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.

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

G&G: "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 tradition-
al 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 drains. 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, $57,418 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 Adrúin 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 1,855 in the previous year.

The most frequent specialties were anaesthesiology and general practitioners.

Continued on page 2
DO YOU WISH TO RECEIVE EUROPEAN HOSPITAL AND THE ONLINE NEWSLETTER?

Yes No

Name

Job title

Hospital/Clinic

Address

Town/City

Phone number

E-mail address

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

1. SPECIFY THE TYPE OF INSTITUTION IN WHICH YOU WORK

[ ] General hospital
[ ] University hospital
[ ] Outpatient clinic
[ ] Specialised hospital/centre

[ ] Other institution (e.g. medical school)

2. YOUR JOB

[ ] Administrator of department
[ ] Chief medical director
[ ] Technical director

[ ] Chief of medical department/centre

3. OTHER INFORMATION REQUIREMENTS - PLEASE LIST

[ ] Medical practitioners

[ ] Other department

4. HOW MANY BIDS DOES YOUR HOSPITAL PROVIDE

[ ] Up to 150
[ ] 151-500
[ ] 501-1000
[ ] More than 1000

[ ] None (not a hospital/clinic)

5. WHAT SUBJECTS INTEREST YOU IN YOUR WORK?

[ ] Cardiology
[ ] Imaging/biophysics
[ ] Intensive Care Units
[ ] Management/Equipment
[ ] Ambulance and rescue equipment
[ ] Pharmaceutical/tems
[ ] Speech therapy/speech
[ ] Physiotherapy equipment/surgery
[ ] Laboratory equipment, refrigeration, etc.
[ ] Nutrition and kitchen supplies
[ ] Woods management
[ ] Information technology & digital communications
[ ] Personal/Professional administration
[ ] Material Management
[ ] Political update
[ ] Other information requirements - please list

ESPECIALLY FOR DOCTORS: Please complete the above questions and we would like you to answer the following additional questions before you are eligible to fill in the lines in an appropriate way.

What is your specialty?
In which department or speciality do you work?
Do you hold a faculty position?
Are you in charge of your department’s budget?
How many members does your department have?
Can you provide an opinion on whether there is a shortage of nurses and doctors in Spain currently?
Do you consider that your department is under-staffed?
Can you provide an opinion on whether there is a shortage of nurses and doctors in Spain currently?

Spanish doctors and nurses emigrate for work

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

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

Maxim 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 where there is a shortage of nurses, and many hospitals are struggling 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 lack of contracts that 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 HCIs services – one of the UK’s leading nursing and medical recruitment agencies – once. The 24-year-old nurse was already in London. He has been having ongoing meetings 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 now jobless. Only those of us who went abroad are now working.

The nurse works in several east London hospitals. She does home visits in the west of the city. She works a 12-hour shift three days a week and has the rest of the time to himself. ‘Working arrangements are much more flexible than in Spain. Employers are looking after, and with what I 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 there’s scope for them in the EU for good friends here, it’s like having a new family.’

Reasons & consequences

It isn’t that there are too many medical specialists in Spain. In 2009, the Health Ministry warned that there was a shortage and that the country needed around 5,200 more doctors. By 2025, at the present rate of reduction, there 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.

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

The country’s medical associations disagree, saying that the problem is not so much a lack of trained medical staff, 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 Rodriguez Sendín, president of Medical 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 money, because there are no real career opportunities within the community. 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 fast losing its highly qualified professionals (the cost of training a doctor is around €200,000 euros). The government will never be able to cover this situation need will at least, a decade.

Spanish doctors in Sweden

Espiktuna is an attractive town around 120 kilometres west of the Swedish capital of Stockholm, the HQ of carmaker Volvo, and the home of Amia singer Frida Lyngstad. This is the home to paediatrician Jorge Socto and ophtalmologist Mercedes López, a Spanish couple both aged 35. Last February they started work at Eskiktuna’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 Socto 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 recently in the UK.

• Australia - Anesthetists, gas- troenterologists and neurosurgeons are among the 30 specialists Australia needs. National average salary: US$44,983.

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

Do you consider your department is under-staffed?

Is your department involved with telemedicine in the community?

Is your department linked to an external computer network?

Director of administration

Director of finance

Outpatient clinic

University hospital

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

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France: Immigrant medics steadily increase

The number of medical practitioners in France is 216,000, among which 13% are foreign doctors. Spain, representing almost 10% of the total, according to the Centre National des Médecins. France only receives foreign doctors, which registers doctors in practice.

Generally, the total number of doctors in stable compared with recent years, as shown in the Atlas of medical demographics recently published by the CNOM.

The proportion of foreign practi- tioners has increased significantly in recent years. In 2008 and 2013. By 2018, the CNOM predicts another 54% 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 coun- terparts, these foreign doctors are mostly salaried practitioners (63.5% against 43%). 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 med- ical 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 prac- tioners 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 special- ity and they want to stay in France where they find a better environ- ment 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.’

Of official data do not take into account a significant number of foreign doctors working in hospitals with a status of ‘associate’ and there- fore are not registered by the CNOM, Michel Legmann stresses.

The CNOM is not in a position to identify them clearly, and it’s a little problematic because these practition- ers 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 doc- tors 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 doc- tors with a training outside the EU reach equality with their French counterparts, sometimes even more’, explains an official of SNAPDHUE, 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 dif- ficulties finding positions in French hospitals, because they actually are needed, they enjoy excellent relations with their colleagues and patients, but regulations are the problem. The competence of foreign practitioners and their qualifications are unques- tioned, but it takes a very long time for them to be considered,’ adds Salima Hanifi, of the SNAPDHUE.

