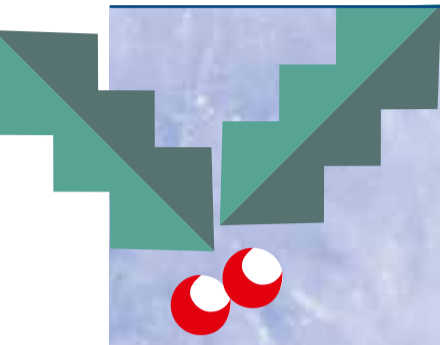


# EUROPEAN HOSPITAL

THE EUROPEAN FORUM FOR THOSE IN THE BUSINESS OF MAKING HEALTHCARE WORK



Season's Greetings  
to all our readers and a great... 2011



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DECEMBER 2010 / JANUARY 2011

**The 1st Global E-Health Forum**  
Focus: Best (e-)practices to sustain healthcare



250 delegates from some 30 countries arrived in Hamburg this November to discuss e-health and share knowledge from their own countries at the first *Global E-Health Forum*.

'We are all aware that we are now facing the probably most severe challenge for humankind: To ensure sustainable healthcare delivery. We have no other choice but to work together since diseases/pandemics do not stop at borders. Globalisation also means globalisation of health services,' said Ljubisav Matejevic, Founder and Director of the Global E-Health Forum. 'We need to develop the concepts for our future healthcare delivery now. Get involved in developing the right strategies, the best solutions and the services needed!'

Ljubisav Matejevic (left) with Dr Dierk Heimann



The experts also included, for example, Prof. Byung-Chul Chang MD PhD, Director of Severance Cardiovascular Hospital in Seoul, Korea, who had travelled to the forum to discuss the future of hospital IT systems.

Harry Reynolds, Chair of the Council for Affordable Quality Healthcare (CAQH) CORE Initiative, presented the characteristics, chances and risks of the USA's Health Reform, from which he believes Europe could benefit from the lessons to be learned.

Samo Fakin, General Director of the Health Insurance Institute of Slovenia, explained how that area has implemented the electronic health insurance card, stressing the advantages and high-level of acceptance.

On the second day, hosted by Asklepios, delegates saw presentations, joined workshops and went on guided tours to obtain insights into modern hospital management.

*The next Global E-Health Forum: 11-13 October 2011*

[www.global-ehealth-forum.com](http://www.global-ehealth-forum.com)

## Transcatheter aortic valve implants bear risks

Despite the lack of clinical evidence, surgeons have boldly charged into the younger population to routinely perform expensive and high-risk cardiac surgeries, *John Brosky* reports

Every year thousands of patients with less than one year to live are denied a heart valve replacement because they are too frail to undergo surgery. These patients tend to be over 75 years of age and suffering from multiple health problems, such as respiratory anaesthesia, end-stage failure of liver or kidneys, or a history of coronary surgery.

Two years ago they were offered a miracle and a chance to live another seven years.

Using minimally invasive techniques, the transcatheter aortic valve implants (TAVI) procedure enables a surgeon to place a new heart valve without cutting open a patient's chest. However, the operation is not without risks, with a higher mortality rate than traditional surgery.

Yet the procedure was approved for use to offer those patients a second chance to live. That decision also created an opportunity for heart surgeons and heart valve manufacturers the chance to accumulate clinical evidence to prove safety and efficacy.

The argument became that if they could make their case by performing the surgery on the sickest of patients, then TAVI would have powerful proof that it is a safe alternative to replace traditional heart surgery with younger, stronger patients who also have a valve insufficiency. Instead of a few thousand patients annually, TAVI could then compete for the tens of thousands of heart valve procedures performed each year across Europe.

It turns out surgeons did not

wait for the clinical evidence before boldly charging into the younger population. A registry compiled among 22 German heart centres in 2009, the first full year of TAVI practice, shows that, despite the dangers, a staggering 60% of the procedures were performed on patients considered at low risk. For these patients the dangers turn out to be a higher mortality rate and a strong chance of wearing a pacemaker.

Where mortality for open surgery to replace valves is around 2.3%, the German registry for 697 patients undergoing TAVI reported 12.4% mortality at 30 days.

The real world cost of the procedure and unproven devices are also an unknown at this experimental stage.

German health insurance funds

*continued on page 2*

## Vivid, vital, visionary

According to Medica organisers, November's medical diary highlight was again a success: around 137,200 visitors from 100 countries entered the massive and many halls of Messe Düsseldorf to scour the world's largest medical fair.

From the world of politics came German Chancellor Angela Merkel, German and Healthcare Minister Philipp Rösler, as well as the Right Honorable The Lord Darzi of Denham, renowned surgeon and former Health Minister of the United Kingdom.

Chancellor Merkel, who toured the exhibition with Philipp Rösler, subsequently remarked in her speech: 'Medica is an impressive shop window on the health industry. However, our leading role in the medical business is not known everywhere. For this reason it is important for this sector to feature centre stage.'

Certainly there was a wealth of innovation for the entire in- and out-patient 'workflow' spectrum, presented by 4,400 exhibitors from 64 nations.

'Process optimisation' were common buzzwords heard in the halls. Innovations from numerous suppliers focused on increased efficiency and flexibility in the operating theatre. In 'hybrid' theatres surgeons can now perform surgery while simultaneously utilising imaging processes for navigation, and a large number of

MEDICA®



Students distributing our EH@MEDICA2010 publications to delegates

computer-based support systems were demonstrated for the surgical sphere, including applications to help plan and simulate surgical operations.

Medical IT and telematics innovations to improve care process efficiency were an inevitable draw, with a particularly high interest in solutions to streamline dataflow between in- and out-patient sectors.

With the movement towards home monitoring of patients gaining ground internationally, the range of mobile health equipment at Medica included compact, easy-to-operate devices that record and transmit the most varied vital parameters for remote monitoring and diagnosis.

## EH@MEDICA

As in recent years, from our European Hospital booth the team distributed all three of our official English language Medica publications, as well as our other medical journals.



Germany's political VIPs, Angela Merkel and Philipp Rösler

We also met up with business partners, dignitaries, readers and medical authors, at the booth, in the many halls of Messe Düsseldorf and during talks and presentations. It was a brilliant and memorable event.

Our entire EH team is looking forward to meeting you there next year! *Diary date:*

**Medica 2011: 16-19 November Düsseldorf, Germany**



The EH booth at Medica 2010

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Our EH-5 competition winner is:  
Markus Loch, Assistant Administrative Director  
at Klinikum Idar-Oberstein, Germany. More competitions in 2011!

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

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

1. SPECIFY THE TYPE OF INSTITUTION IN WHICH YOU WORK

- General hospital  Outpatient clinic  University hospital

Specialised hospital/type \_\_\_\_\_

Other institution (eg medical school) \_\_\_\_\_

2. YOUR JOB

- Director of administration  Chief medical director  Technical director

Chief of medical department/type \_\_\_\_\_

Medical practitioner/type \_\_\_\_\_

Other/department \_\_\_\_\_

3. HOW MANY BEDS DOES YOUR HOSPITAL PROVIDE

- Up to 150  151-500  501-1000  more than 1000
- None, (not a hospital/clinic)

4. WHAT SUBJECTS INTEREST YOU IN YOUR WORK?

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

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ESPECIALLY FOR DOCTORS:

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

What is your speciality? \_\_\_\_\_

In which department do you work? \_\_\_\_\_

Are you head of the department?  Yes  No

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

How much influence do you have on purchasing decisions?

I can only present an opinion  Yes  No

I tell the purchasing department what we need  Yes  No

I can purchase from manufacturers directly  Yes  No

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

relatively modern  Yes  No

state-of-the-art  Yes  No

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

If so, what do you use of this kind? \_\_\_\_\_

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

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

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

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

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

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

This information will be used only in an analysis for European Hospital, Theodor-Althoff-Str. 45, 45133 Essen, Germany, and for the mailing out of future issues and the EH electronic newsletter. EH 6/10

## Transcatheter aortic valve implants bear risks

continued from page 1

reimburse the TAVI procedure at €35,000, yet a hidden cost incurred is the unexpected need for a permanent pacemaker implantation in 39.3% of patients receiving one of the devices, the CoreValve from Medtronic.

More than 84% of patients in the German registry received the CoreValve device. Pacemaker implants for patients receiving the only other approved device -- the Sapien valve from Edwards Lifesciences -- is around 8%.

'TAVI is completely unregulated,' acknowledged Payam Akhyari MD, from the Department of Cardiology, University of Düsseldorf Hospital, following his presentation of the German registry during the Medica 2010 Congress.

His presentation was the first since the registry was made public in May 2010, to disclose publicly the number of low-risk patients included in the data.

Including survival rates of the younger, lower risk patients in registries with the less attractive outcomes among the high-risk patients tends to skew data on device performance and may create a more positive picture for TAVI than if the results only included the originally targeted population.

Even while including a majority of patients with a risk score below the prescribed threshold, the German registry report dutifully includes a statement discouraging the use of TAVI for low-risk patients.

'As there is as yet only limited experience in this field and neither randomised trials nor long-term results are available, the use of new implantation techniques is therefore not recommended for younger patients or patients without comorbidities,' the authors intone.

'What we are seeing is of concern, because though this is called a real world registry,' Dr Akhyari said, 'actually less than one-fourth of the operations are recorded.'

His concern is shared by the professional cardiology societies charged with setting practice guidelines.

In an unusual joint position statement, the European Association of Cardiothoracic Surgery (EACTS), the European Society of Cardiology (ESC) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI) warn of a 'risk of uncontrolled diffusion.'

The joint panel stated: 'TAVI should currently be restricted to patients at high-risk or with contraindications for surgery. It is premature to consider using it in patients who are good surgical candidates. At this stage, TAVI is not recommended for patients who simply refuse surgery on the basis of personal preference.'

Germany is not the only country in Europe to see a rapid adoption of TAVI and an accelerating trend to performing the procedure as an alternative to surgery among patients with a logistic Euroscore of less than 20.

Where 923 implants were reported in April, 2008, one year later that number jumped five-fold to more than 5,000 procedures, 95% of them in Europe where the two commercially available devices are approved for use.

In May, 2010, results from 3,000 procedures were reported by CoreValve in five national registries for Italy, the United Kingdom, Germany, Belgium and France, and the company said it had marked the implantation of 10,000 valves in 32 countries.

# Meeting manufacturers Landwind - winning customers with quality and service



Wang Guozhong

The suggestion that a Chinese company will emerge in the future as the dominant provider of ultrasound systems in Europe made Landwind Managing Vice President Wang Guozhong smile before he then confirmed: 'I'm confident that, with our strengths in research and development and the importance we place on customer service, Landwind can make this happen even sooner.'

Speaking about reactions to his firm's new handheld ultrasound scanner at Medica this year, Wang Guozhong, said it proved to be the most popular product, attracting a surprising range of customers to the firm's stand. 'This palm-size personal imaging instrument can be used anywhere and is very special in the European market,' he pointed out. 'The digital image acquisition creates unique advantages over analogue imaging of other portable scanners.'

The high-resolution, anti-glare display impressed clinicians and veterinarians, who said they were surprised by the high quality from such a small screen, he added.

The touch-screen interface and long-life battery also gained plaudits from customers.

At the high-end of the ultrasound product line, Landwind also introduced to Europe its Mirror2plus, an advanced colour Doppler system.

Designed as a shared service system to support a range of applications, such as general imaging, OB/GYN, cardiology,

peripheral vessels or urology, the Mirror2plus is loaded with powerful features and accessories to enhance diagnostic confidence.

Landwind's R&D efforts are focused on adding further new features to the high-end Mirror product, and customers can expect to see a Mirror3 arriving next year that will include new functionality and an expanded line of probes. Elastography is also being developed for inclusion in future product offerings.

Yet, for Wang Guozhong, Landwind's most important new product is the mobile digital radiography (DR) system. 'We believe that the KeenRay digital radiology systems will become the largest product line for Landwind in the future,' he pointed out. 'There is clearly a steady progression to digital radiography in Europe,' because it offers more functions and greater advantages that are making diagnostics easier, while adding the ability to better process and manage patient images.'

One year after introducing the DR200Mate, Wang Guozhong reports sales in Europe are meeting the company's expectations, while in China this mobile system recently helped to win a large tender that included 28 units.

The C-arm design of the DR200 Mate means diagnostic imaging enables radiology examinations anywhere, including at the

## Welch Allyn - one year on

At Medica 2009, Julie Shimer, CEO of Welch Allyn, described her company's future plans in an interview with *European Hospital*. Medica 2010 brought us another opportunity to meet, this time to hear how those aims were achieved in the past year.

'Last year our focus lay on introducing the technology to fulfil our mission statement, which is to improve access to information, improve workflow efficiency and improve patient outcome. Of course, this is still our main intention but,' added Julie Shimer, 'now we are also concentrating on bringing our solutions into the market. The feedback from our customers is quite encouraging because they acknowledge our mission.'

Welch Allyn had again arrived at Medica, in Düsseldorf, with a large portfolio of new solutions to be displayed at the firm's booth.

On day one the Welch Allyn 1500 Patient Monitor, the first comprehensive bedside monitoring solution, was introduced. This new monitor offers easy-to-use features and options that provide clinicians with access to the information they need. One outstanding feature of the monitor is the 15-inch colour

LCD display -- the largest in its class -- which has a 170 degree vertical and horizontal viewing angle to enable clinicians to see patient data clearly from anywhere in the hospital room. Additionally, its compact size, including a footprint just three inches deep, means



it can be placed almost anywhere without disruption.

The all-in-one Welch Allyn Connex Electronic Vitals Documentation System, also launched at the show, electronically captures and transmits patient data to an EMR, providing clinicians in non-critical care areas

## Contec - bringing innovation to patient

A sharp on products for patient monitor has positioned Contec perfectly to support the growing shift away from in-hospital stays to care delivered at home or in the community setting

While Contec's broad range covers 13 product categories, the accent over the past year has been on enhancing patient-centred devices with fresh features developed by the firm's research & development team.

For example, while the typical screen size for patient monitors is 12-inches, Contec recently introduced models that both increase and reduce that size in response to customer demand.

The 15-inch CMS9100 Patient Monitor, which provides vital signs displayed in a large format, has been popular with staff who like the ability to spot key parameters quickly while caring for a patient, according to international marketing manager Jason Lee.

The TFT screen on the larger scale patient monitor is backlight and the unit can be programmed for visual and audio alarms. Other features include powerfully enhanced data storage and file management and a removable, rechargeable lithium battery.

Meanwhile, Contec also introduced a 7-inch touch screen on the new CMS6500 vital signs monitor, which packs the features and applications of larger monitors in a reduced size designed for home care applications, while the new CMS6000 with its 8.4-inch screen is a portable multi-parameter monitor in a durable case for patient transport.

