESS OF MAKING HEALTHCARE WORK

INSIDE: 12-page focus on CARDIOLOGY

The dark side of healthcare mobility

Professional mobility has always been high on the EU agenda. It is a hallmark of pan-European integration best understood as 'freedom per se' for the individual. In times of economic crisis professional mobility offers a real alternative against unemployment and decreasing salaries. But what are the impacts on the medical sector, if physicians and nurses leave their countries en masse? *Daniela Zimmermann* asked *Günter Danner*, Associate Director of the European Representation of the German Social Insurance in Brussels

Günter Danner MA PhD studied history, economics and international relations at universities in the United Kingdom, Germany, the USA and South Africa. Since 1982 he has worked for the Techniker Krankenkasse in Hamburg, first as a press officer, later as an analyst of political and socio-economic affairs in Germany and abroad and today as the personal advisor to the CEO and the Management Board. Since 1993, in addition to those tasks he has been engaged in the Liaison Bureau of German Social Security institutions in Brussels and, since 1997, has been the institution's Deputy Director. As an international expert on healthcare systems, their administration, performance and guiding political background he receives frequent assignments on EC projects in Central and East-European Countries (CEEC) undergoing social and economic transition, as well as in Russia and China.

The database on professional mobility in the healthcare sector is not sufficient; the EU appears not to know when to act. The economic crisis is obviously making matters worse. When do you think the EU will step into action?

GD: 'We actually do have some data: the Commission actively supported the comprehensive PromeTheus study. However, it does not fully cover the most recent events, for example the visible collapse of socially financed healthcare systems in countries suffering an overwhelming public debt. Legally speaking, the EU is not responsible for the actual functioning of national care systems.

'I personally do not think that the EU, as such, is interested in matters beyond the scope of the implementation of the existing legislations. The day may not be too far away though, when the question of how to avoid a "Third-World reality" of access to healthcare in certain EU member states with signs of economic state-failure may arise.'

What are the driving factors for mobility? Which countries profit from it, which are led into potential disaster?

'There are several explanations for professional mobility. The traditional one is the search for better remuneration and working conditions, for example from former Eastern Europe to Western Europe, which is still going on. A somewhat luxurious variation starts from a comparatively high level, e.g. Germany, to an even better one, for example Switzerland or the United Kingdom.

'The weaker a system, the more it will lose, leaving local public structures stripped bare. The new migration from the West to the North, or to other continents, hits hard at such structures, for example in Greece, Spain, Portugal, Cyprus and maybe even Italy. A young doctor wishing to gain scientific merits will leave an environment where this is no longer possible.

'The on-going Euro-crisis has added another element: many public structures can no longer pay their staff. Small wonder that doctors, still at work, are looking for alternatives. So, in a nutshell, where shrinking official payments are pending and perspectives are gloomy, there's hardly any reason to stay.'

What does that mean for healthcare systems in those countries?

'The effects are already showing devastating consequences, but have to be understood together with the growing lack of funds. In certain areas of the EU, hospitals that haven't paid their bills are denied the most elementary of materials for their everyday work, which is an added element of destructive potential for the future of a healthcare system. Politicians either don't look that way or have given up, since at a certain moment during the process of economic decline, even legally well-founded claims don't help you anymore.

'However, you can't put the blame on those who leave. Research, science and academic education are all suffering from brain drain. This is not restricted to healthcare. But what would you expect with an overall unemployment rate of people under the age of 25 reaching almost 60%?'

Is professional migration or mobility similar between doctors and nurses?

'This is difficult to say with certainty, but most probably yes. Lay-offs normally start with nursing staff, for

Continued on page 2

Spanish doctors and nurses emigrate for work

Report: Eduardo de la Sota MD

From January 2008 till the end of 2012 around 400,000 Spaniards decided to emigrate to find work. Since the first signs of what appeared to be an economic meltdown, between early 2008 and July this year, 357,418 Spanish people went abroad to work, according to the Electoral Census of Spanish Nationals Resident Abroad (CERA), which registers those over the age of 18 who wish to exercise their right to vote in Spain whilst in other countries. In 2008, 1.2 million Spaniards were registered with CERA – that figure has now reached 1.56 million.

With the prospect of unemployment, which the Government admits will be over 24 percent in 2013 and 22 percent until at least 2016, this new exodus, which sociologists call 'selective emigration', is expected to rise. According to a recent study by researcher Adrían Zamoro 'Some would like to go to places like New York, Australia and even Africa, but there is much more work available in central Europe. Germany has a high demand for industrial engineers; the Scandinavians for science and research; and in England, Ireland and France they require professionals for their health sectors.'

Spanish doctors emigration

Last year, 2,405 medical doctors applied for certification to work abroad, according to The Medical Spanish Association – a 75% increase compared with 2011. As non-EU states do not require the certificate, the figure relates to EU migration. Médica Colegial, the body that represents Spain's medical associations, says that, in the first six months of 2013, it issued around 1,350 copies of medical licences required under EU law for doctors and nurses who want to work outside their own country. Last year it issued 2,349 such copies, and 1,835 in the previous year.

The most frequent specialties were anaesthesiology and general practitioners.

Continued on page 2

www.european-hospital.com

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

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 ✘ 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 4/13

Spanish doctors and nurses emigrate for work

Continued from page 1

Máximo González Jurado, president of the General Council of Nursing Colleges

Pablo Rubio, spanish nurse, moved to London after his examination

Rodríguez Sendín, president of Médica Colegial

In 2012, for example, 295 doctors from Valencia (a high unemployment region) applied for the certificate. Interestingly, powerful Catalonia sent 440 doctors abroad. Only in the Basque country (with the highest per capita income and lowest unemployment rates) did doctors' emigration decrease.

83% of doctors seek jobs in Europe (mainly the UK and France) and 7% America. Two in three doctors apply for public hospitals.

Nurses are also leaving

Máximo González Jurado, president of the General Council of Nursing Colleges, is worried about the long-term implications of the medical brain drain: 'Spain continues to train magnificent professionals. It's a tragedy that they are being snapped up by other countries when there is a shortage of nurses, and many hospitals are having to cope with minimum staffing levels.' Spain has about 541 nurses for every 100,000 inhabitants, compared to 797 in the rest of the EU. 'The cuts mean that contracts are not being renewed and people leaving are not being replaced, among other measures – and this means things will get a lot worse.'

Pablo Rubio used HCL's services – one of the UK's leading nursing and healthcare recruitment agencies – once. The 24-year-old nurse was already in London. He has been there for nine months and is happy with his new life. He explains that the only members of the team who graduated from his university in Castellón last year went abroad to find work. All those who stayed in Spain are jobless, 'Only those of us who went abroad are now working.'

The nurse works in several east London hospitals and does home visits in the west of the city. He works a 12-hour shift three days a week and has the rest of the time to himself. 'Working arrangements are much more flexible in Britain than in Spain. Employees are looked after, and with what I'm paid I'm able to live well, pay my rent, food, transport and still have something left to save. I don't know when I'll be going back to Spain. I'll stay here for at least a couple of years more and hope that things sort themselves out in Spain. I've made friends here; it's like having a small family.'

Reasons & consequences

It isn't that there are too many medics in Spain. In 2009, the Health Ministry warned that there was a shortage and that the country needed around 3,200 more doctors. By 2025, at the present rate the shortfall will be around 25,000. The government has talked of increasing the number of university and medical school places, as well as making it easier for overseas personnel to work here.

The country's medical associations disagree, saying that the problem is not so much a lack of trained medics, but rather the poor distribution of specialists.

Either way, the current crisis has hit the sector hard and experts say the brain drain has only just begun. Juan José Rodríguez Sendín, president of Médica Colegial, predicts there will be more than 10,000 unemployed medics within two years. 'There's been no reduction in the number of places to study medicine; around 7,000 doctors qualify each year, and more and more of them will join the unemployed. Their only hope of finding work is to go abroad. Some are happy to seek a new life and career opportunities abroad, but the majority feel that they have no choice,' he believes.

Obviously, the principal reason to emigrate is human resources cuts in the Spanish Healthcare sector, caused by the crisis. The few next years' forecasts are not at all optimistic. Spain's worsening economic crisis -- coupled with deep spending cuts in health that mean working under temporary contracts with little hope of a permanent position in a hospital -- is prompting growing numbers of young medics, whose training has cost the country millions of euros, to leave to work abroad. Thus, Spain faces a scientific as well as economic loss. The country is failing to capitalise on highly qualified professionals (the cost of training a doctor is around €200,000 euros). Full recovery from this situation will need, at least, a decade.

Spanish doctors in Sweden

Eskilstuna is an attractive town around 120 kilometres west of the Swedish capital of Stockholm, the HQ of carmaker Volvo, and the home of Abba singer Frida Lyngstad. This is the home to paediatrician Jorge Sotoca and ophthalmologist Mercedes López, a Spanish couple both aged 33. Last February they started work at Eskilstuna's hospital, which has a catchment area of 400,000 people.

Their reasons for leaving Spain are simple: 'Job insecurity, uncertainty and fear about where Spain is heading, few opportunities for career growth, and the chance to give our daughter a good start in life,' Jorge Sotoca explains.

Job opportunities

- According to the BBC News Website (2013), at least 18 countries in the world are interested in recruiting GPs and specialist doctors, most relevantly:
- Australia - Anaesthetists, gastroenterologists and neurosurgeons are among the 30 specialists Australia needs. National average salary: US$44,983
- Germany - About 5,000 doctors are needed. This is the country's best-paid profession: average salary €49,000 (US$63,741) .per annum.
- United Kingdom - This country needs seven types of specialist practitioners, including paediatricians and gynaecologists, and consultants in haematology and forensic psychiatry. Here the national average salary is US$44,743

*Report based on an August 2012 El Pais article

The Dark Side

Continued from page 1

example in many regions of Spain the newly trained don't stand much of a chance to ever find a job. On the other hand, in Nordic countries, or Germany, institutions are looking for staff, both in hospitals and in the growing sector of long-term care.'

Are any specialities in demand and therefore especially missing in other countries?

'That's hard to tell but, as a physician, the more elaborate your specialty is, the more likely it may be that you are wanted elsewhere. Famous academic teachers and researchers may be looking towards Latin American universities instead of remaining in Spain. It goes without saying that, as a rule of thumb, the most mobile may be those with sufficient professional knowledge and experience, fluent English and probably a network with foreign colleagues.

'Poor countries with inferior infrastructures will have even fewer doctors and nurses in future. It will be difficult to plan resources. This trend is already visible. People start to arrange themselves somehow. A little backhander here, a helping hand from a better-off or well-connected relative there, some money from family members working abroad made all the difference. For those without such resources – the utterly poor and deprived – access to care has always been shamefully difficult. This hasn't changed much, except that the poor have become even poorer and the small middle-class – for example in Hungary – is in real difficulties.

'The shocking reality is that such conditions are no longer confined to traditional hot spots of poverty in the East. The brutal chain of events goes as follows: no economic growth, more public and private debts, no jobs and shrinking public benefits. As for accessibility of care, the differences within the EU are widening almost every month. Brussels doesn't act, nor could it. They are keeping up appearances. This is policy making for the gallery – almost at Brussels prerogative these days.'

France: Immigrant medics steadily increase

Annick Chapoy reports from Paris

The number of medical practitioners in France is 216,000, among which 17,835 were trained elsewhere, representing almost 10% of the total, according to the Centre National de l'Ordre des Médecins (CNOM), which registers doctors in practice.

Globally, the total number of doctors is stable compared with 2012, as shown in the Atlas of medical demography recently published by the CNOM.

The proportion of foreign practitioners has increased significantly in recent years, a 43% jump between 2008 and 2013. By 2018, the CNOM predicts another 34% increase. All areas of France have experienced this growth. In the Région Auvergne, the central area of the country, the number of foreign degree holders has almost doubled since 2008.

As opposed to their French counterparts, these foreign doctors are mostly salaried practitioners (63.5% against 43.1%). Hospitals need them where specialists (e.g. radiologists and anaesthesiologists) are in short supply.

Some are French nationals because, as a result of a quota system in France that eliminates a great number of students after the first year of medical school, some medical students train elsewhere: Belgium, Romania or Bulgaria, CNOM president Michel Legmann points out.

In 2012, almost 25% of newly registered doctors at the Ordre des Médecins, had a degree gained in a foreign country (11.4% in Europe, 12.7% outside it).One third of practitioners holding a foreign degree gained it in Maghreb countries, the most prevalent is Algeria (22% of the total). Second comes Romania (17.7%) and Belgium (8.9%). Morocco, Syria, Tunisia, Germany, Italy and Spain follow.

One reason to choose settlement in France is often potentially better work environment and remuneration. In Hungary, for example, an intern's salary is one fourth of his French counterpart. 'Almost all doctors from outside EU countries arrived here to finish their studies in their speciality and they want to stay in France where they find a better environment for their trade,' explains Renaud Gansey, a Bénin native, working as a nephrologist at the CHU (University Hospital) in Nantes. 'Only a small number stay because of political problems in their countries.'

Official data do not take into account a 'significant number' of foreign doctors working in hospitals with a status of 'associate' and therefore are not registered by the CNOM, Michel Legmann stresses.

The CNOM 'is not in a position to identify them clearly', and is 'a little problematic because these practitioners are hired illegally to fill vacant positions, often under the pressure of local politicians who want to maintain local hospitals in activity,' he explains. 'This is a problem because their degrees are not assessed and their salaries are less than those of French doctors.'

Since February 2012, new legal dispositions make it easier for doctors trained outside the EU, and who have had some experience working in French hospitals, to continue their practice, and opens for them the possibility of taking equivalency tests. Eventually they obtain the same status as their French counterparts and are officially registered by the CNOM.

'It takes an average of 10 years of practice in France before doctors with a training outside the EU reach equality with their French counterparts, sometimes even more,' explains an official of SNPADHUE, the union representing doctors with outside EU degrees. For a decade this union has fought for fair recognition of their qualifications, and the official adds 'newly registered doctors' according to CNOM statistics, are often experienced practitioners who have worked in French healthcare for years under the 'associate' status.

'Foreign doctors don't have difficulties finding positions in French hospitals, because they are actually needed, they enjoy excellent relations with their colleagues and patients, but regulations are the problem. The competence of foreign practitioners and their qualifications are unquestioned, but it takes a very long time for them to be considered,' adds Salima Hanifi, of the SNPADHUE.

In spite of the boom of foreign doctors, France doesn't have a coherent recruitment strategy. A small village will itself hire a GP to replace a retiring GP, or a small hospital will 'go shopping' for an anaesthetist… foreign doctors in effect act like an adjustment variable of healthcare policy. Additionally, there is no standard for French fluency.

Renaud Gansey, a Benin native nephrologist on emigration of foreign doctors

Germany: Promised Land for Spanish medics?

While German medics leave the country in search of better conditions, foreigners fill the gaps. Spain, with its troubled economy, provides a major source. Hubertus Stephan knows about expectations and reality; at his firm, Maleso Global, based in Freiburg, Germany, his bilingual team works extensively with candidates from Spain.

The company, he explains, is based on his extensive human resources background and his work in Spain and Latin America over the past 20 years. Using that expertise and human resources networks the firm particularly places healthcare professionals in Germany. 'We are driven to a greater extent by applicants and less by the customers who, in the end, pay the bill,' he explains.

'We begin by identifying candidates in Spain. After going through an extensive selection process, we work closely with successful candidates to prepare them for their work in Germany. This includes acquiring language skills, and extensive presentations on what awaits them in Germany and how daily routine there differs from providing care in Spain.'

Nurse difficulties

'More often than not, conflicts emerged in cases where candidates were not properly prepared. In most European countries, e.g. education of nurses takes place at the academic level. Their routine includes many tasks that, in Germany, are carried out exclusively by physicians – such as wound management and prescribing medication.'

In Spain and other countries, assistant nurses carry out 'lower-level' tasks, which are on nurses' work lists in Germany. Spanish nurses, unaware of this, may feel relegated. It is part of our selection process to ensure that highly qualified Spanish healthcare professionals are acquainted with these differences, so they are not frustrated – which would impact on themselves, their employers, as well as patients.

Some nurses have decided against Germany for these reasons. In quite a few cases, we go through these induction processes with interested nurses even before we have a concrete placement available.

Physician difficulties

'It's mostly about language competence. The B2 language certificate required by most German states may be sufficient for nurses, but that competence may just not meet real life needs for physicians. This is why we declined scouting for psychologists in Spain – even three years of learning German will not be enough for work that relies heavily on the spoken word. Radiologists have less of an issue because of reduced contact with patients; reports in German are less challenging.

'Regarding qualifications, Spanish physicians typically meet requirements. However, for physicians migrating from Latin America to Spain, where their qualifications are acknowledged, we may find a qualification gap. It won't make sense to go through a lengthy process trying to add necessary qualifications. Filling gaps regarding practical work experience is currently difficult in Spain because of the job market.'

Scouting for candidates

'Our partners in Spain use pin board notices in universities and educational institutions, and speak directly with healthcare professionals in care provider organisations. We place advertisements and banners in portals; our Freiburg team carries out interviews; we travel to Spain frequently.

'The feedback is generally very positive – thanks to the fact that we are diligent in selecting our customers. There are organisations in Germany that will make improper use of the difficult situation of nurses in Spain, Bulgaria, and Romania – our organisation will not accept unfavourable arrangements, and therefore the level of satisfaction is high among professionals placed by us. They communicate back to their colleagues at home, helping us to expand our network and creating the perfect source for new candidates.'

Details: info@maleso.net.

Hubertus Stephan, CEO of Maleso Global GmbH

Further migration reports will be published in EH-5-2013

Shared medical appointments offer hope

Chronic disease

Report: Cynthia E Keen

The global shortage of doctors is worsening every year. With the demographic shift in many countries from a predominantly young to an increasing aging population, a steep increase in chronic disease is also occurring. This is particularly true in the United States, where approximately 140 million residents have been diagnosed with debilitating chronic medical conditions.

Treatment of chronic diseases is estimated to be 75% of healthcare costs in the US Medical treatment of diabetes alone costs an annual $116 billion to treat 26 million patients. The National Institutes of Health projects that, by 2050, up to 20% of the USA's population will be diabetic. Who will take care of these patients?

The shared medical appointment with a doctor by a group of patients with the same medical conditions is one solution. Champions have been promoting the concept for nearly 20 years. Until recently, they've been ignored – but this is changing.

Over the past five years, there's been a steady increase in its use. An annual survey by the American Academy of Family Physicians shows that use has doubled, from 5.7% in 2005 to 11.8% in 2012. AAFP strongly endorses group visits as a way to lower costs, improve patient treatment, and reduce workload overload and stress for physicians. It also leverages a physician's time and helps make them more productive. For patients, group visits help reduce long waits to see a doctor and are more informative. Most patients react positively to fellow patient interactions and manage their disease better.

What a group visit is

In addition to diabetes treatment, group visits are increasingly used to treat patients with asthma, arthritis, Parkinson's disease, pre-surgical consultations about joint replacement, pregnancy disorders, and cardiac disease. There are several types of group visit models. Between six and 15 patients with the same medical conditions are scheduled with a doctor. Chart review is performed in advance to determine if laboratory tests are needed or if medications should be changed. Nurses may briefly see individual patients in advance to record vitals such as weight, temperature and blood pressure.

The doctor typically reviews each patient's case. Each patient is encouraged to discuss his problems or concerns and ask questions. This often leads to a lively discussion by the group, some asking additional questions and others offering advice. The meeting may include an in-depth discussion of a specific topic, but it is presented in a facilitator role to encourage discussion, not as a lecture.

Clinical psychologist Edward B Noffsinger PhD was the first to pioneer and champion the concept. Seriously ill with primary pulmonary hypertension, he was frustrated with the fragmented and rushed care he received from specialists he had waited weeks to see. He introduced the concept of a group visit with his then employer Kaiser Permanente and he subsequently authored two 'how-to' books. 'The first groups that showed interest were the large, well-endowed medical groups: Cleveland Clinic, the Sutter Medical Group and recently Carolinas Medical Centre,' Dr Noffsinger said. 'Then came the mid-sized progressive-thinking non-profit and for-profit hospitals, as well as the US Department of Defence and the Veterans Health Administration, then medical clinics.

'The slowest group to respond has been public hospitals and the public health sector, primarily because they do not have the resources that are initially needed to plan and implement group visit programmes; but public health needs to implement this paradigm health shift the most,' he added.

Dr Noffsinger hopes to develop a curriculum and be invited to teach at a medical school so that new doctors are indoctrinated and the methods of setting up group visits can be propagated throughout both developed and developing countries.

Group visits in Europe

Within Europe, the Dutch Institute for Healthcare Improvement (CBO) in Utrecht set up its first group visit pilot project in 2005. The organisation offers courses on setting up and implementing shared medical appointments as part of their regular programme. By 2011, more than 60 multidisciplinary teams from 35 different hospitals in the Netherlands offered group visits -- in paediatrics, rheumatology, dermatology, neurology, oncology, gastroenterology, urology, gynaecology, internal medicine, HIV and infectious medicine.

Few formal randomised clinical studies have been published about the outcomes of patients assigned to either conventional care or group visit care. The leading study that evaluated outcomes and costs was the ROMEO (Rethink Organisation to iMprove Education and Outcomes) multicentre randomised trial of lifestyle intervention by group care to manage type 2 diabetes.

The ROMEO trial followed 581 patients receiving treatment at 11 clinics in Italy over a four-year period. Principal Investigator Marina Trento, at the University of Turin, and her colleagues showed that group care was more effective than usual care in improving metabolic

Another fine MES for healthcare equipment finance

Managed Equipment Service (MES) contracts have the potential to transform equipment-supply financing for healthcare, according to Siemens Financial Services' Ulrich Stark, Head of Debt Origination for Healthcare in EMEA, and Anthony Casciano, CEO of Project, Structured & Leveraged Finance Healthcare

In September 2012, technology provider Siemens Healthcare signed a contract with University Hospital Southampton NHS Foundation Trust. The deal involved the supply of over 130 pieces of equipment over a 13-year period. Constituted as a Managed Equipment Service (MES) contract, the deal is one of 12 such arrangements between the company and various UK NHS Trusts – with several more still under negotiation.

Ulrich Stark joined Siemens Bank in March 2012 as Head of Debt Origination Healthcare - EMEA (Europe, Middle East and Africa). His team is responsible for loan origination for healthcare transactions across the region, including project finance (including PFI/PPP), corporate loans and large-scale structured equipment financing. Before joining Siemens Bank, he worked for more than 10 years at HSH Nordbank, from 2004 as head of Infrastructure EMEA. Key projects include mandates as financial adviser and lead arranger for the first PPP financing in Belgium (Northern Diabolo Schieneninfrastuktur PPP, 2007) and Norway (E39 Klett-Bardshaug Road PPP, 2003). He was also responsible for structured asset finance transactions for logistics clients.

Indeed, the MES model for hospital equipment supply is proving to be a potential boon for cash-strapped NHS Trust procurement departments. Under MES contracts, major equipment suppliers, such as Siemens, undertake to own and manage the entire equipment requirement on operational facilities or major green field or expansion projects (perhaps a new hospital or hospital extension) for the life of an agreed concession. This includes procurement, delivery, installation and commissioning, user training, asset management and maintenance. It also includes the on-going replacement of equipment, to ensure that it remains state-of-the-art, and disposal. Additionally, it includes the cost risk associated with ownership and planned replacement.

Importantly, the contract is regardless of the manufacturer – meaning that Siemens Healthcare's role is to procure the equipment on behalf of its client, no matter what its provenance. Of the equipment supplied under the agreements, substantial elements are being sourced rather than manufactured by Siemens, which – of course – still employs their considerable knowledge of the healthcare equipment universe.

Feedback from NHS Trusts states that the benefits of the MES arrangement include:

- The certainty that the hospital will source the equipment it needs at a fixed cost for the contract duration.
- A performance guarantee knowing that the equipment supplied will perform as required, or be replaced at the provider's expense.
- The ability to pay less if the performance of a piece of equipment does not meet the agreed standard.
- Having a single technical partner motivated throughout the contract to ensure the equipment supplied is operating optimally.
- Automatic access to equipment-upgrade cycles or future innovations.

For these reasons, we are seeing activity for MES contracts in a variety of jurisdictions. Although such contracts have the potential to transform healthcare equipment supply, each jurisdiction will need to adapt them to suit their own healthcare structures. As well as the UK – where the concept is most developed – MES contracts are also an established equipment procurement route in Spain, with the Netherlands currently implementing the required enabling legislation. Germany, too, has a parallel structure to the MES contract – the *industriepartnerschaften* – although, as it is lease-based, the emphasis on the service aspects of MES contracts are somewhat downgraded.

Additionally, in a November 2012 survey commissioned by Siemens, when asked to compare five value propositions for equipment provision, 200 healthcare executives in the USA found MES the most attractive of the potential models: with around 50% of respondents rating it six or seven in a seven-point scale of attractiveness.

Financing is important

The financial nature of several of the other models listed in the survey (e.g. trusted partnership, linked sales, corporate structured financing and revenue risk models) is revealing – not least because MES contracts dispense with the need for major upfront financing for equipment supply: paying, instead, on a periodic or per-use basis. However, this leaves the equipment supplier having to procure and install the equipment prior to receiving any payment, which may be beyond the capacity of most equipment suppliers – at least without help from a financier. For Siemens, this help comes via its in-house financier: Siemens Financial Services (SFS).

In fact, SFS finances the contract for Siemens Healthcare – structuring the deal via a 'sale of receivables' between the supplier (Siemens Healthcare) and financier (in this case SFS). Such an arrangement alleviates any cash and risk management needs the equipment supplier may have over the duration of the project – allowing them to bring their technical expertise to the fore while maintaining cash flow efficiencies.

In this respect, the role of the in-house financier is important. The equipment supplier can develop a close partnership with the project sponsor while not having to worry about counterparty risk. Meanwhile, Siemens Healthcare has the benefit of improved internal cash flow.

Of course, such a role is a strong use of an in-house financier, although they are becoming increasingly involved across a range of financial situations in healthcare project finance. Partly, this has been driven by the post-crisis hiatus in bank lending for all but the largest corporates. Since 2007, bank constraints for supporting equipment-supply projects have been particularly acute in Europe, although 2013 has seen a strong return of bank lending appetite for project or asset-based financing.

However, institutional investors have yet to develop the strong risk evaluation skills of the banks, which means they rely on trusted intermediaries to source and evaluate deals, as well as act as co-investors. This can be via partnerships with financiers and captives.

Spurred by the changes taking place in today's funding market, captives are expanding their role in financing within the healthcare sector. Of course, in-house financiers such as SFS were set up for such a role – both to support sales of technology and to help finance the value chain (including both suppliers and purchasers) using innovative financing techniques. Yet the recent constraints within the banking mar-

Edward Noffsinger, clinical physiologist, was the first to pioneer the concept

control, along with the participants' health behaviours, knowledge of diabetes and quality of life.

Cost of shared medical visits

Very little information has been published about the cost of a patient treated primarily in a group visit setting, compared to conventional treatment. The ROMEO trial determined that overall costs per patient year were comparable. However, the amount of time a 'group visit' patient spent with a doctor was half that of a 'traditional' patient.

Additionally, a study of 400 patients with chronic illnesses treated at Kaiser Permanente in Colorado showed that hospital admissions dropped from 39% to 27% among those enrolled in group care. Annual emergency department visit rates dropped from 53% to 35%.

NB: See www.european-hospital.com for a more detailed electronic version of this report.

Anthony Casciano BA (econ) MBA, graduated from Drew University and gained his marketing MBA from Rutgers University's School of Business.
Prior to joining Siemens in 2008, he was managing director and head of DB Mid-Market Capital at Deutsche Bank. As senior vice president and general manager at Siemens Financial Service (SFS) in North America, he specialised in leveraged lending to middle market and larger corporate clients.
Today, Anthony Casciano is chief executive officer of the Project & Structured Finance – Healthcare and Leveraged Finance businesses for SFS, where he oversees the growth of SFS activities in the global healthcare market.

ket have brought these roles to the fore, with the potentially structural changes meaning they are unlikely to retreat, despite the evidence of returning liquidity.

Certainly, in-house financiers such as SFS will continue to develop solutions – such as MES contracts – that support the needs of the healthcare market, while highlighting their advisory role in support of client business strategies.

Indeed, banks, project sponsors, specialist funds and institutional investors are all encouraged by the fact the in-house financier of a major supplier is prepared to risk its own balance sheet to support its technology, which – because of their ability to evaluate their own kit – is a role most are happy to play.

Optimising workflow under 'real-life conditions'

Hospital in a lab

The new Hospital Engineering Lab in Duisburg, Germany, which was officially opened in July by Barbara Steffens, Health Minister for the German federal state, is a project of four Fraunhofer Institutes. They partner with more than 80 institutions from industry, networking societies and researchers, to give users, manufacturers and scientists the opportunity to simulate different hospital-related scenarios under real-time-conditions and measure their effects – in terms of costs and quality care.

Report: Meike Lerner

Well-meant is not always well done – this is also true of innovations in healthcare intending to improve quality in care and to optimise standard processes in hospitals. Often enough new products function fine in their own right but do not have any impact on workflow optimisation because they fail to interact with patients or medical staff, existing and established technologies or procedures. The result: Hospitals and healthcare systems are burdened with costs for new investments that bring no financial release in daily business due to improvement of care in return.

Facing a situation in Germany, where every fifth hospital is in the red, this turns out to be an existential problem for hospitals. On the other hand, companies rarely have 'real-life conditions' in which to test their products practically before rolling them out into the market. The Hospital Engineering Lab was established in Duisburg to break through this no-win situation for both parties.

Spread over about 350 square metres, the new lab offers a replica of all relevant hospital areas – operating theatre, rooms for patients, nurses and doctors, as well as supplying and functional units. 'The idea was to set up an environment that helps us to act out hospital processes in different scenarios, adapt experiences from hospitals and modify strategies and technologies in a team. We aim to avoid unnecessary costs and improve quality of care and efficiency by developing intelligent and user-driven technologies,' explained Dr Wolfgang Deiters, Assistant Director at Fraunhofer ISST in Duisburg (ISST=Institute for Software- and System Technology), which hosts the new lab.

Pictures (2): Fraunhofer Institut

Health Minister Barbara Steffens speaking with experts during her walkabout in the new Hospital Engineering Lab

Within this process the first, and maybe most important, realisation is that intelligent does not always mean highly sophisticated as one striking example shows, and noted in Barbara Steffens opening speech. A hospital that invested in new telephone equipment for patient rooms was suddenly faced with many more calls for nurses. The simple reason: older or even dementia patients could no longer operate the high-tech telephones and needed assistance for every call they wanted to make. Consequently, the hospital was doubly stressed – by the investment for the new equipment and by additional work for staff.