In spite of the boom of foreign doctors, France doesn’t have a coher- ent recruitment strategy. A small vil- lage will mesh 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 pol- icy. Additionally, there is no standard for French fluency.

Germany: Promised Land for Spanish medics?

While German medics leave the coun- try in search of better conditions, foreigners fill the gaps. Spain, with its troubled economy, provides a major source. Hubertus Stephan knows about the protective force of his tribe at his firm, Maleso Global, based in Freiburg, Germany, his bilingual firm works extensively with candi- dates 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 profes- sionals in German-speaking hospitals, a task that is more difficult due to a greater extent by applicants and less by the customers who, in the end, pay the bill.

He begins by identifying candi- dates in Spain. After going through an extensive selection process, we work closely with successful candi- dates 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 prescrib- ing medication.

In Spain, other countries, assis- tant nurses carry out ‘lower-level’ tasks, which are on nurses’ work lists in Germany. This human resources disparity of this, may feel relagated. It is part of our selection process to ensure that highly qualified Spanish care professionals are acquainted with these differences, so they are not frustrated when they work 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 con- crete placement available.

Physician difficulties

‘It’s mostly about language compe- tence. The B2 language certificate required by most German states may be sufficient for nurses, but that com- petence may just not meet real life needs for physicians. This is why we declined scouting for psychologists in Spain – even three years of learn- ing German will not be enough for work that relies heavily on the spo- ken word. Radiologists have less of an issue because of reduced contact with patients; reports in German are well understood.’

‘Regarding qualifications, Spanish physicians typically meet require- ments. However, for physicians migrating from Latin America to Spain, where their qualifications are acknowledged, we must find a quali- fication gap. It won’t make sense to go through a lengthy process try- ing 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 educa- tional institutions, and speak directly with healthcare professionals in care provider organisations. We place advertisements and banners in por- 

tals; our Freiburg team carries out interviews; we travel to Spain fre- quently.

‘The feedback is generally very positive – thanks to the fact that we are diligent in selecting our cus- tomers. 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.
Chronic Disease

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 appointment skipping, before joining the workforce, has 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 pregnant with the concept for nearly 20 years, but it has been ignored – but this is changing.

Over the past five years, there’s been a steady increase in its use. An announcement 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 allows them to be more productive. For patients, group visits help reduce long waits to see a doctor and are more interactive. 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, presurgical consultations about joint replacement, pregnancy disorders, and cardiovascular disease. There are a few types of group visit models. Between six and 15 patients with the same medical condition can meet with the doctor. Chart review is performed in advance to determine if laboratory tests are needed or if medical equipment is required. Nurses may briefly see individual patients in advance to record vital signs 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 causes the doctor to spend more time with each patient and 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 a cardiologist who introduced the concept of a group visit with then employer Kaiser Permanente. Noffsinger authored two ‘how-to’ books. The first groups that showed interest were the large, well-endowed medical group Cleveland Clinic, the Sutter Medical Group and recently Carolina’s 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 share gap has widened. By the group, some asking additional questions and others offering advice. The meetings may include a liss discussion of a specific topic, but it is presented in a facilitator role to encourage discussion, not as a lecture.

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 EAME, and Anthony Casciano, CEO of Project, Structured & Leveraged Finance Healthcare.

In September 2012, technology provides Siemens Healthcare signed a contract with University Hospital Southampton NHS Foundation Trust. The deal involved the supply of over 150 pieces of equipment over a 10-year period. As an example of a Managed Equipment Service (MES) contract, the deal is one of 12 such arrangements Siemens Healthcare has with companies and various UK NHS Trusts – with several more still under negotiation. Indeed, the ability 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 planning for upgrade cycles.

Importantly, the contract is regard less of the manufacturer – meaning that Siemens Healthcare’s role is to procure the equipment on behalf of its client, no matter what its provisor. Feedback from NHS Trusts states that the MES arrangements include:

- The certainty that the hospital will receive 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 create a captive equipment-supply model, each jurisdiction will need to adapt them to suit their own requirements.

Siemens Healthcare – structur ing the deal via a ‘sale of receivab le’ facilities between the supplier (Siemens Healthcare) and the 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 efficiency.

For this reason, the role of the in house financier is important. The equipment supplier can develop a captive source of revenue with the project sponsor while not having to worry about counterparty risk. Meanwhile, the financier can benefit from the improvement of internal cash flow.

Of course, such a role is a component of Siemens Healthcare, 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 mean they rely on trusted intermediaries to source and evaluate deals, as well as act as co-investors. This can be via partnerships with financiers or project sponsors.

Sparred by the changes taking place in today’s funding market, Siemens Healthcare is focusing on 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) with innovative financing techniques. Yet the recent studies have shown the banking man 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 allows them to be more productive. For patients, group visits help reduce long waits to see a doctor and are more interactive. Most patients react positively to fellow patient interactions and manage their disease better.

Another win for healthcare equipment finance

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 equipment across the region, including project finance (including PFI/PPP), corporate loans and large-scale structured finance transactions. Prior to joining Siemens Bank, he worked for more than 10 years at HSBC Hongkong, from 2004 as Head of Infrastructure (EMEA), key projects include mandates as financial advisor and lead arranger for the first PPP contract in the United Kingdom (Diaboli Schieneninfrastruktur PPP, 2007) and Norway (E 79 Kort- Kampsbanen Road PPP, 2003). He was also responsible for structured asset finance transactions for logistics clients.
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 ROMED 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 53% 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 more detailed electronic version of this report.