Contec has earned a good reputation for the quality and accuracy of its pulse oximeters

and this year expanded its product line by also engineering new features into a top-of-the-line model, while creating a highly mobile version at the other end of the product offering.

The leading edge CMS50E pulse oximeter includes a true colour organic light-emitting diode (OLED) with orientation for the display in four directions. An unexpected feature is the USB interface that enables connection with a computer for synchronised display on both the computer and oximeter, while this port also can be used to recharge the unit.

Advanced software to aid sleep studies as well as enhanced monitoring are included, along with a unique function switch that automatically powers off the unit when a finger is not inserted for monitoring.

Meanwhile, the new wrist-worn CMS50I oximeter has a compact design convenient for a quick spot check while also being light and comfortable for long-term monitoring. Surprising features for such a small design are the wireless communication capabilities (CMS50IW) and built-in flash memory for data storage and uploading to a PC.

At Medica this year, Jason Lee said his company also introduced to European markets the Contec08 Digital Blood Pressure Monitor with automatic cuff inflation that can be synchronised with PC-based software



Jason Lee

# at MEDICA

bedside, with a large-area flat-panel detector that can be positioned without displacing patients or requiring repositioning that may be difficult.

The ease of operation and optimised clinical workflow include features such as integrated anatomical programmable radiography (APR).

Images are displayed on a 15-inch LCD touch screen and the DR workstation offers advanced pre- and post-processing functions and Dicom compatibility.

Recently, Landwind has also extended its product offering for *in vitro* diagnostics with the LWC 360 automated chemistry analyser capable of a through-put of 360 tests per hour. Wang Guozhong reports that the company is now seeking a CE mark for an enhanced processor that will run 400 tests per hour and offer an automated washing system with low water consumption.

The Managing Vice President also explained that Landwind's strategy is to continue expanding its current line of products for European hospitals while preparing to enter into new areas such as anaesthesia, ventilators, and haemodialysis.

'An important objective for Landwind is expanding our offices for service and training in Europe, South America and Asian markets,' he said. 'Currently we are working with our distributors in these regions to set up offices.'

While Wang Guozhong agrees with other market experts that an increased pressure on pricing is likely in European markets in some product categories, '...our objective continues to be to build on our strong R&D capabilities to assure the highest quality and build trust through good service to our customers.'



Randy Hwan

## SonoScape Growing customers with quality of service

It started with a bright new idea: full colour ultrasound delivered in a portable scanner.

Each year since this first product launch, SonoScape has continued

to introduce new ultrasound systems, expanding its product line and growing sales by double digits.

Can this relative newcomer in European ultrasound continue to report such strong performance?

'It's true that today Europe is becoming a challenging market with new companies and new products arriving each year,' said Randy Hwan, SonoScape's Vice President responsible for European customers. 'The pressure is now increasing on the low and middle end of the market with so many comparable scanners competing, and in this situation,' he added, 'the pricing of these systems will begin to fall dramatically.'

'In this market, where ultrasound systems are forced to commodity pricing, I believe SonoScape will be able to continue to distinguish itself with its high level of service. I believe that in this competition, at least on the low-end scanners, European sales will be dominated at some point in the near term by a Chinese company.'

SonoScape has been able to establish a reputation in a short time for highly reliable

ultrasound performance that has won customer confidence, Randy Hwan emphasised.

Built on a robust base of a Linux operating system, SonoScape is able to respond immediately to customer requirements for service, often with an immediate remote intervention.

The in-house engineering team is also able to modify designs to meet emerging customer preferences. For example, while the slim profile and reduced footprint of the new high-end performance system, the S20 is attractive for customers in countries like Spain and Italy '...our German customers prefer a more solid machine with a larger scale, so we'll be introducing a new design to meet this need,' he explained. The new large-scale design will also feature more powerful features.

He added that the SonoScape R&D team is also developing new systems that include features such as an elastography function that will be offered across the company's line of scanners in the mid- to high-end.

The best-selling S8, an extremely powerful hand-carried portable ultrasound system has enjoyed strong uptake in Eastern European countries at hospital level, whilst in Western Europe the customers tend to be private radiology clinics or individual practitioners.

'As SonoScape designs and manufactures our own systems as well as a full range of transducers,' Randy Hwan concluded, 'I'm highly confident that, in the coming competition, we'll be able to maintain a competitive edge.'



Julie Shimer

with instant access to accurate vital signs. The system includes the Connex Vital Signs Monitor now available with both Welch Allyn SureTemp Plus thermister oral/axillary/rectal and Braun ThermoScan PRO 4000 tympanic ear thermometry options, Accessory Cable Management Stand, Connex Vitals Management Software, and the new Welch Allyn Partners in Care Services programme that provides personalised support and installation.

Resulting from the company's drive for strategic partnerships, the co-branded Healthometer Professional Scales is Welch Allyn's first line of quality professional medical weighing scales within the existing portfolio of vital signs devices. In turn, the leading US scales manufacturer Pelstar, LLC now has the opportunity to expand into various high-growth international markets by utilising the broad distribution channels of Welch Allyn.

'With co-operations such as this, we will further strengthen the realisation of our aims and, for sure,' Julie Shimer confirmed, 'the next Medica will bring new, promising solutions.'

## monitoring devices

through a USB port for accurate analysis of readings and a built-in flash memory handling up to 100 patient data sets. The range of its cuffs cover as many as six kinds, such as for infant, neonate, child, adult, large adult and adult leg. If a probe is added it can also monitor SPO2.

Contec continues to expand the power of its ECG products as well as expand capabilities from the traditional three-channel model to six-channel and 12-channel models and add a popular touch screen to these new versions.

Driving its success, the company, based in the seaside city of Qinhuangdao, China, is a business-to-business model of working closely with medical device distributors and original equipment manufacturers.

According to Mr Lee, some distributors in turn supply networks of distributors across a region and by working closely with a distributor in one major market, e.g. Italy or France, Contec is able to reach markets in the United Kingdom, Germany or Spain, as well as Eastern Europe.

For Contec, Europe represents one of its most well-developed markets worldwide with products well-aligned with the needs for the home care and general practice setting.

The low price the company can offer continues to be an important advantage, he pointed out, along with the quality assurance of products to meet regulatory standards.

Yet, he added, increasingly, it is the rapid response to emerging customer preferences by the Contec R&D engineers that is winning greater market share.



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\*\* Prerequisites include: Internet connection to clinical network, DICOM compliance, meeting of minimum hardware requirements, and adherence to local data security regulations.

Lord Darzi of Denham arrived at Medica 2010 describing himself as an ambassador for healthcare and life sciences and 'proud to be wearing the British hat.'

Had he come as a buyer or a seller? 'A bit of both, actually,' Ari Darzi explained. 'We have some 300 companies here for exporting, and I'm meeting with them, as well as with larger companies, such as Panasonic, who represent an inflow as investors interested in establishing operations in England.'

As Parliamentary Under-Secretary of State (2007-09) and Labour Government Spokesperson (2007-09), Lord Darzi led a year-long review of the National Health Service (NHS) that resulted in a report calling for a controversial overhaul of the system.

The 'Next Stage Review' outlined a plan that would redefine primary care delivery across England and the NHS

in determining the success of outcomes.

'Quality is not based purely on outcomes from the perspective of the clinicians,' he said, 'but quality should also be based on the patients' experience -- on what a patient thinks of the healthcare outcome.'

'We have introduced patient-related outcomes as a formal measure in the NHS. It's no longer me repairing someone's hip and declaring it a good outcome, but including the patient's input saying that they have no experience of any change,' he explained.

'That is how you change healthcare systems. Not by looking at healthcare in terms of the number of hospitals, physicians, or the number of beds, but examining the pathways of care.'

'The motto we repeated when

# The 1st European Forum

## Unity is strength: Participants urge greater European

Across Europe an estimated 3.2 million new cases and 1.7 million deaths occur annually. By intensified cooperation in research, diagnosis and treatment, enormous advantages can be achieved. To progress the integration of knowledge and skills in this field, the first European Forum on Oncology was held this October in Berlin. Initiated by WISO S.E. Consulting and coordinated by the Health City Berlin association, the Forum drew oncology experts, researchers and agents of policy and the health industry

## Experts identify urgent actions to combat cancer

Identifying the most urgent actions to combat cancer in Europe, oncology experts meeting at the European Forum on Oncology are calling for greater international cooperation among all leading institutions -- from research institutes to comprehensive cancer centres and healthcare policy directives. To this end, the Forum participants, in the *Berlin Memorandum*, summarised the most urgent areas of action to combat cancer in Europe.

'Given the complexity of cancer, it is crucial to establish an active and interdisciplinary dialogue between research and healthcare delivery across the EU,' said **Professor Peter M Schlag**, the Forum's scientific advisor and Director of the Charité Comprehensive Cancer Centre Berlin.

Sharing his view, **Professor Michael Baumann**, Director of the Radiation Therapy and Oncology Clinic at University Clinic Dresden and President of the European Cancer Organisation (ECCO) in Brussels, said: 'If we want to convert more swiftly the advances in cancer research to benefit patients in terms of cancer prevention and therapy, then European oncology needs to join forces and speak with one voice.'

### Demands rise for personalised medicine

With the current 3.2 million new cases of cancer annually -- a growing trend -- along with 1.7 million annual deaths, cancer is and will remain a major challenge for Europe. Accordingly, the expectations that cancer research faces are high.

Thanks to molecular diagnosis, scientists have been able to classify ever more types of tumours into specific categories. In ten years, Michael Baumann predicts, breast cancer will be classified into 15 subgroups. However, the growing data volume will correspond to a shrinking number of patients. It is not only the lack of 'critical mass' that poses a challenge to the cancer research scientist. With the increasing number of new discoveries from the laboratory, expectations are also growing regarding personalised medicine (i.e. the right patient receiving the right medication at the right time). **Professor Otmar D Wiestler**, Chair of the German Cancer Research Centre in Heidelberg, put it this way: 'The rapid advance of research increases the pressure to speed up the transfer of laboratory findings into clinical benefits for the patient.'

### 'We need to speak with one voice'

Yes, cancer research is making rapid progress, but -- how can the transfer of cancer research into successful treatments be accelerated? In Berlin this October, that vexing question was up for discussion during the *European Forum on Oncology*. Also on the agenda: How best practice approaches to cancer therapy can be adopted throughout the European Union



Participants decided the most urgent areas for action

It takes a good ten years before a new substance reaches the clinical application stage -- a process that 'urgently needs to be accelerated'.

Only large research networks can meet these challenges. In connection with the *European Partnership on Measures to Fight Cancer*, the European Cancer Organisation is creating EU-wide research networks. 'We want and need large research networks and also need to get the industry more involved in the research of smaller disease groups,' Michael Baumann said.

Combining our efforts with the industry is increasingly important because a growing number of European pharmaceutical companies are transferring their research activities to the USA and Asia. This trend can only be thwarted by creating new structures, according to **Professor Thomas Tursz**, General Director of the Institute Gustav Roussy, Villejuif, France: 'To establish a closer partnership between science and industry we need a new infrastructure that provides us access to know-how, patients, tumour banks, clinical data and access to a transnational research platform.'

Such access is now to be made possible by the *Eurocan Platform*, a network in which 17 national cancer institutes have joined up to improve the coordination of European cancer research. 'Our goal is to create a world class infrastructure for trans-

lational cancer research, so that new findings can be more quickly translated into new strategies for prevention, diagnosis, and treatment of cancer,' said **Professor Ulrik Ringborg**, Karolinska Institute, Stockholm, speaking for the Eurocan Platform.

### Joint efforts must be made

Founded by the EU Commission in 2009, the *European Partnership on Measures to Fight Cancer* has drafted measures to fight cancer in ten areas. More than 300 cancer societies and government healthcare agencies are working towards the goal to reduce the number of new cancer cases by 15% by 2020. One area of action deals with the introduction of national cancer plans which, based on a directive from the EU Minister of Health, should be ratified by all EU countries by 2013. In this regard, the Union is drafting binding quality criteria for implementation by all EU countries.

In another area of activity, scientists led by **Dr Josep M Borràs**, Director of the Catalan Cancer Strategy, Barcelona, are researching the causes of the large differences in EU treatment outcomes. It is still not clear, for instance, which factors to what degree cause the survival rates in Scandinavia to total over 50% and exceed the European average,' he pointed out. 'As a result, we are analysing factors such as early diagnosis, treatment

## Quality is the route to improving healthcare

Changing for the better does not depend on the number of hospitals, physicians or beds you have; it's about eliminating inefficiencies in the pathways of patient care. The organising principle for healthcare needs to be quality. 'It is the one industry where quality is cheaper,' emphasises **Ari Darzi**, renowned pioneer in minimally invasive and robotic surgery, holder of the Hamlyn Chair of Surgery at Imperial College (London), and officially known as The Right Honourable The Lord Darzi of Denham. *John Brosky* reports on their meeting at Medica

and provided £2 million in funding for 10 regional Strategic Health Authorities to support frontline NHS staff in developing innovative ideas.

'Quality needs to be the organising principle for healthcare, which is the one industry where quality is cheaper,' he told *European Hospital*. 'Quality is not only an end in itself for outcomes but a means for reducing expenses. It is not quality that is straining healthcare systems today, but the large-scale of inefficiencies in those systems.'

'When we look at the manufacturing of a diagnostic test seen here at Medica, with the efficiencies of moving it through the supply chain, and then if we map out the inefficiencies in a patient pathway for care where that diagnostic test is used, the contrasts are startling. If we get that right in healthcare, we will save huge sums of money.'

Lord Darzi then illustrated his approach, outlining where he sees waste in the UK's complex patient pathway for treating chronic long-term diseases.

'It is the same when we look at even a more simple case for a patient having planned care,' he said, describing how the patient visits the general practitioner (GP), is sent on to a specialist, then sets an appointment to have medical imaging, returns to the specialist, then to the GP, waits for a decision on a procedure, then waits for a pre-operative assessment. 'The process goes on and on,' he said.

Looking at the same process from a patient's point of view helps to indicate the areas where unnecessary steps can be eliminated.

Similarly, he advocates greater patient participation

A renowned pioneer of minimally invasive surgery, **Ari Darzi** has authored over 450 peer review papers and seven books. For services to medicine and surgery his awards include a knighthood in 2002 and being raised to a peerage in 2007 as Baron Darzi of Denham

His main clinical and academic interest lies in MIS and related technologies. With his research team Lord Darzi covers a broad spectrum, including medical image computing, biomedical engineering, clinical safety and robotics -- his robot-assisted techniques earned him the nickname 'Robo Doc'

redesigning the services is, "Centralise where necessary, decentralise where possible". When we are treating stroke disease, there really is a need for a centralised stroke unit to image the brain and for injecting a thrombolytic agent,' he said. 'But for the treatment of diabetes, why are we bringing everyone into the hospital? Instead we have proposed shifting specialists into the communities. The same can be true for chronic disease, or expertise in rheumatology and gerontology.'