To analyse daily business processes such as this, the Hospital Engineering Lab is equipped with solutions and products of around 60 vendors – ranging from hygiene dispensers to energy supply solutions. These products are tested separately, as well as in combination with the rest of the equipment and within the working process.

Dr Wolfgang Deiters, Assistant Director at Fraunhofer ISST in Duisburg

Remaining a work in progress

In doing so, companies and users can be sure of rolling-out practical solutions with deep impact on the performance of a hospital – in a positive way, of course. The Hospital Engineering Lab is not planned to be completely finished on any particular day; on the contrary, it is designed to re-invent itself continuously by hosting and testing new products and processes regularly. So far, several highlight issues have evolved, for example sensor-based assistance systems. By recognising a patient and optimising the environment accordingly or sounding an alarm – e.g. in the bathroom – these solutions have the potential to optimise comfort and safety for the patients. Another topic is the use of RFID technology, like labels, to survey and document numerous procedures in the operating theatre or elsewhere.

A huge issue in every hospital are the logistics of purchasing and distributing materials and pharmaceuticals. What is needed when, where and in what amount? Answers to these questions are also worked out in the lab. As one of the biggest cost drivers, energy supply is, of course, another issue. At the moment it is testing how an individually regulated wattage can decrease costs by need-based acclimatisation of rooms.

Last but not least, technology not only has the potential to boost recovery directly but also, in an indirect way, by creating an environment in which the patient feels comfortable. That is why things such as light concepts are also a strong focus, along with ways to improve personal care by creating more time for staff to spend with a patient.

Altogether, walking through the lab gives you an idea of a bright future of care – both for hospitals and patients. Whether or not this small 'lab-world' becomes a reality one day, or only remains as a nice try, is the something that cannot be simulated so far.

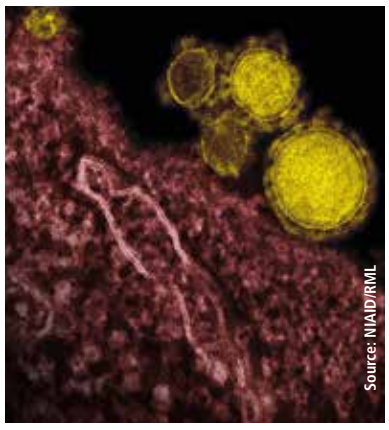
MERS-CoV: Global action needed?

With so much unknown about the pathogenicity of the virus, fears spread over transmission during massive religious gatherings

Report: Mel Poluck

The World Health Organisation (WHO) recently formed an international emergency committee to decide whether Middle East Respiratory Syndrome Coronavirus (MERS-CoV) should be ascribed Public Health Emergency of International Concern (PHEIC) status, amid reports of a lack of information from the worst affected countries.

The 15-strong committee of experts will report to WHO's Director General with technical advice to determine whether MERS-CoV requires the PHEIC, in which case the committee would recommend temporary global measures to control the spread of the virus. MERS-CoV has already killed more than 50% of the 80 people it has infected in nine countries.



Transmission electron micrograph of novel coronavirus particles, coloured yellow

The first emergency talks on the virus coincided with the start of Muslim festival Ramadan, when more than two million international pilgrims make the Umrah pilgrimage in Saudi Arabia – where 66 cases have been recorded. Another mass gathering in Saudi Arabia this October, the Hajj, attracts more than three million pilgrims, which will put MERS-CoV transmissibility to its greatest test.

The committee heard a review of the situation from the WHO Secretariat and briefings from representatives of countries where MERS-CoV has occurred. However, the Director General announced that the committee was to reconvene on 17 July because 'additional information was needed in a number of areas'.

The lack of available information on the virus is explained by a short supply of samples, according to Professor Christian Drosten, Head of the Institute of Virology at the University of Bonn Medical Centre. 'European labs have driven the process, from the discovery of the virus to the development of diagnostic tools and the development of first recommendations for clinical treatment,' he explained. 'However, no samples have arrived in Europe from any affected Middle Eastern countries… The gap is really in the epidemiological field, where research has to be done in – and supported by – the affected countries.'

Professor Drosten has identified the first virulence factor, an interferon induction antagonist, and is now focusing on how and where the virus is spreading and trying to locate its source. 'We're working on a few samples from imported cases in Germany and we've conducted a small collaborative study with a lab in Saudi Arabia.' However, he added: 'Much more would have to be done, with more than one pair of collaborating labs.'

Although the first case was diagnosed in Spring 2012, medical professionals still did not know what the animal reservoir is or why people are becoming infected. In its rapid risk assessment dated 18 June, The European Centre for Disease Prevention and Control said: 'It is unusual to have such a degree of uncertainty at this stage in an outbreak.'

A limited human-to-human transmission

The virus displays limited human-to-human transmission mainly within families, in hospitals (patient-to-patient and patient-to-healthcare worker), and sporadic infections are occurring in towns and villages. A research report from Johns Hopkins University found that MERS-CoV is easily transmitted in a healthcare setting, based on studies in four Saudi Arabian hospitals, one of which was the source of several infections linked to dialysis patients.

However, the pattern is changing. While symptoms usually include severe acute respiratory infection, eight recent cases in Saudi Arabia were asymptomatic. And although the virus has mostly infected elderly individuals, particularly men, four of the eight were female healthcare workers and the other four, children aged between seven and 15 years.

Several European labs continue to investigate the virus, many of which worked on the closely related SARS-CoV, which broke out a decade ago, although it had a much lower death rate of 9%. 'We will have a load of valuable data from the research field coming out this year,' Professor Drosten predicts.

Christian Drosten MD is Professor of Virology and head of the Institute of Virology at the University of Bonn Medical Centre, Germany.
He studied medicine at the University of Frankfurt/M Medical School and joined the Virology Department at the renowned Bernhard Nocht Institute for Tropical Medicine in Hamburg, where, in 2002, he became laboratory head for Molecular Diagnostics before accepting his current role in 2007. The Institute's diagnostic laboratories serve a 1,300-bed University hospital, covering all human viruses with a full spectrum of diagnostic techniques and strong focus on molecular diagnostics. Research focuses on emerging viral diseases, using coronaviruses, alphaviruses and flaviviruses as main model organisms.

UPDATE: MERS-COV FOUND IN DROMEDARY CAMELS

Antibodies specific to MERS-CoV has been found in dromedary camels, according to research published in The Lancet Infectious Diseases.
An international research team led by Dr Chantal Reusken, at the National Institute for Public Health and the Environment in Bilthoven, the Netherlands, gathered 349 blood serum samples from livestock in various countries (Oman, the Netherlands, Spain, Chile), which included dromedary camels, cows, sheep, and goats, as well as some animals closely related to dromedaries.
The blood serum samples were analysed for the presence of antibodies specific to MERS-CoV, as well as antibodies reactive to SARS coronavirus, and another strain of coronavirus labeled HCoV-OC43, which can also infect humans and is closely related to a bovine form of the virus.
The Netherlands researchers found no evidence of cross-reactivity between antibodies for MERS-CoV and those for SARS or HCoV-OC43, confirming those findings using highly specific virus neutralisation tests.
The results suggest that the presence of MERS-CoV specific antibodies is likely to indicate previous infection with MERS-CoV, or a closely related virus, at some point in the animal's history.
No MERS-CoV antibodies were found in blood serum taken from 160 cattle, sheep, and goats from the Netherlands and Spain. However, antibodies specific to MERS-CoV were found in all 50 serum samples taken from dromedary camels in the Oman – samples originating from a number of several locations there, suggesting that MERS-CoV, or a very similar virus, is circulating widely in Oman's dromedary camels.
Lower levels of MERS-CoV-specific antibodies were also found in 14% (15) of serum samples from two herds of dromedaries (105 camels in total) from the Canary Islands, not previously known to be a location where MERS-CoV is circulating.
No antibodies specific to the virus were detectable in tests on 34 animals closely related to the dromedary, such as Bactrian camel, alpaca and llama sampled in the Netherlands and Chile.
'The dromedary camels that we tested from the Middle East (Oman) were more often positive and had much higher levels of antibodies to MERS-CoV than the dromedary camels from Spain,' the researhers pointed out. 'The best way to explain this is that there is a MERS-CoV-like virus circulating in dromedary camels, but that the behaviour of this virus in the Middle East is somehow different to that in Spain.
'As new human cases of MERS-CoV continue to emerge, without any clues about the sources of infection except for people who caught it from other patients, these new results suggest that dromedary camels may be one reservoir of the virus that is causing MERS-CoV in humans.
Dromedary camels are a popular animal species in the Middle East, where they are used for racing, and also for meat and milk, so there are different types of contact of humans with these animals that could lead to transmission of a virus.'
The team called for further animal studies for MERS-CoV in the Middle East, to identify the virus that triggers these antibodies in dromedaries, and compare this with the virus from human cases. It also urged follow-up of new human cases to gather information about patients' contacts with animals and animal products, such as camel milk.
Further details: http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(13)70164-6/abstract

Manufacturing World Japan 2013

Successful? Yes. 76,701 people arrived in three days

Certainly this is among the world's largest manufacturing exhibitions. Held in June this year, at Tokyo Big Sight, Japan, the event included the 17th Mechanical Components & Materials Technology Expo (M-Tech); the 4th Medical Device Development & Manufacturing Expo (MEDIX); the 24th Design Engineering & Manufacturing Solutions Expo (DMS) and the 21st 3-D & Virtual Reality Expo (IVR), 1,930 exhibitors. Among the 1,930 exhibitors, 223 came from 23 overseas countries – including Austria, Belgium, China, Finland, France, Germany, Hong Kong, Hungary, India, Ireland, Israel, Italy, Korea, Malaysia, Pakistan, Russia, Singapore, Spain, Switzerland, Taiwan, Thailand, USA and Vietnam.

Unveiled front-line technologies

The 17th Mechanical Components & Materials Technology Expo (M-Tech) featured products that aim to reduce manufacturing time and streamline manufacturing. The 24th Design Engineering & Manufacturing Solutions Expo (DMS) showcased the latest 3-D printers from small-size low-price units for personal use to high-definition units capable of producing millions of colours for professional use. Some exhibitors also provided hands-on demonstrations.

Special seminars held in each of the four concurrent shows offered technical and management talks by top-notch executives, researchers and government officials: Honda R&D Co., Ltd., Manufacturing Management Research Centre of the University of Tokyo, Ministry of Health, Labour and Welfare, Disney Research Pittsburgh, and more, packing the rooms with hundreds of professionals. Lively business meetings were also conducted in each booth at the exhibition.

DIARY DATE:
Manufacturing World Osaka 2013
2-4 October 2013

As western Japan's largest manufacturing technology trade fair, and given the umbrella title Manufacturing World Osaka 2013, this event will include the 16th Mechanical Components & Materials Technology Expo Osaka (M-Tech); 16th Design Engineering & Manufacturing Solutions Expo Osaka (DMS) and the 4th Medical Device Development & Manufacturing Expo Osaka (MEDIX).

The show organiser, Reed Exhibitions Japan Ltd., predicts a turnout of over 900 exhibitors and 32,000 visitors from around the globe.

As home to many local companies, the Western Japan area, centred in Osaka, has led the Japanese manufacturing industry for years. Hence, the event always attracts decision makers and industry professionals from Asian countries as well as Japan. This year, Taiwan, Korea and Thailand will have their own pavilions, creating a meeting place to see and discuss Asia's most advanced technologies.

Details: http://www.japan-mfg.jp/en/osaka/

The National Health Service Taskforce

A new organisation is formed to help end serious surgical errors

Report: Mark Nicholls

A taskforce has been set up in England after it emerged that more than 750 patients had suffered as a result of serious preventable mistakes in hospitals over the past four years. The incidents included cases of surgeons operating on the wrong part of a patient's body or leaving surgical instruments inside after a procedure. Such incidents are categorised by the Department of Health as 'never events' because they are deemed to be so serious that 'they should never happen'.

Now, the Royal College of Surgeons has stepped in to help take steps to ensure that such errors – which should never happen if national safety recommendations are followed by medical staff - are cut significantly. The President of the Royal College of Surgeons, Professor Norman Williams, said: 'The recent survey of "never events" in hospitals in England shows unacceptable levels of preventable mistakes are still happening. However rare these incidents are, we believe never should mean never and avoiding such errors should be the priority of every surgeon.

'Together with NHS England, we have formed a taskforce, which will look at ways to put an end to such errors. The group will be working with patients, individuals and

organisations to learn from what has happened in the past to understand how to prevent them in the future.'

The number of incidents came to light following a Freedom of Information request to National Health Service (NHS) Trusts with findings that there were 322 cases of foreign objects left inside patients during operations; 214 cases of surgery on the wrong body part; 73 cases of tubes, used for feeding patients or for medication, being inserted into patients' lungs; and 58 cases of wrong implants or prostheses being fitted.

In one example, a mother-of-four was left with seven-inch forceps inside her for three months following keyhole surgery to remove her gallbladder. The mistake was only discovered after the patient was sent for an MRI scan, which added to her agony when the magnetic field from the scan caused the metal inside her body to move.

As part of the on-going drive to reduce such incidents, the World Health Organisation's patient safety checklist has also been adapted for use in hospitals in England and Wales.

Professor Williams added: 'The World Health Organisation Surgical Safety Checklist is instrumental in reducing "never events" and we have supported its development and putting it into practice. Surgery is about team-working and the checklist allows all members of the theatre team to raise any concerns and is central to preventing avoidable mistakes.'

Dr Mike Durkin, director of patient safety for NHS England, has ordered a review and said that NHS England – which sees some 4.6 million hospital admissions for surgery annually - has already started to collate data to help educate staff on better practice and avoid such incidents. He said that the number of 'never events' occurring in English hospitals was too many, adding: 'We need to understand what it is, in some systems and in some hospitals, that that team working hasn't produced an effective outcome and a mistake, and a 'never event' has occurred. 'This is not just the concern of one operating theatre in one hospital. It should be the concern of the leadership of that organisation, of the trust, so that they lead that trust and support both the staff in the operating theatres to work effectively, but also recognise their responsibility for leading safety across the whole of the trust.'

Consultant colorectal surgeon **Professor Norman Williams** is President of the Royal College of Surgeons (since July 2011). He is Professor of Surgery and Director of Innovation at the Academic Surgical Unit of Barts and The London, Queen Mary's School of Medicine and Dentistry and National Centre for Bowel Research and Surgical Innovation. His main clinical interests are sphincter preservation and reconstructive surgery, and his scientific interests are concentrated on GI motility and anorectal physiology.

Hygiene:Back to basics

Two statements from publications by Dr Stephanie Dancer, Department of Microbiology, Hairmyres Hospital, East Kilbride (UK) prompted *Ralf Mateblowski* to interview Professor Markus Dettenkofer, Acting Director of the Institute for Environmental Medicine and Hospital Hygiene, Freiburg University Medical Centre about environmental and infection control

In 2009 Dr Dancer stated: 'We simply don't know how to clean our hospitals in order to create the safest environment for patient care.'

'The situation is indeed still difficult,' Prof. Markus Dettenkofer commented. 'Who has actually been interested in relevant clinical studies on cleaning and infection control in hospitals? There was a lack of lobbying and financial opportunities such as those available for studies into antibiotics. There was also a lack of randomised and multi-centric approaches. However, the situation is improving: There are now current studies, especially in the USA, and also by Stephanie Dancer – an encouraging development.'

In 2011 she said: 'Comprehensive cleaning is also easier to implement than persuading busy staff to wash their hands or by reducing empirical antimicrobial use.'

'Hand hygiene is not given enough importance. In that respect, I find Stephanie Dancer's statement a little too provocative. Hand hygiene is the most important part of the entire process! No allowances should be made in this respect, with focus only on surface disinfection. No. Hand hygiene is and will remain number one. Antibiotics stewardship is also of the greatest importance, because effective cleaning and disinfection management alone is not enough, without strict antibiotics control and comprehensive antibiotics management.

Will classic cleaning with detergents, the basic prerequisite for successful disinfection, fall into oblivion?

'This may be the case in some hospitals, especially when there is a lot of financial pressure. However, in Freiburg we have – and I say this with pride – never forgotten about cleaning! Prof. Daschner spoke out against undirected surface disinfection in favour of proper cleaning early on. We employ our own cleaning team – a rarity, as most hospitals outsource cleaning to external companies, which often results in significant problems with quality. We don't experience these problems with our in-house staff. Fluorescence markers, for instance, are suitable for simple quality control. Located in critical positions, they will remain in place after insufficient cleaning and become visible under UV lighting.

'Floors and walls are not critical surfaces – these types of surfaces are in fact hardly ever the sources of nosocomial infections – but objects and surfaces with frequent hand contact are – and here there are repeated, large shortcomings in the daily cleaning process.'

That's despite the fact that Germany is the 'world champion' in setting out guidelines. Are we good theorists but bad practitioners, and therefore third-class in our MRSA ranking?

'That's only part of the explanation; the somewhat modest performance also can be put down to modern medical routines. One advantage is that we hardly have any waiting lists here. Admittedly, there are weaknesses in our high performance medicine when you go into details. Compared to the Netherlands or Scandinavia, our infection control is still not good enough. Over the last few decades we've expanded capacities in surgery, intensive care etc. but have frequently forgotten that controlling the spread of resistance particularly depends on the details.

'We are at a critical point in Germany: Specialists as well as the general public are aware that we must carry out consistent infection prevention and control in our modern medicine. But this has its price and involves hard, interdisciplinary work. It's not simply a case of the respective hospital departments for infection prevention and control organising everything, compiling standards and then everything happening of its own accord… to the contrary. It will continue to be intensive, detailed work in daily clinical practice, without a cure-all, such as the miracle antibiotics we used to dream about. 'The significant differences between individual European countries are a challenge for us. My urgent appeal: We have to learn from one another!'

Professor Markus Dettenkofer MD, head of the Section for Hospital Infection Prevention and Control at the Institute for Environmental Medicine and Hospital Hygiene, Freiburg University Hospital since 2008, is currently Acting Director of the Institute. A specialist in Infection Prevention and Control and Environmental Medicine, he began his career as a scientific assistant in 1993. His personal commitment and 20-year experience benefit national specialist associations such as the Future Hygiene Network (NZH) and German Society for Infectiology (DGI) as well as international organisations such as the European Society for Clinical Microbiology and Infectious Diseases (ESCMID).

Interactive patient care

Previously, we outlined how interactive technologies at the point of care support the goals of personalizing the patient experience and improving patient satisfaction. Interactive services at the bedside – including high-quality entertainment, communication, education, and feedback options – are the first steps towards increasing patient focus and allowing healthcare providers to position themselves for success.

Interactive patient care also addresses other key challenges in today's healthcare industry, including staff shortages and budget constraints. Opening up opportunities to streamline clinical workflow and tap into new revenue streams, interactive technologies improve both hospital efficiency and profitability.

Bedside access to critical patient clinical data

Using the power of existing IT systems, interactive patient care gives healthcare professionals access to a host of hospital applications (e.g. HIS, EMR, PACS). Capturing information electronically directly at the bedside reduces the time spent on non-clinical tasks and enables a more patient-centric workflow.

It's this constant drive to improve the quality of care that is fuelling the quick adoption of interactive solutions. A study in The Annals of Family Medicine found that 80% of error chains in medical cases are caused by miscommunication between physicians, misinformation, and inaccessible medical records. Powerful computing functionality at every bedside could literally save lives.

Streamlining routines saves money

Clinical access at the bedside dramatically reduces the burden of administrative and other non-clinical duties, translating into tangible benefits. A study performed by Deloitte found that clinical access at the point of care delivers financial benefits worth at least €465,000 per year in a typical 500 bed hospital and would save the equivalent of 14 members of staff per year.

Interactive patient care offers additional tools to streamline everyday hospital routines, including meal ordering, room and bed control, and nurse service calls. Automation allows patients to manage these routines themselves, driving patient independence while freeing busy staff for other duties.

Additional sources of revenue

Spurring improvements in clinical workflow and the quality of care, interactive technologies provide hospitals with real cost savings as well as new revenue streams.

Beyond doubt, empowering healthcare staff to increase their productivity and throughput will benefit the hospital's bottom line. The consolidation of various hospital systems (telephony, television, Internet, etc.) into a single interactive IT platform reduces the total cost of ownership, producing additional savings.

On top of that, these systems allow up-selling and promotion of local services, such as pre-packaged entertainment bundles, through various advertising options. By fostering awareness of available services, patients are encouraged to consume more, which maximizes yield and helps hospitals get the most out of their investment in IT.

Not optional, but critical

In today's highly competitive healthcare industry, the investment in interactive technologies generates multiple benefits for every stakeholder in the hospital. With an increased focus on patients, in a time when budget constraints and staff shortages make the delivery of care challenging, interactive patient care isn't optional, but it *is* critical. (mr)

Pinprick and needlescopic surgery without even small incisions – does it, or could it work?

Natural orifice translumenal endoscopic surgery

A record 1,700 participants from 84 countries confirmed the dimension and international importance of the European Association of Endoscopic Surgery Congress held recently in Vienna, where *Hans-Christian Pruszsinsky* caught up with Congress President *Professor Selman Uranüs*, Head of the Section for Surgical Research, Medical University of Graz, for our EH interview.

In relation to this year's scientific programme, which included 312 scientific sessions, 222 free papers in 20 sessions; 118 free videos; 522 posters with three award sessions; 20 grants and five award sessions (Karl Storz, Olympus, Gerhard Buess Technology, EAES video and European Cup), our correspondent first asked Prof. Uranüs for his assessment of the event in terms of surgical practice and which new trends in endoscopy and minimally invasive surgery are emerging. The professor confirmed: 'Remarkable results were indeed introduced. Fundamentally, we can say that the trend in minimally invasive surgery is heading further in the direction of reduced port surgery. This means a reduction in the number of surgical access points, as well as a further reduction in the diameter of the instruments required, which in some cases are now a mere 3mm or even 2mm. Where until recently the key word for laparoscopic interventions was 'keyhole surgery,' we are now talking about 'pinpricks', i.e. needlescopic surgery, which does not even require small incisions.

Surely it won't be possible to reduce the size that much more – so is this as good as it gets?

SU: 'Not at all – the tendency is towards a single port, i.e. an intervention via just one access point or the utilisation of natural body orifices respectively, which is what surgeons refer to as NOTES – natural orifice translumenal endoscopic surgery. For certain types of operations, such as in gall bladder surgery for instance, these methods are already being used, but it is mainly the hybrid procedures, such as conventional laparoscopy together with NOTES, which are being performed.

Who is driving force these developments –surgeons who would like their work to be more patient-friendly and precise; or increasingly beauty-conscious patients; or manufacturers of endoscopic devices who need to find new markets?

'We surgeons are essentially the drivers of this development because we are searching for ever more precise and patient-friendly procedures. However, I must note that, in the case of NOTES, we have not yet achieved a real break-through, despite being very optimistic in the beginning – around six to seven years ago. Despite the success mentioned for some surgical interventions the procedure is, to some extent, still in its infancy.

To what do you attribute this?

'There are a number of factors that are, in parts, mutually dependent. The development of flexible instruments that – after being guided into the operating area, can be made rigid again towards the front – must be advanced. Certain problem areas, such as the danger of infection, lumen enlargements or lighting control, which is also being trialled independently through magnetic movement, must also be considered. 'However, the biggest stumbling block appears to be the fact that, in direct comparison between needle laparoscopy and NOTES-based procedures, no real quantifiable benefit for the patient can currently be shown. No significant improvements can currently be seen, neither in pain reduction, nor cosmetic advantages, nor shorter hospital stays. The single port procedure with an incision of only 2mm in size near the navel is also confronted with this finding.'

How does a cost comparison look?

'When it comes to cost efficiency, traditional minimally invasive procedures are presently superior. However, despite this fact, some hospitals push the NOTES, or single port procedure respectively, to attract a certain type of clientele. In principle, the new procedures definitely have advantages for certain interventions, but at the moment they are not dominant enough to cover the entire minimally invasive range of surgery. But development continues and the emergence of further advances will soon also result in patient and cost-relevant improvements.'

What direction could device-related improvements take? Surely nothing can be made much smaller?

'Miniaturisation and mini-robots that can be inserted into the body, telemetrically controlled and handled and which can carry out surgery. There are small research groups across Europe – among others, here in Graz, and also in the Netherlands – that are working on this exciting topic.

'A further essential focus at the EAES was on the enormous advances in 3-D technology. Over the last few years there has been a real surge of development, which is particularly beneficial for work in the laparoscopic field. The significantly improved capabilities for the assessment of tissue are easing surgery, the improve precision, lower the error rate and improve treatment outcome. Colleagues who do not yet have much experience with minimally invasive surgery particularly appreciate this helpful technology, and the experienced "sly old foxes" are pleased about the additional benefits of clearly improved images.'

Professor Selman Uranüs,head of Surgical Research at Medical University, Graz, Austria

Apropos of better images – do modern imaging procedures have an impact on endoscopy and if so, what?

'Modern imaging procedures lower the rate of complications and increase treatment outcome, and the error rate falls. Improved early detection and more precise diagnostics are also very important. Collaboration with radiology departments is very cooperative and integration is becoming progressively tighter,' Prof. Uranüs concluded. 'Interdisciplinary cooperation serves an efficient workflow as well as the wellbeing of patients.

'Wet and warm' laparoscopy produces better results

Risks from cold and dry gas insufflation become history

Light microscopy images from the Davey study show the effect of warm and humidified insufflation gases compared to dry cold and dry heated insufflation

Report: Michael Reiter

Modern laparoscopy, the technique of looking inside the abdominal cavity, is a major medical innovation driven initially by physicians from Germany as well as by Swedes and Americans. Following its inception, around 1900, the technique found its way into routine clinical practice. Use of a video camera mounted on the laparoscope greatly facilitated minimally invasive methods in the 1980s: manipulating the scope was managed by a second person and images displayed on a monitor freed the surgeon's hands.

Pumping gas ('insufflation') creates space to provide visibility and room to move. However, serious issues remained unsolved, as Dr Jonathan Sackier from the University of Virginia explained at a recent event in Berlin, Germany addressing top surgeons from renowned hospitals. The gas used for these procedures, he pointed out, is conventionally delivered cold and dry, potentially harming the patient, and one of the numerous medical technology innovations in emanating from New Zealand now helps avoid the problems caused by 'cold and dry' insufflation.

'Physicians should never forget the lessons they have learned in surgery or indeed in any other discipline,' Dr Sackier stressed. 'However, there are new lessons to be understood, and we should all use our best judgment for the benefit of all our patients'. Laparoscopy, over the years, has turned out to be a brilliant approach; it allows patients to leave hospital sooner, and significantly reduces postoperative pain. However, several issues remain: 'The established standard has been to fill the abdominal cavity with carbon dioxide creating a pneumoperitoneum or gas-filled space. In our laboratory, we studied the effects on the peritoneum and general physiology of inflating with cold and dry gas.'

Cold and dry gas kills cells

In various countries, regulations rule out intra-operative cooling, he explained. In open surgery, warm and moist pads are used to pack away organs; this is done to avoid exactly the effects that, in laparoscopy, cold and dry gas produces: fat dries out and darkens, organ surfaces blanch and swell, cells desiccate and die. 'Look at the peritoneum', Dr Sackier pointed out. 'It's a very delicate monolayer, which covers a surface area larger than the skin. Damage to the peritoneum causes pain and inflammation and can lead to adhesions.'

So, while laparoscopy was inspired by reducing the harm physicians do, insufflation of gas at an average temperature of 15°C and zero humidity causes morbidity, the possibility of impaired fertility and even increased mortality in the medium and long term.

Warm and wet should become the gold standard

'Warming and humidifying insufflated gas, serves to significantly limit the negative effects which I have described,' he continued. 'The technology now in use delivers water molecules mixed in with the gas – very clever!

'Fisher and Paykel Healthcare have developed a device that suits these requirements; it helps to improve core body temperature, reduces pain and adhesions, speeds recovery and return to normal activities.'

Good surgical practices, Dr Sackier believes, clearly favour deploying this easy-to-use device.

Professor Jürgen Kleinstein,

Ikegami's Full HD video system

Ikegami as introduced a new full HD video system for medical applications, which consists of the MKC-210HD Full HD medical camera and the MLW-2150HD Full HD (3G) LED medical grade monitor.

'With its 1/3' sensor and Full HD resolution (1920x1080 Pixel), the MKC-210 HD gives superb picture quality, especially when combined with MLW-2150HD, 21.5' Full HD 3G multi-format LED monitor,' the manufacturer reports, adding that the 'remarkable picture quality produced by this equipment combination is available at a very competitive price'.

As an optional function, the MKC-210HD camera will also stream video over IP (H.264 compression), the company adds, so it 'can be used for any kind of telemedicine application or for simple recording to PC'.

Another bonus is that, according to Ikegami, the system can be mounted easily on older microscope systems (C-Mount and VESA mount) and therefore is 'ideal for upgrading your SD microscope video system to Full HD resolution'.

Further details: www.ikegami.de or contact: medical@ikegami.com

MKC-210HD

Surgeon **Jonathan Sackier MD** has helped to introduce laparoscopic techniques and his studies have been widely published. He left the UK to work at the George Washington University, Washington, D.C. where he co-founded the Washington Institute of Surgical Endoscopy. There, in addition to research activities, students and residents, as well as physicians from all over the world, are taught laparoscopy techniques. Today, he is Professor of Surgery and Medicine, teaching at the Department of Surgery at the University of Virginia in Charlottesville.

Director, Magdeburg University Hospital for Reproductive Medicine and Gynaecological Endocrinology, agrees: 'We've been using the system from Fisher & Paykel and have seen very good results, for example a reduced number of adhesions. During the procedure, benefits include a smaller amount of narcotics is needed, because the stimulus targeting the peritoneum is reduced… We will not do laparoscopic procedures without this system from Fisher & Paykel Healthcare; I strongly recommend colleagues should embrace it.'

Combating surgical infection risks

Shocking: Air quality checks are infrequent and insufficient in operating theatres. The good news: a new device can now measure pathogens circulating during surgical procedures, John Brosky reports

Surgical masks, special clothing and sterile packages – precautions taken to create a squeaky clean operating room are impressive, giving the surgical team confidence. Yet, this is exactly the space where the patient faces the highest risk of acquiring a deadly infection, with body opened, exposed to gloves, instruments and perhaps most importantly, to air.