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: Melike Lerner

Well-meaning 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 550 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 IZST in Duisburg (IZST-Institute for Software- and System Technology), which hosts the new 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.

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 testing 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 activation of rooms.

But last not least, technology 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: Mal Pulock

The World Health Organization (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 a report of a lack of information from the worst affected countries.

The 13-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 people it has infected in nine countries.

The first emergency talks on the virus coincided with the start of the 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 treat- ment,’ 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 virology factor, an inter- feron induction antagonist, and is concerned that the virus is spreading and trying to locate its source. ‘We’re working on a few samples from suspected cases in Germany and we’ve conducted a small collaborative study with a lab in Saudi Arabia,’ he added. ‘Much more would have to be done, with more than one pair of collabo- rating labs.’

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 samples from various countries (Oman, the Netherlands, Spain, China), 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 coronaviruses; 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 161 cattle, sheep, and goats from the Netherlands and Spain. However, antibodies specific to MERS-CoV were found in 30 serum samples taken from dromedary camels in the Oman – samples 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 (115 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 24 animals closely related to the dromedary, such as African 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 researchers 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. No new cases of MERS-CoV continue to emerge, without any clues about the sources of infection except for people who have paid very close attention to the virus, so there are different types of contact of humans with these animals that could lead to transmission of the 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 cases centralised to gather information on patients’ contacts with animals and animal products, such as camel milk.

Further details: http://www.thelancet.com/journals/lancet/article/PIIS1473-3099(13)70154-4/fulltext

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), 1,950 exhibitors. Among the 1,930 exhibitors, 225 came from 25 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 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:

As western Japan’s largest manufacturing technology trade fair, and given the umbrella title Manufacturing World Osaka 2013, this event will include the 17th 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 turnover of over 900 exhibitions 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 manufac-turing industry for years. Hence, it is only natural that companies, designers, decision makers and industry professionals from Asian countries as well as from the rest of the region, healthcare and Thailand will have their own pavilions, creating a meeting place to see and discuss Asia’s most advanced technologies.

Details: http://www.osaka.mfj.gr/pinipai/
Two statements from publications by Dr Stephanie Dancer, Department of Microbiology, Hammersmith Hospital and Marc Dettkenkoerper, 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 Dettkenkoerper commented. ‘Who has actually been interested in relevant clinical studies on cleaning and infection control in hospitals? There was a lack of following and financial opportunities such as those available for studies into antibiotics. There was also a lack of randomised and multi-centre 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 a busy hospital staff to wash their hands or by reduc- ing empirical antimicrobial use.’

‘This is an often overlooked importance. In that respect, I find Stephanie Dancer’s statement a little too simple.’

A new organisation is formed to help end serious surgical errors

A taskforce has been set up in England after it emerged that more than 4,400 patients are cut significantly during operations; 214 cases of foreign objects left inside patients during operations; 75 cases of tubes, for feeding patients or for medication, being inserted into patients’ lungs; and 58 cases of wrong implants or prosthesis 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 infections in hospitals, the 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’s 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 team to raise any concerns and is central to preventing avoidable mistakes.’

Dr Mike Durkin, director of patient safety for NHS for England, has ordered 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: ‘Many of the never events occurring in English hospitals was too many, adding: ‘We need to address what is, in some systems and in some hospitals, that team working hasn’t produced the expected results and a ‘never event’ has occurred. This is not just the concern of one operating theatre in one hospital. It’s not simply a case of looking 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 122 cases of foreign objects left inside patients during operations; 214 cases of surgery on the wrong bodily part; 75 cases of tubes, 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 contact are – and here there are repeated, large shortfalls in the daily cleaning process.

That’s despite the fact that Germany is the second-class country in our MRSA ranking?

‘Only part of the explanation: the somewhat modest perfor- mance also can be put down to mod- ern medical routines. One advantage we have here in many cases is that, in some cases and in some hospitals, that team working hasn’t produced the expected results and a ‘never event’ has occurred. This is not just the concern of one operating theatre in one hospital. It’s not simply a case of looking 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.’

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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 surgical wards and operations. Use of a video camera mounted on the laparoscope greatly facilitated minimally invasive methods in the 1980s: manipulating the scope was by a 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. This was 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 about the insufflation process,’ 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 intraoperative cooling, he explained. In open surgery, warm and moist pads are used to pack away the tissue and thus 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 described. ‘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.

Wet and warm laparoscopy produces better results

Warming and humidifying insufflation gases helps to avoid the problems caused by ‘cold and dry’ insufflation. ‘Physicians should never forget the lessons they have learned about the insufflation process,’ 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, despite this fact, some specialists push the NOTES, or single port procedure respectively, to attract a certain type of clientele. In principle, the new procedures definitively have advantages for certain interventions, but at the moment they are not dominant enough to cover the entire minimally invasive range of surgery. But developments continue 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, tele- metrically controlled 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 advancements in 5-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, traditional minimally invasive procedures are presently superior. However, despite this fact, some specialists 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 developments continue and the emergence of further advances will soon also result in patient and cost-relevant improvements.’