Among the vast displays of products at Medica, Lord Darzi sees the future in Halls Two and Three, which were dedicated to bio-chemical assays. 'The impact of molecular diagnostics is going to be a complete disrupter and will force a rethinking of the models of healthcare,' he said. 'There are tremendous opportunities in diagnostics for pre-emptive treatment, more personalised care and greater patient participation in that care.'



Lord Darzi

# on Oncology

## collaboration to tackle cancer



Ulf Fink



Otmar Wiestler

**Professor Otmar Wiestler**, Chair of the German Cancer Research Centre in

Heidelberg, gave an overview of cancer research in Europe, focused on four essential and promising areas, stem cell research, genomics, immunotherapy and medical physics, finally turning attention to the great importance of preventive oncology – long disregarded, although around 50% of patients already had metastases when cancer was diagnosed, he said.

For many of these, the latest treatments failed due to the late stage of disease. Recommending improvement in the early detection of risk factors in healthy people, he then referred to two big epidemiological projects that aim to identify cancer risk factors by collecting data of healthy: the population-based SHIP-Study of health in Pomerania and prospective Helmholtz Cohort organised by Helmholtz Health Research.

The two-day forum attracted some 120 participants and 50 speakers. Along with cancer research, diagnosis, treatment and prevention, the programme,

organised by scientific advisor **Professor Peter Schlag**, director of the Charité Comprehensive Cancer Centre, Berlin, included an overview of the current status and prospects of EU political coordination.

Before closing, participants introduced the 'Berlin Memorandum', calling for greater international cooperation among all leading institutions – from research centres to comprehensive cancer centres and healthcare policy directives. This has been submitted to key players in oncology and healthcare policy makers at EU level.

In Europe, basic organisational conditions and the quality of early recognition, diagnosis and therapy of cancer is still diverging. 'For example, the general survival rate of cancer patients in Germany is lower than in the Scandinavian countries,' said **Ulf Fink**, the first European Forum President, Founder and Shareholder of the WISO-Group

and Chairman of Health City Berlin. Basic research is still very fragmented, he cautioned, the speed of transfer to a hospital takes too long. 'To shorten the run, we need to benefit better from an already existing infrastructure in Europe, to share expertise and jointly develop and implement quality criteria.'

Lecturing on research,



Michael Baumann



Peter Schlag

standards, and psycho-sociological healthcare delivery in order to identify best cancer practices and to harmonise the treatment guidelines throughout the EU.'

The amount that ultimately should be spent on cancer therapy – that is a matter decided by the country concerned. However, in the future, institutions such as NICE, in the United Kingdom, or the Joint Federal Committee in Germany, will need to communicate more closely to develop transparent cost benefit evaluations in the EU, the experts urged.

The Berlin Memorandum is being submitted to key players in the oncology community and healthcare policy makers at the EU level.

The Berlin Memorandum will now be submitted to key players in the oncology community and healthcare policy makers at the EU level.

The Berlin Memorandum states:

1. The institutional and interdisciplinary cooperation involving the early detection, diagnosis and therapy must continue to be expanded.
2. Oncology centres have an important role to play in implementing the interdisciplinary work throughout the regions.
3. Translational Research – the swift transfer of basic research findings into the networks of clinical studies needs to be strengthened.
4. The adoption of proven advances in medical technology into the routine treatment of cancer patients needs to be accelerated.
5. Outdated procedures need to be abandoned sooner.
6. The implementation of a quality management system for cancer therapy, which covers the ambulatory and stationary care areas is of essential importance and needs to be supported by compatible IT systems that take account of data protection regulations and the specific requirements of each country's healthcare system.
7. The drug approval process needs to be changed to reflect the new requirements of an increasingly individualised, molecular based and flexible cancer therapy.
8. Incentives need to be established to carry out wide-scale health services research even after prescription drugs have been approved.
9. The cost-benefit analysis of cancer therapy in the EU needs to be organised in a fair, transparent and accountable manner.
10. The close cooperation between clinical research and healthcare delivery at a national and EU wide level is essential and needs to be improved.

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## Reading tissues Pathologists enable targeted cancer therapy

The trend towards personalised medicine implies the development of targeted cancer therapy. Tissue based examinations by pathologists play a key role in this trend. However, the relevance is still underestimated as pathologist **Professor Manfred Dietel** noted in his lecture at the European Forum on Oncology 2010 in Berlin, which explained what pathology already actually renders to targeted cancer therapy and where its future potential must be seen

'Today, cancer therapy is experiencing a shift towards targeted medicine, but the predictive power of tissue based analyses is still underestimated,' declared Professor Manfred Dietel, Director of Institute of Pathology at Charité Medical School, Berlin. Currently, routine detection of a predictive biomarker is a crucial prerequisite in the individualised or targeted treatment of the three 'killer' carcinomas (around 35% of all tumours): cancers of the breast, colon (metastasised, first and second line) and non-small cell lung cancer (stage IIB and IV). Further, predictive analyses are common in the treatment of the more seldom gastrointestinal stromal-tumour (dose determination) and several types of lymphomas.

Targeted therapy rather started with the agent Trastuzumab, used against metastatic breast cancer. The agent's FDA approval was gained in 1998 and EU approval came in 2000. 'The development of a monoclonal antibody with the trade name Herceptin, by Roche, was the big breakthrough,' the professor said.

The monoclonal antibody interferes with the HER2 receptor, but will only have therapeutic effects if an amplification of the HER2/neu gene or an over-expression of its protein can be verified in advance. Therefore early and accurate HER2 testing of all breast cancer patients at primary diagnosis is essential for optimal disease management.

This eligibility test is realised by morphologic and cytologic examinations. 'We can show in one section of tissue if there is an amplification of Her2 gene or over-expression of protein. That assures a relatively high dependability,' Prof. Dietel said, though admitting: 'Nevertheless, in approximately 25-30% of the cases we can have the problem of adequate quantification due to borderline staining.'



Manfred Dietel

This challenge is faced by Prof. Dietel and his Charité team by using virtual microscopy to scan histological slices, which then can be scaled up very easy and hence the problem of quantification corrected. 'This method is still not routine, but in two or three years I think we will be able to verify the important molecules in the tissue with such instruments in an objective way.'

In the treatment against invasive colorectal cancer, predictive examinations are also inevitable. Two new substances have been introduced to clinical practice, Cetuximab and Panitumumab, both antibodies that attack the EGFR-receptor. But they will only operate if the tumour cells have a wild-type K-RAS gene (mutation excluded).

Whereas, in non-small cell lung cancer (NSCLC), targeted therapy proved effective only if mutation of the EGFR-receptor is ensured by molecular pathology. In April 2009 European Medicines Agency, the European FDA, gave only a conditional approval to Iressa (Gefitinib), a drug to treat NSCLC. 'This was the first time, worldwide, that a drug approval was definitively associated with an eligibility test,' Prof. Dietel explained, and again emphasised the necessity of pathological tissue-based examinations. 'We need tissue-based examinations for almost all predictive eligibility tests. Whether we can detect gene mutations in a non-invasive way, as indicated by developments in molecular imaging, time will tell.'

# Reasonable complements in cancer therapy

## Interventional and endoscopic procedures become realistic options



Thomas Vogl

'Interventional radiology procedures are a reasonable option particularly for the treatment of unresectable hepatic tumours and metastases,' explained **Prof. Vogl**, Director of Institute of Diagnostic and Interventional Radiology at the University Hospital Frankfurt, Germany. 'A survival up to five years can be proven in patients with unresectable liver metastases after thermal ablation,' he said, then quoting a six-year study (ending 12/2009), which examined the survival rate of patients with liver metastases after a laser-induced thermotherapy (LITT). On average patients treated with curative intention survived 4.2 years and patients treated with palliative intention 3.1 years. The rates of complications and recurrence, he emphasised, are moderate. 'In lesions up to 4 cm the recurrence rate is around 2-3%. Almost every procedure nowadays achieves this rate.'

Whether hepatic ablation or hepatic resection is favourable is frequently questioned by surgeons, radiologists and colleagues within the interventional discipline, because randomised studies are lacking that prove the best therapy for patients, particularly those with tumours and metastases less than or equal to 5 cm, he explained. According to one survey (Isbert, Gemer et al. British Journal of Surgery 2002; 89:1252-1259) hepatic ablation delays and reduces residual intrahepatic tumour growth and macroscopic peritoneal tumour spread in comparison to hepatic resection, he said. Therefore, an ablation seems favourable. Prof. Vogl promotes an interventional therapy strategy for liver metastases in a third-line protocol. He himself favours a neo-adjuvant chemo-embolisation or perfusion and a response LITT- or RFA-therapy for less than or equal to five metastases with a diameter of less than or equal to 5 cm. For bigger size metastases

( $\leq 8$  cm) he proposes a palliative chemo-embolisation or perfusion and a response therapy with LITT or RFA. Multiple tumours should be treated by symptomatic chemo-embolisation or perfusion if all systemic chemotherapy protocols failed.

Considerably more vexing is the question of when interventional treatment is indicated in lung cancer or metastases. According to Prof. Vogl, the crucial question is whether resection or thermal ablation is indicated and, in consequence, if a combination of chemo- or autoimmune therapy should be considered. Although he quoted encouraging results of thermal ablation, he called for evidence-based studies in general and a genuine study that compares thermal ablation with stereotactic radiotherapy, to ascertain the best therapy.

Endoscopic cancer therapies appear to be a reasonable alternative to treat gastrointestinal neoplasia, as **Professor Alexander Meining**, Head of Endoscopy division of Klinikum rechts der Isar, Munich, suggested: 'Endoscopic cancer therapy is feasible and, under the right preconditions, surgical standards can be achieved.' This method, he added, is also the cheapest solution with minimal invasiveness.

The basic prerequisite for successful endoscopic cancer therapy is to determine the risk of lymph node metastasis (LNM). The risk differs in relation to location and depths of tumour infiltration. Prof. Meining quoted several studies that prove no risk if only the mucosa is infiltrated. An exception has to be seen in the treatment of oesophagus squamous, where an incidence of LNM from 0-5% seems possible. When the upper third of submucosa is affected (500  $\mu$ m), the incidence of LNM rises from 2-7%, except for the colon, where no risk could be proved. Hence submucosal invasive carcinoma can also be removed almost safely by endoscopic therapy. Whereas revision surgery appears to be necessary if the oesophagus is affected by submucosal invasive carcinoma.

Until now, interventional and endoscopic therapies have held little importance in common cancer treatment. However, given the trend towards personalised medicine and targeted cancer therapy, increasing attention is being paid to reasonable complements to traditional cancer surgery. During the 1st European Forum on Oncology, renowned experts **Professor Thomas Vogl** and **Professor Alexander Meining** discussed the potentials and limitations of interventional radiology and endoscopic treatment



Alexander Meining

In endoscopic cancer therapy three different methods are used -- endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD) and the rather rarely used endoscopic mucosal ablation (EMA) -- but particularly used for high-grade dysplasia or Barrett's oesophagus cancer.

The method of choice depends on location, endoscopic and histological criteria. Compared with ESD, EMR is faster (about 10 minutes), safer and relatively simpler. However, the disadvantages are not insignificant: EMR is limited to smaller lesions (smaller than or equal to 20 mm) and there is a higher risk of recurrence (around 20%). Nonetheless, ESD remains more difficult to handle, takes more time (about 60 minutes) and has a higher complication rate. The risk of perforation of 5-10% is particularly significant when compared with standard EMR.

In conclusion, Prof. Meining called for further technical innovations to enable a simpler, quicker and therefore widely available endoscopic therapy.

## Biomarkers

### The hallmark of personalised medicine

'One size fits all' -- the phrase is a fact of life in terms of the drugs available to treat cancer patients today. This solution can bear tragic results. Only 25% of cancer patients currently respond to this 'one size' drugs administration. In addition, 100,000 patients die annually, in the USA alone, from the side effects of those drugs.

Personalised therapies that are devised to suit patients on an individual basis, promise to be more effective and to be less prone to undesirable side effects. For this reason, researchers worldwide are working to facilitate this approach. Personalised treatment requires accurate, molecular diagnosis of the disease state in patients. Biomarkers for *in vivo* or *in vitro* diagnosis are lynchpins in that process.

Today, PET/CT using the molecular imaging biomarker [18F]-fluorodeoxyglucose (FDG) allows us to stage cancer and to monitor the effectiveness of treatment to some extent. However, FDG-PET just measures glucose metabolism in tissues, allowing us to visualise cancerous lesions, which usually aggressively consume glucose, but other processes, such as muscle and brain activity or inflammation can get in the way. At the European Forum on Oncology, in Berlin, Hartmuth Kolb PhD, Vice President, Siemens MI Biomarker Research, stated: 'The development of new and more specific PET markers is a key activity that must take place for personalised therapy to become a



Hartmuth Kolb

reality. These new biomarkers will be linked to patient outcomes and they will either predict a patient's response to treatment, or allow early response determination.'

PET imaging scientists are concentrating on [18F]-fluorothymidine (FLT), a PET imaging biomarker for measuring cell division. Because cancer cells divide rapidly, tumours can be identified with greater specificity and FLT-PET promises to allow better treatment response monitoring.

Angiogenesis and hypoxia, i.e. the growth of new blood vessels and oxygen starvation, respectively, are additional biological processes worthy of imaging. Cancer treatment often involves anti-angiogenesis drugs, and angiogenesis imaging agents may be able to monitor the effectiveness of these drugs in patients. Hypoxic tumours are less sensitive to chemotherapy and hypoxia imaging may allow better and more individualised radiation therapy planning.

'These markers are currently undergoing clinical trials with the goal of linking

# The role of surgery in oncology

**Cornelis Van De Velde**, Professor of Surgical Oncology at the Leiden University Medical Centre, in the Netherlands, and President of the European Society of Surgical Oncology (ESSO), describes the work and aims of the society within the EU

'Surgery remains the most important component of cancer treatment,' said Professor Umberto Veronesi, speaking at the 2006 ESSO congress. 'For solid tumours, the old saying, *No surgery, no cure*, is still valid for the majority of cases. For this reason surgical oncologists have a great responsibility towards their cancer patients and towards the progress of science.'



Dr Cornelis Van De Velde

The surgical oncologist has principal access to cancer patients and primary responsibility for establishing the diagnosis and staging of a cancer. The entire diagnosis and treatment procedure of a wide variety of cancers, including surgery, chemotherapy, radiation therapy, supportive care is then provided comprehensively.