Despite all the efforts made to prevent contamination, the Department of Health and Human Services recently estimated two out of every 100 surgical procedures in the USA result in surgical site infections (SSIs) and that healthcare-associated infections (HAIs) account for 1.7 million infections and 99,000 associated deaths each year.

The causes of infection remain a mystery despite prevention practices and advanced operating theatre technologies, such as horizontal flow ventilation or ultraviolet germicidal irradiation of upper room air.

Professor Daniel Talon MD believes you cannot prevent what you cannot measure. Head of Hygiene Services at the University Hospital Centre Jean Minjoz (Besançon, France), Prof. Talon developed the first device to measure pathogens circulating in the operating room during a surgery. Presented at the MEDTEC France exposition in May, ScreenAir was recognised as the top innovation in medical technologies at the event.

Currently, he said, standard practice in a hospital is to measure air quality in an operating theatre when no one is in the space. These air quality checks are performed every few months.

'This completely ignores the fact that any contamination in the operating room is created in *situ* by the surgical team,' he said, by their clothing, particles of skin that circulate, by their movements and even the number of time the door to the operating room is opened.

The ScreenAir device pulls the ambient air through a filter, programmed to sample the air at regular intervals during a surgical procedure. Each filter is indexed for the time of sampling to better identify when any contamination took place, thanks to a camera linking an image to the sample period. Each filter is then sent to the hospital lab for analysis using standard techniques to cultivate colonies of pathogens.

Early identification of a pathogen potentially hazardous to the patient enables the surgeon to consider administering a therapy of antibiotics before the infection can take hold. 'What we need is an ability to trace and quantify sources of infection,' Prof. Talon stressed. 'Checking the air every two months, or six months doesn't tell you much.'

The ScreenAir device is designed to be used for what Talon called clean surgery, procedures that do not involve the respiratory, gastrointestinal or genitourinary tracts, such as orthopaedic implantations, interventional cardiology, or laparoscopic procedures.

A professor at the University of Franche-Comté in Besançon, Dr Talon is a recognised authority on hospital hygiene and infections. He has authored 127 publications and his work has been cited 915 times in other publications.

He has studied the pathogens that infect patients, as well as the sources of contamination in the operating theatre by water, hands and clothing. In his field of expertise, shoes, gloves and the fabrics used for surgical gowns are subjects for intensive study and discussion. Floor bacteria, for example, has been found to contribute up to 15% of airborne bacterial contamination in operating theatres. Microscopic particles of the patient's own skin floating in the air may carry flora that can establish a colony of fast-growing bacteria on freshly exposed tissue.

Professor Daniel Talon, head of Hygiene Services at the University Hospital Centre in Besancon, France

The ScreenAir device measures and quantifies the potential for aero-biocontamination during surgery

The professor first suggested bacteriological testing is crucial in a paper published in 2006, *'Air cleanliness in operating rooms: on-site controls and biological testing.'*

'Today there is nothing available to measure and quantify the potential for aero-biocontamination of a patient during surgery,' he told European Hospital, adding: 'We are unable to say if an infection was caused by an operation or not. Now there is a device with ScreenAir,'

The device was developed in a tight collaboration between Prof. Talon, the Clinical Investigation Centre affiliated with the University hospital and STS Industrie. The director of STS Industrie, Dimitri Fournier, said the partners are now looking for opportunities to win regulatory approval for the device and begin commercialisation.

Exceptional versatility

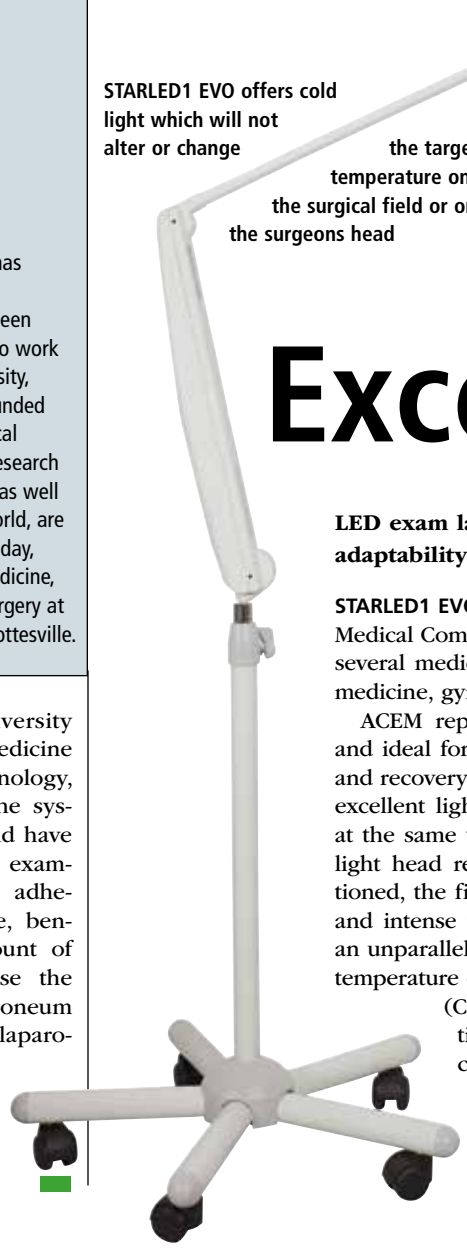
LED exam lamp promises superior adaptability and control

STARLED1 EVO, an LED lamp manufactured by ACEM Medical Company in Italy, has been developed to suite several medical specialities, e.g. dermatology, general medicine, gynaecology, dentistry.

ACEM reports that it is multifunctional, versatile, and ideal for diagnostics, cosmetic medicine, first aid and recovery room. 'It's a reliable product that assures excellent light intensity and low consumption (12W) at the same time. 'The lamp is easy to move and the light head remains steady during its use once positioned, the firm adds. Its light beam is homogeneous and intense with 60.000 lux at 50 cm and produces an unparalleled quality of light together with a colour temperature of 4.900 °K and a colour rendering index (CRI) of 95.' Additionally, using the innovative I-SENSE touch panel light intensity can be adjusted to a desired light level for different needs. The lamp is available with an articulated or flexible arm and, according to its final use, can be provided with wall, rail and table clamp or configured as ceiling or adjustable height trolley version.

One further important point, the firm explains: 'The lamp has a smooth and easy-to-clean surface to allow the best cleanliness.'

Details: www.acem.it or info@acem.it



STARLED1 EVO offers cold light which will not alter or change the target temperature on the surgical field or on the surgeons head

Tumour boards

German radiologists believe that they are essential; however, although many advantages exist, there's also a problem, *Daniela Zimmermann* reports

About 20 years ago the first tumour boards were set up in Germany. Initiated and led by surgeons, they not only invited oncologists, radiotherapists and radiologists to conferences but also, increasingly often, pathologists. That is how, in the 1990s, Professor Hermann Helmberger MD, Senior Consultant at the Centre for Radiology and Nuclear Medicine at the Dritter Orden Clinic in Munich-Nymphenburg, experienced the introduction of tumour boards at the Klinikum rechts der Isar at the Munich Technical University. The trigger for the formation of tumour boards, he recalls, was the emergence of neo-adjuvant therapy concepts. 'At that point in time, where tumour treatment had clearly become more complex and individual steps of therapy had to integrated, it made sense to coordinate the treatment approach right from the very beginning.'

Obvious advantages

Around ten years ago specialist medical associations followed the trend towards structured quality assurance in cancer treatment by introducing the certification of treatment centres. The interdisciplinary exchange during tumour board conferences is a central point for quality audits and is decisive for successful certification through OnkoZert and the German Cancer Society. The certification of a centre depends on them. This approach initially became established in breast cancer treatment.

In Germany, the impulse for this was given very strongly by patients and their self-help organisations, which exerted pressure on politicians as well as medical staff to standardise and improve treatment. 'Up to this point, treatment was very much dependent on the ability and decision of the doctor in charge. It mostly consisted of surgical removal of a tumour without structured follow-up treatment,' said Prof. Helmberger, adding that it is unlikely that particular tumours will be treated anywhere other than in certified treatment centres.

'The importance of tumour boards increases parallel with advances in individual medical fields. Nowadays, no two breast cancers are treated in exactly the same way, and the whole spectrum of diagnoses and therapy can only be offered by a hospital that specialises in providing it all day, every day,' he explained. The situation is slightly different in the case of Bowel Cancer Centres, which were certified after the Breast Cancer Centres, but are not as numerous. Surgery on a life-threatening intestinal obstruction, often resulting from cancer, must to be carried out there and then – notwithstanding if the respective hospital has achieved certification or not.

Professor Dr Hermann Helmberger is Medical Director of the Department of Diagnostic and Interventional Radiology and Nuclear Medicine at Klinikum Dritter Orden and Nymphenburg Radiology and Nuclear Medicine Centre, Munich, Germany. He began his medical career 1981 at the University of Regensburg. During his clinical training at the Klinikum rechts der Isar in Munich he chose radiology as sub-specialty. He completed his residency at Nymphenburg Hospital and at the Klinikum rechts der Isar where from 1996 to 2000 he was Senior Resident and later Managing Senior Resident and Deputy Director of the Institute of X-ray Diagnostics before was appointed to his current position.

Tumour boards create staffing problems

According to the professor, with all the advantages that come with the work of tumour boards, particularly regarding patient outcome, the expenditure of time required from all medical disciplines involved remains a difficult problem to solve. 'It takes up numerous man hours, particularly those of the best in their respective fields, since the boards are made up of at least one specialist or, even better, a consultant. Unlike in the USA, and in German university hospitals, smaller radiology departments cannot train a specialist for each tumour conference. Although this gives us an advantage because tumour boards enable doctors to broaden their horizons beyond their own specialist medical field, there is a problem, because these specialists are also needed in the clinic, so conferences have to be held outside peak hours, i.e. either early in the mornings or late in the afternoons, which does not help to make them popular.'

The use of additional contract staff just for the tumour conferences is no solution, he believes, on the one hand because this expense would not be covered by medical insurers and, conversely, because doctors need to be available for their clinical colleagues and to make decisions on site throughout the week. 'It would be an illusion to believe that decisions about therapy are only made during tumour board conferences. Although this is where they are approved and logged, in urgent cases images have to be discussed and treatment concepts developed at any time during the week,' he pointed out.

Prof. Helmberger also believes that employing more staff is not necessarily the answer as there would not be enough work on days when no tumour board conferences are held. He believes the best way forward would be to broaden the base and ensure a healthy mix of experienced and less experienced colleagues. 'It would be desirable to have a few more doctors with comprehensive, general radiological training as well as a specialty. But their deployment must not lead to cuts in the number of junior doctors because,' he concludes, 'one day this may lead to a lack of qualified junior staff.'

UK: Multidisciplinary teamwork will stay

With the effectiveness of 'tumour board review' in the USA questioned in a 2012 study published in the *Journal of the National Cancer Institute*, Mark Nicholls sought the opinion of UK-based consultant urological surgeon Ben Challacombe

In the UK, a multi-disciplinary team (MDT) review for all cancer patients has been a requirement for a number of years and was established under Improving Outcomes Guidance (IOG) issued within the National Health Service (NHS).

Whilst the phrase 'tumour board review' is not in common use in the UK, the concept of having input from a variety of medical experts is embraced in the MDT approach, where surgeons, pathologists, oncologists, radiologists, palliative care specialists, and specialist nurses (to liaise between clinicians and patients) gather on a weekly basis to discuss patient care and treatment plans.

The concept, although in place in many institutions beforehand, was formalised in the mid-2000s through IOG to ensure that everybody who has a new cancer diagnosis has their case discussed at weekly multidisciplinary meetings, which can last between an hour-and-a-half to half a day. Yet, while the approach is mandatory, there are questions within the UK over its effectiveness.

Ben Challacombe, a consultant urological surgeon at Guys and St Thomas' NHS Foundation Trust in London, offering complex surgery of the prostate, bladder and kidney, commented: 'I've seen audits in the south-east of England region in urology that have shown the number of cases where the multi-disciplinary meeting makes a significant difference to patient care is quite limited. This is often the case in smaller hospitals with less complex cases.

'Somewhere between 80-90% of the time it doesn't make a measurable difference because diseases are becoming so structured in how we manage them; you know how big the tumour is, where it is, what type it is, there is a standard pathway as to how that particular person would be managed.' Where they do prove invaluable, he added, is in more rare tumours and unusual situations where collaboration can identify a specific approach.

The MDT meetings in which he is involved bring together up to 40 health professionals through telelinks across four hospital sites in south-east London.

While many cases are 'routine' and do not need lengthy discussion, he said it gives a patient reassurance that a number of different consultants have discussed their case and agreed their course of treatment; it also benefits the clinician who will see the patient shortly after the meeting and be familiar with their case; and it maintains a link with smaller referring hospitals.

'It's a conduit for good communication between the trust's hospitals,' he said. 'The team getting together once a week is another benefit and has helped us work better together as a group, particularly between surgeons and oncologists. It has helped that collaboration.'

However, he remains concerned that some cases needing little discussion can take more time than necessary, leaving less time for the more difficult complex cases and for many examples, there are already clear treatment guidelines in place to which the team must adhere, particularly in prostate cases, which are 95% protocol-driven. 'We get through 50 people in 90 minutes, so we only have one or two minutes on each patient. What would be better is ticking off 30 because they are all easier cases and fully discussing those where there is a real diagnostic or treatment dilemma.'

There is also the fact that the patient is not present and often other factors, such as a patient's weight, other medical problems and co-morbidities are not known. 'There is a case for having patient involvement,' Ben Challacombe believes, 'or having more information to allow you to really consider it from the actual point of view of what the patient wants.'

Although there are time constraints and frustrations, he does acknowledge the benefit of having combined expertise present. 'There have been times when I was going to do one thing and someone in the team has come up with another better way to proceed. You have more people's "eyes"; particularly useful is the radiologist who may spot, for example, that not only is there a tumour in the kidney but one in the lung, too.

'You can be saved from doing the wrong type of operation, or even operating at all, by having a large number of people all looking through the scans and pathology, so I think it's a safety belt for us a lot of the time as well.'

Despite the mixed view of MDTs (tumour boards), they are set to remain in place in the UK with the NHS maintaining that 'multidisciplinary team working is vital for the improvement of outcomes for cancer patients'.

Ben Challacombe MD was appointed consultant urological surgeon to Guy's and St Thomas' Hospitals in London in 2010. Previously, he has worked at a number of hospitals in the London area and the Royal Melbourne Hospital, Australia. A Fellow of the Royal College of Surgeons, he conducts complex surgery of the prostate, bladder and kidney, with a particular focus on laparoscopic and robotic procedures. He is involved in academic research into prostatic disease having written over 70 peer-reviewed publications and 20 book chapters on this subject.

EUROPEAN HOSPITAL

WWW.EUROPEAN-HOSPITAL.COM

CARDIOLOGY 2013

NEWS AND TECHNOLOGY UPDATES FOR CARDIAC CARE

AMSTERDAM • NETHERLANDS 31 AUG - 04 SEP 2013

Turbulence in ultrasound

Ultrasound expands its role in cardiac imaging with disruptive applications. Fasten your seat belt. Cardiac diagnostics is entering a zone of turbulence. Manufacturers of leading systems continue to mine data from the sonic signal that opens new fields for research. *John Brosky* reports

By merging the stunning three-dimensional (3-D) images with traditional X-ray, new systems are providing novel capabilities for diagnosis and navigation. 'I believe that 3-D echo is the cornerstone for the non-invasive diagnosis of cardiac diseases,' says Jose Zamorano MD, head of Cardiology at the University Hospital Ramón y Cajal in Madrid. 'There can be no doubt. You can see the anatomy of the heart, and you can see the function.' He cites as an example the turbulence created by blood flow in the cavities of the heart that is now revealed by technology called vector flow mapping developed by Hitachi-Aloka.

The heart is not a simple pump but a hard-working muscle, twisting, contracting and pushing a pulsing stream of blood. A closer look shows that this flow is not so simple either, swirling and churning in intricate patterns as it encounters resistance.

Nobel Laureate Richard Feynman once described turbulence as the most important unsolved problem of classical physics. It may also be the key to unlocking unsolved problems in cardiac diagnosis.

'It's back to physiology,' Dr Zamorano said. 'From the work in our lab we can now see the vectors and the vortices for normal blood flow, and we have seen the way turbulence is affected by abnormal physiology and different pathologies… What is certain is that this will help in evaluation, and it could become a prognostic indication for the patient. It opens a new area of research to correlate what we are observing with the pathologies of patients.'

Vector flow mapping is an innovative ultrasound application derived from colour Doppler velocity data that adds new mathematical methods to display flow distribution without angle dependency. This quantification tool enables researchers at the University Hospital Ramón y Cajal to visualise, measure and analyse more than a dozen parameters of blood flow distribution.

'Most people think that Doppler ultrasound is an analysis of the blood flow itself, but we need to clarify this understanding, because Doppler only shows velocity,' Dr Zamorano explained. 'With vector flow mapping you truly can see how the blood behaves entering the left ventricle and how it is ejected into the system.'

In the case of an aortic stenosis, he pointed out that the turbulence which appears in the left ventricle outflow is characteristic and 'absolutely different from a normal patient'.

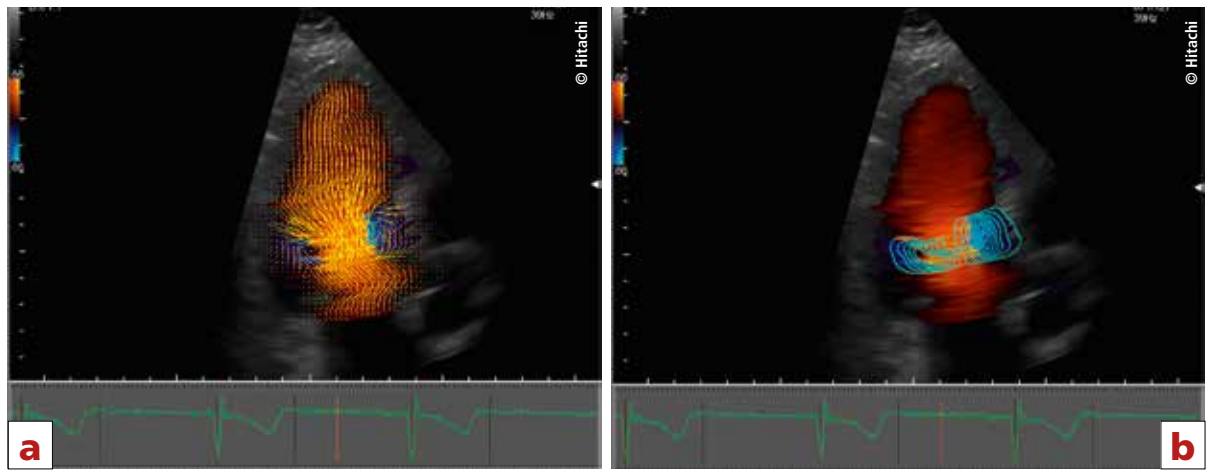
Research is currently being conducted using a two-dimensional ultrasound system and while the technology is not yet ready to show the flow in 3-D, he is confident this product evolution will come.

In early September, at the European Society of Cardiology (ESC) Congress in Amsterdam, Dr Zamorano will discuss the evaluation of valvular heart disease in 3-D with echography. 'Valve anatomy is in three dimensions and 3-D echo assesses the morphology of the valve much more accurately than other modalities,' he explained.

Fusion imaging that combines 3-D echo images with 3-D CT scans today provides a complete picture of the heart for cardiologists. The CT view of the coronary arteries of a patient can help determine if there is a coronary disease and at which level, he pointed out, while 3-D echo displays the abnormal function that is related to that stenosis.

In the cardiovascular research facility in Madrid, he is currently testing a new advance in fusion imaging developed by Toshiba for its CardioVascularFusion (CVI-Fusion) system that creates a revolutionary capability for the assessment of ischaemia. 'At ESC we will reveal a new technique, one that is quite unique, and which no one else is doing,' he promised. 'We will demonstrate the feasibility of using stress echo in fusion imaging, which in my opinion becomes crucial. Stress echo induces ischaemia, but here for the first time we will show the ischaemia. 'By combining these views we can see the stenosis, the location of the stenosis and now how the stenosis impacts on the prognosis.'

Continued on page 12



VFM Vectors: velocity vectors to highlight the flow patterns (a). VFM Vortex: automatic vortices detection (b). The integration and synchronisation of X-Ray images and 3-D ultrasound images provides up to two additional ultrasound views in real time. The ultrasound beam is shown in the live X-ray image and the viewing angles are automatically rotated in a synchronised movement. Placed markers are automatically transferred in an anatomically correct position into the other screens (c). CardioVascularFusion (CVI-Fusion) (d).

Jose Luis Zamorano Gomez MD is the Head of Cardiology at the University Hospital Ramón y Cajal in Madrid. A Fellow of the European Society of Cardiology (ESC), currently he is the Chair of the ESC Guidelines Committee and a past-President of the European Association of Echocardiography of the ESC.
Dr Zamorano is also on the editorial board of many leading journals, including the European Heart Journal and JACC Cardiovascular Imaging.

OPENING A WINDOW ON THE HEART

Recent advances in echocardiography, especially tissue Doppler imaging and speckle tracking, have sharpened the focus on cardiac muscle. Yet, there has not been a link established between the observed blood flow and morphological patterns in the myocardium and cardiac cavities.

Now that link is being observed and quantified using a novel and non-invasive technique developed by Hitachi Aloka called Vector Flow Mapping (VFM). 'With vector flow you really see how blood behaves, which is not something we have seen before,' explained Jose Zamorano MD. Contracting muscle fibres and the chambers of the heart create vortices and turbulence that are specific to patient pathologies, he added.

In his studies using VFM he has documented how the turbulence inside the left ventricle is different and characteristic if the patient presents with a disease such as severely depressed ejection fraction after an infarction compared to a patient with a normal left ventricle but an aortic stenosis. VFM begins with velocity data derived from colour Doppler echography to generate velocity fields on a 2-D image. Engineers at Hitachi Aloka then moved beyond data received in the direction of the beam by applying unique algorithms that enable an estimation of the radial component. Now the flow distribution can be displayed without angle dependency.

In addition to displaying flow distribution through vectors, VFM also provides the mainstream lines. The application can detect and display the intra-cardiac vortices and quantify the different parameters.

Suddenly a window on the heart opens to reveal the intricate interactions at the interface between pulsing blood and cardiac fibres. This data can be visualised, measured and analysed across a complex array of parameters that describe the spatial and temporal distribution of blood flow. In other words, this data can be translated into diagnostic and prognostic information to inform clinical decisions, according to Partho Sengupta MD, lead author of an article entitled, 'Emerging Trends in CV Flow Visualisation,' published in the *Journal of the American College of Cardiology.*

Implanting aortic heart valve prostheses percutaneously will become more common than surgical replacement, according to Dr John Webb

TAVI will surpass heart surgery for aortic valve replacement

Interview: John Brosky

Each year the case grows stronger for transcatheter aortic valve replacement (TAVI). And it is only six years since the procedure was introduced in Europe.

The strongest clinical evidence, which continues to fuel debate, is based on the first-generation of valves and delivery devices. It is also based on a population that was deliberately restricted to the very sickest of patients with an average age of 83 years and suffering from co-morbidities that meant they were unable to undergo traditional surgical aortic valve replacement (SAR).

Today, a new and improved generation of valves and delivery systems has arrived in the clinic. There is greater experience among interventional cardiologists, as well as improved outcomes for patients. Increasingly in Europe the procedure is being performed on 'intermediate risk patients,' those who suffer from a failing heart valve but who are typically younger and better able to withstand the rigors of traditional surgery.

How far are we from a turning point where TAVI will be preferred to surgery? The question is provocative because TAVI remains contentious in the cardiology community. Which patients? Who makes the decision? How reliable are these new valves? What about the high cost?

John Webb MD, from St Paul's Hospital in Vancouver, was a pioneer in the development of TAVI and has performed or supervised over 1,500 procedures worldwide. He is a leading authority on the technique and technology and author on over 300 publications in peer-reviewed journals, including Circulation and the Journal of the American College of Cardiology.

Ahead of the meeting of ESC 2013, we asked Dr Webb for his views and future directions.

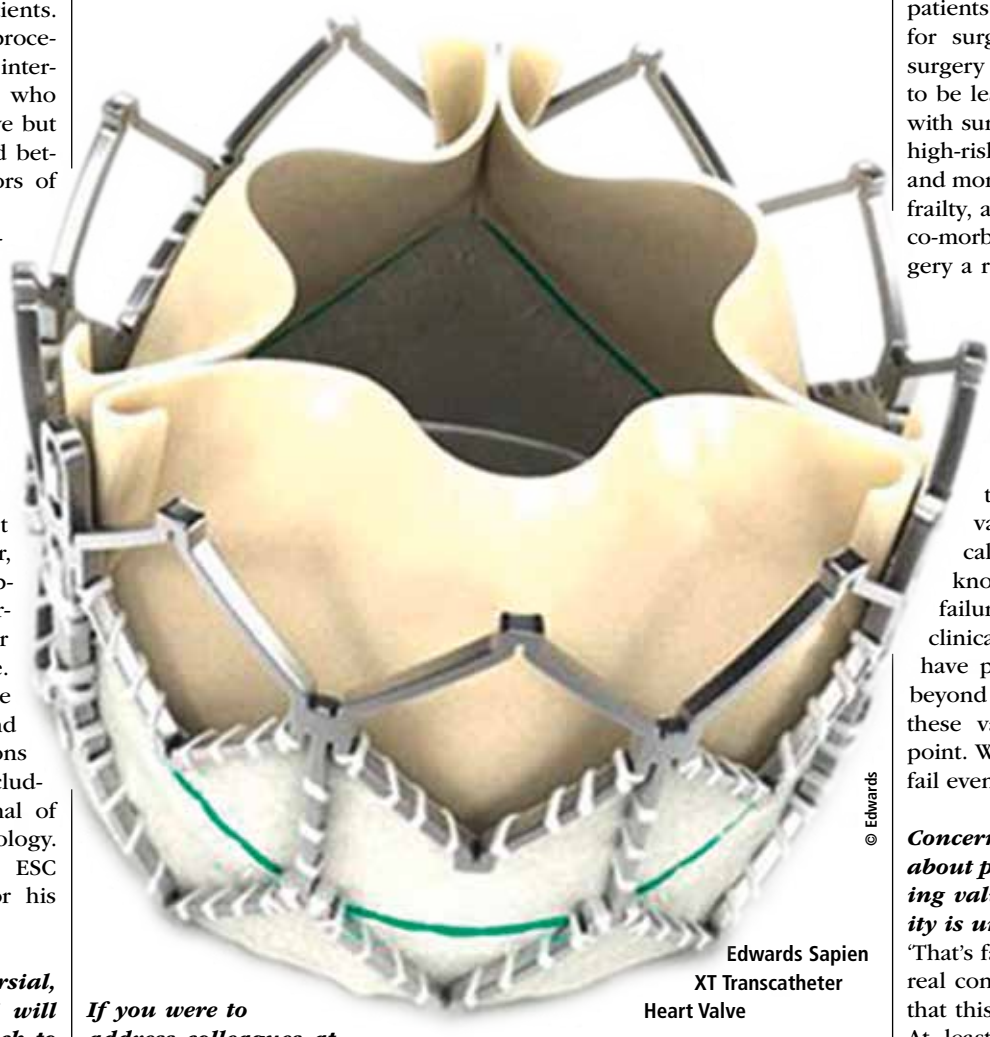
While it remains controversial, you have stated that TAVI will become a dominant approach to aortic valve disease.

Dr Webb: 'I believe so, yes, because as we move into intermediate risk patients with newer devices in experienced centres, the risk of mortality becomes quite low and is competitive with surgery in intermediate risk patients with much less morbidity. Many centres are doing this on awake patients. Early discharges are becoming more common. Certainly patients are mobilised earlier at the hospital stage. Hospital stays are shorter. ICU stays are shorter. And I think the cost of TAVI is going to come down and become competitive with surgery for intermediate risk patients.'

Will TAVI replace open-heart valve replacement surgery?

'There will always be patients who need open-heart surgery. There are obvious advantages to that approach. But I do believe that TAVI will become more common than surgical replacement. There are patients who do not have valves that are suitable for a transcatheter approach, or they have other things that need to be corrected. There are advantages to surgical valves as well for patients who can undergo surgery at relatively low risk.

'In the future, I don't think the issue is going to be whether patients are not candidates for surgery, but just that they would be better off with TAVI. This is the direction we are moving in Canada as well. We are asking who is better off with TAVI. The key message here is that the procedure needs to be done on patients who are going to benefit. This needs to be the focus. Cardiologists need to consider if their patient is going to have a significant improvement in quality of life; that they will live long and prosper.'



© Edwards

Edwards Sapien XT Transcatheter Heart Valve

If you were to address colleagues at the ESC congress in Amsterdam, what would you tell them?

'One of my big concerns about Europe is that this is a procedure that can be done at much lower risk by groups that have a high level of expertise. It is not a procedure that should be performed by low-volume operators. My concern is that there are an increasing number of low-volume centres in Europe and they can do better. There needs to be a balance between availability and ability. If I were to give a number, I'd say that individuals doing less than 50 cases in a year are not at a sufficient volume for expertise.

'Also, there shouldn't be groups competing within a single institution to the point where people who do not have sufficient expertise are performing this procedure. There should be programmes that involve both interventional cardiologists and surgeons who have relatively high volume practices and do high quality work.'

Many cardiologists may scoff at the idea that TAVI should only be performed in consultation with a 'heart team'. Many have never been invited to share in the decision.

'The true heart team is a relatively new concept. Traditionally, surgeons have made up their own minds about whom they will perform surgery on and what kind of surgery they will do. Interventional cardiologists are used to doing the same thing with coronary revascularisation.

But I think that when we have patients who are complex and there are different alternatives, it makes sense for there to be a group discussion about the best choices. 'In the United States this approach has become artificial in some ways because the regulatory requirement is that both interventional cardiologists and surgeons must participate in all procedures. It seems to be overdoing it and may be driven by factors other than the procedure. The main principle to a heart team is that the patient is evaluated by a group with different skills and knowledge. There should be a discussion about which form of valve replacement is better with an evaluation and a discussion of the alternatives available. But the idea of a heart team does not necessarily mean they all need to be in the room doing the chosen procedure.'

Can you compare the development of TAVI in the USA and Europe?