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 Heiss Technology, EAES video and European Cup), our correspond- ents recorded: ‘We surgeons are essentially the devices who need to find new markets? Who is driving these developments – surgeons who would like their work to be more patient-friendly and precise, or increasingly beauty-conscious patients? It 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 ‘old foxes’ are proud about the additional benefits of clearly improved images.’

‘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 diag- nosis are also very important. Collaboration with radiology depart- ments is very cooperative and inter- disciplinary cooperation serves very efficiently and equally well as the wellbeing of patients.’

Professor Jürgen Kleinstein, Head of the Section for Surgical Research at Medical University, Graz, Austria

Surely it won’t be possible to reduce the size that much more – so is this as good as it gets? ‘Not at all – the tendency is towards a single port, i.e. an interven- tion via just one access point or the utilisation of natural body orifices respectively, which is what surgeons refer to as NOTES – natu- ral oriﬁce transluminal endoscopic surgery. For certain types of opera- tions, such as in gall bladder surger- y for instance, these methods are already being used, but it is mainly the hybrid procedures, such as conven- tional laparoscopy together with NOTES, which are being performed. 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 men- tioned for some surgical interven- tions, we still have 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 instru- ments that – after being guided into the operating area, can be made rigid again towards the front – must be advanced. Certain problems areas, such as the danger of infec- tion, lumens enlargements or lighting control, which is also being trialled independently through magnetic movement, must also be considered. ‘The biggest stumbling block appears to be the fact that, in direct comparison between needle- laparoscopy and NOTES-based pro- cedures, no real quantifiable ben- eﬁt for the patient can currently be shown. No signiﬁcant improvements can currently be seen, neither in pain reduction, nor cosmetic advan- tages, nor shorter hospital stays. The single port procedure with an incision of only 2mm in size near the navel is also confronted with this funding’

How does a cost comparison look? ‘When it comes to cost efﬁciency, the improved 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 ‘old foxes’ are proud about the additional benefits of clearly improved images.’

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Say what you attribute this? ‘There are a number of factors that are, in parts, mutually dependent. The development of flexible instru- ments that – after being guided into the operating area, can be made rigid again towards the front – must be advanced. Certain problems areas, such as the danger of infec- tion, lumens enlargements or lighting control, which is also being trialled independently through magnetic movement, must also be considered. ‘The biggest stumbling block appears to be the fact that, in direct comparison between needle- laparoscopy and NOTES-based pro- cedures, no real quantifiable ben- eﬁt for the patient can currently be shown. No signiﬁcant improvements can currently be seen, neither in pain reduction, nor cosmetic advan- tages, nor shorter hospital stays. The single port procedure with an incision of only 2mm in size near the navel is also confronted with this funding’

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Ikegami’s Full HD video system

Ikegami as introduced a new full HD video system for medical applications, which consists of the MKG-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 MKG-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 MKG-21HHD camera will also stream video over IP (H.264 compression), the company adds, so it can be used for any kind of teleremedicine application or for simple recording to PC.

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

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

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.

AECM reports that it is multifunctional, versatile, and ideal for dermatology, 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 6.000 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 9. Additionally, using the innovative 1-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

Surgical infection risks

Combating surgical infection risks

Shock: 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 Broksy 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 in May, Scerendeo believes you cannot prevent what you cannot measure. Head of Hygiene Services at the University Hospital Centre Besançon, France, Prof. Talon developed the first device to measure pathogens circulating in the operating room during a surgery. Presented at the MEDITEC France exhibition in May, Scerendeo 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 theatre is opened.

The ScreenAir device pulls the ambient air through a filter,pro-
Tumour boards

About 20 years ago the first tumour boards were set up in Germany. Initially 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 Klinikum rechts der Isar 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 treatment had clearly become more complex and individual steps of therapy had to be 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 remaining a difficult problem to solve.

In Germany, the impetus 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 dependant on the ability and decision of the doctor in charge. It mostly consisted of surgical removal of the tumour and chemotherapy, followed by 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 therapies 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 be carried out there and then – notwithstanding if the respective hospital has achieved certification or not.

**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 makes it 'very difficult to solve.'

'At times, no more than 15 percent of the specialists involved in the work of tumour boards, particularly in the USA, and in German university hospitals, smaller radiology departments cannot train a specialist for each tumour conference,' he said. 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 radiologists are already 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.'

For occasional contract staff just for the tumour conferences is no solution, he believes, on the one hand because these doctors 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 doctors. While it does not help to have a few more doctors with comprehensive, general radiological knowledge, he believes that 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.'
Turbulence in ultrasound

Ultrasound expands its role in cardiac imaging with disruptive applications. Fasten your seat belt. Cardiac diagnostics is entering a zone of stunning three-dimensional images. 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.

Opening a window on the heart

Continued on page 12

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.

Jose Luis Zamorano Gomez MD is the Head of Cardiology at the University Hospital Ramon 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 Cardiowascular Imaging.
TAVI will surpass heart surgery for aortic valve replacement

Interview: John Brosky

Each year the case grows stronger for transcateter aortic valve replace-
ment (TAVI). And it is only six years since the procedure was intro-
duced in Europe.

The strongest clinical evidence, we believe, is that TAVI uses a device, based on the first-generation of valves and delivery systems. It is also based on a population that was deliberately restricted to the very sickest of patients with an average age of 84 years and suffering from co-morbidities that meant they were unable to undergo traditional surgic-
al aortic valve replacement (AVR).