Surgical oncologists collectively and alongside other health professionals strive to improve the overall care of cancer patients. Surgical oncologists are represented by the European Society of Surgical Oncology (ESSO), which aims to advance the art, science and practice of surgery for cancer treatment, and to promote the highest standards of surgical care in the management of patients with solid tumours. Through the dissemination of knowledge and expertise, the society strives to ensure that the highest possible surgical standard for cancer patients throughout Europe.

As is known, surgery cures the majority of cancer patients. However, because surgical oncology is not recognised as a sub-specialty in all European countries, another ESSO aim is to have the field established as an important speciality in oncology.

## The European Union

In Europe, surgical oncologists in various countries are organised in national societies, and there are several organ based surgical oncology societies. In many cases, these societies are affiliated with ESSO. If not, the society invites them to join the

the PET imaging results with outcomes and to obtain regulatory approval,' Dr Kolb said. '*In vivo* imaging will be synergistic with *in vitro* tests and, together, these techniques will pave the way for personalised treatment. The objective is to apply *in vivo* imaging procedures based on the results of specific blood or tissue tests with the goal of identifying disease early and to devise patient-specific treatment regimens, which can be monitored through molecular imaging.'

A more precise determination of the disease should obviously result in more targeted treatment -- the long term objective. 'I think that the times of "blockbuster drugs" have gone, particularly in the field of cancer. Companion drugs, the effects of which can be proven with the help of new tracers, are where the future lies. However,' Dr Kolb pointed out, 'it will probably take another ten years before these companion diagnostics/therapy solutions are on the market.'

Then, once approved, they could not only lower costs but also improve patient outcomes and quality of life.

surgeons either expand their experience or learn new techniques by working in another specialist centre.

In addition, the ESSO Education and Training Committee has developed a Core Curriculum in surgical oncology, with recommendations for both trainees and the cancer centres.

The society has also developed a surgical oncology examination in conjunction with the Surgical Board of UEMS. Open to suitably qualified European candidates, the exam provides validation of a surgeon's continued professional development in surgical oncology, as well as

indicating his/her competency to practice in this field.

Young surgeons can also participate in ESSO's Flims workshop on clinical cancer research methods, organised jointly by ECCO (European Cancer Organisation), AACR and ASCO.

Multi-disciplinary collaboration in cancer patient management is also fostered by the society, which, in partnership with other cancer organisations, actively contributes to multidisciplinary educational courses and projects on specific tumours.

In Germany the surgical oncologists are organised under the German Society for Surgery in the CAO (Chirurgische Arbeitsgemeinschaft Onkologie).

A separate working group is established and working to promote and organise the specifics for surgical oncologists in that country. The mandate for this working group is to present surgical oncologists to other societies; address special issues relevant to the discipline; define contact and organise surgical oncology in Germany, as well as be involved with other disciplines to establish studies, and be involved in the expanding process of certification of specialised surgical oncology centres.

To strengthen the German surgical oncologists' influence on the European agenda, ESSO invites the CAO to join ESSO to strengthen the profession further in Germany and Europe.

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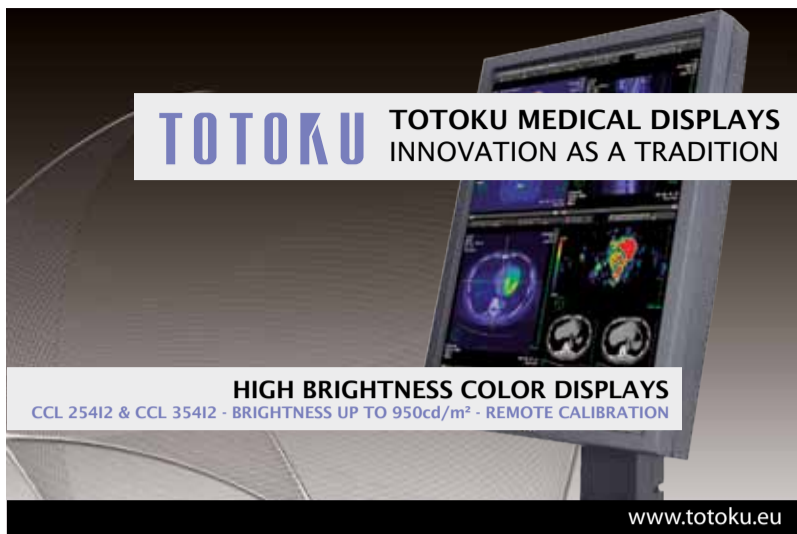
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# ONE SYSTEM COVERS ALL

## How Belgium's UZ Gent managed to combine a vast network of multimedia

With over 6,000 employees serving over 50 different departments, the 1,062-bed university hospital UZ Gent is Belgium's largest single hospital campus. Managing all the imaging data from such a huge institution – as well as establishing a network with about 30 partner hospitals and other caregivers – suggests a quite tricky task. Tricky, but not impossible, as **Professor Bart Sijnave** (above), Chief Information Officer at UZ Gent, explained during an interview with *Meike Lerner*. What he needed was a hospital-wide system that was more than just a bolted together jumble of software. His recipe for success: Good preparation, a transformation in working practice and the right partner



Carestream: 'The archive provides a single access point to clinical images and other stored clinical information, such as video clips, laboratory and biopsy results. Two servers provide the digital storage needed – a requirement that is growing by approximately 100 terabytes a year as imaging quality improves and evolves.'

service contacts the other hospital in the back-end and requests the data and then streams the images up to the requester.

The advantage is that you are always sure to get the latest images. When you start copying data onto the central system, and the other hospital forgets to stream up the most recent data, then you are working with old data, which is dangerous, of course.

For our external partners a system like 'SuperPACS' can have several advantages, for example regarding second opinions that can be performed easily and just in time. For them it could also be a gain that they can access the system and obtain the images from the other connected hospitals and they have more easy access to this information even if the patient has forgotten his DVD. They can access the data immediately online. Internally, of course, their gain depends on their structure. If they have not changed their way of working their benefit is very limited.

So, a concluding message when thinking about such a centralised PACS: It is not only an IT system on top of the current way of working – it is a new way of working that needs a completely new structure!"

This growing reliance on digital storage and a move away from discs and tapes to a central storage unit necessitates a robust Disaster Recovery policy and a Business Continuity plan. Both are in place at UZ Gent – there are two redundant data centres and, in the event of a serious failure, the hospital can retreat to local access only, using a direct connection to scanners.

The basic work for centralised image data collection was carried out about five years ago when the UZ Gent – like many other hospitals – switched from analogue to digital. The implementation of a PACS was quite a huge success because it was immediately connected to our Electronic Health Record System as well as the RIS. At the same time, we invested a lot into learning and changing management aspects – a quite important point, because observing radiological images at the computer is something you must become used to and a digital workflow is completely

different compared to working the analogue way.

Once we experienced that, we could gain a huge increase of workflow and efficiency and we began to think about connecting other sections, modalities and medical equipment to the PACS.

Of course, there was a lot of prospective management to do, because not all disciplines had the same idea about combining their modalities. So we began to look at combining all the different data stored in different PACS solutions into one central and hospital wide PACS system. Then again, at the same time we had a big chance to build a network of hospitals, which means sharing information with other hospitals and general practitioners (GP) or homecare institutions. In this context, we faced the problem of sharing images from even more PACS vendors.

So, we needed to think broader and had to answer different questions, such as: *How do we get these images out of*

*the hospital to the GP or to other hospitals, knowing that diagnostic images not only have a couple of kilobytes but megabytes and gigabytes that must be transferred to have full precision of the images?*

At that time, looking into the market there was only one system (in the Netherlands) that provided a general imaging exchange. However, it was a system where the images first had to be centralised in one place before they could be distributed. This was not what we wanted – it was against our view of modern healthcare, meaning the data source remains where it is created. Also, not to make data copies, whether in pure text data or imaging data, to ensure that you always connect to the latest information.

Then, two years ago, we began to experiment with our own implementation to get these images distributed without having to centralise them. However, after a short time we recognised that our

self-made solution was good enough for viewing, not for diagnostic purposes. We concentrated on the original question, namely to combine all modalities in our own hospital and we started a tender for a hospital-wide PACS system. We chose Carestream Health for a solution because it had a solution that not only covers the needs of the hospital itself but also to share images between different care givers.'

### Central image storage

Within our Electronic Patient Platform we have what we call the *Mediacentre*, where all media information, such as radiology images in DICOM, as well as JPGs and sound files are stored.

We only store data from our hospital itself, not data from the other hospitals. The only thing we track is that there are data in another hospital. When someone needs data from another hospital, and is connected to our portal, then our web

Professor László Solymosi, head of neuroradiology at University Hospital Würzburg, Germany, has been testing the Large Display there for two years. His department, part of a head clinic established in 1974, was the country's first of a kind and among the earliest centres of interdisciplinary medical cooperation. The trio of neurology, neuroradiology and neurosurgery is complemented by an ENT clinic

## NEW The multi-window monitor for interventional imaging

and eye clinic. His clinic, explains Prof. Solymosi, has become one without borders, by allowing the physicians to offer the complete

Necessity is the mother of invention, an old saying but particularly true in interventional radiology. Whenever minimally invasive procedures need monitoring from different angles and by different modalities, physicians and technicians in angio labs muster all their DIY skills and build huge monitor towers often with eight screens. Now, however, the new *Large Display* jointly developed by Siemens and Eizo opens several windows on one screen -- and the physician can even rearrange windows during an intervention. Features include 142 cm (56") active full-colour medical-grade monitor; 8 megapixel resolution at 4 x HD (3840 x 2160 pixel); fully integrated tableside control; over 200 layout options; connect over 20 image sources



range of diagnostics and therapies for neurological diseases, including surgical interventions that need team performance, e.g. skull base surgery.

For neuroradiologists and neurosurgeons interdisciplinary cooperation opens up increasing possibilities for the joint treatment

of patients, particularly since major diagnostic imaging examinations, e.g. angiography, have become interventional procedures. Today in Würzburg a radiologist treats 75% of all cerebral aneurysms and the strategy is planned in advance in an interdisciplinary consultation.

In angiography exams,



Aneurysm intervention: Configuration for an aneurysm intervention. The working projection is important and thus enlarged, while other images are minimised



Standard size of an angiography with additional 3-D angiogram and MR image



Angiogram in maximum size

neuroradiologists are supported by monitors functioning as a surgical microscope. Resolution, brightness and contrast play crucial roles, since they ensure even minute vasculature is displayed in diagnostic image quality.

The new *Large Display* offers brilliant images in full HD-TV quality on a single 56" screen. According to the professor, its major advantage is outstanding flexibility: 'You can view images not only in the same way as with a wall of monitors, but also adjust window size and layout to your individual requirements and preferences. So, I can enlarge the one image I am particularly interested in during a certain phase of the intervention while maintaining the other, smaller ones, such as the optical path, X-ray image or reference images.' A keypad offers access to 12 different window layouts that can be reprogrammed any time, even during an intervention.

Professor Solymosi's clinical experience contributed significantly to the development of the *Large Display's* multi-window functionality. He suggested equipping the system with a window displaying physiological parameters, such as pulse oximetry, and with access to 3-D angiographies, which are usually not processed in the angiography suite but on a separate workstation. All imaging modalities integrated into the PACS can easily be called up on the monitor.

'Enhanced visualisation and flexibility of the *Large Display* allow us to optimise both workflow and precision of the intervention', he points out. 'This multi-window monitor technology has the potential to affect the work of an interventional radiologist positively, thus I am sure it will soon be a standard feature of any angio lab.'



## Europe's first AIRIS Vento LT

November saw the opening of the private Avicenna Clinic in Berlin, a clinical 'gem' set in the heart of Berlin, not far from the famous Kurfürstendamm. This spinal hospital is also the first in Europe to have installed the AIRIS Vento LT, Hitachi Medical Systems' latest generation of open MRI systems in its AIRIS Series.



'In our old premises we worked close to the limits of our capacity, spatially as well as our concept of being able to offer comprehensive treatment. Radiology and physiotherapy were outsourced, which was very inconvenient for our patients,' explained the clinic's director Dr M Sabarini. The clinic's new home, on Paulsborner Strasse, was an office block totally destroyed during World War II, then rebuilt. In ten months Dr Sabarini and his team fully renovated and refurbished it.



M Sabarini

The clinic's 16 beds include four for recovery and two for intensive care. Various medical specialties, including oral and maxillofacial surgery, neurosurgery, plastic surgery, trauma- and joint surgery and sports medicine are now under the same roof, easing interdisciplinary cooperation.

The radiology department provides X-ray, ultrasound, and open MRI – the latest generation from Hitachi. 'This innovative technology is the perfect solution for our requirements. The Vento LT is an extremely compact whole body MRI scanner, which we could integrate into our premises without problems. Moreover, the 0.3 Tesla cover the entire diagnostic spectrum – from spinal and joint images to neurological and vascular images,' Dr Sabarini explained. The scanner also needs no helium, and the magnetism no power supply. Thus energy costs can be lowered by up to €40,000 annually. Direct connections on the magnet also ensure the production of respiratory, pulse and ECG triggered images.

Although a private clinic, Dr Sabarini is convinced that the open architecture of the MRI will also attract patients prepared to pay for state-of-the-art medicine themselves: 'Demand for innovative and top class medical approaches is continuously increasing and patients are increasingly on the lookout for opportunities to improve their own diagnosis and treatment. Therefore, the open MRI is aimed at those patients who would not be suitable for an examination in the "tube", such as claustrophobic patients, older people and children.'

According to the principle 'open to everyone', up to 10 patients a day are due for examination in the MRI scanner – all with an unobstructed view of the treatment room.

# ECR 2011

European Congress  
of Radiology

At the Austria Centre, Vienna, the next European Congress of Radiology (ECR) will again provide an expert-led programme, trade fair and range of unique peripheral services, and the European Society of Radiology

(ESR) annual meeting will also present top radiological science, education and technology.

Two new courses in the programme chosen by ECR 2011 Congress President, Professor Yves Menu, are *KISS (Keep It Simple and Straightforward)*; *Musculoskeletal MRI* – aiming to help general radiologists to report on common pathologies seen on everyday musculoskeletal MRI scans, and *CLICK (Clinical Lessons for Imaging Core Knowledge): Common Clinical Cases*, focusing on the combination of clinical and imaging knowledge and particularly how radiologists should apply clinical know-how in determining whether and how to



Yves Menu

3-7  
March  
book now!

undertake an imaging examination.

A range of new mini courses on the pancreas and cancer imaging, as well as sessions held in partnership with societies such as the European Organisation for Research and Treatment of Cancer (EORTC), European Association of Nuclear Medicine (EANM), and Radiological Society of North America (RSNA).