'In the USA the practice is influenced to a much greater degree by the requirements of the FDA, starting with the original trials. For example, in the PARTNER trial patients could only be admitted if they fulfilled very specific criteria and had a very high STS score, a high risk of mortality. Some of these patients are too old, too frail to benefit. So the bar is set perhaps too high in the USA, with the majority of patients at extreme risk for open heart surgery. That bar has been lower in terms of surgical risk for patients in Europe, driven more by the reduction in morbidity in some of the lower risk patients.

'In Europe there has been a more clinically driven approach, which sometimes differs from what was required in the original trials.'

You have asked whether the high-risk patients enrolled in the original trials should be considered for the therapy in the first place.

'That is a problem. Some patients are at such high risk that the benefits may be limited. Where the benefit might be much greater for patients who could be candidates for surgery, but the morbidity in surgery would be high. There tends to be less morbidity with TAVI than with surgery among intermediate to high-risk patients. In Europe, more and more the indication is becoming frailty, advanced age, without major co-morbidities that would make surgery a risk for these patients.'

An open question, especially as Europe moves to younger patients, is how long do these devices last?

'We know that with in-vitro testing, in the lab, the TAVI valves last as long as surgical prosthetic valves. And we know that very, very few valve failures have been seen in the clinical experience to date. We have published our outcomes out beyond five years and failure of these valves is quite rare at that point. We can assume that they will fail eventually, as do surgical valves.'

Concern was expressed in Europe about patients in their 70s receiving valves for which the durability is unknown.

'That's fair enough to say and a very real concern. I guess I would argue that this is not the end of the story. At least with TAVI, valve replacement is a fairly repeatable procedure in that you can place a TAVI valve inside a TAVI valve.

'One of the things people were most interested in (at the Transcatheter Valve Therapeutics event in Vancouver in June, 2013) was the new information on valve-in-valve implants where transcatheter valves are placed inside failed surgical valves. It seemed that in many people's minds this is moving rapidly to a standard of care.

All valves, surgical and TAVI, will wear out in time and repeat surgery is always a higher risk than first-time surgery. Many of these patents, of course, have become older. There are lots of 70-year-old people who received a surgical valve and, as their valve fails, TAVI becomes an attractive option for these older patients.'

What is encouraging about the newer valves produced?

'There are marked improvements in deliverability, profile and sealing with the newer generation of valves. Newer valves are, in general, more easily implanted. The lower profile means they go through smaller sheaths, through smaller arteries with a lowered risk of vascular injury. They tend to be more easily positioned, with features incorporated into the catheter, or in the valve itself, so they tend to be deployed at the correct height and the correct angle in the aortic annulus. So positioning is improving. They tend to have features that reduce paravalvular leak with the better seals.

'In addition to improvements in the valves, there are dramatic improvements in techniques used. Early on, people had a limited idea of where to put the valve and now this is much improved. Early on there was poor understanding about how to pick the correct valve size, and here there have been dramatic improvements in understanding the three-dimensional anatomy in the annulus, which is related to imaging with 3-D CT and 3-D TEE.

'All the new valves need to be proven. To some degree their use can depend on a predicate device. But if there is a dramatic change in how a valve functions, it really needs to be evaluated to see if it is going to be as reliable as a precedent valve.'

John Webb MD is director of interventional cardiology, fellowship training, research at the Centre for Valve Innovation at St Paul's Hospital in Vancouver. He is also an advisor to a number of biomedical companies and the government of Canada and McLeod Professor of Heart Valve Intervention at the University of British Columbia.

Turbulence in ultrasound

continued from page 11

The technique is a non-invasive complement to fractional flow reserve (FFR), which is an invasive procedure, he added.

While FFR is given the highest recommendation in ESC guidelines, the invasive nature of the procedure to assess ischaemia has slowed its adoption.

Dr Zamorano reserved his greatest enthusiasm for advances in ultrasound for the newest arrival in the university hospital, the EchoNavigator from Philips Healthcare: 'I just came from performing two TAVI interventions and can say this system is incredible, very innovative.

'Usually we work with X-ray in a cath lab but now, by superimposing real-time 2-D and 3-D interventional echo on the fluoroscopy, I can see the valves opening and closing… Remember that with X-ray we can't see the valve; we can see only calcium.

Now I can mark exactly where the valve needs to be positioned. Using fluoroscopy I can guide the catheters to that precise position.'

Cardiac disease death rates fall in the EU

Mortality more than halves in many European countries

Report: Mark Nicholls

Death rates from cardiac disease have more than halved in many EU countries since the early 1980s, according to new research published in the *European Heart Journal*. The majority of countries have seen on-going steady reductions in heart disease death rates in both sexes and most age groups, including among younger people – despite increases in obesity and diabetes during this period.

However, heart disease remains a leading cause of death in Europe and the study's researchers say their analysis shows little evidence for the hypothesis that the reduction in deaths from coronary heart disease (CHD) might be beginning to plateau among younger Europeans.

There is significant variation between individual countries, with evidence of a levelling off in some countries and increases in heart disease deaths among some age groups in other countries. 'It's clear that there are some countries in which trends are cause for concern, where overall rates of decrease in CHD mortality do appear to have slowed, and a small number of countries in which CHD mortality rates have begun to increase significantly in recent years in younger subpopulations,' explained Dr Melanie Nichols, a Research Associate from the British Heart Foundation Health Promotion Research Group (BHF HPRG) in Oxford.

'In addition,' she pointed out, 'we should emphasise that cardiovascular disease remains the leading cause of death in Europe, and it is important that we continue to focus efforts on primary prevention, including reducing smoking, improving diets and physical activity levels.'

With her colleagues in the Oxford research group, Dr Nichols looked at trends in deaths from coronary heart disease between 1980 and 2009 in both sexes and four age groups: under 45, 45-54, 55-64 and 65 and over. They found that almost all EU countries had a large and significant decrease in death rates from CHD over the last three decades in both men and women when all ages were considered together. Denmark, Malta, The Netherlands, Sweden and the UK had the largest decreases in mortality for both sexes during this time. The exceptions to these significant decreases were among men in Hungary, Latvia, Lithuania and Poland, where the decreases were small, and in Romania where there was an increase. Among women, decreases were found in Greece, Hungary, Lithuania, Poland, Romania and Slovakia. There was some evidence that the downward trends were beginning to plateau in those aged under 45 among men and women in Italy, Latvia, Lithuania and the UK, among men in Poland and Slovakia, and among women in the Czech Republic and France.

In the 45-54 age group, there was evidence of a possible plateau in both sexes in Latvia and the UK, and also in Lithuania among women and Sweden, Austria, the Czech Republic and Slovakia among men. In Greece, women aged 45-54 showed a significant increase in death rates. Dr Nichols said: 'Overall, across the EU, rates of death from coronary heart disease have continued to fall in most age groups in most countries. There are some exceptions, however, and there remain wide disparities across Europe in both the absolute rates of death from heart disease and the rates of improvement.'

The study authors state that the increase in risk factors for coronary heart disease, such as smoking, obesity and diabetes, could still have an impact on death rates in years to come but felt 'there may still be time for public health policy and action to have an impact on these risk factors.' The team also add that continuing future research is crucial to monitor trends in CHD risk factors and mortality across the EU and to examine the relationships between preventable risk factors and CHD among younger adults.

With funding from the British Heart Foundation (BHF), the study arises from the European Heart Health Strategy II project (EuroHeart II), which has received co-funding from the European Union, in the framework of the Health Programme.

Dr Melanie Nichols joined the BHF HPRG in October 2011 to lead the Oxford work package within the EuroHeart II programme, which aimed to describe and document the burden of CHD across Europe and geographic variations in coronary heart disease trends across the member states of the EU.
She has now returned to Deakin University in Australia as a Research Fellow at the World Health Organisation (WHO) Collaborating Centre for Obesity Prevention at Deakin. Her research interests include the epidemiology of chronic disease risk factors, inequalities in health, the role of communities and environments on lifestyle and chronic disease and evaluation of complex interventions to prevent chronic disease.

Hope or hype in hypertension? Cardiologists remain cautious

Renal denervation

A new procedure may help people with persistent hypertension. By burning or ablating the nerves in the renal arteries, blood pressure levels can be reduced significantly. Can we hope? If true, this promising procedure would mark a breakthrough. The medical and social burden of arterial hypertension is staggering, contributing to two-thirds of all cases of stroke and half of all cases of heart disease. Or is it hype? To date there is no evidence high BP simply disappears by waving a magic wand. Here are two reports on the medical miracle called renal denervation offering the perspectives of clinicians and industry.

Felix Mahfoud, cardiologist at Saarland University Hospital

Report: John Brosky & Holger Zorn

Clinical point of view: Rising tension in hypertension therapy

With two in three over 60-year-olds suffering arterial hypertension, this is among the commonest chronic diseases.

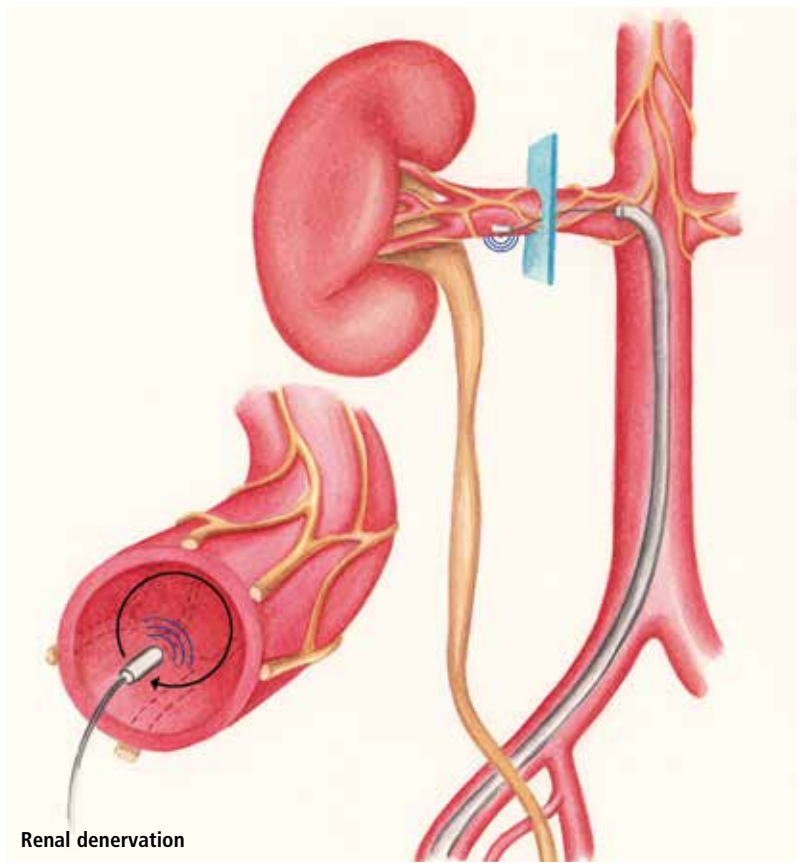
Drug treatment results in only 5-17% of those patients achieving their target levels. However, in about the same percentage of patients conventional treatment fails despite good compliance and the administration of three, five or even more antihypertensive drugs. Their blood pressure (BP) readings often remain much above the level of 140/90 mmHg set in the current ESH/ESC guidelines – an incentive for the development, trial and evaluation of different therapies.

The two most important new developments being discussed are presented below: renal sympathetic denervation and baroreceptor stimulation. While the former is already an established procedure – particularly in Germany where almost half of all interventions are performed – the latter is frequently accompanied by severe adverse effects but is nevertheless considered very promising by many cardiologists.

Renal sympathetic denervation

The debate around renal sympathetic denervation (RDN) is as hot as the procedure itself, which involves heating up the renal arteries intravascularly in several places for a maximum of two minutes focally to up to 70 degrees Celsius to denervate the sympathetic nerves in the adventitia of the arterial walls.

The kidneys not only control the circulation volume but also release a hormone, renin, which affects the constriction of the blood vessels and the heart frequency via the renin-angiotensin-aldosterone system and is therefore a cause of the development and persistence of arterial hypertension. The entire procedure requires just one puncture of the femoral artery, normally takes less than an hour and is carried out under fluoroscopic guidance.



Renal denervation

The European Society of Hypertension (ESH) calls these results 'promising' and has decided to revise its guidelines, which had been jointly developed with the European Society of Cardiology, 'since numerous studies have been published over the last year providing more data about the rationale, therapeutic efficacy and safety of RDN' *(Source: EuroIntervention. 2013 May 22;9 Suppl R:R58-66)*.

Symplicity HTN-1 and HTN-2

The feasibility of the procedure was demonstrated by three Australian and two European hospitals, including the Cardiovascular Centre at the Sankt Katharinen Hospital in Frankfurt and the Jagiellonian University in Krakow, under the direction of Professor Henry Krum at the Centre of Cardiovascular Research and Education in Therapeutics, Monash University, Melbourne, Australia.

Forty-five patients taking an average of 4.7 hypertensives, with a mean BP of 177/101 ±20 /15 mmHg and rated as treatment-resistant, underwent RDN between June 2007 and November 2008. Their mean BP fell by 14/10, 21/10, 22/11, 24/11 and 27/17 mmHg after 1, 3, 6, 9 and 12 months *(Source: Lancet 2009; 373: 1275–81)*. During an extended follow-up observation over a 24-month period BP also did not rise again – reason enough for the authors to believe that once the nerve fibres have been denervated they do not regenerate and no new ones are being formed; the antihypertensive effect therefore works in the long-term *(Source: Hypertension 2011; 57: 911-7)*.

Between June 2009 and January 2010, 106 patients, whose BP remained at a mean of 178/96 mmHg despite the administration of a median of 5.3 antihypertensive drugs, were included in the following, prospective randomised controlled study; 52 of these patients were treated with renal denervation and showed a significant decrease in BP by 32/12 mmHg after six months. Every fifth patient was able to reduce the number or dose of drugs taken. However, BP amongst the 54 members in the control group did not change. Three hypertensive events occurred in the treatment group and two in the control group *(Source: Lancet 2010; 376: 1903-09)*.

In a clinical study at the Saarland University Hospital, 600 patients – the largest cohort worldwide – were examined. Dr Felix Mahfoud, physician at the Clinic for Internal Medicine III, University Hospital, and ardent supporter of the procedure, is convinced that the pathophysiology is correct. 'We do know that the vegetative nervous system is overactive in patients with hypertension. When medication no longer offers a promising option, RSD is an interesting therapy approach. However the patients selected for the procedure have to fulfil certain conditions, as described in the guidelines recently published by the European Society of Cardiology.' According to these guidelines, RSD is indicated for truly resistant hypertensive patients, while patients with organ-related hypertension, impaired renal anatomy, e.g. due to a stenosis or impaired renal function, are excluded. 'The data that are available today, which were collected worldwide, are very promising. We now need further studies that corroborate the initial results,' Dr Mahfoud said. Nevertheless he recommends the procedure for the time being to be limited to medical centres with research capabilities where patients receive systematic follow-up.

The industry: Slowed by hyper-resistant doctors

As fast as the first device for renal denervation received a CE mark in 2010, the pioneering company Ardian was immediately snapped up by medical technology giant Medtronic. With great fanfare the procedure was introduced the following year at EuroPCR, the largest gathering of interventional cardiologists in Europe.

Six million people in Europe suffer from persistent hypertension, unable to bring their systolic BP below 160 millimetres of mercury. Some take three or four different medicines every day, but the condition can resist this drug-based therapy.

The potential for treating such a large population was neither lost on cardiologists nor on other medical technology companies. This year at EuroPCR six new devices for renal denervation were presented, all with the CE Mark, ready to be sold to hospitals.

Yet market leader Medtronic has fallen far short of sales targets. Despite a large footprint covering 70 countries, the company shipped less than half the number of devices it expected to ship. It turns out that physicians are as resistant as the hypertension of their patients. Doctors want to see proof of the claim that charring nerve endings in the renal artery is an effective, safe and sustained treatment for this chronic condition.

Justin Roberts is arguably the point man out on the bleeding edge of this innovation in medical practice. The Senior Director for Renal Denervation Global Market Development for Medtronic, he shared some of the lessons learned in pushing adoption of renal denervation. He commented: 'There are people who believe this is a billion-dollar market; that if they push a magic button patients will suddenly come raining down from the sky,'

The biggest challenge is not the technology, not the next shiny toy, he added, pointing to the growing number of competitors on the exhibition floor at EuroPCR. Instead the challenge is to build clinical evidence to convince very conservative referring physicians.

Medtronic is turning its investment in renal denervation to a clinical programme aimed at building what the company hopes will be a substantial body of evidence.

Enrolment was recently completed in an ambitious pivotal clinical trial in the USA of the Medtronic Symplicity renal denervation system for treatment-resistant hypertension. Data from this trial is expected to be a significant component of an unusual and rigorous parallel review by the USA's Food and Drug Administration (FDA) and the Centres for Medicare & Medicaid Services (CMS) that could lead to approval and reimbursement.

Meanwhile, Justin Roberts believes that companies also need to help build expertise in this new field to win the confidence of referring physicians.

Renal denervation centres capable of appropriately screening patients need to be built, he pointed out. 'Hospitals, even with reimbursement, will continue to operate with very tight budgets. They need to decide if they want to open a service line for renal denervation. These decisions will vary by country, by local guidelines.'

St. Jude is a fast-follower for both technology and clinical trials for renal denervation. More than 5,000 patients will be studied in a robust portfolio of studies in collaboration with a multi-disciplinary physician advisory board as part of the EnligHTN Clinical Evidence Development Strategy. It is the brand name of St. Jude's device for the renal denervation procedure.

The portfolio of related studies represents a significant investment in building clinical evidence that will culminate in EnligHTNment. This landmark work is expected to be the largest randomised renal denervation study ever undertaken with a primary endpoint of major adverse cardiac outcomes and secondary endpoints to include reduction in office and ambulatory BP measures, changes in renal function and cost-effectiveness measures.

Bogged down on the long road to building evidence for renal denervation, Medtronic and St. Jude have lost the first-to-market advantage as more companies roll out new devices.

The technical barriers to entering the renal denervation competition are relatively low. Most companies already have some kind of device for ablation and adapting it to the renal arteries is quickly done.

All the firms will need to conduct clinical studies, but these will be small efforts focused only on proving that their new device is safe for use. For clinical evidence of effectiveness the new players will need only point to the evidence published by Medtronic and St. Jude to win over physicians.

While some new devices are based on follow-the-leaders technology, innovation in the pipeline may prove to make a difference for patients in the long run.

ANOTHER OPTION: BAROREFLEX STIMULATION

Anne Carlsten, a physiologist at the University of Gothenburg, researched the treatment of depression through electric stimulation of the nerves in the carotid sinus and discovered that this also has a cardiovascular effect (source: Act Physiol Scand 1958; 44(2): 138-145).

Baroreflex activation therapy (BAT) stimulates the parasympathetic fibres of the vagus nerve, lowering heart frequency, stroke volume and BP. Electrodes are placed either side of the carotid artery under general anaesthetic and then connected to a pulse generator, which – like a pacemaker – is implanted below the collarbone.

The feasibility study carried out in the Netherlands, Germany, Switzerland, the Czech Republic, Poland and Latvia, under the direction of the Cardiocvascular Research Institute Maastricht (CARIM), included 45 patients with therapy-resistant hypertension whose BP prior to the intervention was a mean of 179/105 mmHg, with a heart frequency of 80/min and a median of five antihypertensive drugs taken.

Three months after the implantation of the Rheos system manufactured by CVRx Inc. of Minneapolis, BP was lowered by a mean of 21/19 mmHg and, after two years, by a mean of 33/22 mmHg in 17 patients who continued with the trial. However, almost every fifth patient suffered severe complications such as stroke, glossoplegia, infection or device displacement (source: J Am Coll Cardiol. 2010;56(15):1254-8).

Although the randomised, placebo-controlled clinical trial of 265 patients did not show a significant acute responder rate in the group receiving baroreflex stimulation, it did show a significant sustained responder rate (source: J Am Coll Cardiol 2011; 58(7): 765-73) – enough potential for future debate.

Heart failure

Remote monitoring in Lorraine reduces hospital re-admissions

Report: Brigitte Dinkloh

About 500,000 people in France people suffer heart failure (HF). In Europe the figure is six million and the same in the USA. While pharmaceutical innovations such as ACE inhibitors, beta blockers and mineralocorticoid receptor antagonists help to decrease mortality in HF patients with reduced ejection fraction, much needs to be done, says Professor Patrick Rossignol, nephrologist and deputy physician at the Inserm Centre d'Investigation Clinique Plurithématique Pierre Drouin (CIC-P) in Nancy, France, because the prognosis remains unfavourable.

The professor is particularly concerned about the high number of hospital re-admissions. 'About 20 percent of all patients with heart failure are re-admitted to a hospital within a month of the initial event and roughly one third of the patients die within a year.' Poor follow-up, he emphasises, is to blame for this dire situation.

Case in point: One year after their discharge many patients receive the same medication without dose optimisation as upon their discharge. While international guidelines recommend disease management programmes (DMP) for HF patients, Patrick Rossignol points out, many patients are either not included in such a programme or it does not follow harmonised standards.

In the Lorraine region, the 'réseau lorrain des insuffisants cardiaques' (ICALOR – Lorraine network for cardiac insufficiency patients) was introduced in 2006, a DMP unique in France because it covers an entire region and currently includes 3,000 patients. Each patient is closely monitored at home by nurses, on top of the usual out-patient follow-up by physicians. Results are collected in a patient record that can be accessed by the patient and hospital-based and/or office-based physicians.

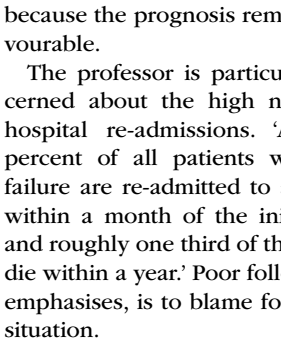
The programme results are very encouraging: the implementation of the ICALOR programme was associated with a reduction in HF hospitalisations in Lorraine, estimated by an absolute difference between the number of hospitalisations observed in the Lorraine region, and than expected had it been similar to that observed in the whole country of -7.19% in 2010. The estimated annual hospital cost saved by ICALOR was €1,927,648 in 2010. (REF). Nevertheless, Professor Rossignol stresses, much remains to be done to ensure that the course of HF is less dramatic: 'Hospital re-admission is a severe event for the heart failure patient because at that time cardiac function is already seriously compromised. The alarm signs indicating deterioration of the pump function must be recognised earlier.'

Together with Professor Faïez Zannad, who heads the Heart Failure and Hypertension Unit in the Department of Cardiology, Nancy University Hospital, Patrick Rossignol developed a new procedure for telemedical monitoring of heart failure patients. All the patients need do is introduce a drop of blood every day into a box that assesses a set of renal and cardiac biomarkers. The data are encrypted and forwarded to a telemedical monitoring centre. When the values show signs of deterioration, the primary physician is informed who can initiate a therapy adjustment, with the help of a dedicated decision support system. 'The extremely simple procedure for patients is based on the same principle as blood sugar monitoring in diabetics. It's a response to the problem of frequent re-hospitalisation of cardiac insufficiency patients.'

Currently being piloted, the first prototypes of the device are expected to become available later this year. Application will then be made for the CE mark.

Next year, a clinical study with several hundred patients throughout is planned and Prof. Rossignol is confident this may prove that the device helps reduce follow-up complications in HF patients. The project, which was awarded funding of €1.9 million from the Lorraine region and the European Regional Development Fund (ERDF), is carried out by a consortium headed by Cardiorenal Diagnostics, a company founded by Professors Rossignol and Zannad with Gerard Houis.

* Ref: Agrinier N, Altieri C, Alla F, Jay N, Dobre D, Thilly N, Zannad F. Effectiveness of a multidimensional home nurse led heart failure disease management program-A French nationwide time-series comparison. Int J Cardiol. 2013 Jun 25



Nephrologist **Patrick Rossignol MD PhD** is Professor of Therapeutics at the University of Lorraine, France. Since 2007, he has been deputy physician at Nancy University Hospital's Inserm Clinical Investigation Centre, headed by Professor Faïez Zannad, and an Inserm UMR_S1116 researcher, as well as being a consultant at the University Hospital Heart Failure and Hypertension Unit and haemodialysis clinics. The professor's research priorities are clinical trials and biomarker studies in the context of heart failure, chronic renal insufficiency, hypertension, and vascular diseases such as abdominal aortic aneurysms.

The time machine

While the benefits of extracorporeal membrane oxygenation (ECMO) as a temporary respiratory support for adult patients are still debated, it is undisputed that for many infants ECMO is the only chance to survive, because it provides them with time to strengthen their lungs, says EH correspondent *Holger Zorn*

If a baby's lungs are not properly unfolded upon birth they can be supported mechanically for a few days, as Dr Robert Bartlett of Orange County Medical Centre in California (cf EH 2/13 p. 15) showed almost forty years ago. In extracorporeal membrane oxygenation (ECMO) the blood is drained from the body and pumped into an artificial system. In a membrane carbon dioxide is removed and oxygen is added before the blood is returned to the body (Fig. 1). Dr Bartlett was aware of the poor outcomes in adult patients: A national study had been discontinued after 92 patients, due to a mortality rate of 90% in both the ECMO and the control group.

Despite those results, he continued to use ECMO after his initial successful treatment of a neonate and he achieved survival rates of 75% in neonates and infants – clinically speaking quite a success, scientifically far from a validated procedure.

The problem was less of a technical one than an ethical one. How can a study with neonates be designed in which one group receives the treatment that needs to be validated, while the control group is refused this potentially life-saving procedure? Dr Bartlett went for a unique study design: 'Play the winner'.

Following his medical studies and the completion of his doctoral degree at the University Tübingen, Germany, **Dr Thomas Schaible** received specialist training at the Paediatric University Hospital Ulm. In 1996 he joined the Intensive Care Unit of the Paediatric Clinic of the University Mannheim.

The first patient has a 50/50 chance to receive either ECMO or the conventional therapy. If the patient survives, the next patient receives a chance at ECMO and the rate would be 2:1. If this second patient dies the chance to receive ECMO treatment decreases to 1:2. The result was convincing: the first patient received ECMO and survived; the second patient received conventional treatment and died. The third patient now has a 3:1 chance to receive ECMO. The patient did receive ECMO and survived. The study was halted after twelve patients: eleven neonate patients had received ECMO and survived, only one patient – the second – had not received ECMO and had died *[source: Pediatrics. 1985 Oct;76(4):479-87]*.

ECMO prevailed and today more than 50,000 ECMO therapies have been registered with Extracorporeal Life Support Organisation (ELSO) in Ann Arbor, Michigan, USA. Two thirds of these therapies were performed on neonates (Fig. 2). The types of lung failure that are being treated with this technology have different causes: hypoplasia, meconium aspiration syndrome, sepsis and pneumonia, but also congenital diaphragmatic hernia (CDH).

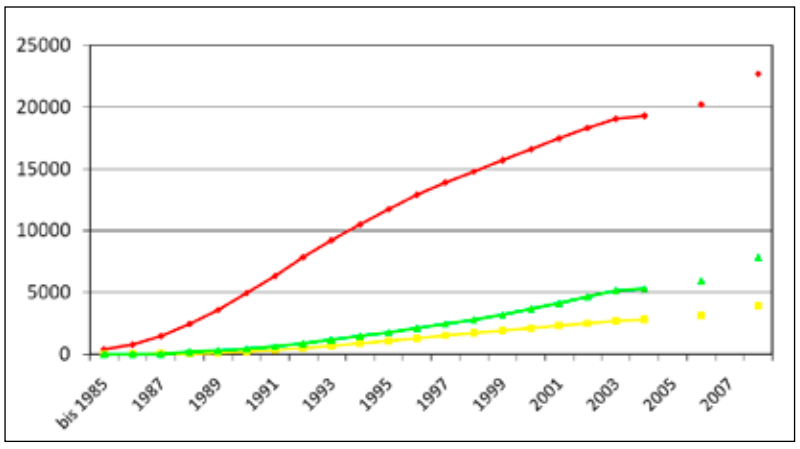


Fig 2: ECMO cases with respiratory indication in neonates (red) and paediatric patients (1 month to 18 years – yellow) as well as cardiac indication in children of 0 to 5 years (green) were reported worldwide with the ECMO register of Extracorporeal Life Support Organisation (ELSO) in Ann Arbor, Michigan

In Europe one of the biggest ECMO centres is at the University Hospital Mannheim, where 500 neonates were treated since the centre's opening in 1987. Dr Thomas Schaible, head of the children's ICU says: 'ECMO can be initiated as a temporary respiratory support measure when ventilation and other additional measures did not yield the desired outcomes. Most acute ECMO cases are to be found in neonatology; when lung failure occurs in children, ECMO is not necessarily the immediate option. For example if the oxygen concentration cannot to be reduced to less than 80 percent after five days of ventilation, ECMO comes in. Thus ECMO is a safety net in all critical ventilation situations and yields a survival rate of at least 70 percent.'

Moving a patient to an ECMO centre requires complex transport logistics that provide all intensive care options. If necessary, the transport can be done with ECMO running – in adult patients this is a routine procedure, but in neonates, with their small and fragile vessels, cannulation and ECMO should only be initiated by an experienced team in a safe environment.

The success of ECMO is also evident on the international level: ELSO, which has been maintaining its register since 1990, recorded a mere 83 participating hospitals and 1,644 cases in the first year. In 2012 a total of 200 centres reported 3,545 cases. Altogether, 53,190 ECMO cases are documented in the non-mandatory register, of which 32,043 were neonates. ECMO therapy, which usually lasts only a few days, secured the survival of 32,303 patients, of whom 21,900 were neonates (source: ELSO).

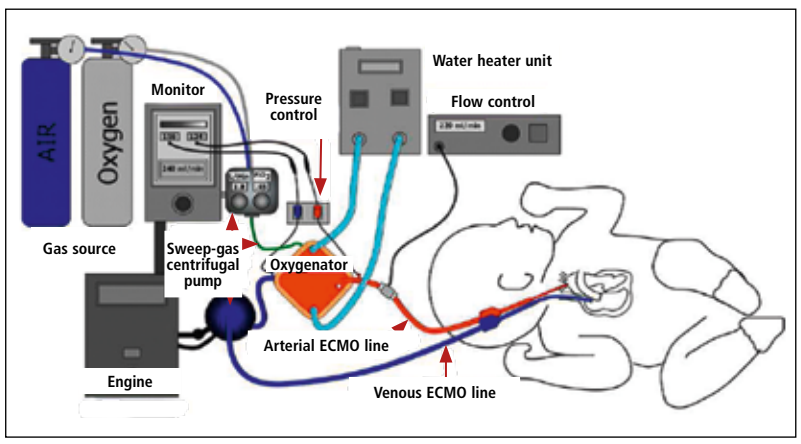


Fig 1: Veno-arterial ECMO circuit with neonate

Cardiovascular medical technology

Berlin's Biotronik celebrates 50th anniversary of quality and innovation

A little over five years ago, when Frank Busch began to work for leading cardiovascular technology manufacturer Biotronik, he noticed certain changes in the way the company carried out its business. 'Instead of being cost-driven, suddenly I was working in an environment that was people-driven, with a focus on developing new, cutting edge technologies of the highest quality. Before, business was just about downsizing.