Today, a new and improved gen-
eration of valves and delivery sys-
tems is in the pipeline. There is greater experience among inter-
ventional cardiologists, as well as improved outcomes for patients. Increasingly in Europe the proce-
dure is being performed on ‘inter-
mediate risk patients,’ those who suffer from a failing heart valve but who are typically younger and bet-

ter able to withstand the rigours of traditional surgery.

How far are we from a turn-
ing point where TAVI will be preferred to surgery?

The question is provocative because TAVI remains con-
zesting. The procedure involves bringing a prosthesis to the heart via the femoral or other artery. TAVI remains con-

sidered a fairly new concept. Traditionally, surgeons have made up their own mind about what kind of surgery they will do. Interventional cardiologists are used to doing the same thing with coronary revascu-
arisation.

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 dis-
cussion about the best choices.

In the United States this approach has become more and more common because the regulatory requirement is that both interventional cardio-
ologists and surgeons must participate in all procedures. It seems to be overdone and may be driven by factors other than the proce-
dure. The main principle to a heart team is that the patient is evalu-
ated 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 neces-
sarily mean they all need to be in the room doing the chosen procedure.

An open question, espe-
cially 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 surgic-

al 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 beyond five years and failure of these valves is quite rare at that point. We can assume that they will fall eventually, as do surgical valves.

Concern was expressed in Europe about patients in their 70s rece-
ing valves for which the durabil-
ity 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 replace-
ment is a fairly repeatable proce-
dure 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, 2015) was the new information on valve-in-valve implants where transcatheter valves are placed inside failed surgical valves. It seemed that in many peo-
ple’s minds this is moving rapidly to a standard of care. All valves, surgical and TAVI, will wear out because the heart is a living organ and surgery is always a higher risk than first-
time surgery. Many of these pa-
ients, of course, are older patients.

There are lots of 70-year-old people who received a surgical valve and, as their valve ages, 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 pro-
file 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 incorporat-
ed into the catheter, or in the valve itself, so they tend to be deployed at the correct height and the cor-
rect angle in the aortic annulus. So positioning is improving. They tend to have features that reduce paraval-
var leak with the better sealing.

In addition to improvements in the valves, there are dramatic improve-
ments in techniques used. Early on, people had a limited idea of where to put the valve and now there are different ways. There was also a time when 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 aortic annulus, which is important in imaging with 3-D CT and 3-D TEE.

All the new valves need to be proc-
ed in clinical trials, and these can be performed in low-volume centres.

In Europe there has been a more ag-
gressive approach, or they have other things to do. In Europe the procedure was introduced five years before in the United States.

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 recommenda-
tion in ESC guidelines, the invasive nature of the procedure to assess ischaemia has slowed its adoption.

Dr Zamaro reserved his greatest enthusiasm for advanced techniques in ultrasound for the newest arrival in the university hospital, the EchoNavigator from Philips Healthcare. ‘I just came from per-
forming 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 ultrasound, the Tenia procedure, the interventional echo on the fluoroscopy, I can see the valve opening and closing…’

To test with X-ray we can’t see the valve; we can only see cal-
Cmation.

Now I can mark exactly where the valve needs to be positioned. Using fluoroscopy I can guide the cath-
ers to that precise position.’
Cardiac disease death rates fall in the EU

Mortality more than halves in many European countries

Report: Mark Nichols

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 sub-populations,’ 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.

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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. 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.

Clinical point of view: Rising tension in hypertension therapy

We live in an era over 60-year-olds suffering arterial hypertension, this is among the commonest chronic diseases. Drug treatment results in only 17% of those patients achieving their target levels. However, about the same percentage of patients conventional treatment falls short of 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 a lot of hype, which is not but necessarily 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 arterial intravascularly in several places for a heating up the renal arteries intra. The entire procedure, as it were, is performed under fluoroscopic guidance.

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, efficacy and safety of RDN (Source: EuroIntervention. 2013 May 22-24; hypoth: R56-66).

Symplicity HTN-1 and HTN-2

The feasibility of the procedure was demonstrated by three Austrian 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 for Cardiovascular Research and Education in Melbourne, Australia.

Forty-five patients taking an average of 4.7 antihypertensives, 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: 1277-81). During an extended follow-up observation after a 24-month period BP also did not rise again – reason enough for the authors to believe that since the nerves 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 among 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: 903-9).

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 serves as a promising option, RDN is an interesting therapy approach. However the patients selected for the procedure are not always fulfilling certain conditions, as described in the guidelines recently published by the European Society of Hypertension.’ According to these guidelines, RDN 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: Slowly towards hyper-resistant doctors

As fast as the first device for renal denervation received a CE mark in 2010, the pioneering company Ardian – which has been snapped up by medical technology giant Medtronic – with great fanfare the procedure was launched in the following year at EuroPCR, the largest gathering of interventional cardiologists in the world.

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. By the end of the condition can resist this drug-based therapy.

The potential for treating such a large population was neither lost on cardiologists nor on 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 ablating 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. As renal denervation lead investigator for Renal Denervation Global Market Development for Medtronic, he shared insights into the company’s efforts to push adoption of renal denervation. He commented: ‘There are people who know what a $1 billion dollar market; that if they push a magic button patients will suddenly come raining from the sky. The biggest challenge is not the technology, not the shady story, 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 successful business. 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 US 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 need to help build expertise in this new field to win the confidence of referring physicians.