Collaboration will be highlighted in the ESR Meets programme, when the United European Gastroenterology Federation (UEGF) presents gastroenterology as a partner discipline. The UEGF session – Optical and Virtual Colonography: Friends or Enemies? – will show the relationship between the two techniques from a gastroenterologist's perspective, examining the

relative merits of optical and virtual colonography and discussing integrated strategy. Other ESR Meets sessions will feature the radiological societies of France, Brazil and Iran, each demonstrating their countries' radiological strengths.

In the huge (26,000m<sup>2</sup>) technology exhibition over 300 manufacturers, from the smallest publishers to giants such as Siemens, GE Healthcare and Philips will provide an unrivalled chance to catch up with the industry that drives radiology.

With so many offerings, as well as the beautiful host city Vienna – who would want to miss this? Better book early!

Details: [www.myESR.org](http://www.myESR.org)

Registration: [myESR.org/registration2011](http://myESR.org/registration2011)

Vienna  
March 3-7

ECR  
2011  
European Congress  
of Radiology

Register online now at  
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European Diploma in Radiology

1<sup>st</sup> examination at ECR 2011  
Information and application at  
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# FOCUS ON LABORATORIES



ANDREAS REH

**Standards in autoimmune diagnostics, pre-analysis mistakes and new tumour and sepsis markers\* and allergy diagnostics were topics for intense discussion during this year's meeting in Salzburg**  
**Michael Krassnitzer reports**

the same establishment the same equipment does not necessarily arrive at the same results; a small difference in the brightness of an immunofluorescence lamp for instance is enough to cause discrepancies.

The ANA test, i.e. screening for antinuclear antibodies by examining human epithelial cells (HEp-2 cells) via immunofluorescence, and the ELISA procedure (enzyme-linked immunosorbent assay), which

expected to deliver concrete advice,' explained Prof. Herold, who also heads the Austrian EASI group. A first step in the right direction is to ascertain the status quo. The Netherlands, Austria and Portugal were the first countries where surveys established which procedures were being used in the different laboratories.

Prof. Herold advised all laboratory operators against a switch to a different, allegedly better test procedure before there

measures for quality assurance do not capture the pre-analytic error sources,' Dr Endler pointed out, prior to a plea for the determination of transparent acceptance criteria for samples, and communication, in writing, with the senders. Samples with ambiguous patient identification, insufficient labelling and insufficient allocation should be rejected, along with samples of insufficient size, or of the wrong material, as well as samples that

free sample tubes. 'Attention! Sterile does not mean free of DNA,' he warned, then citing a criminal case in Germany where erroneous laboratory results led the police to chase a phantom for years. DNA traces of an assumed major, female criminal, possibly responsible for murders, burglaries and other crimes across half of Europe, turned out to be contamination through a female employee of the firm that had manufactured the swabs.

## The 3rd Annual General Meeting of the Austrian Society for Laboratory Medicine and Clinical Chemistry

### Autoimmune diagnostics -- seeking standards

Different tests bring different results, and results of the same types of test vary from laboratory to laboratory. 'In the case of test procedures for autoimmune diseases there are incredible discrepancies,' confirmed **Professor Manfred Herold**, head of the Laboratory for Rheumatism at the University Clinic for Internal Medicine One, Innsbruck. The reason: 'There are no standards for the test procedures currently available.'

Around 2% of Europe's population is affected by autoimmune diseases. Some very effective, highly specific treatments are available that can often achieve complete freedom from symptoms for patients. However, treatment needs to begin in time – and this requires quick, clear diagnostics. In the case of rheumatoid arthritis, for example, the process of joint destruction sets in within a few weeks of the onset of the disease. However, quickly obtaining the correct result is not a matter of course. 'The test results are extremely dependent on the technology,' the professor pointed out. Thus different laboratories achieve different test results – even if they work with equipment supplied by the same manufacturer. Likewise, even in



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can detect antibodies in the blood serum, often come to completely different results – e.g. in the determination of the Anti-Ro/SSA antibodies, which have an important diagnostic significance for Sjögren's syndrome or systemic Lupus erythematosus (SLE). 'It might be that the same sample shows a high positive ANA and a negative ELISA test result. How are we to interpret these results?'

The European Autoimmunity Standardisation Initiative (EASI) aims to unify autoimmune diagnostics in the European Member States, along with producing guidelines on their correct implementation, application and interpretation. 'This is a delicate balancing act. We are not allowed to advertise the products of certain manufacturers, but are still

are any binding recommendations. 'There is no "correct" test for any respective clinical picture. It would be best to stick to whatever current procedure is being used,' he emphasised.

### Pre-analysis errors

'The most common errors in the laboratory happen in pre-analysis. 95% of pre-analytical mistakes occur outside the laboratory,' said **Dr Georg Endler**, of the Central Laboratory at the Wilhelminenspital, Vienna. 'Inaccurate pre-analysis always means inaccurate results: rubbish in – rubbish out,' he said, during his lecture suggesting ways to reduce such errors.

The wrong patient, lost samples, contamination or inadequate storage are common in pre-analytical errors. 'Conventional

have been in transit for too long. The only exception: Samples that cannot be taken again, e.g. smears taken during surgery, fluid or bone marrow. 'In these cases, results should be established, but with reservations,' he advised.

A relatively common mistake that can occur in the laboratory itself is contamination with DNA or RNA. For avoidance, Dr Endler recommended a clear definition of responsibilities, unidirectional flow of samples and separate areas for sample retrieval and DNA isolation, implementation of the polymerase chain reaction (PCR), amplification and analysis of the PCR products.

'Contamination through DNA and RNA must also be avoided at all costs outside the laboratory,' he emphasised, and recommended the use of DNA- and RNA-

A further error source during pre-analysis was mentioned by **Professor**



Manfred Herold

**Stylianos Kapiotis**, who heads the Medical Central Laboratory of the Vinzenz Group (a private operator with several hospitals across Austria). New coagulants are increasingly found in samples. 'Direct anticoagulants – particularly the new oral substances – can have a strong effect on coagulation tests,' he explained. Quantitatively the results can then only be interpreted with considerable limitations. His strategy to counter this: 'Blood should be taken just before medication is taken.'

### Molecular allergy diagnostics

The comparison is akin to a modern mobile phone and an old dial telephone, said **Professor Rudolf Valenta**, of the Division of Immunopathology, Department of Pathophysiology and Allergy Research Centre for Pathophysiology, Infectology and Immunology at the Medical University of Vienna, when describing the difference between a conventional skin test and the modern chip test in allergy diagnostics. Molecular allergy diagnostics is far superior to the prick test and other procedures, he pointed out.

For some time, German pathology has only been in the background of the medical disciplines. However, during the last ten years the profession stepped up to the fore. In the face of molecular medicine developments, the German Association of Pathologists redefined its members position with revived self-confidence. In May, at its 10th Congress, a future strategy was presented that takes into account the increasing impact of prevention, diagnoses and therapies on molecular cancer.

With the discovery of a direct correlation between gene structure and type of cancer, a new branch of molecular pathogenesis has evolved, accompanied by the development of novel, molecular targeted diagnosis, therapy and preventive strategies, as well as agents, to treat cancer.

Special indicators in the gene-structure -- predictive biomarkers -- can prove the probability of cancer and detect the possible response to a targeted cancer therapy via gene muta-

## German pathologists Protecting a specialty and warding off commercialisation

tion; hence predictive biomarkers facilitate the choice of the best individual cancer treatment.

Molecular pathology has developed several tests to validate personalised cancer therapies. But, in the past, the application of molecular pathology methods for diagnoses was mainly focused on rare tumours, such as malignant lymphoma or sarcoma. Within the last two years, however, the demand for molecular pathologic performance increased. As Professor Thomas Kirchner, head of the Institute of Pathology at Ludwig-Maximilians-University, Munich, explained: 'Nowadays, prior to medication, gene mutation has to be verified to vali-

date the respond for targeted therapy in the case of colon and lung carcinomas, the most common types of carcinoma.'

### The German model

The strategy of the Association of Pathologists to keep pace with the general trend towards molecular cancer diagnostics and treatment was presented in the 'Focusing our strengths' session.

Also referred to as 'The German model' by Gisela Kempny, the association's managing director, the strategy is based on four objectives.

First, the Association aims to main-

tain its peripheral (decentralised) centres of pathology. Currently Germany has around 450 pathology centres, she pointed out. With this first aim, the pathologists are trying to counteract the general trend towards the centralisation of pathological laboratories.

To ensure a decentralised structure, knowledge is important. To this end, the Association compiled a molecular pathology guide. This includes the most important molecular pathology examinations, possibly occurring procedural problems, and advice for drawing up an account. At first place, the guide (to be released in a few months) covers, for example, K-RAS (Kirsten Rat Sarcoma) mutation testing.

Second, the pathologists want to keep all the necessary diagnostic steps in their hands. In the case of a tumour, this means the optical or morphological identification, withdrawal of tissue or cells (dissection), morphologic or molecular examination and, finally, interpretation of findings. Prof. Kirchner called these steps a 'one-stop' diagnosis.



Thomas Kirchner

Component-resolved diagnostics (CRD) facilitates the precise, quantitative detection of even the smallest concentrations of specific immunoglobulin E-antibodies with the help of micro-arrays. This enables the compilation of a detailed sensitisation profile of a patient, so that the risk of severe allergic reactions can be assessed, and cross reactivity patterns and the patient's suitability for a specific immune therapy evaluated. Additionally, CRD can be used to monitor treatment progress during immune therapy.

Molecular allergy diagnosis offers enormous advantages, particularly in the case of cross reactions. It answers the question of whether a patient has indeed been sensitised against two or more allergy sources (co-sensitisation), or whether he shows cross sensitisation due to cross reactive allergens. Over the last ten years, a number of molecules have been identified as the main allergy sources. This showed that some allergens are exclusively produced in certain allergy sources and can be used as specific marker allergen components. However, other compounds act as cross reactive marker allergen components in different, not even related, allergy sources, e.g. birch and grass pollen. The existence of IgE antibodies against specific marker allergen components confirms the actual sensitisation against this allergy source. IgE antibodies against cross reactive marker allergen components explain the reaction to different, non-related allergen sources.

To ensure the patient knows exactly which molecule he has a reaction to – and not just which allergy source – is particularly important in allergies against plant-based foods. 'Being sensitised against apples is not the same as being sensitised against apples,' Prof. Valenta emphasised. In an apple allergy it makes a big difference whether the patient is sensitised to the Bet v 1-molecule or non-specific lipid transfer proteins. Unlike the main apple allergen, lipid transfer proteins can cause a massive, systemic anaphylactic reaction, he warned.

Precise CRD results also disprove the common misconception that a patient's allergy reaction pattern changes over the years, as Prof. Valenta explained. 'If you have an allergy then you can increase your reaction through allergen exposure and decrease it through avoidance of the allergens – but the allergy profile will always remain the same.'

\* Reported in EH issue 5

which guaranteed a diversity of methods, preventing confinement to only one test method -- easily resulting in a test monopoly. The latter could entail increasing costs, for example for the kits, and would implicate a narrowed number of users.

Due to the increasing impact of cancer treatment in the future, the pharmaceutical industry is very interested in molecular pathology of cancer sector. Prof. Kirchner quoted an evaluation from IMS Health, a firm that provides information and consulting services to the healthcare market. This company predicts worldwide sales of cancer drugs to be between US\$75 - 80 billion in 2020. In 2007, sales reached only US\$41 billion. This indicates high healthcare interest in cancer diagnostics and therapy. Therefore, Prof Kirchner concludes, independence from industry, apart from production partnerships, will remain as essential as always, to guarantee patient-oriented cancer treatments and acceptable costs.

# The future of mass spectrometry in laboratory medicine



Mass spectrometer

**T**he world consists of molecules – so do we. With the progression of measurement tools such as microscopes, centrifuges, or spectrometers, mankind is becoming better and better in identifying the substances from which our world is made. Today, with the technical developments in mass spectrometry, biomolecules can be weighted with the highest precision and accuracy ever known, placing it among the booming analytic technologies conquering the field of clinical chemistry, microbiology and toxicology, says Prof. Dr. Denis Hochstrasser, Chairman of the Genetic and Laboratory Medicine Department of the Geneva University Hospital, Switzerland. **Karoline Laarmann reports**

Until now it has only been possible to measure the properties of molecules in time-consuming, expensive and often less specific laboratory procedures. With high-performance mass spectrometry the molecular mass itself can be measured (mass-to-charge-ratio) with a breath-taking speed and sensitivity in nominal concentrations, which makes it extremely helpful in drug detection, e.g. to monitor therapeutic drugs, as well as to analyse non-specific samples.

However, mass spec had to undergo some significant techni-

cal developments before it became performable in clinical practice – it had to become more precise, much faster, and much simpler explained Dr Hochstrasser. 'Mass spec consists of three steps: ion creation, ion separation and ion detection. In the past, to prepare the family of molecules in the chromatograph (ion creation) before mass spec, it took a highly trained person. With the automation of the technology, any lab technician can now do it with a press of a button.'

Many different instrument types are available for this. Until recently, gas chromatography mass spec (GCMS) was the most common, as it is easy to use and has excellent databases available. The downside? As the name 'gas chromatography' implies, blood samples have to be volatilised first. Recently, therefore, the major progress in mass spec has been in liquid chromatography mass spec (LCMS), where the fluid samples no longer need to be derivatised and extracted.

## Electron ionisation

There are two main streams in LCMS to prepare the ion for the mass spec: matrix-assisted laser desorption/ionisation (MALDI) and electrospray ionisation (ESI).

With MALDI, the test sample is put on a target together with a matrix in the form of a weak organic acid. A laser beam is then shot

on the target and the H+ proton of the matrix jumps on the sample. The now positive charged sample is then vaporised by the laser energy and can enter the mass spec.

By contrast, with ESI a fine metal needle is placed at the end of a tube. The needle is then charged with electricity. Next, when the fluid sample is pushed through the tube it comes out as a very fine aerosol – as if blown through a drinking straw. The droplets are now charged with high electric voltage from the needle. If they enter the mass spec, the highly charged droplets dry and evaporate. What remains are positive charged ions.

## From flying to tandem

The next step is to separate and detect the ions in the mass spec. For this, various technologies are also used. A powerful technique, called MALDI-TOF-MS (Matrix-Assisted-Laser-Desorption/Ionisation –Time-Of-Flight-Mass-Spectrometry), is

ing. It is available in the moment by only two companies, Bruker and Shimadzu.'

MSMS (tandem mass spectrometry) is another method – most popular in toxicology. Nowadays, MSMS is moving from gas chromatography to liquid chromatography. Instead of only one, there are up to three mass analysers involved: The first quadrupole measures the size of the molecules, the second breaks them into pieces, and the third measures the size of the fragments. The sizes of what is called the parent ion and of the fragments are then identified in a database.