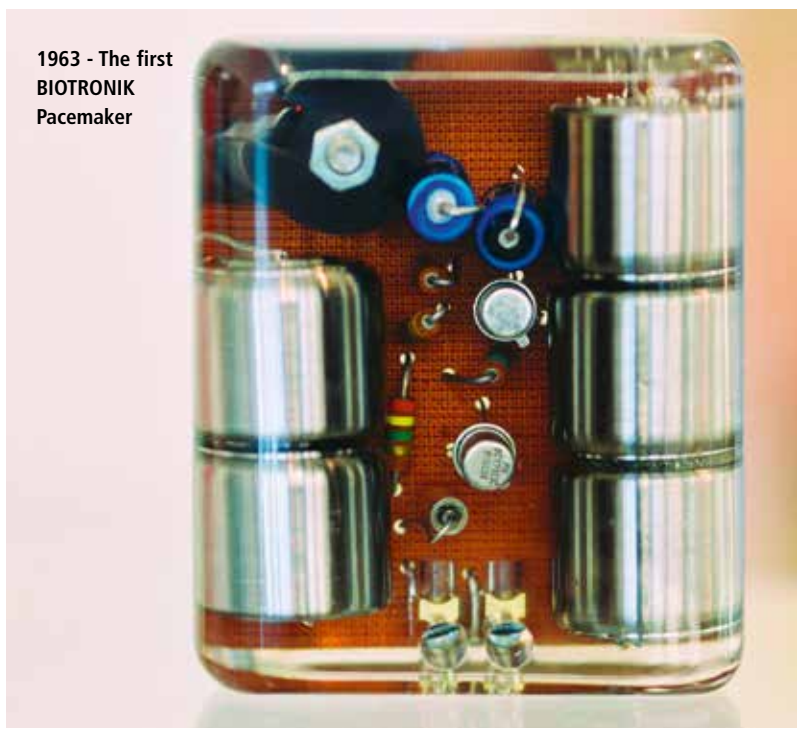
Now, with Biotronik, it's all about growth.' As manufacturing director Frank Busch can certainly speak from experience. The office where he sits is only temporary, built until a more permanent one can be constructed. In other words, the firm is expanding faster than it can find space. 'Good news for a company that can look back proudly on 50 years of excellence, quality, and innovation since 1963,' Biotronik points out.

Back then, physicist Max Schaldach and electrical engineer Otto Franke started a biomedical engineering revolution when they developed Germany's first implantable pacemaker. Today, Biotronik specialises in three business areas: cardiac rhythm management, electrophysiology and vascular intervention, with a focus on in-house research and development. Continuous innovation keeps the firm at the forefront of patient care, says Frank Busch: 'We make sure that people still understand the company's ethos, because everyone needs to know what it means in his or her daily work to be consistently living up to the highest quality standards.'

In the last decade the firm has implemented a number of technological solutions to ease physician-patient interaction and ongoing care. For example its ProMRI technology has been used in cardiac devices and leads since 2010, enabling patients with a cardiac implant to safely undergo MR scans. Indeed, it is the world's only company which allows ICD, IPG and heart failure patients access to those scans.

In 50 years, Biotronik has been able to grow tremendously while remaining true to its early pioneering spirit, the company points out. 'Today, it is represented in more than 100 countries worldwide, and has 5,600 employees.

Importantly, the focus is on patients, as Frank Busch explains: 'I like keeping up the awareness in everybody's mind that they are working on implants for actual people…and one of those people could be their grandmother.'



1963 - The first BIOTRONIK Pacemaker

Cardiology drives innovation

A leading Austrian professor commends scanner advances

Report: Michael Krassnitzer

'Cardiology is one of the most innovative medical disciplines. Many modern technologies, such as catheterisations or imaging procedures, were triggered by cardiology,' declared Professor Gerald Maurer MD, Head of the Department of Cardiology at Allgemeines Krankenhaus Wien (Vienna's General Hospital) and Director of the University Clinic Internal Medicine II at Medical University Vienna. In our EH interview, held during the annual meeting of the Austrian Cardiology Society in June, Prof. Maurer outlined the most recent technological developments in cardiology.

'MRI images of heart structures are becoming increasingly precise and with increasing resolution,' he said. This includes the late enhancement, contrast MRI technique, where the contrast agent Gadolinium-DTPA provides detailed information on the metabolism and status of heart muscle cells, supporting tissue differentiation and allows a more precise diagnosis of the cell vitality. The cardiologist can see whether a sub-endocardial infarction occurred where the necrosis, due to a lack of perfusion, is limited to the innermost layer of the heart muscle while the outer layer of the heart muscle is not involved. With myocarditis late enhancement has become the most important diagnostic indicator.

Today in cardiac ultrasound, so-called strain imaging provides new functional information. In 2-D imaging the speckle tracking technology tracks several points in the heart muscle throughout the entire heart cycle and can thus look at the deformation (strain) of the myocardium.

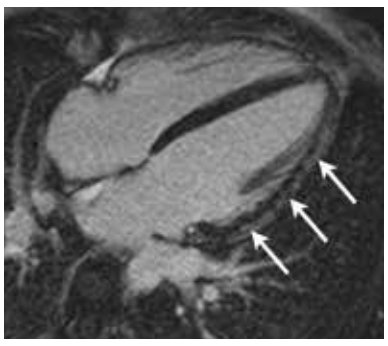
This is particularly relevant in patients with heart failure (HF) with preserved ejection fraction (HFPEF). For a long time cardiac insufficiency was thought to be solely associated with the lack of the heart's contraction ability. However, around 50% of cardiac failure patients show normal ejection fractions. While some of these patients show a diastolic dysfunction, systolic abnormalities can also contribute. In those patients the myocardial longitudinal shortening is inadequate – a dysfunction that can be detected in strain imaging. 'In an aging population HFPEF is a growing public health problem,' Prof. Maurer points out.

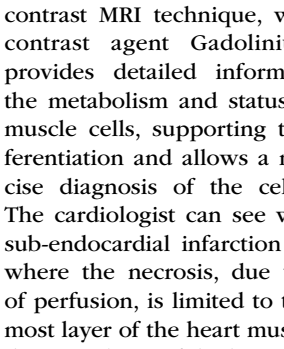
He believes that cardiac computed tomography (cardiac CT) will also play an increasingly important role. Cardiac CT visualises the coronary vessels well and helps determine the calcium or Agatston score, an important indicator of a coronary disease. 'While this method does not replace the catheter, it allows the exclusion of significant coronary heart disease with high probability,' he explains, adding that a further development is the measurement of cardiac profusion with contrast-enhanced CT.

In the area of cardiac implants, bio-absorbable stents are an important innovation. 'One of the problems with conventional stents is the fact that in young patients they may be associated with long-term risks. In an 80-year-old patient this is not that much of an issue, but there are many patients between 20 and 40 years of age who suffer CHD and need an implant.'

While conventional stents remain intact for several decades, bio-absorbable stents, which are made from polylactide, dissolve within two to three years – with water and carbon dioxide absorbed by the body. In most cases the endothelium fully recovers and the patient receives a conservative therapy with cholesterol and BP medication and anticoagulants. Large long-term studies are currently being conducted but final results are not yet available.

CMR image of a patient with myocarditis; the lighter coloured lateral wall (arrows) is caused by late enhancement





Professor Gerald Maurer MD, who has headed the cardiology department at AKH (General Hospital) in Vienna since 1993, is also Director of the University Clinic Internal Medicine II at Medical University Vienna. He gained his medical degree and doctorate at Vienna's medical school and completed his specialist physician training in the USA (American Board of Internal Medicine; Subspecialty Board, Cardiovascular Disease). He became a professor at the University of California (UCLA), Head of Non-invasive Cardiology and Interim Head of Cardiology at Cedars-Sinai Medical Centre in Los Angeles before returning to work in Austria. Prof. Maurer is Member of the Board of the Austrian Cardiology Society (ÖKG) and currently Editor-in-Chief of the European Heart Journal – Cardiovascular Imaging.

Cardiac magnetic resonance imaging

The potential of cardiac magnetic resonance imaging (CMRI) is still largely untapped. One novel application might be ablation follow-up. The first MRI-guided cardiac interventions were performed at Herzzentrum Leipzig, but, as far as coronary imaging is concerned, MDCT remains superior to MRI

The diagnostic potential of CMRI has not yet been fully explored. 'Myocardial tissue differentiation – the detection of inflammation, fibrosis and scar tissue – will be further improved and objectified,' says Professor Matthias Gutberlet (Fig. 1). The Director of the Department of Diagnostic and Interventional Radiology at Herzzentrum Leipzig and professor for cardiovascular imaging at the University Leipzig expects MRI to play an increasingly important role in prognostic evaluation of patients with infarction, cardiac myopathy or inflammation.

'Another big issue in CMRI application will be therapy follow-up in rhythmology and the evaluation of pathological cardiovascular haemodynamics with 4D flow,' he points out (Fig. 2). While MRI is already the method of choice for volumetric and functional analyses no single cardiac imaging procedure, Prof. Gutberlet says, has or will have a monopoly. More likely, hybrid imaging procedures, such as MR/PET or PET-CT and image fusion technologies, will prevail (Fig. 3). 'No single modality will be able to offer one-stop shopping capabilities,' the radiologist predicts.

With regard to coronary imaging, the professor is sure that multi-detector computed tomography (MDCT) will retain its advantage (Fig. 4 a). 'Unlike MDCT, MRI has not advanced significantly in the past few years,' he explains, and he doubts it will gain substantial ground soon. However, CMRI may well conquer image-guided cardiac interventions. 'In our institution, together with the rhythmologists we quite successfully performed MRI ablations in 10 initial patients with atrial fibrillation (Fig. 5). The rhythmologists are so excited that we will definitely continue our cooperation,' he confirms.

Rhythmologists consider CMRI particularly promising because the length of the ablation procedure is accompanied by high radiation exposure. Moreover, fluoroscopy does not provide sufficient anatomical detail. 'MRI offers clearly enhanced visualisation of the substrate pre- and post-intervention (Fig. 4 b, c and Fig. 5 b, c). Although we are far from routine use, we made huge progress in terms of feasibility and were quite surprised how well the procedure worked – albeit in a rather simple intervention,' he reflects optimistically, and underlines that the foremost aims are the reduction of radiation exposure followed by enhanced visualisation of anatomy and the arrhythmogenic substrate, as well as therapy success generally.

MRI despite a pacemaker?

Patients with implants, such as a pacemaker or ICD, require particular attention prior to MRI examination. 'These patients are not per se excluded,' Prof. Gutberlet says. 'They can well undergo MRI even if they do not have a so-called MR conditional device.' While the manufacturers continue to develop MR-safe devices, most of those available are not suitable for MR. 'Before an MRI exam, the device has to be checked by a cardiologist and set to a certain mode,' the professor explains. The patients must be informed that a certain risk remains due to the antenna effects of the ventricle electrodes. These are mostly thermal effects that might damage the device. MR conditional implant or not – one major problem remains unsolved: artefacts created by the device or the electrodes (Fig. 6). A pacemaker that is implanted on the left side causes artefacts right where the heart sits and the lead in the right ventricle can provide misleading information in imaging (Fig. 6).

*Reprint from 'RöKo HEUTE 2013', the official publication of the German Radiology Congress

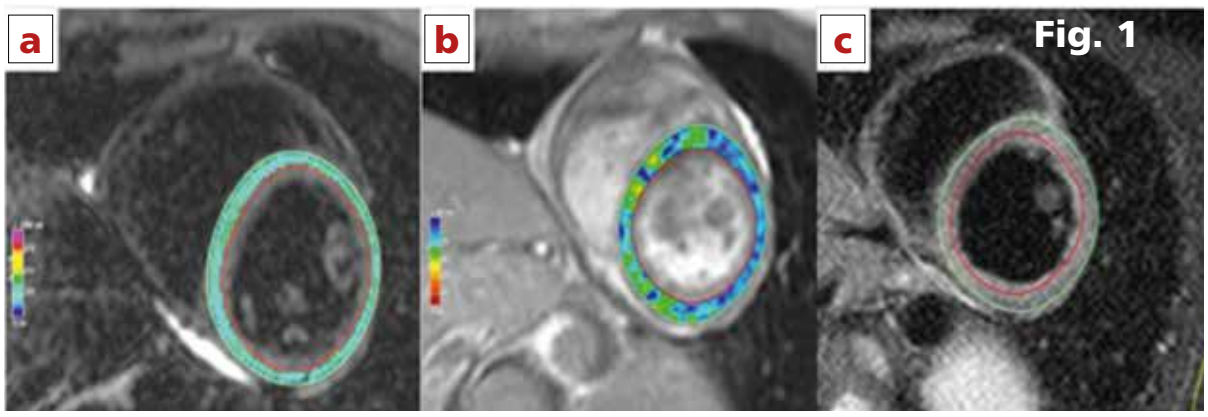


Fig. 1

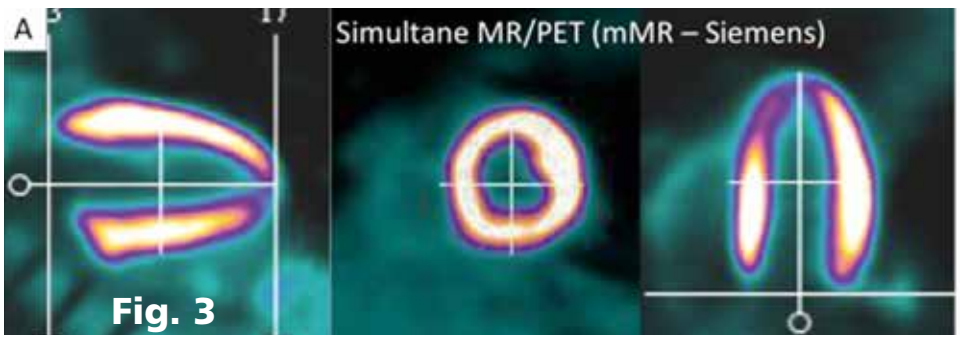


Fig. 3

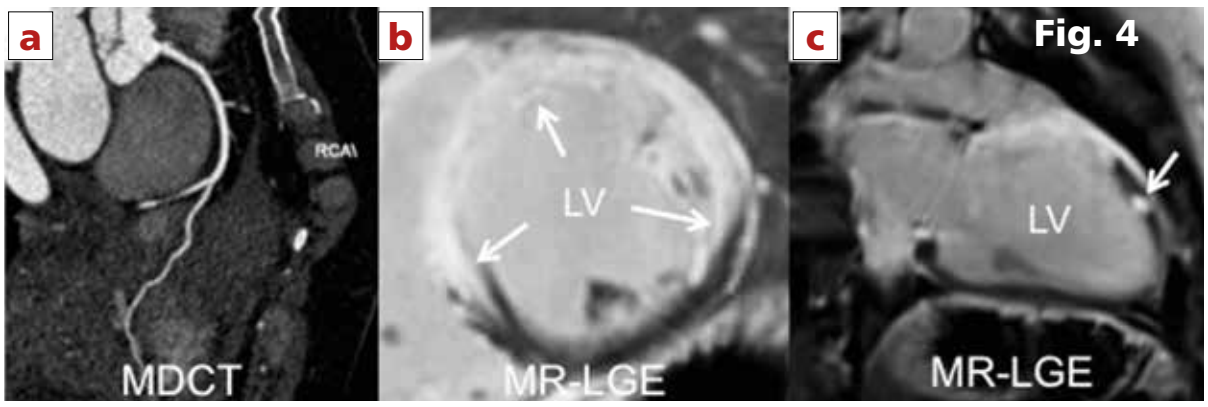


Fig. 4

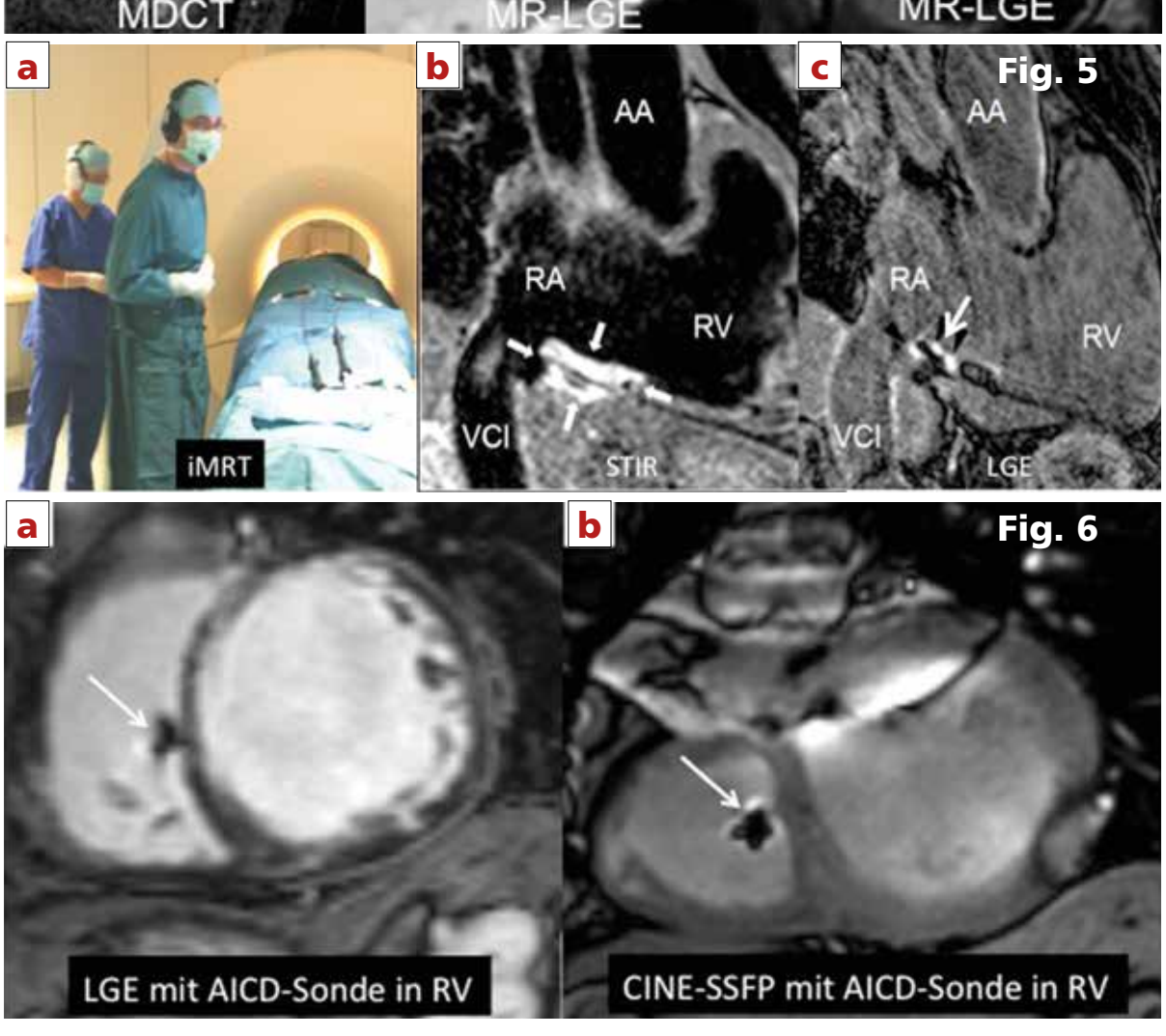


Fig. 5

Fig. 6

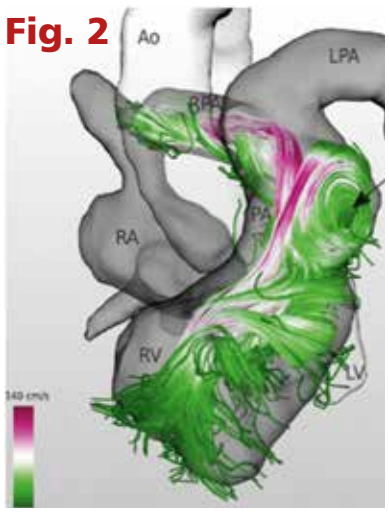


Fig. 2

Fig. 1: (a) T1 mapping after CM, (b) T2 mapping with focal elevation in the lateral wall area and (c) oedema ratio (here increased at 2.5) from STIR sequence in a 29-year-old patient with suspected acute myocarditis (T1 and T2 mapping created with CVI42 using WIP sequences by Philips and Siemens)

Fig. 2: Visualisation of the turbulent flow (arrow) in reconstructed RVOT with aneurysm in a patient with repaired tetralogy of Fallot. (Image from: S Born, M Pfeifle, M Markl, M Gutberlet, G Scheuermann. (2013), IEEE Trans Vis Comput Graph. Jun;19(6):900–912)

Fig. 3: (a) Enhancement of the volumetric and functional analysis as well as vitality and inflammation diagnostics with simultaneous MR/PET with MR/PET overlay (images created with Corridor 4DM) and (b) systemic diseases with cardiac involvement, such as sarcoidosis. (Images: Prof. O Sabri, Prof. T Kahn and Prof. M Gutberlet – Leipzig University)

Fig. 4: (a) Exclusion of CHD with MDCT (here Curved MPR of the RCA) in a 41-year-old patient with ventricular tachycardia. (b) Late Gadolinium Enhancement (LGE) (PSIR image (arrows)) in the short and (c) long axis of the same patient shows clear subepicardial to transmural LGE following myocarditis with scar tissue. In electro-anatomical mapping the vital muscle bridge (arrow) was identified as rrhythmogenic substrate and was ablated. (Images: PD C Piorkowski, Prof. G Hindricks, PD M Grothoff, Prof. M Gutberlet – Leipzig University)

Fig. 5: (a) Setup of interventional MRI (iMRI) for MR-guided ablation of atrial flutter at Herzzentrum Leipzig. (b) Result of the ablation of the cavotricuspid isthmus in patient with atrial flutter in edema visualisation (STIR sequence) and (c) LGE with scars successfully visualised (arrow) (Images: Priv.-Doz. Dr C. Piorkowski, Priv.-Doz. Dr M. Grothoff, Prof. G. Hindricks and Prof. Gutberlet – University Leipzig)

Fig. 6: Patient after Dor procedure and AICD implant. (a) IR-GRE sequence to visualise scar with LGE and RV probe (arrow) shows only few artefacts compared to the CINE-SSFP sequence (b).

Professor Matthias Gutberlet MD has directed the Department of Diagnostic and Interventional Radiology at the Herzzentrum (Heart Centre) of Leipzig University since 2007. His research and teaching priorities are Doppler ultrasound and cardiac CT and MRI, above all in patients with congenital heart defect, cardiomyopathies, myocarditis and coronary heart disease (CHD).
The professor studied medicine at Marburg and Berlin, where he submitted his habilitation thesis on diagnostic radiology on *MRI in patients with congenital heart disease*. In 2012 and 2013, jointly with Professor Holger Thiele, he was scientific director of the German Cardiac Diagnostics Symposium in Leipzig.

Computed tomography

CT will remain an imaging heavyweight

Computed tomography (CT) is the modality of choice for many diagnostic issues. Whilst currently its major strength is the visualisation of anatomical detail, future technological improvements may also reduce radiation exposure.

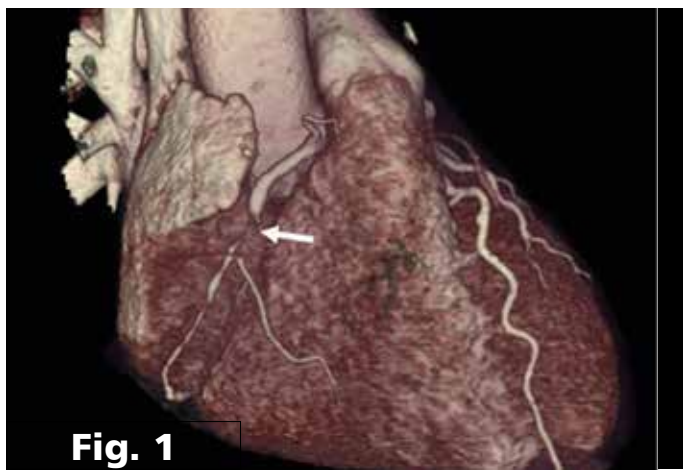


Fig. 1

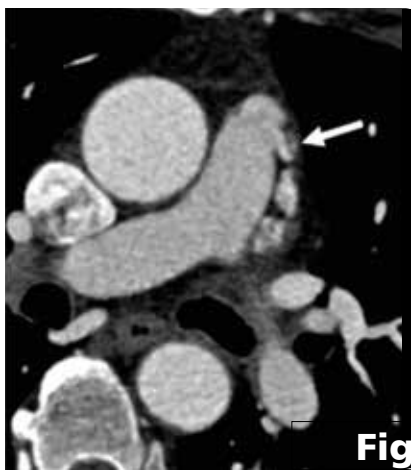


Fig. 2

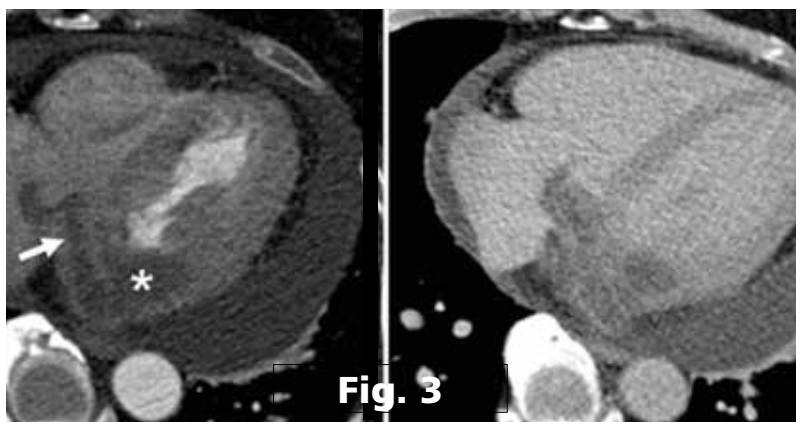


Fig. 3

Professor Gabriele A Krombach MD studied medicine and specialised in radiology at Aachen medical school, later receiving her teaching certification for diagnostic radiology in 2003. In 2006 she became chief senior resident at the Radiological Diagnostics Clinic at Aachen University Hospital and was appointed adjunct professor in 2008. Two years later she became Director of the Diagnostic and Interventional Radiology Clinic at University Hospital Giessen, where cardiac imaging, MRI, interventional radiology and pulmonary imaging are her research priorities.

Fig.1: CTO (chronic total occlusion) of the right coronary artery
Fig. 2: Fistula between left coronary artery and pulmonary artery
Fig. 3: Tumour infiltration (bronchial carcinoma) with tumour thrombus in the coronary sinus (arrow)
(Image courtesy of Christian Schneider MD, chief senior resident, Clinic of Diagnostic and Interventional Radiology, University Hospital Giessen)

FREQUENT INDICATIONS FOR CT

- Patients for cardiac surgery not involving the coronary arteries, such as valve replacement or cardiac tumour resection
- Patients with intermediate risk who should not undergo a coronary angiography
- (Suspected) coronary anomalies
- Evaluation of bypasses (problems: calcification of the native vessels, evaluation of the anastomoses), also in case of repeat surgery to visualise existing bypasses
- Method of choice for percutaneous valve replacement
- Visualisation of cardiac veins prior to the implementation of a bi-ventricular pacemaker
- Visualisation of the pulmonary veins prior to ablation with arrhythmias
- Visualisation of the pulmonary veins post ablation (suspected stenosis)
- Anomalous pulmonary venous connection

'Today, computed tomography is the best imaging modality to detect stenoses in patients with intermediary pre-test probability where a coronary angiography is not immediately indicated,' according to Professor Dr Gabriele A Krombach, Department Director at the Clinic of Diagnostic and Interventional Radiology at University Hospital Giessen and Marburg (UKGM). The degree of anatomical detail, she adds, is much better in CT than in magnetic resonance imaging (MRI). 'In malignant variations of the descending artery, where the coronary artery is compressed between aorta and pulmonary artery, CT is currently the diagnostic method of choice.'

CT is also the modality of choice for visualising coronary stenoses. With low-risk patients without suspected coronary stenoses who require cardiac surgery, e.g. to remove a cardiac tumour, a CT scan can provide valuable information on possible coronary stenoses and help predict surgical outcome.

A further important indication for CT is the visualisation of plaque to risk-stratify patients with medium pre-test probability, Dr Krombach adds. 'With an asymptomatic patient who has a risk of 10 to 20 percent to develop coronary heart disease over the next ten years, quantification of coronary calcification with CT in indicated.' However, with higher risks CT is not indicated and the patient has to undergo an invasive angiography right away. Similarly very low risk (below 10 percent) asymptomatic patients do not need a CT. 'In such a cases,' she explains, 'we simply wait and see.'

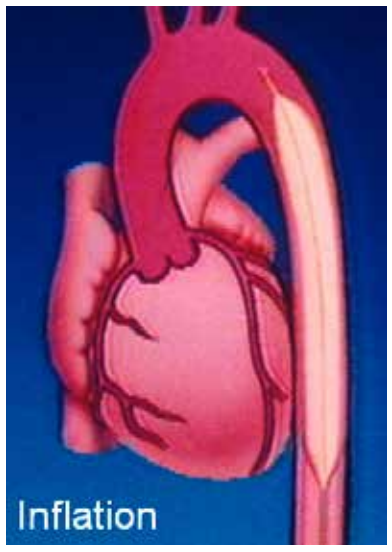
The radiologist particularly appreciates CT in percutaneous aortic valve replacements (TAVI), recently experiencing a veritable boom. According to the *Herzbericht 2010* by Dr Ernst Bruckenberger, the number TAVI procedures increased from 93 in 2006 to more than 4,800 in 2010. 'When planning a percutaneous aortic valve replacement the diameter of the ring and the distance of the coronary artery ostia to the valve have to be determined – this is done best with CT,' Dr Krombach explains. As a radiologist she does not expect CT to fall into obscurity any time soon, primarily because no single modality can do everything. The coronaries, for example, cannot be visualised in echocardiography. Additionally, technological progress in CT might open access to new patient groups. The alpha and omega of CT development is the reduction of radiation exposure and indeed new kinds of detectors are being designed that aim to decrease radiation to submillisievert level.