Renal denervation centres capable of appropriately screening patients are rare around the world. ‘Hospitals, even with reimburse- ment, will continue to operate with very tight budgets. Practitioners will decide if they want to open a service line for renal denervation. Successful adoption will be driven by country, by local guidelines,’ St Jude is a fast-forwards for both device development and renal denervation. More than 5,000 patients will be studied in a non-inferiority trial to establish safety and efficacy. The senior director for clinical development with a multidisciplinary physician advisory board as part of the company’s implantation 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 renal denervation that could culminate in EnViiHTNent. This landmark work is expected to inform how denervation studies 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 competitors roll out new devices.

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

All the firms will need to conduct clinical studies, but the early small efforts focused only on proving that their new device is safe and effective. Proving evidence of effectiveness the new players will need only point to the evidence for the existing competing devices 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.
Heart failure

Remote monitoring in Lorraine reduces hospital re-admissions

Report: Brigitte Dinkloh

About 500,000 people in France people suffer heart failure (HF): 20% of these patients die within a year. Poor follow-up, he stresses, is to blame for this dire situation.

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 physicians. The programme results are very encouraging: the implementation of the ICALOR programme was associated with a reduction in HF 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 annu-
al hospital cost saved by ICALOR was €1,927,648 in 2010. 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 physi-
cian 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 prin-
ciple as blood sugar monitoring in diabetics. It’s a response to the prob-
lem of frequent re-hospitalisation of cardiac insufficiency patients.’

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

Next year, a clinical study with several hundred patients through-
out 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 car-
rried out by a consortium headed by Cardiorenal Diagnostics, a company founded by Professors Rossignol and Zannad with Gerard Houis.

Patrick Rossignol points out, many diabetics. It’s a response to the prob-
lem of frequent re-hospitalisation of cardiac insufficiency patients.’

The professor is particularly con-
cerned 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.

In case of need, the patient 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 prin-
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ed to become available later this year. Application will then be made for the CE mark.
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. 19) 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.

Dr Bartlett went for a unique study design: ‘Play the winner’. 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 patient receives the ECMO treatment decreases to 1:2. The result was convincing: the first patient received ECMO and survived, and the second patient received conventional treatment and died. The third patient now has a 5:1 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].

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.’

Following his medical studies and the completion of his doctoral degree at the University Tübingen, Germany, Dr Thomas Schäuble received specialist training at the Paediatric University Hospital Ulm. In 1998 he joined the Intensive Care Unit of the Paediatric Clinic of the University Mannheim.

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 cardiology devices and leads since 2010, enabling patients with a cardiac implant to safely undergo MRI scans. Indeed, it is the world’s only company which allows ICD, ICD + and heart failure patients access to those scans.

In 2013, 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.’
Cardiology drives innovation

A leading Austrian professor commends scanner advances

Report: Michael Krassnitzer

‘Cardiology is one of the most innovative medical disciplines. Many modern techniques, such as catheterizations 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 2D 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 contractility. 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.

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Cardiac magnetic resonance imaging

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 Guthberlet. The professor studied medicine at Marburg University since 2007. His research and teaching priorities are Doppler ultrasound, and cardiac CT and MRI, above all in coronary heart disease (CHD).

One novel imaging procedure, Prof. Guthberlet says, has already been implemented. More likely, hybrid imaging procedures, such as MR/PE 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 do 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 are very excited about the image guidance 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. Guthberlet 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 RoKo HEUTE 2013’, the official publication of the German Radiology Congress

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 CV42 using WIP sequences by Philips and Siemens).


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 Imaging) and (b) systemic diseases with the virtual implant, 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 a rhythmogenic 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) GRE sequence to visualise scar with LGE and RV probe (arrow) shows only few artefacts compared to the CINE-SSFP sequence (b).

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.

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 CT or PET imaging protocol has yet been established. The diagnostic potential of 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.
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.

**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 (problematic 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

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.
Counterpulsation: The C-Pulse

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 5/2011 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 is 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 before the next heartbeat the balloon is deflated, reducing pressure and helping the heart to eject blood.

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 before the next heartbeat the balloon is deflated, reducing pressure and helping the heart to eject blood.

The procedure had already received a class I 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 IIa.

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 (59.7%) in the IABP group had died and, in the control group, 123 patients (41.3%) had died. The use of intra-aortic balloon counterpulsation 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 Engl 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 501 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 Divyaka Perera, cardiologist at St Thomas’ Hospital, London, explained: Eleft IABP use during PCI was associated with a 34% relative reduction in all-cause mortality compared with unsupported PCI isometric 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 qualified as cardiac surgeon 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 Shanmuganathan 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.

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Counterpulsation: The condemned live longer

Extra-aortic counterpulsation after the intervention.

namically without some restrictions.

ment has been unsuccessful do not access, i.e. the sternotomy.’

outside, most often at just the point be attached to the heart from the

Prof. Krabatsch pointed out, add-

machine and takes less time than the implantation of a classic blood pump whilst still being technologi-

ically complex. The aorta has to be completely exposed so that it can be correctly covered by the cuff, Prof. Krabatsch pointed out, add-

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 treat-

These VADs are usually only implanted when patients are in a state of terminal heart failure, as bridge-to-transplant devices or des-

ination therapy. But the C-Pulse has a different approach. The implan-

tation at an early stage either at least delays or possibly completely removes the need for the implan-

tation 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 indi-
cation for an IVAD within the thera-
petic range. It’s important that car-
diologists 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 ver-
sion. As the system does not require an implantable buffer battery, this technological advance will be pos-
sible 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, hospi-
tals in Milan, Padua and Turin.