## Costs

For the clinical laboratory, the acquisition of a mass spectrometer is a major investment. The instruments can cost between €50,000 and €100,000 up to €1 million. Nevertheless, the systems have proliferated in the lab market. 'A mass spectrometer is costly to buy, but low-priced in usage. The difference



Denis Hochstrasser



Liquid chromatographic cleansing of probe extract for dioxin and PCB analytic



Gas chromatograph linked to a high definition mass spectrometer

mostly used in microbiology for the classification of micro-organisms, such as pathogens and fungus.

The ions are accelerated in an electric field and conducted through a flight tube. A detector then measures their time of flight: small molecules fly fast; if big they fly slowly. 'The precision with which we can measure the atomic mass unit in MALDI-TOF-MS is as precise as the Dalton scale,' Prof. Hochstrasser points out. 'The identification of samples takes seconds, which means you can save between eight hours and four days with MALDI-TOF-MS, because it is no longer necessary to grow colonies of bacteria to classify them. That's why the technology is really boom-

to other methods, such as immunoassays, is that you don't need any reagents', Dr Hochstrasser points out.

As to the future of mass spec, he believes it might be possible even to identify cancer cells in biopsy with this exciting technique. Experimental studies in this new field are already running.

On 19 May, 2011, at the IFCC-WorldLab Congress in Berlin, Prof. Dr Denis Hochstrasser will speak about 'Mass Spectrometry: its future in several disciplines of laboratory medicine'.

Details: [www.berlin2011.org](http://www.berlin2011.org)

# 15th birthday for Lab Automation 2011

29 January – 2 February

Palm Springs, California, USA

**F**ocused exclusively on the rapidly growing field of laboratory automation, Lab Automation 2011 will discuss and demonstrate the latest scientific and technological advances in this field.

Presented by the Laboratory Automation Section (LAS) of the Society for Laboratory Automation and Screening (SLAS), the event is expected to attract more than 4,000 scientists, academics and business leaders.

The education programme will focus on five key tracks:

- Detection and separation
- Micro- and nanotechnologies
- High-throughput technologies
- Informatics
- Evolving applications of laboratory automation, featuring agriculture and food

In addition, the conference will include the World's Top 100 Laboratory Automation Podium Presentations and over 200 poster presentations.



Industry leaders at the event will include Chad Mirkin PhD, George B Rathmann Professor of Chemistry and Director of International Institute for Nanotechnology at North-western University, who, in 2009, was asked by President Obama to participate as a member of the President's Council of Advisors on Science and Technology; John M Butler PhD, a Fellow and Group Leader of the National Institute of Standards and Technology, and Daryl Lund PhD,

Emeritus Professor at the University of Wisconsin, Madison, and Editor-in-Chief of the *Journal of Food Science*, Institute of Food Technologists.

## Exhibits

In 400 exhibition booths, over 250 multi-national companies will show their latest automation technologies related to drug discovery and development, clinical diagnostics, agriculture and food, forensics and security, as well as energy generation

and petrochemicals. Their diverse fields include:

- Drug discovery and development
- Clinical diagnostics
- Agriculture and food
- Forensics and security
- Energy generation and petrochemicals

Details: <http://SLAS.org/LA11>

**LabAutomation 2011**  
Where Science, Technology and Industry Come Together

# Improving biochemical substances research

As November began so did the EU-OPENSREEN project. With a €3.7 million EU subsidy, its three-year mission is to plan a European research infrastructure for screening platforms



Ronald Frank

Chemical substances can bring miracles: they kill bacteria, prevent viral multiplication or stop cancer cell growth. Thus they offer a huge reservoir of potential drugs. However, seeking substances and their biological effects is a mammoth task and cannot be undertaken alone. The Preparatory Phase Project EU-OPENSREEN (European Infrastructure of Open Screening Platforms for Chemical Biology) was initiated to ensure that Europe's many and varied test laboratories can profit from their respective research results in the future. The objective is to build up an infrastructure that will make it possible to generate and collect knowledge and make it publicly accessible all across Europe.

The ambitious project, begun at the Leibniz Institute for Molecular Pharmacology (FMP) in Berlin, is part of the European Roadmap for Research Infrastructures, developed by the European Strategy Forum on Research Infrastructures States, which will be required over the next 10-20 years to ensure Europe remains competitive as a research location. In an interview with *Karoline Laarmann*, EU OPENSREEN coordinator Dr Ronald Frank, of the FMP, outlined the project's potential.

'Research into active ingredients is an extremely broad area because the number of possible substances is almost unending, and the biological effects manifold,' Dr Ronald Frank began. 'No one individual laboratory can carry out in-depth research on its own. This requires coordination that

facilitates the provision of the necessary technologies and collection of substances, collection of knowledge and also helps to avoid situations where several locations carry out research into the same matter. Many automated screening laboratories that test substances as to their mechanism of action at high capacity are already regionally linked. This networking is now to be extended on a European level.'

### What could such an infrastructure offer?

'An infrastructure can be compared to a service organisation. We are the facilitators who provide the high throughput equipment (screening) and the databases in the project's laboratories. The biologists and chemists who use these screening platforms then deal with the actual issues. The platforms allow them to examine tens of thousands of substances as to their different biological effects within the space of only a few hours.'

### Who is involved in the initial project phase?

'Currently, twelve countries: Germany, France, Spain, Sweden, The Czech Republic, Finland, the Netherlands, Norway, Denmark, Austria, Poland and Italy. Each nominated a national institute as a partner to represent the national platforms. Within the three years, we obviously hope to develop a model that will support many competent institutes and countries. This is why we need to negotiate with around 30 ministries to find out if there is any interest in financing certain components of this infrastructure in the

long term, because the EU sponsorship will cease after the three-year planning phase.'

### What does the three-year plan cover?

'Many important issues need to be resolved so that we can work in such a complex, cross-border consortium. Initially, we need to define exactly what the planned platforms are to provide -- and what not. We also need to clarify all administrative, legal and financial prerequisites. The agenda comprises 12 work packages, including standardisation procedures and database development.'

'The database will be run by another ESFRI project -- ELIXIR. They will centrally coordinate the IT for the biological-medical infrastructure, which is constructed in such a way that it can also be networked with other biological databases.'

### Are there national differences in this research area?

'Chemical biology is a comparatively recent branch of research, and has developed at a different pace in the individual EU States -- depending on the research priorities in each country. For example, France and Germany have been developing networked infrastructures for research into the effects of chemical substances on biological processes for over ten years. Other countries have only just begun to plan these infrastructures nationally. A network such as the one resulting from EU-OPENSREEN helps colleagues from the world of science to convince their ministries that sponsorship makes sense.'

Bedside testing of parameters has been introduced in clinical practice much earlier than laboratory testing: In past centuries, not only were temperature or pulse rate taken at the point of care (POC), but also qualitative blood or urine analysis were performed right next to a patient's bed.

Today, POCT is defined by the German Society of Clinical Chemistry and Laboratory Medicine as 'diagnostic testing at or near the site of patient care, with an easy-to-use instrument, under the immediate health care (e.g. emergency room, operating room, intensive care unit) and not by laboratory personnel'. Clinicians put it simpler: POCT is any analysis done close to the patient that delivers exploitable results within minutes and drives to immediate therapeutic decisions. Synonyms

# POCT

heart surgery would not have been possible without the systemic application of heparin, its antidote protamine and standardised test methods to control the effect of both drugs immediately. Neither catheter-based interventions in cardiac and vascular surgery nor dialysis procedures could be performed without anticoagulation and its testing.

**Europe** - Coagulation tests are among the smaller proportion of the total POCT market. Other fields, in order of relevance: diabetes, infectious diseases, fertility, haematology, cardiac marker, and blood gas and electrolytes (pic. 1).

5. An almost fully equipped, high-end POC workplace. Different devices are necessary to analyse the whole blood coagulation and lysis process directly in the theatre. Currently, no manufacturer offers a complete programme



COURTESY OF UNIVERSITY HOSPITAL ESSEN, GERMANY

are Near-Patient Testing, Bedside Testing, Alternate Site Testing or Decentralised Testing.

**History** - Modern POCT entered clinical practice in the 1960s: the wide use of heparin to avoid intravascular clotting during major surgery would be impossible without suitable test methods for immediate diagnosis of its effect. Due to a short half-life, a remarkable inter-ethnic and a 4-fold inter-individual variability in heparin response, this drug requires close monitoring of clotting time.

The rapid development of open

Frost and Sullivan (F&S) a consultancy with strong focus on growing markets, published a 158-page market analysis in 2010 (on revenues from €1.87 billion and 8.2% growth rate in 2009, the analysts calculate the potential revenues --maximum future market size -- of €3.89 billion, with a compound annual growth rate of 10.9% (pic. 2). This is a remarkable growth, considering that the 2008' growth in the entire IVD market, reported by the European Diagnostic Manufacturers Association (EDMA), was only 4.2%. This

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## Diagnosis of obesity-related diseases made easy

Two trends can be observed in healthcare across Europe: the increase in obesity-related diseases and increasing cost pressure. On the one hand, this means that precise information about body weight- and height is therefore becoming more important. Obesity, and its most common concomitant diseases Diabetes mellitus, lipid metabolism disorders and high blood pressure, is the fastest growing health risk worldwide. On the other hand, it means that ever fewer doctors have to care for ever increasing numbers of patients. This has led to digitisation of medical technology to relieve staff, carry out examinations faster and avoid mistakes while doing so.

The seca 360° wireless system supports the doctor in the best possible way in diagnosing and advising patients with obesity-related diseases. Through the wireless transfer of data on body weight and height to a printer or PC, the interpretation of measurements, as well as the transfer of results and analysis to a patient database, seca helps surgery and hospital staff to save time and work without mistakes on a daily basis. Moreover, the seca 360° wireless system, particularly the PC software seca analytics 105, supports the doctor in the early detection of, targeted treatment for, and demonstrative advice for patients with obesity-related diseases.

The possible applications are manifold: The seca analytics 105 software, for example, facilitates long term monitoring of body weight through the module *development/growth*. Furthermore, the energy module safely and quickly calculates the *energy* requirement in the context of a dietary plan and determines the recommended energy intake to achieve a certain target weight or BMI.

The *cardiometabolic risk* module is a convenient assistant for cardiologists to diagnose a metabolic syndrome. The module also facilitates the estimation of the 10-year risk of coronary disease based on defined risk scores.

Paediatricians can safely and easily monitor growth and weight changes in infants and children in percentiles with the seca 376 wireless baby scale, the seca 285 measuring station and the seca analytics 105 software.

# Advancing POC diagnostics

Engineer **Frédéric Breussin**, expert in microfluidics for diagnostics and life sciences and Microfluidics Project Manager for Yole Développement, explains how new technologies can enable the development of more sophisticated point-of-care testing

Improvements in microfluidics and detection technologies are beginning to expand the range of point-of-care diagnostics beyond simple blood chemistry tests to sophisticated immuno-assays and molecular diagnostics. Though yet to see much adoption in European hospitals, these point-of-care (POC) diagnostics are coming into use in the USA, initially in emergency rooms and ICUs where fast results are most critical. But, gaining full advantage from some of these potentially game-changing innovative technologies will require re-thinking some conventional ways of doing things.

Despite major investment and big strides in microfluidics technology, in 2010 the sales of POC diagnostic devices still only reach about US\$200 million, not including reagents. However, the capability for fast, low cost testing for many more conditions is spurring growth, with demand on track to average 38% annually for the next five years, to become a US\$770 million market by 2014, according to the Yole Développement latest analysis of market trends (Report: *BioMEMS 2010*) as developers and potential users of the technology learn to integrate disparate

Frédéric Breussin has supported many companies in their innovation and product development strategy in making the bridge between micro systems technologies and their applications in life sciences, diagnostics and medical device industries



technologies into integrated systems for simple, low cost tests, and to focus on the right markets with real benefit to patients and medical practitioners.

Due to recent advances in the microfluidics technology used in research labs, it is now possible to make low cost polymer slides that can actively pump, mix, separate and heat and cool samples and reagents through complex pathways and test regimens. This makes possible a growing selection of disposable slides or cartridges to do chemical tests of drops of blood in ~10 minutes or less, for US\$4 to US\$20.

Commercial tests are now available for multi-chemistry blood analysis, blood gases, electrolytes,

BD Max platform (previously known as the HandyLab Jaguar)



cardiovascular diseases, inflammation and diabetes from various suppliers. Companies such as Biosite offer systems for immunoassays to diagnose cardiac conditions in about 15 minutes. The polymer microfluidics systems bring the cost of the device down to a few dollars, bringing total cost, with reagents, IP and marketing, to US\$30-US\$100 per test.

However, it has taken some time to find the right applications with the right balance of medical benefit, efficiency and cost to get real benefit from these new technologies. The compelling advantage of true POC diagnostics is, of course, fast results right where they're needed, where getting test results in minutes in an emergency can enable immediate critical treatment of things like heart attack, stroke, drug overdose, or sepsis, and cost is not a major issue. However, only a handful of these critical applications are

# BRINGS VALUES

Holger Zorn points out that whilst point-of-care testing helps in earlier clinical decisions, thus saving hospitals money, it also profits manufacturers

growth is based on a moderate saturation – from 20% for the cardiac marker segment up to 90% for the fertility segment, mean saturation 30%) and driven by a quick turnaround time, self-monitoring devices for home care, updated medical guidelines and encouraging initiatives from European governments – and hampered by inconsistent reimbursement schedules.

**Time matters** - For certification as a chest pain unit in Germany, for example, the clinic must be

a point-of-care test unit on site to determine cardiac markers is mandatory'. Background: In 1999 a study demonstrated the comparable efficiency of a test strip reader and the laboratory-based ELISA test for cardiac troponin T (cTnT) in patients with suspected myocardial infarction (Source: Mueller-Bardorff M, Rauscher T, et al. Clinical Chemistry. 1999;45:1002-08). And troponin is a powerful predictor of in-hospital mortality, short and long term clinical outcome in patients admitted with an acute ischemic event.