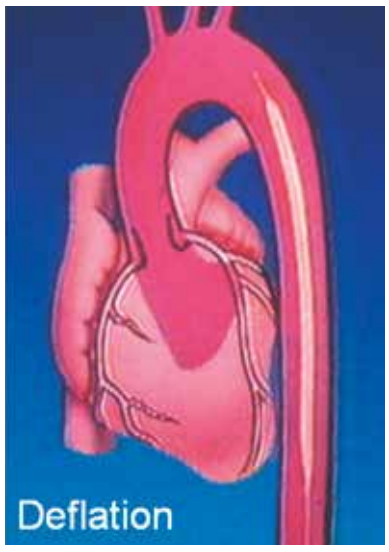
'If we could realise dose reduction in CT by using the different spectra of X-rays, we could also examine younger patients, such as those with congenital heart defects' – patients who today undergo MRI, she stresses.

Counterpulsation: The

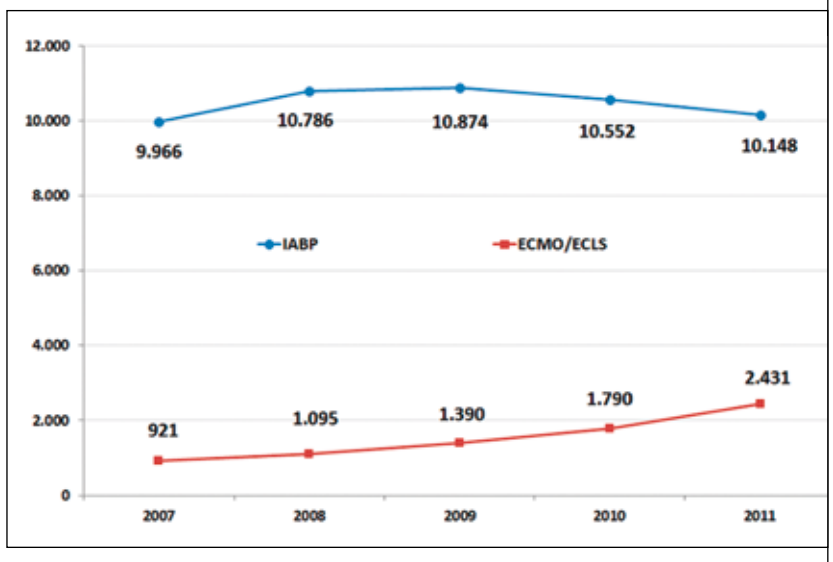
'The report of my death was an exaggeration,' Mark Twain precisely commented in the New York Journal in June 1897. That quote could be applied to those that have appeared in some places since, at last year's European Society of Cardiology gathering, the demise and funeral of the counterpulsation procedure were reported. Along with intra-aortic counterpulsation, an established procedure (the benefit of which is sometimes disputed), there is now also extra-aortic and even external counterpulsation. Having discussed the subject with cardiologists, cardiac and vascular surgeons and manufacturers, in the following three sections *EH Correspondent Holger Zorn* reports that speaking about a funeral would be a 'exaggeration'.

Intra-aortic balloon pump pros & cons





Left: The balloon is quickly inflated immediately after the left ventricle ejects blood into the aorta, thus blocking the aorta and increasing blood flow to the coronary arteries, improving blood supply to the cardiac muscle, which at this point is relaxed. Right: Milliseconds before the next heartbeat the balloon is quickly deflated, reducing pressure and helping the heart to eject blood



IABP vs. ECMO/ECLS in Germany. The number of patients receiving an IABP peaked in 2009 and has since been slightly decreasing. At the same time, the use of extracorporeal systems has increased constantly; in 2007 the ratio was 10:1, in 2011 this fell to 4:1. *[Own presentation based on data from the DRG statistics of the German Federal Statistical Office (Destatis)]*

Since cardiac surgeon Adrian Kantrowitz, of the Maimonides Medical Centre, Brooklyn, first introduced intra-aortic balloon pulsation (IABP) into clinical practice in 1967 *(Surg Clin North Am. 1969 Jun; 49 (3) :505 -11)*, the technique has been considered the method of choice for short-term mechanical cardiac support following a heart attack.

The principle is impressively simple. Connected to a helium pump, a cigar-shaped balloon is ECG triggered, folded and inserted into the femoral artery in the groin and pushed into the descending aorta to the point where the tip rests just under the aortic arch. After the left ventricle has ejected its blood into the aorta, the balloon is quickly inflated. The aorta is blocked, blood cannot flow out peripherally and so flows into the coronary arteries improving blood flow in the now relaxed cardiac muscle. Milliseconds prior to the next heartbeat the balloon is abruptly drained, creating a slight vacuum effect and making it easier for the heart to eject the blood.

The procedure had already received a class 1 recommendation in the treatment guidelines. However, only every fourth patient in cardiogenic shock is treated with this method and there is some doubt as to its effectiveness. The recommendation was recently downgraded to class 11a.

In August 2012, a randomised multicentre study was presented at the European Cardiology Congress in Munich. Out of 600 patients with cardiogenic shock (CS) after acute myocardial infarction (AMI) 301 received IABP and 299 did not. Both groups received percutaneous coronary intervention (PCI).

After 30 days, 119 patients (39.7%) in the IABP group had died and, in the control group, 123 patients (41.3%) had died. 'The use of intra-aortic balloon counter pulsation did not significantly reduce 30-day mortality in patients with cardiogenic shock complicating acute myocardial infarction, for whom an early revascularisation strategy was planned,' said Professor Holger Thiele, cardiologist at the Heart Centre at the University of Leipzig, representing the authors of the SHOCK-II-Trial *(N Eng J Med. 2012 Oct 4;367 (14) :1287-96)*.

Some experts were surprised, others not – i.e. those who had not necessarily been following the class I recommendation unconditionally. Maybe simple semantics could help here. Where nothing pulsates, i.e. during cardiogenic shock, there is nothing to counter pulsate.

Meanwhile, a further study was published that examined a different patient population and collated long-term data. This study came to a different conclusion. Out of 301 patients with impaired cardiac function and severe coronary disease, 151 received high risk PCI with IABP, and 150 without. Mortality data for the entire cohort were available after a median 51 months. Overall, 100 patients (33%) died, with 42 of those in the group that had received IABP and 58 in the group that had not.

Dr Divaka Perera, cardiologist at St. Thomas' Hospital, London, explained: 'Elective IABP use during PCI was associated with a 34% relative reduction in all-cause mortality compared with unsupported PCI' *[Circ. 2013 Jan 15;127 (2):207-12]*. Professor Marco Tubaro, cardiologist at the San Filippo Neri Hospital, Rome, put it this way: 'Even if a reduction of mortality has not been demonstrated with IABP in association with primary PCI, the bulk of evidence and everyday clinical practice are in favour of IABP use as haemodynamic support in patients with AMI complicated by cardiogenic shock non-immediately responsive to volume expansion and inotropic stimulation.'

Professor Andreas Markewitz, Lieutenant Colonel in the German medical corps and cardiac surgeon at the German Armed Forces Hospital in Coblenz, sees another aspect. Out of all patients in the SHOCK-II-Trial only a little over a third (38%) were completely revascularised. 'IABP is only of benefit if the heart is given a chance to completely recuperate,' Prof. Markewitz believes. Additionally, in patients with multi-vessel disease this is often not achieved with PCI; coronary bypass surgery (CABG) is the superior procedure here.

The professor therefore believes that IABP should continue to be considered very important for cardiac surgery. 'Soon,' he said, 'there will be a new, interdisciplinary S3 guideline that will confirm this.

Since 2010, **Colonel Professor Andreas Markewitz, MD** has directed the Department XVII, at the Cardiovascular Surgery Clinic, German Federal Armed Forces Central Hospital, Coblenz. He gained his medical degree and specialist training in surgery at the University of Tübingen. In 1994, he wrote his habilitation and a year later he became a senior consultant at the Coblenz hospital. He qualified as cardiac surgon in 1996. The professor is very active in the German Society for Thoracic and Cardiovascular Surgery, the German Cardiac Society and the German Interdisciplinary Association for Intensive Care and Emergency Medicine.

After gaining his medical degree at the Free University of Berlin, **Professor Holger Thiele** specialised in internal medicine at the Leipzig Heart Centre and the German Heart Institute in his home town, Berlin. Following a research period alongside Professor Mohan Sivananthan in Leeds, UK, he became a consultant and, in 2006, senior consultant under Professor Schuler at the Leipzig Heart Centre. Since 2009 Prof. Thiele has held an extraordinary professorship at the University of Leipzig.

The C-Pulse in its packaging (left) and in situ (right)

Extra-a counte

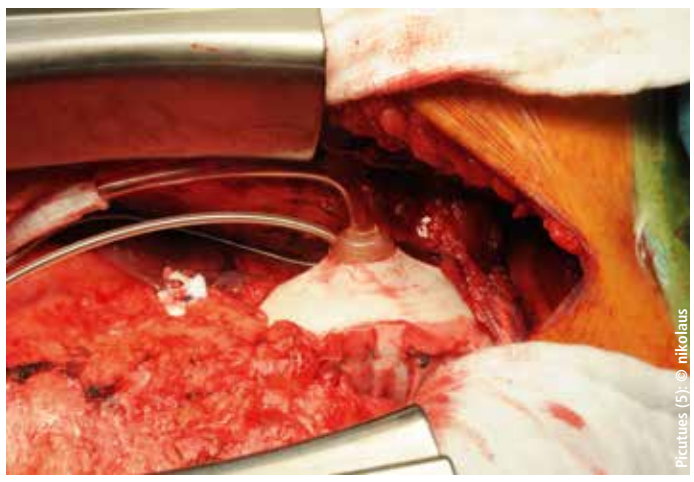
The C-Pulse, manufactured by Australian-American company Sunshine Heart, Inc. is neither a pulsatile artificial heart nor one of the well-known non-pulsatile left heart support systems *(EH 5/2006 p.23 and 3/2011 p.3)*.

However, the device appears to be suitable to help slow down or even stop symptoms in patients with moderate chronic heart failure. The technology is innovative: the principle of counterpulsation (CP) is not applied intra-aortically but extra-aortically. A cuff is placed around the ascending aorta and triggered by an ECG-electrode attached to the left cardiac apex epicardially (image 1, 2). When the left ventricle contracts and the blood has been ejected into the aorta, the balloon inside the cuff is blown up and compresses the aorta slightly so that more blood is retained and flows into the coronary arteries, directly improving the heart's oxygen supply. Draining the balloon just before each contraction of the ventricle temporarily also lowers resistance in the aorta and alleviates work for the heart.

The device was first used in humans in May 2005 at Auckland City Hospital in New Zealand. Dr William S Peters, the system's inventor, has been implanting the C-Pulse in Australia since 2010 *(source: J Heart Lung Transplant. 2010;29:1427-32)*.In May 2013 he oversaw the first European implantation of the system at the German Heart Institute Berlin (DHZB). Professors Roland Hetzer and Thomas Krabatsch, of the DHZB, and Dr Holger Hotz, of the Cardio-Centrum Berlin, have now fitted three patients with the C-Pulse (image 3) who had not responded to prior cardiac resynchronisation therapy (CRT) in the context of a pan-European, multicentre study. Prof. Krabatsch sees two advantages: 'The system does not come into contact with the patient's blood circulation; therefore there is no need for permanent anticoagulation therapy. Moreover, the patient can turn the system off temporarily or even disconnect it – for example, to take a shower. Of course, this is not possible with other pumps that are fitted intra-aortically.'

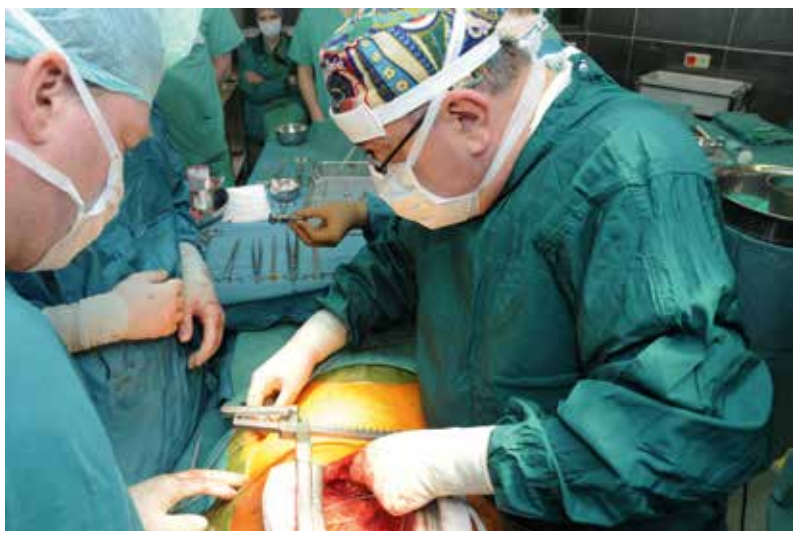
The operation can be carried out without using a heart-lung

condemned live longer



Picutues (5): © nikolaus

ortic r pulsation



Prof. Roland Hetzer (right) and Dr Holger Hotz (left) during the implantation

machine and takes less time than the implantation of a classic blood pump whilst still being technologically complex. 'The aorta has to be completely exposed so that it can be correctly covered by the cuff, Prof. Krabatsch pointed out, adding: 'The ECG-electrode also has to be attached to the heart from the outside, most often at just the point that's furthest away from surgical access, i.e. the sternotomy.'

Failing hearts in which drug treatment has been unsuccessful do not tolerate such manoeuvres haemodynamically without some restrictions. One patient required a Ventricular Assist Device (VAD) just a few days after the intervention.

These VADs are usually only implanted when patients are in a state of terminal heart failure, as bridge-to-transplant devices or destination therapy. But the C-Pulse has a different approach: The implantation at an early stage either at least delays or possibly completely removes the need for the implantation of a VAD. Dr Peter Göttel, Medical Director for Europe at Sunshine Heart, added: 'The C-Pulse system bridges the gap between CRT-Non-Responders and the indication for an LVAD within the therapeutic range. It's important that cardiologists who treat these types of patients mostly as out-patients are aware of the existence of new, less invasive methods of cardiac support such as extra-aortic counterpulsation. The C-Pulse alleviates patients' symptoms with minimal impact on quality of life. In the future, we will also offer a fully implantable version. As the system does not require an implantable buffer battery, this technological advance will be possible soon.'

Studies involving 20 patients in Canada and the USA, and 50 patients in 11 hospitals across Europe, will now test the results gathered so far. These include, in Germany (alongside the DHZB), hospitals in Hannover, Duisburg, Düsseldorf and Erlangen in Britain a hospital in Glasgow, the Royal Brompton in London and Harefield Hospital, Middlesex; in Italy, hospitals in Milan, Padua and Turin.

Professor Thomas Krabatsch gained his medical degree at the Humboldt-University of Berlin and trained as a cardiac surgeon at Berlin's German Heart Institute. He has been Consultant for Thoracic & Vascular Surgery since 1999. In 2002 he wrote his habilitation on 'Examinations of the clinical relevance and underlying mechanisms of transmyocardial laser revascularisation'

Personal shear rate therapy

In 1839 Richard Thoma was the first to observe that arteries respond to flow: he identified a fundamental relationship between blood flow and arterial calibre. This important physiological mechanism currently has a renaissance in vascular medicine: Enhancing arterial flow and flow velocities rather than pressure is an important activating mechanism in the growth of biological bypasses (arteriogenesis). This can be achieved non-invasively by externally compressing arteries after a systolic pulse wave in such a way that a diastolic augmentation is achieved.

This involves fitting cuffs around the calves, lower and upper thighs and buttocks, which are then inflated and deflated by a compressor. Whereas researchers believed that the haemodynamic changes in blood pressure would be the underlying mechanism of clinical improvement, it is now shown that this mechanism is far more complex, according to Dr Ivo Buschmann, a specialist in vascular medicine at the Charité Clinic in Berlin: 'The effect of blood volume redistribution is probably overestimated, however blow flow is accelerated, in a similar way to what would happen during a gentle run, without a significant increase in heart rate. The objective of this personalised shear rate therapy is the induction of arteriogenesis – a rescue mechanism of the vascular system during occlusion or stenosis. It stimulates pre-existing but not fully developed collateral vessels across the entire coronary circulation to grow.

In a prospective study, 23 patients aged 61+2.5 years with stable coronary disease (CHD), and at least one haemodynamically relevant stenosis, were split into two groups. Sixteen patients in the therapy group received 35 one-hour treatment sessions of external counterpulsation over seven weeks; the seven patients in the control group did not. In the therapy group, the collateral flow index (CFlp) increased from 0.08 + 0.01 to 0.15 + 0.02 and the fractional flow reserve (FFR) also increased significantly from 0.68 + 0.03 to 0.79 + 0.03; P = 0.001; however, no change was observed in the control group [source: Eur J Clin Invest. 2009;39:866-75].

Tailored treatment

'The extent of volume shift from the legs towards the heart is not really that important,' Dr Buschmann explained. This also might be the reason why Cochrane and the FDA do not recommend an older system such as enhanced extracorporeal counterpulsation (EECP). Potential risks, in particular due to high pressures, can be harmful. However, it is not the compression ratio in the cuffs that is decisive, but the velocity impulse which results from the inflation of the cuffs. This impulse changes the flow profile in the blood vessels. The flow not only increases, but also the shear rate across the arterial walls. This sets off morphological and biochemical processes and eventually leads to a proliferation of the vessels [source: Development 2010].

That impulse is shown graphically on a novel vascular ultrasound 'tachometer' to measure blood flow, volume and pulse rate being developed in connection with the Herzhose® (literal translation heart pants – describing the cuffs system) which serves as a basis of calculation for the correct setting of this personalised shear rate therapy. Each treatment is individually adapted to the patient.

Given one-hour training sessions, the heart requires three to six weeks to develop the growth of natural bypasses sufficiently. This period of time depends largely on the individual blood flow acceleration of each individual patient, Dr Buschmann explained, adding: 'We now know that the effect lasts for around a year, so repeated training is needed – an ideal passive addition to active cardio exercise.

Health insurers in Germany have started to cover this personal shear rate treatment, but not all; it has neither NUB (new examination and treatment procedures) status nor does it qualify for an additional reimbursement. Meeting the costs is always negotiated on an individual basis.

However, there is considerable interest. Apart from the Charité, another 20 clinics – in Germany, Austria and Switzerland – plan to offer this patent protected personal shear rate treatment this year.

The procedure is suitable to treat stable CHD and particularly diffuse CHD, i.e. patients who cannot be revascularised interventionally or surgically. In addition, patients with peripheral vascular disease (PAD) also benefit from the treatment, especially if they are also diabetics. Several clinical trials are currently being initiated to confirm the beneficial effects in larger patient cohorts.

The system can also be used to treat erectile dysfunction, a disease estimated to affect every other male over the age of 40 and which can frequently be a precursor of systemic vascular disease.

Ivo Buschmann fits a patient with a personal shear rate therapy system. Inflatable cuffs are placed around the calves, upper and lower thighs and pelvis, then connected to a computer-controlled compressor via a pneumatic hose

© Funke

PD Dr Ivo Buschmann studied medicine at the University of Hamburg, where he also began his career in the cardiology department with Professor Thomas Meinertz. Awarded a Max Planck Society scholarship he moved to Prof. Wolfgang Schaper's group, where he participated in several high impact papers in the field of therapeutic arteriogenesis. With a grant from the Volkswagen Foundation's excellency programme (2000 – 2006) Dr Buschmann continued his research at the Albert Ludwigs University of Freiburg. In 2004 his research group initiated the Richard Thoma Laboratories (RTL) for Arteriogenesis at the Charité Berlin in the Centre for Cardiovascular Research (CCR). The focus of the RTL is the generation of molecular experimental data and translation of the latter into clinical practice.
Clinically, Dr Buschmann directs the interventional angiology at the Charité Berlin (Campus Virchow) and is a founding member of ESVM – the European Foundation for Vascular Medicine.

Cardiology & therapy

Healing hearts 1: Bioresorbable stents

Cardiologists believe they can restore coronary arteries thanks to a new generation of stents that help the body to strengthen collapsed vessels. Elsewhere, patients' own stem cells are being programmed to rebuild cardiac muscle in HF patients. John Brosky reports

Not every patient needs to be cut open to replace or bypass clogged coronary arteries. Some 30 years ago we learned arteries could be reopened with a balloon in a minimally invasive procedure. More recently interventional cardiologists learned they could keep the artery open by inserting a metal tube.

Unfortunately, the body does not agree and fights this foreign object. Patients with metal stents face a risk of the artery closing again inside the tube. Thousands of patients today are being treated with an innovative stent made of biocompatible materials that holds the artery open long enough for the body to heal the vessel naturally, and then dissolves into the blood.

The results from clinical trials are so good that cardiologists are speaking for the first time about 'healing' coronary arteries. Dozens of these new stents are being pushed through product pipelines by companies specialising in cardiovascular technology.

In May of this year, at Europe's largest gathering of interventional cardiologists, the combination of solid evidence from the clinic and new product announcements from companies reached what is called an inflection point, a moment when the tide turns.

'We have reached the point of no return,' said Patrick Serruys MD, stopping in his tracks on the way to speak at a scientific session devoted to these revolutionary devices, which he calls bioresorbable vascular scaffolds (BVS).

Christoph Naber MD, of St. Elisabeth Hospital Essen, Germany, has personally implanted 200 of the new scaffolds

The Editor-in-Chief of the journal *EuroIntervention*, and recognised as a co-developer of metal-based drug-eluting stents (DES), Dr Serruys has been preaching the need for this new technology.

'Seven years! It's like a biblical time to wait, but now it's here,' he said, clearly enthusiastic about the cascade of good news during the EuroPCR congress in Paris. 'I will have to check, but I have the impression that bioresborbables were used in half the live sessions this week.'

'We are calling it vessel restoration therapy (VRT),' said Dr Serruys, a professor of Interventional Cardiology at Erasmus University (Rotterdam, the Netherlands), where he is also the Director of Clinical Research in the Catheterisation Laboratory. Bioresorbable scaffolds are revolutionary, disruptive for a coronary revascularisation market that is expected to reach $10 billion annually by 2016.

Because DES scaffolds are made of metal, no matter how thin, or how carefully coated with a therapeutic drug, they continue to irritate arterial tissue creating a risk of blockage, or restenosis. BVS are made with magnesium or various combinations of synthetic copolymers derived from amino acid l-tyrosine, such as polycarbonates and poly L-lactic acid (PLLA). Medical imaging studies show these bio-friendly materials hold their form reinforcing an arterial lesion for four to six months as the tissue repairs itself, and then they begin to degrade until absorbed by the body and almost completely disappear at 24 months.

Abbott Vascular's advanced bioresorbable vascular scaffold

Christoph Naber MD, from St. Elisabeth Hospital in Essen, Germany, said he has personally implanted 200 of the new scaffolds and colleagues at his hospital have used more than 400 each. 'This is the first generation and we need to watch for any safety concerns, anything to show that this therapy is a problem,' he said. 'But, so far, with something like 10,000 devices implanted, there have been no signals of concern.'

A leading cardiac interventionalist, Dr Naber was a panelist for the Great Debate during EuroPCR and spoke for other panelists when he concluded, 'the principle to treat and leave nothing behind is the way to go'. Co-chair of the Great Debate, Michael Haude, from the Städtische Kliniken in Neuss, Germany, noted that BVS are now moving out of simple lesions with more advanced designs. He also introduced a note of caution saying that, while safety data is proving to be 'very good, we need long-term data to show these scaffolds have a superiority to the established standard of care, which remains new generation drug-eluting states (DES)'.

Doctors Naber and Haude both agreed with a conclusion during the Great Debate that DES will continue to be the predominant stent used, but that in 10 years it will be replaced by BVS as the standard of care. 'Yes we all agreed with that in the discussion to be polite,' Dr Naber told *European Hospital*, 'but internally at my hospital, everyone believes it will be more like five years.'

Bioresorbable scaffolds are being developed by all major players, with Abbott Vascular the most advanced, but followed by major competitors Medtronic and Boston Scientific. Smaller companies introducing more novel devices include Kyoto Medical Planning (Japan), Biotronik (Germany), Elixir Medical (USA), Reva Medical (USA), Arterial Remodelling Technologies (France), Amaranth Medical (USA), OrbusNeich (Hong Kong), Huaan Biotechnology Group (Laiwu, China), and Xenogenics/MultiCell Technologies (USA).

Healing hearts 2: Stem cell cocktails

Nothing new has been invented in heart failure in the last 15 years, according to Christian Homsy, CEO of Belgian-based Cardio3 Biosciences. This explains the excitement surrounding an emerging treatment among cardiologists, patients and investors.

The innovative technique for turning stem cells into cardiac muscle was developed at the celebrated Mayo Clinic in the United States.

One of the first cardiologists to get caught up in the excitement over this new approach was William Wijns MD, from the Cardiovascular Centre Aalst in Belgium. In 2007, Wijns and Homsy founded Cardio3 BioSciences in order to license the technology and bring this American innovation to patients suffering chronic heart failure. 'Dr Wijns is totally out of his element when it comes to questions about the market potential of this new procedure,' Christian Homsy explained. 'He's 120% dedicated to treating patients and the expertise he brings is knowing the outcome needed for patients and how to test it with patients.'

However, investors in Life Sciences businesses, which are very much focused on market potential, also caught the excitement. Homsy was able to gather €60 million in several financing rounds to bring the science out of the laboratory and into the long process of experiments and clinical trials.

Following a successful Phase II study with 45 patients, the company boldly went public in July 2013, raising a further €23 million on the NYSE Euronext stock exchanges in Brussels and Paris. Homsy said this fresh funding will allow Cardio3 to complete its European Phase III study, the final step in an intensive clinical development programme before seeking the regulatory approval that will finally make the treatment available to patients.

The treatment is only available in Europe. With successful results in the Phase III clinical trial, Cardio3 will be able to discuss with the USA's Food & Drug Administration (FDA) the start of a clinical trial there. Millions of people are waiting, some who may not live long enough to see this therapy arrive in the hospital. In Europe alone, 3.6 million people are diagnosed each year with HF, a very serious condition in which a damaged heart cannot pump enough blood to meet the body's need. This number is expected to double over the next 10 years. One patient in three who is diagnosed with HF will die within the year.

Called C-Cure, the new therapy is a three-step process. First, cells are harvested from the patient's bone marrow in the hip, using a catheter and performed using local anaesthesia. These cells are sent to Cardio3's processing centre where they are re-engineered with the 'cocktail' invented at the Mayo Clinic. Called Cardiopoiesis, the reprogramming process takes 30 days, teaching the new cardiac progenitor cells to behave like those cells that have been lost to heart disease. This highly personalised batch of cells is frozen and sent to the hospital where it can be injected through a minimally invasive procedure into the patient's heart muscle using a specialised catheter developed by Cardio3.

'We believe C-Cure has the potential to go beyond symptom relief towards healing heart tissue and could mark a significant step forward in treatment for heart failure patients, Homsy says in the cautious language required before the results of the Phase III trial are known.

In June 2013, the first patients were enrolled in the CHART-1 trial (Congestive Heart failure Cardiopoietic Regenerative Therapy). This is a prospective, multi-centre, randomised, blinded study, comparing treatment with C-Cure to a sham treatment. More than 240 patients with chronic advanced HF of ischemic origin will be enrolled. The primary endpoint of the trial is a composite result at nine months after treatment that includes mortality, morbidity, the Six Minute Walk Test, quality of life, and left ventricular structure and function.

The result from the Phase II trial that generated the excitement behind C-Cure, said Homsy, is that the heart became smaller for treated patients. In chronic HF, the heart progressively becomes larger to keep up with the body's needs until finally it fails. Among patients in the Phase II trial, 'it was as if the heart had regressed back to an earlier stage in the disease history, at a moment when the patients were less sick than they are now,' he explained. In terms of heart function, the heart's ability to pump blood, measured as the left ventricular ejection fraction, improved by 25% after six months. The improvement in a patient's physical capability was an increase of 77 metres during the Six Minute Walk Test.'This progress has not been seen before in a chronic disease,' said Homsy. 'We have results out to two years now and this can be considered long-term results for patients who had a 12-month life expectancy. It is not a guarantee of success for the CHART-1 trial, but it points in the right direction.'

Christian Homsy, CEO of Cardio3 Biosciences

William Wijns MD, Cardiovascular Center Aalst

'What is important here, what makes this unique are these results combined with the physical remodelling of the heart,' he said.

The name of the product, C-CURE derives from the full description of Cardiopoietic stem Cell therapy in heart failURE and, despite its hopeful sound, Homsy cautioned that the therapy it is not a cure. 'Cure means you become healthy again, that your heart has been reconstructed in its entirety,' he said. Small animal trials showed that C-Cure could do that, but bringing the treatment into humans is a completely different case. 'Heart failure in humans is a complex disease,' he said. 'We have shown that C-Cure can regress the disease by remodelling the heart. But to heal a patient completely? We are not there yet.'

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 Brosky, Michael Reiter
Executive Director: Daniela Zimmermann

Correspondents
Austria: Michael Kraßnitzer, Christian Pruszinsky. **France:** Annick Chapoy, Jane MacDougall.**Germany:** Anja Behringer, Annette Bus, Bettina Döbereiner, Jennifer Eletr, Jörg Raach, 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, Jacquie Michels

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: WVD, Mörfelden-Walldorf, 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

The ultimate in ultrasound

A joint meeting combining the Euroson and Three Countries congresses creates a veritable European summit on the state-of-the-art in ultrasound, John Brosky reports

Always considered the orphaned child of radiology, ultrasound is growing up fast, expanding so rapidly that even experts find it difficult to keep up with developments.

By joining forces, the leading professional societies for ultrasound in medicine hope to create a comprehensive conference to survey advances in the science while also offering intensive, hands-on training and education.

From 9-12 October 2013 Stuttgart will welcome the 25th Euroson Congress and the 37th Dreilaendertreffen, or Three-Country Meeting, together representing over 30,000 members.

Pioneering research in oncology and neurology with ultrasound imaging will be presented respectively by Nathalie Lassau MD and Daniela Berg MD.

Also to be presented, the PRIMUS study, demonstrating how putting ultrasound expertise on the front-line in emergency means faster, better care for patients plus hospital cost savings.