In 1839 Richard Thomas was the first to describe the effect of external counterpulsation to flow: he identified a fundamental relationship between blood flow and arterial caliber. This impor-
tant physiological mechanism cur-
rently has a renaissance in vas-
cular medicine: Enhancing arterial flow and flow velocities rather than pressure is an important activat-
ing 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 inflat-
ed 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 blood 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. These VADs are usually only

The VADs are now marketed in several high impact papers in the field of therapeutic arteriogenesis. With a grant from the Volkswagen Foundation’s excellence programme (2000 – 2006) Dr Buschmann continued his research at the Albert Ludwig 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 bundling member of EVM – the European Foundation for Vascular Medicine.

Tailored treatment

The extent of volume shift from the legs towards the heart is not real-
ly 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 pres-
sures, can be harmful. However, it is not the compression ratio in the cuffs that is decisive, but the veloc-
ity impulse which results from the infusion 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 graphi-
cally on a novel vascular ultra-
sound ‘tachometer’ to measure blood flow, volume and pulse rate being developed in connection with the Herzohse® (literally translation heart pants – describes the cuffs)

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 system) which serves as a basis of calculation for the correct setting of this personalised shear rate therapy. Each treatment is individually adapt-
ed 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 individ-
ual 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 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 dif-
fuse 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 diabet-

ics. Several clinical trials are cur-
rently 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 effect every other male over the age of 40 and which can frequently be a precursor of sys-
temic vascular disease.
Cardiology & therapy:

Healing hearts: 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 Broosky reports.

Not every patient needs to be cut open. Patients who have bypassed clotted coronary arteries. Some 30 years ago we learned arteries could be regrown using 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 treating coronary arteries. Dozens of these new stents are being pushed through the most prestigious companies specialising in cardiovascular technology.

Maryann’s, at this year,欧洲最大的gathering of interventional cardiologists, the combination of solid evidence from the clinic and new patented stent designs from competing companies reached what is called an inflection point, a moment when airflow is steady.

“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 European Heart Journal, Dr. Christian Homsy, welcomed the first new cardiac progenitor cells to the final step in an intensive clinical study which is the ideal combination biology and medicine.

Everything is knowing the outcome and treating patients and the expertise the market potential of his element when it comes to questions about the new procedure, Christian Homsy explained. He’s 120% dedicated to treating patients and the expertise he brings is knowledge needed for patients and how to test with patients.

How-Is patients in Life Sciences businesses, which are very much focused on market potential, also cancer was a completely different case. ‘Heart disease is a completely different case. ‘Heart treatment is a major challenge for all patients who have undergone ion therapy have a treatment room with a proton therapy cancer service.

The MedAustron, based in Villach in Austria, is the sole facility of its kind in Europe.

Fewer side effects are seen with proton therapy, with the reduced accelerator, Yves Jongen, IBA’s founder, explained. ‘We have experienced delays.’

The MedAustron is the right decision that we didn’t have to choose.

So far only 10% of patients who have undergone ion therapy have a treatment room with a proton therapy cancer service.

The name of the product, C-CURE derives from the full description of Cardiostem Cell therapy in heart failure and, despite its hopeful sound, Homsy cautioned that the therapy is not a cure: Cure means you become healthy again, that your heart has been reconstructed in its entirety. ‘It is the heart that has been engineered and, in terms of heart function, the heart’s ability to pump blood, measured as the left ventricular fractional shortening, improved by 25%.

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’. He highlighted the results 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 stents are a safe and sustainable treatment to the established standard of care, which remains new generation drug-eluting stents.

Doctors Naber and Haude both agreed with a conclusion during the Great Debate. ‘Remodelling of the vessel is not a given’, Abbott Vascular the most advanced, but followed by major competitors Medtronic and Boston. ‘But the small companies introducing more novel devices include Kyoto Medical Planning (Japan), Biotronik (Germany), Elixir Medical (USA), Reva Medical (USA), Arterial Remodelling Technologies (USA), OsbruNeich (Hong Kong), Huan Biotechnology Group (Larwil, Switzerland), and Precision for Medicine/MultiCell Technologies (USA).

Bioresorbable scaffolds are being developed by all major players. ‘The current 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.

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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 and the 57th Deutscher Ultraschallexpertentag or Three-Country Meeting, together representing over 50,000 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 PRIMUM study at the congress, demonstrating how putting ultrasound expertise on the frontline in emergency means faster, better care for patients plus hospital cost savings.

Education in practice

Yet interactive learning sessions will remain a focus of activities over the four days of the congress, according to Andreas Schuler MD, who leads the organisation of the scientific programme by 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, refreshers courses, or categorical courses,’ he said.

The Ultrasound Learning Centre will offer practitioners an opportunity to learn through 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 as 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 is applied across medical specialisations for contrast-enhanced ultrasound, for example, 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 300 scientific abstracts as well as state of the art lectures and refreshers courses, will enrich their conference experience and exposure to developments across Europe.

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 neurological practice 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.

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Andreas Schuler MD is head of hospital and head of the Internal Medicine Department at University Hospital Klinikum rechts der Isar (UKI) in Munich, Germany. After his studies at university Witten-Herdecke andBehaviour-Tests, he obtained internal medicine (1995) for gynaecology and obstetrics, and the certificate for ultrasound (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.

At the joint congress in Stuttgart, Schuler Dr Schuler could not disclose specific findings, 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 PRIMUM 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 systemic sclerosis, lung diseases, and obstetrics.