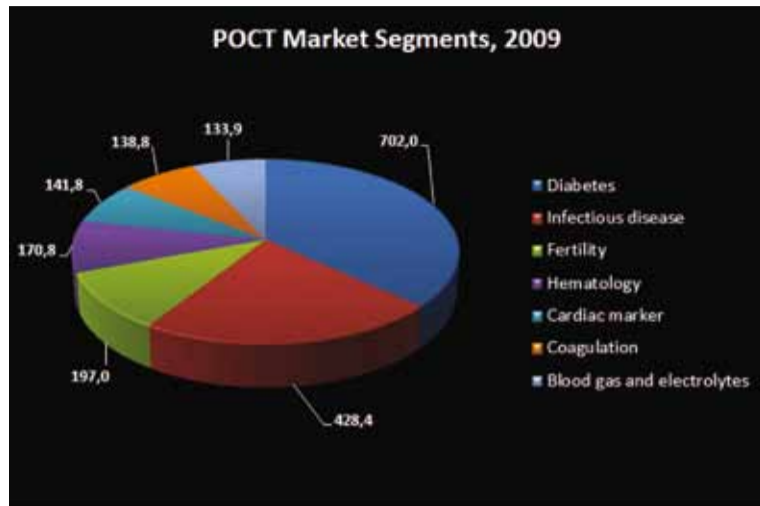
Professor Gerd Heusch, chairman of the Institute of Pathophysiology at the University of Essen and past president of the DGK, started this certification process in 2008, intending: 'What the Stroke Unit is for cerebral infarction, the Chest Pain Unit must be for a heart attack', and it hoped about 300 hospitals would be certified nationwide. Actually, there are 99 chest pain units in Germany.

**Cost** - Anaesthetist, critical care specialist and senior physician at the University Hospital Halle, Dr Jens Soukup looked at time and costs of troponin testing in 2007, when the DRGs were introduced in his clinic: the centralised lab needs 55 minutes and takes €9.50, the Triage system (Alere GmbH, former Inverness Medical, Cologne) takes 20-25 minutes and €25-30, and the i-Stat system (Abbott Point of Care Inc.,

the operational benefits to the system of increased efficiency and reduced costs might be huge – from eliminating the constant shuffling of many blood samples and test results back and forth between the lab and dialysis centre, say, or eliminating the need for doctors to schedule additional time for follow-up phone discussions of results with every patient who has lab tests. These benefits may not be so obvious, and they might require significant changes in established practices of sending samples to the lab and later receiving the results.

The most promising coming application for the more specific and sensitive nucleic-acid-based tests now becoming possible with low cost microfluidics is testing for infectious diseases, which offers calculable economic benefit over the old immunoassay systems by identifying the genetic differences in the pathogens that determine how resistant or virulent they are, and speeding up diagnosis from days to hours, to begin treatment sooner and to prevent the disease spreading through the population.

Automated lab equipment that can run these tests for infections like HIV, hepatitis, flu or MRSA in several hours in the hospital lab, is now available from most of the major players, though the systems remain relatively large and expensive. Acquisition of small suppliers by the medical majors, such as the BD Diagnostics' acquisition of HandyLab, will help bring these completely automated systems into wider distribution.



1. Segments of the Western European POC market and its shares in 2009. Diabetes, fertility and infectious diseases account for more than 2/3 of the total market. This reflects the high proportion of home care and out-patient clinics



2. Revenue Forecasts of the Western European POC market. Based on 2009, the preview goes to 2016. The volume rises from €1.87 to €3.89 billion, a compound annual growth rate of 10.9% is predicted

Princeton, NJ) 10 minutes and €11.

For blood gas analysis, there are different results. In 1999, Kendall and co-workers compared POCT with standard lab testing, with special regard to costs. Finding: 'About 7% of patients who needed urgent blood testing had changes in treatment in which timing was considered to be critical when POCT was used'. However, 'patients did not spend less time in the accident and emergency unit even when test results were available more quickly and patient management decisions were made more quickly.' He concludes: 'This



3. Patient monitor at an intensive care unit. A POC analyser type i-Stat from Abbott Point of Care Inc. is fully integrated into the monitor (lower right)

suggests that the availability of test results is not the factor that slows down the arrangement of further care' (Source: BMJ 1998; 316: 1052-57). But the time until the doctor became aware of the result of arterial blood gas measurement ranged from 48 to 91 minutes with POC, compared to 65 to 100 minutes with lab testing – the mean difference of 21 minutes (3 to 44 minutes) was not statistically significant. Today, POC devices may be fully integrated in the patient monitor (pic. 3), and less than three minutes elapse from blood sampling to obtain the result and make a clinical decision.

**Recent technologies**

Depending on the parameters to be measured, there are different measuring principles; mechanical, optical (photometric) and electrochemical methods were used. The i-Stat analyser shown (pic. 3) is an example of the electrochemical method. Initially developed for whole-blood-based testing of blood gas and electrolytes, the device now functions as a platform technology and allows a wide range of bedside tests, including cardiac markers and coagulation, by choosing the appropriate cartridge. Regarding the Activated Clotting Time (ACT), the end-point of the reaction is indicated by the conversion of a thrombin substrate, which has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. Thrombin cleaves the amide bond at the carboxy-terminus of the arginine residue, because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. This reaction produces a compound that is detected amperometrically, converted in elapsed time and displayed in seconds.

The main competitors in coagulation testing, International Technidyne Corp. (ITC) and Medtronic Inc, rely on mechanical methods, derived from the original method introduced by Lee and White in 1913: A blood sample is mixed with celite or kaolin as activator and then moved back and forth until a clot is formed, which either blocks the measuring channel (Hemochron Jr. and Signature series, ITC), sweeps a pre-held magnet away (Hemochron tube technology, ITC, the reference in ACT measurement), or restrains a previous-

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ly movable plunger (ACT Plus and HMS Plus, Medtronic Inc.). The HMS Hemostasis Management System (pic. 4) allows a patient-specific testing and drug dosing – a step towards individualised medicine in the operating theatre. Currently high-end is a POC workplace with which all four phases of blood coagulation – primary haemostasis, plasma coagulation, clot formation and lysis – can be determined directly in the operating room (pic. 5).

**A missed trend** - Clinical chemists, the laboratory physicians have almost missed this trend – in Germany at least up to April 2008, when the 'Directive of the German Medical Association on the Quality Assurance of Tests in Laboratory Medicine' was published. Now, regular checks with both electronic and liquid quality control as well as IT-based documentation are required, under the responsibility of the central laboratory - which has dampened the zeal of users and increased costs for hospitals, profits for manufacturers.



available, which has limited early adoption of the technology.

Intensive care units and emergency rooms are finding real advantage from instant blood test results in the USA. Abbott Point of Care, for example, sells some 20 million units a year of its bedside i-STAT blood chemistry tests with a handheld reader, which give medical personnel immediate information on blood chemistry for US\$4 to US\$20 a test set cartridge, using capillary forces to drive the sample through analysis, and measuring changes with thin film electrodes.

i-STAT systems are used by Baystate Health System, in Springfield, Massachusetts, for example, for >100,000 blood gas tests a year out of some 600,000 ambulatory visits and 140,000 emergency intakes.

In other cases, it may require changes in the system to capture the benefits of immediate POC information. Sometimes the true medical benefit to the patient of obtaining a diagnosis in minutes, not days, may be marginal, but

Around 18,472 angioplasty procedures and 4,752 stent procedures were completed in Germany in 2008. By comparison, only 7,710 angioplasty procedures and 438 stent procedures were completed in the same year in the UK.

PAD, also referred to as peripheral vascular disease (PVD) is the hardening and narrowing of the arteries in the limbs, caused by a build up of fatty deposits (cholesterol and scar tissue) in the lining of the arteries, which reduces blood flow to the legs. PAD can be treated in a number of different ways: angioplasty (PTA) stenting or surgical intervention (bypass).

**PAD symptoms and related risk factors**

Intermittent claudicatio (IC) is usually diagnosed due to a history of muscle leg pain on exercise that is relieved by a short rest. Patients with claudicatio experience reversible muscle ischemia during walking, characterised by cramping and aching in the affected muscle. These symptoms result in a severe limitation in exercise performance and walking ability. There are various risk factors for PAD. The relation between smoking and PAD was recognised in 1911. A PAD diagnosis is made approximately a decade earlier in smokers than in non-smokers. Heavy

# Leading the field in PAD treatment

More procedures to treat peripheral arterial disease (PAD) are carried out in Germany than most other countries in Europe, particularly the UK, reports radiologist Dr Kai Wilhelm, from University Clinic in Bonn

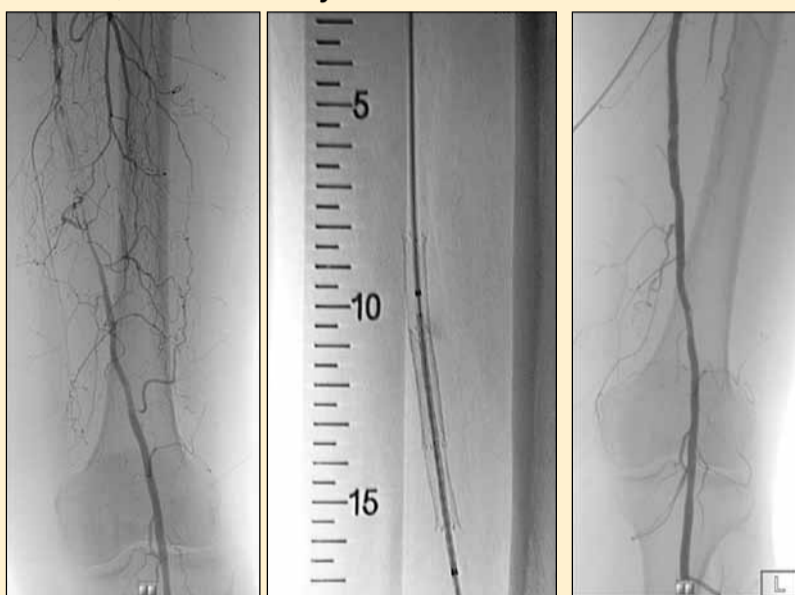


Fig 1: Before implantation bare-metal stent in-stent stenosis

Fig 2: Implantation Nov 2009, 680 mm ZilverPTX stent

Fig 3: Follow up DSA, 12 months after ZilverPTX stent. No re-obstruction

It is interesting to note that the UK lags behind other European countries when it comes to treating the femoral arteries (the most difficult to treat artery in the leg, which is often most affected by PAD), with 8,148 procedures in 2007, compared to 23,224 procedures in Germany during the same year.

PAD is quite common and affects around 6.8 million people in the UK, France, Germany, Italy and Spain. The prevalence of PAD is quite similar across all these regions, and lies between 3.83 and 4.46 percent.

The question is: Why are many more patients treated in Germany compared to, for example, the UK?

**What is PAD?**

PAD, also referred to as peripheral vascular disease (PVD) is the hardening and narrowing of the arteries in the limbs, caused by a build up of fatty deposits (cholesterol and scar tissue) in the lining of the arteries, which reduces blood flow to the legs.

**How common is PAD?**

PAD is quite common and affects around 6.8 million people in the UK, France, Germany, Italy and Spain. The prevalence of PAD is quite similar across all of these regions, and lies between 3.83 and 4.46 per cent increasing to 15 per cent to 20 per cent in persons over 70 years.

**What causes PAD?**

PAD is the hardening and narrowing of the arteries in the limbs, caused by a build up of fatty deposits (cholesterol and scar tissue) in the lining of the arteries, which reduces blood flow to the legs. PAD can be treated in a number of different ways: initially a conservative method of walking training and pharmaceutical intervention is advised. However, if symptoms are more advanced, with long lesions or occlusions, more invasive methods of treatment such as angioplasty (PTA) stenting or surgical interventions (bypass) become necessary.

smokers have found a four-fold higher risk of developing intermittent claudicatio.

**Testing for PAD**

The initial clinical assessment for PAD is a history and physical examination. Palpable pedal pulses on clinical examination have a negative predictive value of over 90% that may rule out the diagnosis in many cases. The primary non-invasive PAD screening test is the ABI (Ankle-brachial Index measurement). Measuring the pressure in the ankle arteries has become a standard part of the initial evaluation of patients with suspected PAD. A reduced ABI in symptomatic patients confirms the existence of hemodynamically significant occlusive disease.

Imaging is indicated in those patients if some form of revascularisation (endovascular or open surgery) would be advised if a suitable lesion is demonstrated. Angiography, using digital subtraction technique, is considered the 'gold standard' imaging test and can be combined with interventional procedures such as stent implantation (see Figures). Pre-interventionally colour-assisted duplex ultrasound is an attractive alternative, in expert hands, that can provide most of the essential anatomic plus functional information to plan an intended interventional therapy.

**PAD treatment options**

Patients with intermittent claudicatio, who continue to experience limitations to their quality of life after appropriate medical therapy, are candidates for revascularisation therapy. When anatomic localisation is suitable, less invasive interventional procedures are the method of choice. In the case of long-distance occlusive lesions, surgical procedures may become necessary.

Why are there such huge differences in the numbers of procedures carried out across different countries within Europe?

It's probably due to a number of factors including eating habits, better diagnostic treatment of patients and earlier referral to the correct clinician.

# New service contracts for reprocessing endoscopy systems

Smooth, flawlessly running reprocessing systems ensure regulatory hygiene standards as well as the constant availability of all endoscopes. To this end, along with the established Partnership and Complete Coverage Contracts for endoscopy, Olympus Deutschland GmbH has developed CDS Care and CDS Care+ Contracts and a Validation Service

Olympus Partnership and Complete Coverage Contracts are powerful tools for the all-around security of endoscopy systems, including maintenance, repairs and, depending on the type of contract, supplies. Thus, endoscopy teams can gain significant time to concentrate on their main tasks.

This service is now extended to reprocessing. CDS stands for Cleaning and Disinfecting Systems. The new CDS Care Contract comprises maintenance, repairs and also validation of Endo-Thermo-Disinfection (ETD) systems.

The contract is available as CDS Care Standard or CDS Care+ and consists of different modules.

The validation considers systems control and performance control, Dominik Adams, Head of Medical Service at Olympus points out. 'The advantage is that Olympus, as a system supplier, can also measure additional parameters.'

**Well protected: CDS Care**

The standard form of CDS Care provides basic coverage for the systems. It contains maintenance planning and execution, including all wear and tear parts listed in the service manual, e.g. tubes or dosing pumps, and also transportation and labour costs. Additionally, Olympus



New service agreements for reprocessing of endoscopes: CDS Care and CDS Care+ also cover maintenance and validation of ETD Double reprocessing systems

provides a cost-free technical hotline, keeps the systems up to date with the latest software and offers the possibility of error diagnosis and treatment via remote maintenance, depending on the communications infrastructure of the respective hospital.

**Validation included: CDS Care+**

The CDS standard agreement is expandable. By signing a CDS Care+ contract, customers can choose the option of full coverage of service costs by Olympus. This also implies - in the worst case of repair - the provision of rental machines and transportation of the damaged ETD systems. Another option is the validation of the reprocessing machine according to currently valid regulations by Olympus' Mobile Medical Service.

This consists of the inspection of cleaning capacity and microbiological testing of the rinsing water, providing certified

assurance for the customer. Two more modules consist of training for in-house medical technicians, provided either at the hospital or Olympus' premises. In both cases basic technical knowledge and error diagnosis are also part of the contract and covered.