Andreas Schuler MD is head of hospital and head of the Internal Medicine Department at Helfenstein Klinik (HKS) in Geislingen, Germany. After his studies at university Witten-Herdecke and Eberhard-Karls-University Tübingen he became internal medicine (1995) consultant for gastroenterology, tumour therapy (1996), diabetology (2002), emergency medicine (2001) and palliative medicine (2007). From 2008-2012 he chaired the internal medicine division and he is member of the German guideline board for diagnostics and therapy in hepatocellular carcinoma.

Education in practice

Yet interactive learning sessions will remain a focus of activities over the four days, according to Andreas Schuler MD, who leads the organisation of the scientific programme by DEGUM, the German society for ultrasound in medicine.

'Traditionally the education component is the strongest point for the conference, whether in state-of-the-art lectures, refresher courses, or categorical courses,' he said.

The Ultrasound Learning Centre will offer practitioners an opportunity to learn though hands-on training with the 25 ultrasound systems, with experts available for one-to-one coaching, teaching and exploring how to perform specific examinations from head to toe. This year's systems will also be available for team training in endoscopic ultrasound.

Expansion of the 2013 programme to encompass 16 full-day categorical courses devoted to a single area of practice is proof of how broadly ultrasound is applied across medicine today. 'A good example is the session called, Emergency Meets Chest Ultrasound, Dr Schuler said. 'This will be about the FAST and eFAST exams, of course, but also a demonstration of how ultrasound goes beyond being a first-use imaging tool to become a strategically essential aspect of imaging.'

Often diagnosis of hospital patients can be extended over two or three days, he explained, where ultrasound can play a vital role from the first minutes.

To test this argument, the PRIMUS clinical trial enrolled more than 1,400 patients to determine the influence of ultrasound on a medical team's decisions when a diagnosis is conducted within the first 24 hours of patients arriving in hospital.

The completed study, now being prepared for publication, will be presented at the joint congress in Stuttgart.

Dr Schuler could not disclose specific finings, but noted an abstract of preliminary findings was presented at last year's Three-Country Meetings, and 'The final results continue to support the early findings… that early ultrasound helps to make accurate early diagnoses, leads to early treatment, and, significantly, avoids additional days of hospital stays.'

Significantly, the size of the patient population in the PRIMUS trial allows a study of subgroups presenting with abdominal pain, vascular disorders, chest pain or heart failure, he added.

Whilst ultrasound does not always play a decisive role with every patient, it proves very effective in these symptomatic subgroups for directing patients to the right place for the right care, and to determine those who need to be admitted and those who can be treated on an outpatient basis, he said.

Fusion and CEUS

Scientific sessions devoted to technologies and state-of-the-art lectures will try to keep pace with developments racing ahead at the speed of sound, covering new methods and practices such as elastography, contrast enhancement, imaging for ultrasound guided interventions and imaging in oncology.

Fusion imaging that combines dynamic ultrasound images with MRI or CT will be on the leading edge of disruptive change discussed at the congress. The application of fusion imaging in practice areas such as the early stages of chemotherapy also links to recent developments for contrast-enhanced ultrasound imaging, where ultrasound is now achieving the same levels of effectiveness as its bigger brothers, MRI and CT, Dr Schuler said.

Other frontiers to be explored at the congress include musculoskeletal (MSK) ultrasound that is rapidly being taken up from primary care to specialists, he added.

'In the past, if there was ever a question about MSK, the patient was sent for an X-ray or MRI. Now ultrasound is finding a place among radiologists and specialists because it provides a real-time examination that is dynamic, making it appropriate for studying the mechanics of articulations.'

Ultrasound in neurology is playing an ever greater role in neurology, he said, effective for the early assessment of markers for degenerative diseases like Parkinson's or for examining vascular structures for stroke assessment.

Where the Three-Country Meeting is traditionally German speaking, this year's joint congress with Euroson will be conducted in English, creating a unique opportunity, Dr Schuler believes. On one hand European colleagues will have access to more than 200 abstracts submitted by German scientists in the English language. And for German speaking clinicians and scientists, the international participation brought by Euroson members, with more than 150 scientific abstracts as well as state of the art lectures and refresher courses, will enrich their conference experience and exposure to developments across Europe.

The 33rd German Society for Senology Congress

Report: Anja Behringer

Like any other cancer – breast cancer is a highly individual disease, shaped by many factors such as age, health status or genetics. Due to the complex web of molecular pathological processes and resistance mechanisms it is very difficult to select the most effective therapy for each patient. Even official recommendations have to be taken with a pinch of salt, since they are usually based on large cohorts.

At the annual meeting of the German Society for Senology, focused on interdisciplinary discussions on up-to-date breast cancer diagnostics and therapy, Congress President Professor Axel-Mario Feller urged acceptance that, 'the omnipotent single physician no longer exists… since highly specialised knowledge is required to the benefit of the patient to be able to efficiently apply multimodal therapy concepts'. Programme topics ranged from developments in medical technology to specialised drugs, new examination methods, integration of complementary medicine and the role of the breast nurse in the British cancer follow-up care model.

A new test for individual cancer medication

Recently approved for clinical use, SpheroTest is an evidence-based tool that helps select the most effective drug for each individual cancer patient. Its manufacturer Spherotec is a spin-off from the Grosshadern Surgery Clinic, near Munich, and a brainchild of PD Dr Barbara Mayer, a biologist, and PD Dr Ilona Funke, a surgeon.

In a late 1990s research project these two researchers wanted to learn why cancer therapies outcomes are so poor despite the availability of so many therapy options. They developed and patented a procedure that grows 3-D microtumours from patient tissue samples – within 48 hours. Since the in-vitro tumours are almost identical to the original tumour they can be used to reliably identify the most effective cancer medication.

Providing information on the chemo-sensitivity and resistance of the individual patient's immune system SpheroTest makes trial and error approaches obsolete. German

Continued on page 24

Emergency medicine

The potential of ultrasound looks inexhaustible

Experts from DEGUM, the German Society for Ultrasound in Medicine, are convinced that the use of ultrasound in preclinical and clinical emergency medicine can be further optimised, according to interim study results that indicate, in cases of unclear symptoms, the diagnosis and therefore decision for appropriate A&E treatment can be accelerated by using ultrasound. The overall hospital length of stay can also be shortened significantly. *Bettina Döbereiner* reports

Be it to detect an abdominal aortic aneurysm quickly or to treat a pneumothorax with the help of ultrasound – the advocates of ultrasound are convinced of the procedure's immediate benefit in preclinical and clinical emergency medicine. 'For us, ultrasound is part of the clinical examination,' says Professor Joseph Osterwalder MD, Senior Consultant in the A&E department at the St. Gallen Cantonal Hospital, Switzerland, and speaker of the Working Group for Emergency Ultrasound at DEGUM. 'And,' he adds, 'for me it's the stethoscope of the future.'

He particularly points out that, when a patient is in considerable pain and screams, this kind of imaging is ideal. 'When there's a high level of noise it's impossible to auscultate the heart and lungs and to go into the finer details, but with ultrasound what's wrong with the patient is immediately visible.'

Source: DRF German Air Rescue

DRF German Air Rescue has used devices such as GE Healthcare's Vscan since 2011. Although no explicit evaluations are yet available, experiences so far have been good, according to Stefanie Knapp, press officer for DRF German Air Rescue.
The mobile ultrasound scanner, one of the smallest available, weighs around 400gm, has a visual field of 75° and a penetration depth to 25cm maximum. The transducer frequency is 1.7 – 3.5 MHz


© Döbereiner

Professor Joseph Osterwalder MD, Senior Consultant at the Central A&E Department of the St. Gallen Cantonal Hospital, Switzerland, studied medicine at Swiss universities in Fribourg and Zurich and wrote his doctorate on a clinical-epidemiological topic in neurosurgery. He also gained a Masters in International Health at Harvard University, USA.
A fellow of the European Society of Emergency Medicine, Prof. Osterwalder has worked in clinical emergency medicine for 25 years, gained numerous additional qualifications in this field, also working for years as a medic in war zones for the International Committee of the Red Cross.

However, is a comprehensive use of ultrasound in emergency medicine really necessary? Do investments in the hardware and training – especially for preclinical medicine – actually pay off? Currently, not many studies exist on this topic – if only because randomised controlled studies in these acute emergency situations are not possible for ethical reasons.

This is also the problem which Andreas Schuler MD, Member of the Board at DEGUM and senior consultant at the Helfenstein Klinik Geislingen faced. As head of the first multi-centre study worldwide into the benefit of ultrasound in A&E, he and his team wanted to prove scientifically that the early use of ultrasound by trained staff in the hospital A&E department accelerates diagnosis and therapy and helps to shorten the duration of hospital stays.

To date there are only preliminary results of this PRIMUS Study (Primary Ultrasound as an Imaging Method for Patients in the Emergency Department) available. As stated in the previous article (page 23), the study was carried out in the A&E departments of six different hospitals with more than 1,400 patients. Only patients with unclear symptoms where a diagnosis could either be confirmed or excluded by using ultrasound were involved.

These patients were initially treated according to the instructions of the doctor in charge of the department at the time. If there was an urgent indication, and as long as the situation in the respective A&E department permitted it, the ultrasound examination was carried out immediately (within the first 24 hours: group 1) or later (after 24 hours: group 2).

In a comparison of these two groups, it becomes apparent that the average duration of stay amongst patients in the first group is almost 40%, i.e. significantly shorter than those of the second group. Biometricians are currently comparing the respective diagnosis groups (ICD groups) to rule out other causes for the different durations of stay, and the results of this analysis are due this year.


© Döbereiner

From left: Joseph Osterwalder, moderator Anna Voormann, Andreas Schuler and Stefan Nöldeke (DEGUM president)

A further interim result of the study: the immediate use of ultrasound resulted in an immediate indication for further treatment in more than 50% of cases examined; in around 47% of cases it was helpful for differentiating the diagnosis and in only 2.6% of cases did ultrasound have no impact at all on treatment decisions. However, Dr Schuler said, professional experience with ultrasound is the prerequisite for full utilisation of the procedure's potential. At all times during day and night, the doctor in charge, irrespective of his medical specialism, should be comprehensively trained in the use of ultrasound for acute emergency situations, in A&E as well as the preclinical medicine.

To ensure this, DEGUM has developed a simple training programme. 'One of the reasons why emergency ultrasound has to date been used far too infrequently is the dogma that ultrasound diagnostics should be the responsibility of the specialists of the respective medical fields,' says Prof. Osterwalder – who was involved in the development of this curriculum with the Working Group for Emergency Ultrasound. The patient should receive an ultrasound examination directly at the initial location of treatment by the first doctor in charge – the key demand made by the DEGUM specialists. They are therefore calling for comprehensive use of ultrasound for emergency situations, in the A&E department as well as in preclinical medicine.

Air Rescue is ahead of rescue services on the ground, which to date have only been equipped with mobile ultrasound scanners in the context of studies or projects. The DRF German Air Rescue was the pioneer – it has gradually been introducing mobile ultrasound scanners and training staff since 2004. Since 2013 training has been based on the curriculum developed by DEGUM, press officer Stefanie Kapp explains.

ADAC Air Rescue also places considerable importance on ultrasound according to Michael Gässler MD, of the ADAC medical division. With an experienced user, he says, ultrasound can quickly result in the confirmation of a suspected diagnosis. However, he also warns: 'on the other hand, insufficient experience with the procedure and the equipment can lead to delays and incorrect diagnoses.' Comprehensive training and instructions are therefore indispensable. The ADAC Air Rescue runs its own training programme.

* Pilot study results on PRIMUS were published in the Journal of Medical Ultrasound: Benefit of early abdominal ultrasonography in non-surgical patients admitted to the emergency department: a pilot study by David Arkadij Albrecht et al. (Journal of Medical Ultrasound;Volume 38, Number 4, October 2011, pp. 203-208)

The 33rd German Society for Senology Congress

continued from page 23


© DGS

private health insurers already reimburse the costs of these diagnostic procedures. Any individualised cancer therapy requires the tumour to be assessed correctly. Last year, the WHO published a new classification of breast carcinoma indicating 37 invasive types that can be identified using predictive markers and that are treated either surgically or medically.

High-value advances include elastography

Thanks to new generation systems and radio frequency sonography today breast ultrasound is more than a mere complement in breast cancer diagnostics. Modern transducers can differentiate structures. High frequency transducers (10 to18 MHz) can visualise microcalcifications. Colour and Doppler ultrasound, 3-D ultrasound and elastography enhance the results of conventional breast ultrasound.

EFSUMB (European Federation of Societies for Ultrasound in Medicine and Biology) developed guidelines for sonoelastography that recommend using the technology as an additional tool to assess and possibly re-grade benign-appearing lesions that are stiff and consider them for biopsy. Moreover conventional ultrasound that did not yield clear results regarding benignity or malignancy of lesions can be supported by sonoelastography.

In 2012, DEGUM, the German Society for Ultrasound in Medicine, surveyed the more than 600 members of the breast ultrasound working group about elastography. Results showed 20 percent of the specialists already use sonoelastography, mainly as a complementary diagnostic tool in BI-RADS-US 3 and 4 results and for research. 85 percent of those who do not use the technology yet, are interested in elastography as an additional diagnostic instrument, particularly for earlier, more precise cancer detection.

Image guidance by ultrasound enhances robotic surgery

Finally surgeons can look beneath the surface

Report: Michael Reiter

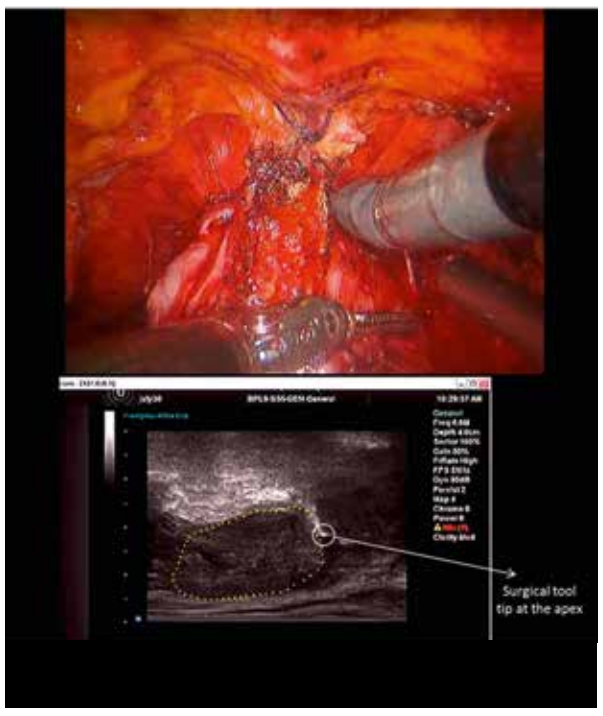
Use of ultrasound for guidance is gaining ground, researchers explained during the 4th IPCAI, the International Conference on Information Processing in Computer-Assisted Interventions held during CARS 2013 in Heidelberg. The technique has been shown to help increase precision in taking biopsies by percutaneous insertion of needles. Additionally, interest in guidance by ultrasound has increased in recent times with regard to enhancing surgical procedures, explained Professor Tim Salcudean from the University of British Columbia in Vancouver/Canada.

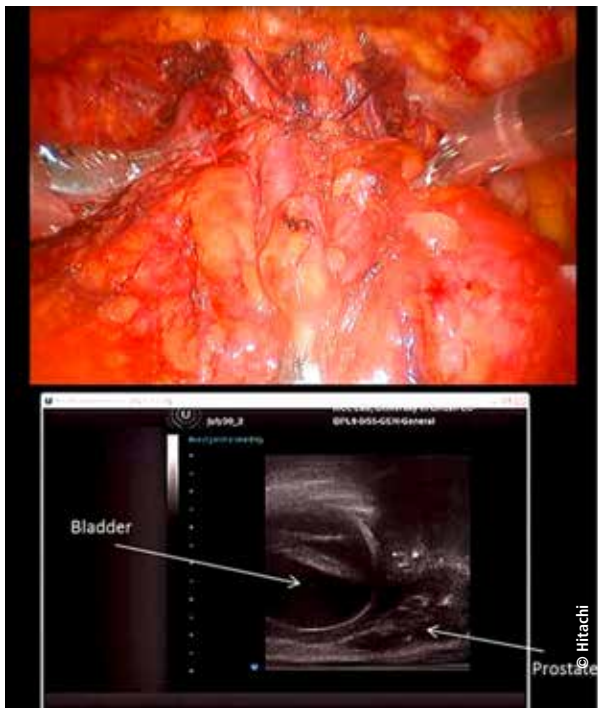
Integrating ultrasound with the da Vinci surgical robot is one of this expert's key areas of interest: 'The robot provides an easy way of coordinating the laparoscopic camera view with the ultrasound view,' he explained. 'Researchers look mostly into prostate surgery – in North America, 80 percent of these procedures are carried out by robots; that makes this application highly interesting.' However, further potential areas of application, such as kidney surgery, keep coming up, he pointed out. What matters most is patient outcomes. The use of ultrasound may make the use of the surgical robot even more attractive, especially for novice surgeons, and can speed up procedures.

A better view of vessels and organ boundaries

Benefits researchers hope to derive from ultrasound guidance during procedures include visibility of vasculature and organ boundaries. 'We also expect to improve the detection of cancer,' Prof. Salcudean added. 'Additionally, use of ultrasound technology should allow us to bring pre-operative images into the operating room: pre-operative MRI images can be superimposed, by using intra-operative ultrasound and ultrasound-MRI image registration, to provide augmented reality, enabling the surgeon to better decide on margins.'

The application of ultrasound guidance in the operating theatre (OT) is still restricted to a few centres because, he explained, an ultrasound technician is needed to set up the machine in the OT and position the transducer. Ultrasound is then manoeuvred remotely from the surgical console. 'However, it's a very uncommon situation for the surgeon – who is acting remotely – to work cooperatively with someone else,' Prof. Salcudean pointed out. 'Embracement of ultrasound guidance by surgeons using robots is therefore a difficult issue.'





Left: The endorectal ultrasound transducer is registered to the robot and programmed to track the da Vinci tool during surgery. You see here a sagittal image of the prostate showing the tool tip artefact at the prostate apex
Right: Sagittal image of the prostate and bladder
Images courtesy of PhD student Omid Mohareri, who works with Professors Salcudean and Larry Goldenberg MD, head of Urologic Sciences at the University of British Columbia, who performed the surgery at Vancouver General Hospital

It will also be important to progress regarding image processing to make them meaningful and easier for surgeons to understand. Furthermore, controlling ultrasound machines needs improvement, for example through various pre-sets and automatic adjustment. According to the Canadian expert, 'these kinds of advances would help surgeons to use ultrasound guidance without a huge amount of training.'

Guidance as part of numerous ultrasound advances

So far, Prof. Salcudean's University of British Columbia team has applied the technology to one animal and eight patients. However, that approach is part of a multi-faceted application of ultrasound, and guidance is becoming part of the bigger picture. 'We've had many patients who have been imaged using that particular ultrasound system, and we've correlated tissue elasticity and viscosity with prostate cancer for 20 patients. We have also applied ultrasound to delineate the prostate in ultrasound images for radiation therapy for close to 40 patients. In those cases, by adding elasticity we've been able to improve the contrast-to-noise ratio in localising the prostate by a factor of five.'

Benefits make this an obvious trend

Ultrasound guidance allows surgeons to look beneath the surface of organs – this major benefit will support acceptance, Prof. Salcudean believes. The cost of ultrasound is reducing, and flexibility to programme the devices will help to increase ultrasound use in guidance. 'My vision is that there will be applications in robotic surgery where easily accessible ultrasound guidance will be the standard method, similar to the embracement of the laparoscopic camera, for example.'

Da Vinci robot

Professor Tim Salcudean holds the C.A. Laszlo Chair and a Canada Research Chair at the University of British Columbia in Vancouver, Canada. He is interested in medical robotics, image guidance and imaging the mechanical properties of tissue, with applications particularly in urology and prostate cancer.

AACC: Shortened replacement cycles and tightened budgets

Once again the joint annual meeting of the American Association of Clinical Chemistry (AACC) and American Society for Clinical Laboratory Science (ASCLS) proved itself as the world's largest gathering in the clinical laboratory sector, attracting a huge crowd of lab managers and pathologists from the USA, Canada and overseas. Hundreds of companies presented equipment and solutions. Following extended service cycles, buyers showed a pronounced interest in new diagnostic products and technologies – this was the basic message from the exhibition floor. However, a drive to cut cost is impacting on lab technology investments in many countries.

Diagnostics: Market trends

Nat Whitney, President of Whitney Research, sums up the ups and downs of the international IVD market and reports on a fitting finale for 17 years of dedicated service

This year's International Market Briefing (IMB) at AACC Clinical Lab Expo in Houston was a fitting transition. 17 years ago Herb Burklund of Scherago and Jerry Goldsmith, former Vice-President of the AACC, created this informative programme as a value-added service to exhibitors – and it grew from 75 attendees in the first year to 600-700 dedicated participants over the past few years. The quality of the information presented at the 2013 session was, perhaps, the best of the best and a testament to Herb as he departs.

'International' has meant different things to different people, now that Clinical Lab Expo includes many non-US companies. As an example, since 2010, the Chinese exhibitors have grown from 26 to 82 companies. To them, China is not international, but Europe is.

So this year Europe was included as an International Market, and Dr Juergen Schultze, President of the EDMA, presented the market data that is gathered and shared amongst companies who send in their sales data to the European Diagnostics Association, comparing country-by-country and segment-by-segment results.

In these troubled times in Europe, he compared the declines. Overall, European IVD (in vitro device) sales declined 2-3% in 2012, and are expected to decline again for 2013. The biggest markets, Germany, France, Italy and Spain, all showed declines, but Greece, Poland, and Portugal were more severely hit with declines in double digits.

The upside is that several countries expect to grow in 2013, with Poland and the Czech Republic leading the way.

'How the Small Fish Swims in a Sea with Big Fishes' was the title for the presentation by Stefano Gradi, former Director of International Sales for Diesse, Italy, and founder of IVY Diagnostics, srl. He presented data on the 'fastest five' Southeast Asian markets – Indonesia, Malaysia, Philippines, Thailand and Vietnam – and compared their growth and industrialisation with China and Singapore. These five countries have common characteristics of growing consumer expectations, aging populations, lower cost, skilled workforce, the rise of academic medical centres, government incentives for improved healthcare, and a large population of young people graduating from the universities. For comparison the US spends 14% of government budget on education while these countries average 18%. The most striking similarity of these countries is their diversity within.

While the total IVD market is still very small compared with developed countries and China, Stefano's recommendation was to get in early and establish the brand. As opposed to the West, where 'Self-actualisation' is at the top of the motivation pyramid, for people in these countries, 'Status' is at the top.

Emerging markets

Once again, Greg Stutman, Vice-President of Boston Biomedical Consultants, analysed the changes in the IVD markets worldwide and compared 2012 to 2011. He confirmed that the growth in the emerging developing markets were what was keeping IVD companies afloat as the developed markets matured and were affected by pricing, austerity measures and growing market consolidation. Greg forecasted that the total IVD market would grow by 5% CAGR from $49.2 billion to $62.8 billion from 2012 to 2017, led by the emerging markets, which are predicted to be larger than the US market by 2017. By segment categories, 'Infectious Disease and Blood Processing', 'Select IA segments', 'Haematology and Coagulation', and 'Emerging/Novel' (which includes molecular) will lead the way with above 5% growth. Diabetes, which has suffered the worst declines, will continue to lag.

Noel Maria Adachi, Vice President of CAP International, talked about the growing demands for increased quality in the developing markets as incomes in those regions have increased. Government regulators have been implementing new requirements. She focused on the largest developing markets of China and India, the components of quality certification and how IVD companies can help laboratories comply, whether certified by CAP, China National Accreditation Service, or other certifications and quality control monitors. The CAP V-P discussed where most of the laboratories' errors occur and how IVD companies can help the customer understand and control. Manufacturers must play a larger role in educating and designing products and services that improve and control quality in the hands of the users in the developing markets.

Nat Whitney, President of Whitney Research, Littleton, USA and Bejing, China

High expectations: POCT

With a market growing faster than central lab markets in the developing world, Point of Care (POCT) was the subject of David James of Invetec, one of the sponsors of IMB. He defined POCT as 'fast results from minimally invasive sampling methods, using affordable consumables'. He described a cycle of expectations that start with 'technology triggers', proceed to 'peak of inflated expectations', then a 'trough of disillusionment', and on to the productive part of the curve he called 'slope of enlightenment' and then on to the 'plateau of productivity'. With the developing market so price sensitive and the populations and potential demands so large, he discussed the benefits to cost of the increasing demand for consumables like test cartridges. His message was to include most of the complexities in the instrument and keep the consumable simple and easy to manufacture, so as to take advantage of economies of scale. Herb Burklund wrapped up the session with a sentimental [address] and a wish for the meeting to continue and flourish. The annual evaluation and suggestion survey of attendees is not yet in, but the expectation is that the 2013 edition will rank high.

Thermo Fisher advances LC-MS to next generation

As evolving applications continue to push the limits of instrument performance, Thermo Fisher Scientific has introduced a new-generation liquid chromatography-mass spectrometry (LC-MS) platform

Built from the ground up the platform features an automated sample preparation/liquid chromatography system coupled to a triple quadrupole LC-MS configuration capable of delivering extreme sensitivity, productivity, precision and usability.

According to Bradley Hart, Market Development Director for the Chromatography and Mass Spectrometry Division at Thermo Fisher, the high-performing technology is integrated with the new Prelude sample prep/LC system and new TSQ Quantiva and TSQ Endura LC-MS systems.

'These systems respond to the needs of clinical research labs for rapid analysis that is very reproducible, very easy to use and very robust without a need for frequent service, which responds to emerging customer requirements,' he said.

The TSQ Quantiva LC-MS brings a powerful new tool for scientists performing quantitation experiments in proteomics. With an industry leading sensitivity, the TSQ Quantiva breaks the 'attogram barrier with the absolute lowest levels of detection', according to the company. An attogram is a particle six magnitudes smaller than a milligram.

In experiments the enhanced level of sensitivity with Active Ion Management (AIM) in the TSQ Quantiva have delivered an unprecedented level of performance. This capability is expected to greatly improve results in applications such as peptide quantitation, metabolomics and biopharmaceutical QA/QC compared to previous systems.

The TSQ Quantiva MS system bristles with new features that make it extremely productive with an ability to perform 500 selected reaction monitoring (SRM) scans per second to produce higher quality data than standard instruments.

The new TSQ Endura LC-MS system is also optimized to minimise maintenance requirements for industry-leading uptime while delivering the sensitivity of previous high-end instruments. Stress tests using a challenging synthetic serum sample demonstrated a three-fold improvement in robustness over previous systems. Together with the Thermo Scientific Prelude SPLC system these LC-MS systems enable users to focus on demanding aspects of clinical research associated with detecting and quantifying very low level amounts of compounds in complex biological samples such as blood, urine and oral fluid.

Typically, advanced LC-MS systems can only be operated by highly specialised scientists, said Bradley Hart. 'But if this person is gone for a week, no one can run the tests. We have made this advanced technology easy to use so that trained clinical lab technicians can run the instrument.'

'Improved usability was a core goal of this project', said Iain Mylchreest, vice president of R&D for chromatography and mass spectrometry with Thermo Fisher Scientific. 'We know many customers use both our hybrid and our triple quad technologies, and we have created an environment that makes it as easy as possible to leverage both systems in the same laboratory.'

Moving mass spec into the clinical lab

Mass spectrometry has been applied in advanced clinical research and drug discovery and development. Continual innovations have created capabilities to address complex analytical challenges qualitatively and quantitatively with unparalleled speed, sensitivity and accuracy

A specialist in analytical technologies, the company introduced the 3200 MD system, the first of a family of in vitro diagnostic devices to identify inorganic or organic compounds in human specimens for clinical use – and now the firm is introducing to Europe a series of reagent kits to harness this advanced technology for routine clinical applications.

'The lead test in the Sciex IVD-MS portfolio is focused on vitamin D analysis. This kit is designed to help clinicians make diagnoses of vitamin D deficiencies, with the ability to quantitate both 25-0H-Vitamin 02 and 25-0H-Vitamin 03 in a single run,' AB Sciex points out. 'Adequate levels of vitamin D have been known for decades to be essential for strong bones. Recent research has linked vitamin D to be important in the prevention of multiple common and serious diseases, such as type 1 diabetes, cancer and heart disease.'

Rainer Blair, President of AB Sciex: 'With the new family of Sciex IVD-MS reagent kits, coupled with our 3200MD CE-IVD instrumentation, we can provide complete solutions to European hospitals and clinical laboratories to improve diagnostics.'

The new Sciex IVD-MS Kits work with the AB Sciex 3200MD CE-IVD series of MS systems, including the API 3200MD and 3200MD Q-TRAP LC/MS/MS systems, recently launched in Europe. 'The 3200MD systems are sensitive and specific for the analytes most commonly requested in screening programmes, routine testing and research projects in a number of key areas of clinical diagnostics,' the firm explains, adding: 'Designed as compact bench top systems, the instruments are robust, easy-to-use tools that are rugged enough for continuous high-throughput operation. Intuitive software and a full complement of automation features enable these systems to fit seamlessly into the workflows of any clinical diagnostic laboratory.'

The equipment is designed to help diagnose vitamin D deficiencies

Miminising by innovation

From lab to bedside

908 Devices has good reason to be based in Boston's Innovation District. A start-up founded in 2012, the company plans to disrupt the field of chemical analysis with what Vice President Chris Petty calls 'ridiculously small, and elegantly simple' mass spectrometry technology.

'How do you successfully bring analysis to samples rather than samples to laboratories?' he asks in a blog posted on the company website. '908 Devices is working to liberate Mass Spectrometer capabilities from centralised labs' by reducing cumbersome, complex systems to tiny, revolutionary tools.

At the heart of the rugged and portable systems are molecular traps a thousand times smaller than those in conventional mass spectrometers. Miniaturising traps that can operate closer to atmospheric pressures enables the systems to use dramatically smaller pumps, ionisers, detectors and electronics than large-scale mass spectrometers.

The results are battery-operated handheld chemical analysers reliable enough to meet clinical requirements for the detection and identification of targets, while being robust enough to be immediately available.

The key to success is determining specific uses for the technology. Where conventional, large instruments used in centralised labs today are designed to accommodate a wide variety of applications, 908 Devices is designing what the firm calls 'tools built for a specific purpose'. Because results are delivered at the point of need, outside centres where specialists generate and interpret data, the new devices must be able to provide answers to non-expert users.

'We believe passionately that people will do fantastic things when they have these capabilities right in their workspace, or are able to carry them in a pocket,' Chris Petty predicts.