The 33rd German Society for Senology Congress

The annual meeting of the German Society for Senology, focused on interdisciplinary discussions on up-to-date breast cancer diagnostics and therapy, was held in Stuttgart. President Professor Axel-Marie Feller urged acceptance that, the omnipresent 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.
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 Dehreiner 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 at 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.’

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 Schueler 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. Biometicians 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.

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 that ultrasound diagnostics should be the domain of the specialist 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.

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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 Ganser 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 diagnosis. 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 Araki/Albrecht et al. (Journal of Medical Ultrasound, Volume 38, Number 4, October 2011, pp. 203-208)

The 33rd German Society for Senology Congress

The 33rd German Society for Senology Congress
Finally surgeons can look beneath the surface

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 pointed out. ‘Embracement of ultrasound guidance will be the standard method, easily accessible ultrasound guidance as part of numerical ultrasound advances

Imaging the mechanical properties of tissue, with applications particularly in oncology and prostate cancer.

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 oncology and prostate cancer.

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.’

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.’

‘Embracement of ultrasound guidance by surgeons using robots is therefore a difficult issue.’

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.’

‘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

Report: Michael Reiter

Left: The endorectal ultrasound transducer is registered to the robot and programmed to track the da Vinci tool during surgery.

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.

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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

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 has 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 minimize 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 SPC 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 day or so one can run the tests. We have made this advanced technology easy to use so that trained clinical lab technicians can run the instrument.'
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 quantify both 25-OH-Vitamin D2 and 25-OH-Vitamin D3 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 32000MD CE-IVD series of MS systems, including the API 3200MD and 32000MD 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.’

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.
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.

Increased efficiency of laboratory workflow is key to decision making and patient planning, CEO Dave Hickey underlines: ‘Labs are constantly asked to reduce operating budgets and managing 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, urinometrics, and all the way to point-of-care. Our automation solutions provide the pivotal basis for meeting these challenges.’

‘At the AACC we’ve introduced the new APTIO Autoanalyzer. This is the product of the VersaCell family to be released 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 3-hydroxybutyrate (78%), 3-HB is the most prevalent of these ketones and during an incidence of ketoacidosis, it may rise to an 8:1 ratio of 3-HB to acetoacetate. This makes 3-HB the most specific and earliest indicator of ketoacidosis, as well as the best predictor of its resolution due to maximised treatment effectiveness.

Type I diabetic patients are the most at-risk group of developing ketoacidosis, this is why rapid diagnosis of diabetic ketoacidosis (DKA) is essential because delay in starting insulin treatment is problematic because they only react to 3-HB production, but not to acetone and acetoacetate (just 22% of 3-Ketone), 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 endocrine hospitals test for DKA with 3-HB LiquiColor® * (Top 25 diabetic and endocrinology hospitals as ranked according to US News and World Report, 2011)] have now implemented 3-HB testing, making it a new standard for ketone testing. While nitroprusside methods are still often used, the transition to better testing using 3-HB is underway, as indicated by a recent College of Pathology in Diabet Med 1996,14:482-486). Since 3-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 EKF Diagnostics new STAT-Site M 3-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 3-Keto), are not quantitative and indicate result lagging when using urine samples. Whereas dry reagent testing using a test strip, such as STAT-Site M 3-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 3-HB meter’s strip technology enables quick and easy delivery of a quantitative measurement of 3-HB from just 10 µL of serum or plasma in under 60 seconds. This means that the presence of a single 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 improving costs and in an intensive care unit setting for example [M. Yamelle, G. Chiari, G. Cipriano, R. Issac, A. Bernardini, T. Giacchino. The direct measurement of 3-beta-hydroxybutyrate 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 accident jab from a needle from an infected patient has a 30% probability of infection in the case of 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 level of 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.

A 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 mecha- nism when removed from the vein.

Developing a new standard of care in Ketone testing

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.

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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 belt 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.
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 Hannover Medical School (MHH) about the financial and clinical benefits of decentralised laboratory measurement devices.

Supramaximal medicine often means that not just one or two specific parameters are required quickly but an entire profile – blood gases, metabolites and osmolarity, inclusive of CO-oximetry, electrolytes, glucose and lactates. For example, for comatose patients admitted to A&E, a neurologist is consulted. ‘Patients is not the case, a neurologist or toxicologist is consulted. ‘Patients often move through the hospital county 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 methemoglobinemia 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 to provide 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 running costs of the resource inclusive of spare parts to well below 100,’ he explained. ‘Based on this ratio alone, the rate of discovery for equipment not 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 the result at less than two euros a time.

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

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 fulfill 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 used 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.’

Far beyond sample storage
What makes biobanks different from simple sample storage? Biobanks should fulfil more requirements than to store, identify, and band out samples – and they depend largely on IT to do that. Their portfolios 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-analyses 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 IT systems, adding clinical information, including co-morbidities, medication, response to therapy, as well as 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 stored in the IT system. To create value for all actors in the research community, study management should include the backend processes 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 given 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.

Report: Michael Reiter
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.

‘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 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 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.’

**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 organon 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 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 hIE4 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 example from India and Africa to identify development candidates, 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.

**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, RAI 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 6000. 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.’

**Power of Maglumi**

No.1 supplier of CLIA system in China
Over 18 years focus on CLIA system only
Exported to over 80 countries & regions
Over 2500 units installation base within first 3 years

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

**Lucy Liu, vice managing director of Snibe**

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.’
Be part of the No. 1!

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