908 Devices has secured exclusive license to a broad portfolio of patents that enable these simple-to-operate, ultra-compact chemical detection and analysis tools.

Currently IVD attracts about 3% of investment in hospitals, yet delivers up to 65% of diagnostic insight

Raising awareness of in vitro diagnosis values

Labs need to optimise their costs as well as accommodate increasing volumes – and new tests are continuously demanded. At this year's gathering of the American Association for Clinical Chemistry (AACC) in Houston, Dave Hickey, CEO of the Chemistry, Immunoassay, Automation & IT Business Unit at Siemens Healthcare Diagnostics Inc., outlined the firm's response to those challenges

Dave Hickey, CEO of the Chemistry, Immunoassay, Automation & IT Business unit at Siemens Healthcare

Increased efficiency of laboratory workflow is key to decision makers during long-term planning, CEO Dave Hickey underlines: 'Labs are constantly asked to reduce operating budgets and manage staffing levels, while increasing workload volumes. How can they handle the sheer volume of activities that is being thrown at them? To address those challenges, the right instruments and right type of automation solutions need to be developed and implemented. In designing our workflow excellence strategy, Siemens looks at the complete picture of laboratory testing disciplines – including chemistry, haematology, haemostasis, immunoassay, and all the way to point-of-care. Our automation solution provides the pivotal basis for meeting these challenges.

'At the AACC we've introduced the new VersaCell X3. This is the first product of the VersaCell family to connect three instruments through a single robotic interface. For anybody who does not require high-end automation, this is a very suitable solution. Anyone requiring track-based automation should look into our Aptio Automation product family.'

What makes Siemens' suites stand out in the market?

'We offer a complete solution,' he explains. 'The track may be a means of transporting samples; but, looking at the configurations of the track, there is now more demand to automate the pre- and post-analytical processes and Siemens provides a very comprehensive portfolio in this area. Analysers, middleware and data management are also important. It's the integration of the entire end-to-end solution that should be evaluated.

'Labs also want manufacturers to bring new tests to market. To name a current example, we have had a very successful year with our fully automated Vitamin D assay. There is also a lot of dialogue around the role that companion diagnostics and sequencing will have in the future.

'Our strategy for clinical excellence is driven by defining new tests and developing them as an integral part of our R&D pipeline. It's a matter of developing the right clinical tests, and making them available on platforms that help address the workflow challenges.'

What size labs does the unit target?

'Our portfolio fits all testing needs, ranging from fully automated laboratory suites to numerous smaller-scale low-end hospitals. Take the USA, for example. We have a significant presence in 5,000 hospitals, as well as in the large reference and research labs.

'The US is a key market for us, and we are a major player in all segments. Integrated delivery networks – IDNs – are a crucial part of the US healthcare system and they typically include large as well as community-level based providers.

Individual needs may differ, but the common goal of IDNs is to standardise technology.'

Which market trends influence where you invest your R&D dollars?

'There's a continuing trend towards automation, an area in which we are market leaders. The global demand for track-based systems is expanding. On the assay side, labs are focusing on new immunoassays, in particular vitamin D and infectious disease parameters. Europe and North America are mature IVD markets with single digit growth rates, whereas emerging markets – BRIC and the Middle East – show double-digit growth. We consider all these aspects as part of how we decide where to invest our R&D funds.

'Labs in all markets seek to raise their own profiles, and expand their service offering. One demand we see increasing is for fully automated allergy tests.'

The status of laboratory medicine is not great. How can Siemens help to improve that?

'We do a lot, for example around scholarships to raise advocacy for labs and the great value they provide in healthcare delivery. We work closely with organisations to drive that awareness. We have to reverse the value equation of IVD, which currently attracts roughly three percent of investment in hospitals, but delivers up to 65 percent of diagnostic insight. Health economics and evidence-based medicine will support this by showing hospital CEOs and CFOs the significant contribution of labs to cost and quality parameters.'

Developing a new standard of care in Ketone testing

Diagnosing and monitoring Ketoacidosis

Acute pathological ketosis, or ketoacidosis, occurs when the body can no longer use glucose as a fuel source and fat is broken down instead. This leads to the release of ketones in the body, with their subsequent excessive build-up resulting in acid/base imbalance.

If not diagnosed and treated, ketoacidosis is potentially fatal. While the normal composition of ketones consists of acetoacetate (20%), acetone (2%) and ß-Hydroxybutyrate (78%). ß-HB is the most prevalent of these ketones and during an incidence of ketoacidosis, it may rise to an 8:1 ratio of ß-HB to acetoacetate. This makes ß-HB the most specific and earliest indicator of ketoacidosis, as well as the best predictor of its resolution due to maximised treatment effectiveness.

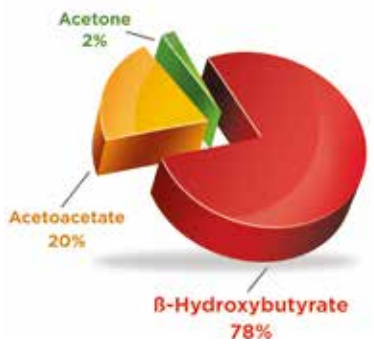
Type 1 diabetic patients are the most at-risk group of developing ketoacidosis. For this patient group, rapid diagnosis of diabetic ketoacidosis (DKA) is essential because delay in starting insulin treatment is associated with increased morbidity and mortality *[Singh RK, Perros P, Frier BM. Hospital management of diabetic ketoacidosis: are clinical guidelines implemented effectively? Diabet Med 1997:14:482-486].*

Since ß-HB testing gives the earliest detection of clinically significant ketosis, it is the most accurate tool that allows physicians to rapidly diagnose and monitor patients to adjust their treatment as required. Currently, there are several ways to administer such a test including: liquid chemistry reagents, such as the ß-HB LiquiColor Reagent System, utilised on general chemistry systems; dry reagent-based hand-held devices, such as EKF Diagnostics' new STAT-Site M ß-HB meter; and nitroprusside-based tests, such as urine dipstick colorimetric testing. However, nitroprusside methods are problematic because they only react with acetone and acetoacetate (just 22% of ketones), are not quantitative and indicate result lagging when using urine samples.

Many of the top US Endocrinology Hospitals *[13 of the top 25 diabetes and endocrinology hospitals test for DKA with ß-HB LiquiColor* (*Top 25 diabetic and endocrinology hospitals as ranked according to US News and World Report, 2011)]* have now implemented ß-HB testing, making it the new Standard of Care in Ketone testing. While nitroprusside methods are still often used, the transition to better testing using ß-HB is underway, as indicated by a recent College of Pathology (CAP) survey.

Liquid chemistry reagents are best suited for use in larger hospitals where they see high volumes of DKA patients.

The STAT-Site M ß-HB hand held analyser



Whereas dry reagent testing using a test strip, such as STAT-Site M ß-HB, is a better fit for those facilities where DKA patients are fewer and testing is sporadic. Strip testing allows these smaller facilities to minimise costs, and at the same time improve clinical management and patient quality of care.

Recently released and CE marked, the STAT-Site M ß-HB meter's strip technology enables quick and easy delivery of a quantitative measurement of DKA from just 10 µL of serum or plasma in under 80 seconds. This means that the presence and degree of ketosis can be very rapidly and highly accurately assessed. In turn, this provides useful information to provide quality care when monitoring DKA in newly diagnosed patients, whilst also reducing time and costs in an intensive care unit setting for example *[M. Vanelli, G. Chiari, C. Capuano, B. Iovane, A. Bernardini, T. Giacalone. The direct measurement of 3-beta-hydroxy butyrate enhances the management of diabetic ketoacidosis in children and reduces time and costs of treatment. Diabetes Nutr Metab 2003: 16(5-6):312-6.].*

Goodbye to needle-stick injuries

All hospital professions can be affected by injuries resulting from cuts and needlesticks, whether they are doctors, nurses or cleaners. The risk of infection is high – an accidental jab from a needle from an infected patient has a 30% probability of infection in the case of Hepatitis B, a 3% risk for Hepatitis C and, in the case of HIV, the risk of transmission is still 0.3%

Raising awareness of infection prevention has progressed in recent years. At best, the time spent on ensuring the highest possible protection against needlestick injuries should generally be cut down to a bare minimum.

Active awareness and consideration should preferably be replaced by automated mechanisms – passive rather than active safety!

The latest product development at Greiner Bio-One, the VACUETTE Tube-Touch Safety System, meets this high standard, the firm reports.

The big advantage of this passive safety product compared to conventional products is that the activation of the protection mechanism does not require additional manual handling. Activation is automatic during blood collection. The unique safety needle is already integrated into the blood collection holder. Inserting the blood collection tube into the holder activates the safety shield without manual activation by the user.

The process

The tube is inserted into the holder. Pressing the tube cap into the rear part of the needle automatically activates the safety shield. It moves towards the front and is in light contact with the patient's skin. After activation, the safety shield also remains flexible. The safety needle is then closed by a spring mechanism when removed from the vein.

Taking blood samples can be carried out as normal; there is no need for additional steps – to the contrary, the company explains, specially positioned grips on the holder ensure a flatter venipuncture angle and recesses for finger placement improve ergonomics. A special bevel design minimises patient discomfort and the position guide on the safety shield even visualises the depth of penetration.

The automated activation provides maximum safety even in case of interruption or abrupt termination of blood collection. The blood collection set, which is ready for use quickly, consists of the needle, tube holder and safety shield, and the entire set is always disposed of as a whole.

'The system is easy to use, offers the highest level of comfort and reduces the risk of infection caused by needlesticks to a minimum,' the manufacturer concludes.

Point of care testing

Carefully selected devices reward MHH with 50% cost cuts

In intensive care units (ICUs) little can be automated to relieve staff pressures – with the exception of point of care testing (POCT). The most up-to-date tools help to save costs as well as improve treatment quality, as demonstrated from *Holger Zorn's* discussion with Josef Hollenhorst, Head of Strategic Investment Management, at Hanover Medical School (MHH) about the financial and clinical benefits of decentralised laboratory measurement devices

The ABL800 FLEX analyzer from Radiometer measures any combination of pH, blood gas, electrolyte, oximetry and metabolite parameters

Pictures (2): © Radiometer

Supramaximal medicine often means that not just one or two specific parameters are required quickly but an entire profile – blood gases, metabolites and oximetry, inclusive of CO-oximetry, electrolytes, glucose and lactates. For example, for comatose patients admitted to A&E this type of comprehensive blood gas analysis immediately provides orientation. If the problem is metabolic or related to oxygenation this points towards a water-electrolyte imbalance, or diabetes – but if this is not the case, a neurologist or toxicologist is consulted. 'Patients often move through the hospital contrary to predictable patterns,' Strategic Investment Manager Josef Hollenhorst pointed out. 'Each time we have a problem that doesn't fit with the POCT profile at the place of treatment we run the risk of not sufficiently detecting and not scrutinising a critical situation, such as methemoglobinaemia or carbon monoxide poisoning.'

A sophisticated strategy

Up to three years ago the MHH had eight different types of devices from three different manufacturers available for bedside blood gas analysis, with fewer than 700 resources. 'We wondered what would happen if we worked with just one supplier and one type of device and worked out that this would bring down the number of resources inclusive of spare parts to well below 100,' he explained. 'Based on this ratio alone, the rate of turnover for equipment with regards to POCT resources would increase by factor seven, and capital commitment would therefore fall drastically.

'We realised that we had to adapt the profiles at a relatively high level and ensure that the same profiles were being measured everywhere.' In 2011, the project was put out to tender across Europe. The requirements were high: around 550,000 samples a year in 34 locations requiring full profiles, with an availability of 99.7% and a back up across all locations.

'Roche, Siemens, Radiometer, IL and Abbott replied to the tender, and all devices were evaluated in all areas in 14-day tests.' Not only the handling was evaluated: 'We measured energy consumption, and,' Joseph Hollenhorst recalled, 'we realised that, across the board, the new generation of devices almost halves energy consumption.'

More LEDs are used in the new devices than halogen bulbs – with operation around the clock over 365 days a year this factor cannot be underestimated. Electricity costs at MHH have doubled over the last seven years. A comprehensive look at decentralised laboratory diagnostics makes you realise that the picture manufacturers like to paint is not quite accurate.

Up to 2008, anaesthetist **Josef Hollenhorst** headed the Anaesthesiology Clinic at MHH and administered a turnover of €25 million in that role. From 2002-2008 he implemented the DRG cost per case calculations of the InEK (Institute for the Hospital Remuneration System) for the anaesthesiology department's running costs.
Since 2008 he has managed the department for strategic investment management at MHH and, since August 2011, has also been head of the investment planning section. Since that year he has also overseen the preparation for the calculation of the investment-related flat rates of the German DRG Institute (InEK).

'One sample, one price – this slogan is just not true,' he stressed. 'POCT, much to the contrary, is an example of complex cost structures, i.e. ranging from acquisition to maintenance contracts, chemicals and liquid quality controls. Paper is often purchased as a generic, a savings option. Process-related, there is a colourful range of cost types and also of creditors.'

The total cost of ownership

Barbara Weichselbaumer has evaluated the life cycle cost of POCT systems based on the current costs at MHH across the periods and used an approach that so far has mainly been known in the business world. The Total Cost of Ownership (TCO) concept captures the total costs of an acquisition across its life cycle. The central idea is that the acquisition price represents only part of the total cost and therefore should not be the only decision criterion for an acquisition (Source: Barbara Weichselbaumer. Total Cost of Ownership – A Feasible Approach in the Hospital? AV Akademikerverlag Saaarbrücken 2012, ISBN 978-3-639-38896-1). 'The acquisition cost represents only 2.6% of the total costs over the life cycle in one type of device examined and in the other type only 0.8%,' she determined. 'The total personnel costs, especially those related to carrying out measurements, represent more than 65% of the total costs for both types.' (See table).

Prior to the tender, the creditor-related costs were almost €4 per examination. Additionally, there were internal costs, the taking of samples and the time it took staff to carry out measurements. The decision was finally made to purchase a system where up to three samples can be simply deposited at the same time before the staff member can immediately return to the patient. The device provides fully automated and homogeneous sample mixing, scanning the barcodes, recognising them automatically, measuring them consecutively and transferring the results to the patient data management system (PDMS) via the laboratory information system (LIS).

Barbara Hollenhorst has checked and projects: 'With each measurement we save almost three minutes of staff time using this equipment. With around 550,000 samples this works out at 1.65 million minutes, i.e. the annual number of working hours for 14-15 nurses!' The MHH strategy is to relieve pressure on nurses wherever at all possible. They are the most valuable resource on each ward and should spend as much time as possible with their patients, so this is to their advantage and represents real added value for the hospital.'

Meanwhile, the European tender has been implemented and MHH has 35 identical devices, in A&E, operating theatres, intensive care wards, cardiac catheter labs. Only the paediatric cardiac catheter lab has a different type of device supplied by the same manufacturer. Shunt measurements to determine cardiac defects, 7-8 measurements in minute cycles, require the shortest possible turnover.

The creditor-related costs per measurement were halved and cut to under €2 – a delivery model with a cheque-price. MHH virtually does not pay for the device, only for the finished result.

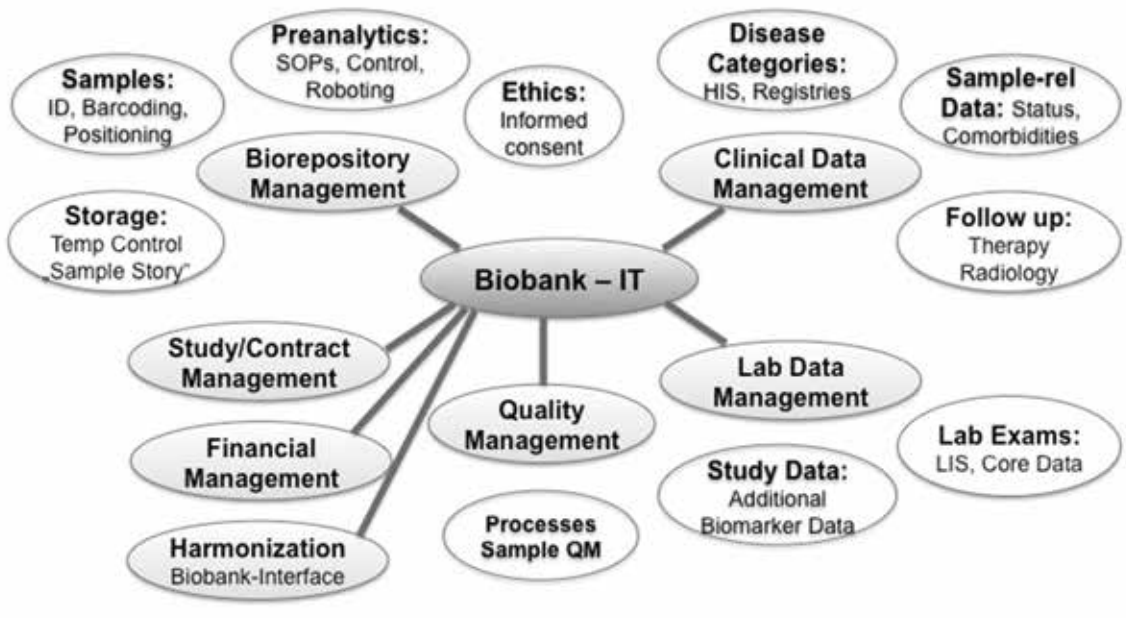
This price almost encourages even more measurements, Josef Hollenhorst declared, significantly happy. 'Being able to achieve a result at less than two euroes a time and to say I need to readjust the ventilation, I've detected an increase in lactates at an early stage and could trace where it came from – the procedural as well as the cost benefit is always for the patient and the hospital.'

Type of cost	Device # A	Device # B
Cost of acquisition	5,800	19,850
Overall staffing costs:	533,910	523,940
a) Carrying out measurements	523,790	523,790
b) Internal quality control	9,970	0
c) Safety-related control	150	150
Materials and equipment (chemicals, test tubes, gases, etc.)	114,520	183,340
Maintenance costs	19,050	22,330
Repair costs	13,330	16,780
Energy costs	1.100	680
Total Cost of Ownership	687.710	766.920

Breakdown of costs (in euros) of the main POCT devices used at MHH prior to the tender – a list of all identifiable, relevant costs that can be directly and indirectly allocated to the devices over a lifespan of ten years

Lab and biobank IT systems need to converse together

Creating the essential link



While clinical labs and lab IT solutions appear to be able to meet current requirements, biobanking presents a whole new world of challenges to data flows and IT systems. Dr Stefan Holdenrieder from the Institute of Clinical Chemistry and Clinical Pharmacology at Bonn University Hospital in Germany, describes major trends, and explains why information technology should help to build the bridge between labs and biobanks

Report: Michael Reiter

IT requirements in the lab include the management of sample identification and workflow, organisation of materials and staff, provision of a systemic computerised order entry function, administration of the hospital point of care (POC) system and data storage. Quality management plays a key role; results must be validated technically and medically, i.e. Were the analytical processes carried out correctly? Do the sample and medical results correlate with the information about the patient? Finally, IT needs to facilitate the creation of a detailed report describing the findings and conclusions regarding the case.

According to Dr Stefan Holdenrieder the available lab IT systems fulfil many of these requirements, while each solution has its strong and weak points. Solutions differ widely with regard to medical plausibility checks and have to be optimised for each laboratory. Convenience in handling the systems also varies greatly; good examples are the creation process of complex reports for, e.g. protein analyses of urine and cerebrospinal fluid.

The particular challenge

He emphasises that total quality management is a particular challenge for lab IT systems since all lab processes need to be defined and documented. SOPs of these processes including equipment and test configurations and internal workflows have to be kept up to date, controlled regularly and stored in data repositories as directed documents. Thus given processes and SOPs related to them can be tracked back to the time they were carried out. Any process modifications and updates should be communicated in a way that allows the staff to comply with new regulations. RiLiBÄK, the lab guidelines of the German Board of Physicians, have added enormous challenges to IT systems, according to the expert but, over recent years, they have made routine lab work a lot easier and more reliable.

Commercially available IT systems, Dr Holdenrieder concludes – in general – do a good job in fulfilling the basic needs in a modern lab. However, it is a considerable challenge for each lab to adapt it to local requirements.

Biobanks are extremely heterogeneous; they range from small operations with a deep freezer to huge robotics-assisted installations, the expert pointed out. The management at his university hospital decided to pull together the numerous isolated activities, and create a central facility where samples from all institutes and clinics across the campus can be stored, administered, and utilised for research purposes. At this time, most of these activities in Bonn and elsewhere are driven and supported by research organisations; the aim ought to be to set up service units where samples can be stored and made available for researchers within or – subsequent to clearance – outside the individual organisation. 'We are now in the process of creating such a service centre,' he said. 'We are orienting ourselves towards successful implementations.' The emerging Bonn biobank holds both biofluid and tissue samples, whereas in other institutions in Germany, pathology departments store tissue separately.

Far beyond sample storage

What makes biobanks different from simple sample storage? Biobanks should fulfil more requirements than to store, identify, and hand out samples – and they depend largely on IT to do that. Their portfolio of tasks includes, e.g. pseudonymisation, disassociating the sample from the real patient name using a unique ID, e.g. 2-D barcoding; the same holds for the sample aliquots.

To link that information to the hospital information system (HIS), or disease registers, adds details about the patient, e.g. his/her tumour status, therapy and outcome, adding significant value for research. Again, quality plays a key role: information about pre-analytics has to be documented – e.g. when the sample was taken and how it was handled. 'Standardisation is the only way this can be achieved,' Dr Holdenrieder believes. 'Time and temperature stamps must be part of the documentation.' Today, samples can only be collected if consent from the patient and an ethics board has been granted; that approval also needs to be stored with a link towards to the sample and its aliquots. While sample documentation is covered well by some commercially available systems, adding clinical information, including comorbidities, medication, response to therapy, as well as adding clinical updates, is a challenge that still needs to be met.

Sample management has to integrate information about contracts with contributors and users, supporting the core aim of a biobank; consent from contributors regarding individual sample requests needs to be recorded in an IT system. To create value for all actors in the research community, study management should include the backflow of study results based on samples used. Handling fees can support the financing of biobanks and the IT supporting their operation.

A valuable link to the lab

'The link to lab IT can open up another source of highly valuable information,' Dr Holdenrieder emphasised. 'Laboratory results provide diagnostic details about the patient that can be pivotal to any research findings.'

Further synergies can be created if biobank and lab processes are integrated. Sample identification, automated sample handling by robotics, quality check and data transfer can be used for both purposes. 'Ideally, lab, clinical and biobank information are merged in a data warehouse that allows efficient data handling and mining,' he added. A close link with clinical study centres would greatly facilitate the performance of clinical studies.

Most universities maintain biobanks, he said. Harmonising approaches across these institutions, across borders, will help advance research on rare diseases, for example. 'In interfacing these actors, IT plays a core role.' Commercial systems that integrate top data security levels and lifecycle management for samples will serve as a basis and adaptation to the givens of the individual institution by a dedicated on site IT team will help create essential solutions for tomorrow's biobanking community. Government-driven subsidies should include support for IT.

Stefan Holdenrieder MD, is a senior physician at the Institute of Clinical Chemistry and Clinical Pharmacology of the University Hospital Bonn. He coordinates the University Biofluid Biobank Bonn that cooperates closely with the University Tissue Biobank and is associated with the Center of Integrated Oncology (CIO) Cologne-Bonn. In his "Biomarkers" research group he develops and evaluates new techniques and biomarkers for their clinical use in diagnosis, prognosis, and therapy monitoring of patients with cancer, (auto) immune, neurological, and inflammatory diseases, as well as trauma.

Snibe is on the road to success in Europe

An international impact on immunoassay

Snibe, the Shenzhen New Industries Biomedical Engineering Company Ltd., is a leading Chinese biomedical technology company dedicated to developing and manufacturing clinical laboratory equipment and in vitro reagents. Founded 18 years ago and a growing force in the Chinese market, the firm is based in Shenzhen, China's fourth largest city, situated in Guangdong Province.

Driven also by subsidies as part of healthcare reform, SNIBE's domestic market includes hospitals in all categories and includes III-A hospitals in Beijing and Shanghai, for example. Currently, 2,500 of the firm's installations are operating in over 80 countries, explained its vice Managing Director Lucy Liu, when at the recent AACC (American Association for Clinical Chemistry) Clinical Lab Expo in Houston, the large annual tradeshow that presents innovative products from all over the world. SNIBE, she explained, is now placing an increasing emphasis on the further internationalisation; AACC and Medica will play a key role in that strategy. In Houston, *Daniela Zimmermann* of *European Hospital* asked Lucy Liu to describe the company and range of products.

Lucy Liu: 'Snibe was established in 1995. During those past 18 years, our company has focused on immunoassays. In 2008, we were the first to successfully develop fully automated chemiluminescent immunoassay machine and reagents. Today we supply a full product portfolio for immunology, biochemistry and electrolyte. This covers all needs of in-house and external clinical laboratories. Our Maglumi range of IVD equipment includes five models of various sizes and throughput requirements for all sizes of hospitals and comes with an integrated system approach.

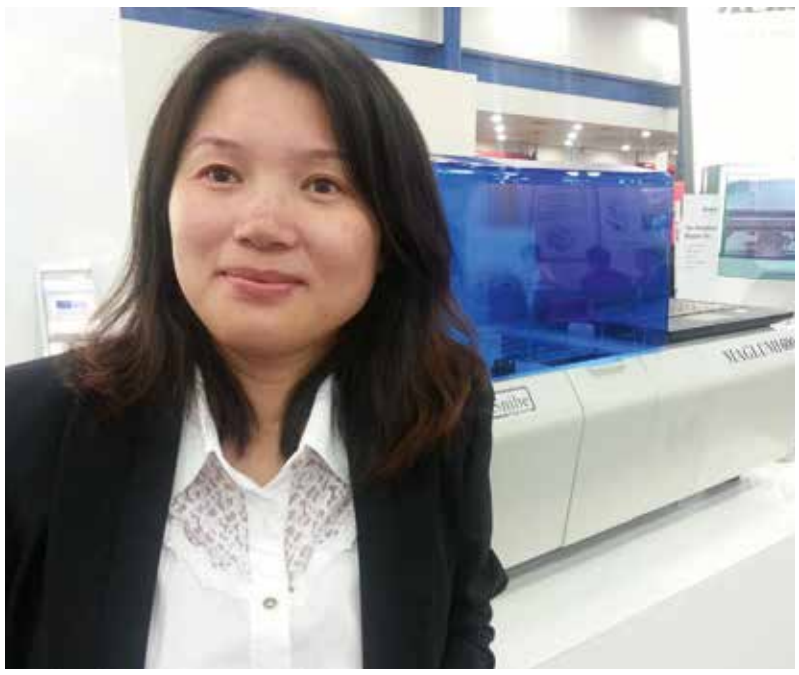
'Our line of reagents covers more than a hundred parameters, most of them were developed based on needs of customers communicated to us – including kidney function, hepatitis, allergen, drug monitoring, infectious diseases, tumour markers and many more. Every year we produce approximately 1,000,000 reagent kits, 1,500 automated immunoassay units and 1,000 automated chemistry units.

'We are the only chemiluminescent immunoassay system manufacturer that produces the family of instruments as well as dedicated reagent kits, with a huge range of parameters. Our complete reagent kits integrate calibrators and internal control. We apply the most advanced nano magnetic microbeads as key separation material for the chemiluminescence system. We use the most advanced synthesised small-molecule organic compound as markers.'

Products offered in Europe

'Our exports focus for Europe is on immunoassay – the Maglumi 600, Maglumi 1000, 2000 and 2000 Plus. We have started, rather recently, and are now in the process of promoting the brand. We work with distributors; we may think of setting up a subsidiary at some later stage. Currently, we export to 18 countries through distributors – for example, DiaSystem Scandinavia AB in Sweden, Medical Systems S.p.A. in Italy, RAL Técnica para el laboratorio,s.a. in Spain, Labteh export-import doo in Serbia.

'At AACC in Houston this year, we presented our Maglumi 600 and 4000. Maglumi 600 is what we call a Super POCT – it lets you perform tests with all roughly 100 parameters on this compact machine. It's perfectly suited, for example, for emergency departments, in small hospitals and small labs.'



Lucy Liu, vice managing director of Snibe, in front of the SUPER POCT Maglumi 600 during the recent AACC in Houston, Texas

R&D team achievements

'The leader of our research team, Dr Rao Wei, is also the Chairman of the Board. Dr Rao is the first researcher worldwide to propose that organic monomers and inorganic nano particles can be compounded at molecular level. On this basis, the expert developed a new composite material – the third-generation nano-composite magnetic beads, a breakthrough innovation. Applying these beads and enzyme immunoassay, as well as small organic molecular labelling technology, Dr Rao developed and industrialised the quantitative immunoassay system that integrates the magnetic separation technique and flash chemiluminescence, filling a gap in the Chinese IVD industry.'

In the pipeline

'Our research and development department is working on further parameters to complement this range; this includes markers such as HE4 for ovary cancer, IA-2 for diabetes, as well as IGF-II, HIV and Syphilis. We collect regional data for example from India and Africa to identify likely development candidates for the needs of individual markets. In addition to our existing research unit in China, which collaborates with the University of Shenzhen, we may install R&D centres in further regions of the world.'

The company mission

'Our overall aim is to improve the life for patients at a global scale– through innovative diagnostic tools and at reasonable cost. We intend to become, within five to ten years, the major international supplier for immunoassay worldwide.'

Snibe milestones

1995 Founded in Shenzhen
1997 Developed enzyme-linked immunoassay system Magimuzyme
2002 Received Shenzhen High-Tech Enterprise award
2005 Developed semi-automated chemiluminescent immunoassay analyser and dedicated reagent kits. Received 'Shenzhen Science and Technology Progress' award
2007 TUV certification ISO 9001, ISO 13485; Received recognition 'National High-Tech Industrialization Demonstration Project'
2008 Developed China's first fully automated chemiluminescence analyser and dedicated kits
2009 Received recognition 'National High-Tech Enterprise'
2010 Launched automated chemiluminescent analyser and dedicated kits
2012 Developed China's first Serum Workstation Area IBE 6000, an integrated system that can load 320 samples at one time.

Chemiluminescent Immunoassay (CLIA)

CLIA uses two techniques: a labelling technology that determines reaction mode and a separation technology that determines the sensitivity, accuracy and precision of the reagents.

MEDICA®

Be part of the No. 1!

20 – 23 Nov 2013
Düsseldorf · Germany

www.medica.de

Basis for Business

Messe Düsseldorf