**Comprehensive protection through qualified service**

Within the CDS Care Contracts, now including reprocessing, the best entry into this new range is the Basic Contract, which enables hospitals to protect some of their systems for the limited period of one year, thus experiencing the advantages of a service agreement without any risk or long-term commitment, Olympus points out.

Those wanting comprehensive protection of their budgets from the beginning can choose the well-established services of a Partnership or Complete Coverage Contract.

# Combinations advance endoscopic diagnosis and treatment

In his presentation on the diagnosis of early digestive tract tumours, Alexander Meining MD, from the Klinikum rechts der Isar, Munich, demonstrated how each new imaging technique developed by different manufacturers has been integrated into the hunt for neoplasia.

Magnification enhanced the traditional use of white light, then autofluorescence and various forms of computed virtual chromoendoscopy (CVC) enhanced mucosal surface contrast, much like using Photoshop on photographs.

Using a blue light to illuminate tissue, Olympus introduced narrow band imaging (NBI) which, he said, '... aids detection by the human eye and significantly improves the learning curve in endoscopy but is not necessarily better for detecting tumours.'

High powered magnification to over 400-fold endocystoscopy system (also from Olympus) further enhances examination of stained cells, but remains a surface examination.

More recently *in vivo* microscopy became possible using confocal laser scanning, a technology, Dr Meining said, which has proved effective in the early detection of tumours, adding that 'virtual histology still has a lot of work to do before it can be adopted for routine clinical practice. 'Again, it's the combination of these techniques that allow us to go from a macro view to microscopic view and then, ideally, they will give us the confidence to per-

**Endoscopy has advanced dramatically in the past decade with innovative technologies introduced by industry and novel procedures pioneered by physicians. Given a choice among the broad range of new tools, endoscopic surgeons simply want it all -- and are asking for more. During the Medica 2010 Congress, the Innovations in Endoscopy session rang with the word 'combinations'**

form a treatment for the condition we see in the same endoscopy session.'

More importantly, he pointed out, 'these tools are teaching us what to look for and to look more closely.'

Presenting Progress in therapeutic endoscopy Pierre Deprez MD, Head of the Department of Gastroenterology at the Catholic University of Louvain, Belgium, said that, beyond the improved imaging, in recent years endoscopy has greatly benefited from the robust development of new tools for minimally invasive surgical interventions.

Combining techniques, such as endoscopic ultrasound with endoscopic retrograde cholangiopancreatography (ERCP) enables the diagnosis and treatment of conditions in the liver and gallbladder.

Crossing frontiers between endoscopy and surgery, innovations in natural orifice transluminal endoscopic surgery (NOTES) have introduced a toolbox of new instruments, including clips, stents, cutting tools and closure devices. 'We used to be afraid of perforations during surgery,' he said. 'Now we routinely cut through lining to reach other organs.' Endoscopy has also benefited from combining experiences by crossing borders, he added.

Techniques advanced by surgeons in Asia have shown that tumours can be fully removed in one piece, rather than cut into pieces -- the dominant Western technique.

Jean Pierre Charton MD, from the gastroenterology clinic of the Evangelisches Krankenhaus, Düsseldorf, pointed out that, from the pioneering pill cameras that first opened a view to the small bowel the technology has advanced to specialised capsules used to examine the colon and oesophagus.

Accepted for routine practice for certain indications, the pill camera presents an opportunity to encourage greater compliance to screenings for a significant patient population reluctant, or unwilling to undergo endoscopic exams.

# Type 2 strategies

## When and how should we start insulin?

Innumerable studies (e.g. Ceriello A., et. al. 2006) have shown that postprandial hyperglycaemia is an independent risk factor for cardiovascular disease (CVD) in all populations. In diabetics, according to IDF figures, CVD is even the major cause of death (some 50 % of all diabetes fatalities) and much disability. 'Therefore, the primary goal in diabetes treatment should be not only lowering blood glucose levels judged by a target HbA1c value of  $\leq 7,0$  mmol/l, but also to significantly control postprandial blood glucose,' says **Professor Bruce H R Wolffenbittel**, Head of the Department of Endocrinology at the University Medical Centre Groningen, the Netherlands. An intensified insulin therapy can help to achieve an adequate PPG – but there are some patient-oriented aspects that should be considered.

Unfortunately, there is limited clinical trial evidence regarding the effects of intensive glucose control on the development of CVD. Why? 'It's difficult to evaluate a clinical trial that separates the effects of intensive insulin therapy on PPG from its effects on HbA1c, because if you lower PPG by insulin treatment, HbA1c goes down, too,' he explains.

As a result, large studies, e.g. ACCORD or ADVANCED, do not concentrate on PPG but typically investigate overall glycaemia respectively HbA1c. Moreover, these kinds of studies were performed in an advanced diabetes group of patients among whom a large section already suffered CVD. 'It may well be that, in this patient group, an intensive insulin therapy results in frequent hypoglycaemia and therefore instead increases the CVD risk,' Prof. Wolffenbittel surmises. The VADT study (Duckworth, W et al.; N Eng J Med 2009), for example, showed the benefit of intensive glucose control in patients with a short duration of diabetes, and side-effects in patients with long (> 15 years) duration of diabetes and in those with severe CVD.

A very recent Japanese study (Nishimura H., et al.; Diabetologia 2008) – till now not published as a full paper – is the first of its kind to concentrate on PPG alone and consider only diabetics free of CVD at the start of the survey. It provides a promising hint that addressing PPG reduced CV damage in the early course of diabetes.

Over 300 diabetics were divided into two study arms, one treated with regular insulin, the other with fast acting insulin analogue (insulin aspart). The trial resulted in same HbA1c values (7.5 mmol/l) between the two patient groups after five years, and lower PPG in the insulin aspart group. Result: a 43% reduction in CV endpoints.

'What we can learn from these various clinical trials is that the potential benefits and risks of intensive treatment need to be assessed in every single patient, taking into account individual aspects such as risk of hypoglycaemia, age, lifestyle and life expectancy,' the professor pointed out. 'Even though it is known that Type 2 diabetes is a heterogeneous disease, all patients are still treated the same.'

In 2008, the treatment algorithm for Type 2 management was adjusted by the American Diabetes Association (ADA) and



H R Wolffenbittel

the European Association for the Study of Diabetes (EASD). It advocates beginning with the addition of one injection of basal insulin, when lifestyle changes and oral agents, e.g. metformin, begin to fail in maintaining an adequate glycaemic control level – the case in every diabetic career, sooner or later. 'Although such therapy schemes are simple for patients and doctors, they can hardly be considered a 'tailor-made' personalised treatment, and it can be questioned whether they provide satisfactory control of PPG,' he pointed out.

'When you begin with insulin therapy, you have a lot of choices. The right insulin injection regime depends on the patient's needs, as well as on the degree of glucose control. Generally, premixed insulin analogues or multiple daily injection regimens can be adjusted to daily activities and lifestyle of patient and are the best way to mimic normal physiology. By this, such insulin regimens are expected to add to the prevention of macrovascular complications.'

Age is one of the most important factors to decide on the right insulin treatment. In younger age, intensified treatment regimes with up to four insulin injections daily allow for an active and flexible lifestyle and prevent long-term future complications. However, in the elderly such a strict glucose control would mean a high burden for the patient with a risk of hypoglycaemia but, up to now, limited evidence for benefit. His conclusion: 'Insulin therapy should always follow life, not life follows insulin therapy.'

# Bayer Healthcare's 7th European Diabetes Nursing Symposium

In November European diabetologists converged on Leverkusen, Germany, to discuss current practices in diabetic management of Type 1 and Type 2 in adults, as well as new technologies, procedures and the need for patients' education

Specialist diabetes nurse Sari Härmä-Rodríguez, from the Diabetes Centre of the Diabetes Society in Finland, emphasised that, along with treatment management, psychological support is significant, reminding participants at the annual Bayer event in Leverkusen that behind all the guidelines and treatment targets there is always an individual with his/her own needs. There are many medical devices to treat Type 1 diabetes, she said, 'But, to get the best results, personal education plays an important role. The measurement of blood glucose, for example, only makes sense if the patient can interpret the results and therefore change behaviour. If patients do not know what to do with the results, they lose the interest of measuring at all.'

Future technologies, such as direct feedback via a mobile phone, might alleviate those processes in the future. Another point is that, although insulin pens and pumps significantly increase the quality of life of Type 1 diabetics, there still is a lot to learn – from patients and physicians. According to Sari Härmä-Rodríguez many healthcare professionals do not know, for example, how to use and recommend insulin pumps.

Whilst that can be solved by education, in the future an artificial pancreas could become an option for diabetics. However, despite efforts, a healing option for Type 1 diabetes is not on the horizon. As long as no potential weapon is found, diabetes remains a huge psychological burden. 'Type 1 patients suffer twice as much from depression as healthy people and often have severe eating

disorders as well as cognitive dysfunctions. Additional mental stress is caused by the omnipresent fear of hypoglycaemia and other phobic disorders as well as by social aspects like restrictions in working and private life,' the Finnish expert explained, imploring colleagues to provide psycho-social support to avoid a diabetes-burnout.

She also appealed for a re-think on adult diabetics' education and use of peer-support and personal coaching methods: 'Adults have a long history of the disease, have lived many therapy options and tried a lot of therapy approaches. So, during their lifetime, they develop a kind of education resistance that only can be overcome by a personal and individualised coaching.'

In his lecture, John Nolan, Professor for Endocrinology and Biochemistry at Trinity College, Dublin, Ireland, supported her: 'In the first line, diabetes treatment should fit to the patient -- even more important because expenditures for the illness will soon overcome national health budgets. In the near future, approximately 10% of the population will be affected by diabetes. Those figures will definitely have a strong impact on the extent and continuity of care,' he explained, pointing out that Type 1 diabetics will be hit even harder from budgetary cuts because, due to the predicted diabetes epidemic and global awareness of type 2 patients, they will slip out of focus.

Urging lobbyists and politicians to create a balanced awareness of both types and that consistent guidelines



Sari Härmä-Rodríguez



John Nolan

be established, he said: 'Only half of all EU-member States have a national diabetes plan, so I request all parties involved – from patients to caregivers – to fight for their rights and urge governments to support a national plan.'

Angus Forbes, Professor for Diabetes Coaching and FEND-Chair of Diabetes Nursing, Great Britain, echoed the need for coaching: 'The current diabetes epidemic has the power to cave in healthcare systems across Europe, destabilised recent advances and negatively affect future developments. A huge challenge for care providers will be to develop evidence-based approaches that will feed this need.' Such approaches must be more efficient and more effective models to support behaviour and diabetes self-management. He also sees the need for a more personalised therapy and suggested a shift from the average person to the individual: 'Treatment needs to be more selective and targeted. This includes a huge challenge for nurses, because models of care will become far more complex and, in future, there will be a greater complexity in decision-making. There will be more therapy options to choose from, a wider metabolic management, the consideration of obesity management etcetera.'

Solving this dilemma, Prof. Forbes concluded, will mean improving primary prevention, self-care support and the care system as a whole.

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## 27th Korea International Medical + Hospital Equipment Show

More than 1,200 companies from 35 countries and 60,000 visitors from well over 80 countries are expected to fill-up 36,000 sqm of exhibition space in KIMES 2011

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This October, the millennial Goslar, a picturesque half-timbered town in the Harz Mountains in Germany, hosted the first European Scientific Symposium on Applied Cryobiology. What do the 50 participants from Europe and the USA want? A thousand years of healthy life.

On the table for discussion was the current state of cryonics, a branch of physics and physiology first described 1962 by American physicist Robert Ettinger: 'No matter what kills us, whether old age or disease, and even if freezing techniques are still crude when we die, sooner or later our friends of the future should be equal to the task of reviving and curing us,' he wrote in his privately published book *The Prospect of Immortality*. Since 1977, when he hung his own mother in a home-built refrigerator, Robert Ettinger has been considered the 'father of cryonics'.

The first speaker in Goslar, Ben Best, runs the Cryonics Institute (CI) near Detroit, Michigan. He defines cryonics as 'the practice of preserving legally dead humans and animals at cryogenic temperatures in the hope that future science can restore them to healthy living'.

The CI has 96 clients stored in tanks filled with liquid nitrogen. The Alcor Life Extension Foundation, in Scottsdale, Arizona, a non-profit organisation like CI, has 98 patients, and KrioRus in Alabushevo, near Moscow, Russia, the first provider outside the USA and the first commercial one, has 12 frozen clients. If civilisation endures, all of these have been guaranteed unfrozen at the time of

their choice – although no one can be sure of re-animation.

Nonetheless, over 1,400 people worldwide have signed and paid for a contract as future clients. Former professor of anatomy Klaus Sames is among them. An initial cost of US\$1,250 bought him a lifetime membership of the Cryonics Institute. On the day he dies a further US\$28,000 dollars is due for his long-term storage, at -196°C, in the cryostat. It is a long and expensive route from his home in Senden, near Ulm in southern Germany, to the CI in Clinton Township near Detroit, Michigan. Nevertheless, Prof. Sames is not worried; he knows the effort and cost because he has already accompanied patients on that particular final journey. 'A term life insurance is an effective way to cover all these costs', he said.



Cryostats, filled with liquid nitrogen, store patients at -196°C. The world's biggest cryostat (not shown) can hold 14 people

However, the professor has real concerns regarding the effectiveness of preparatory steps for that trip: today's technique of whole body preservation is ultimately the most crucial point: Cells must be protected from destruction by necrosis and apoptosis; brain cells in particular are highly sensitive. To avoid damage as much as possible, while cooling, ice formation in cells and tissues must be prevented. Therefore,

# CRYONICS

## An ambulance travelling through time – or the coldest grave ever?

Who has not dreamt, at least once, of living in future times? Who would not wish that a cure for one's own incurable disease might be discovered in the future? Long-time cryopreservation immediately after death is a betting ticket for that future winning goal. EH correspondent *Holger Zorn* reports on the first European Scientific Symposium on Applied Cryobiology



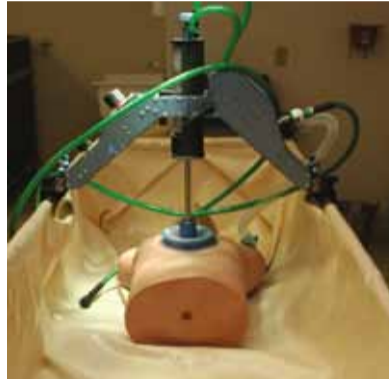
the neck or femoral vessels are cannulated, an extracorporeal circuit is established and the blood completely replaced by an antifreeze solution. This vitrification process leads to an amorphous, glass-like structure of body liquids. However, this process is also the most unsolved problem at present: the Circle of Willis, a connection of cerebral arteries that allows blood to take a detour on its way to the brain if one artery is clogged, thus helping to prevent a stroke, is the reason why it cannot be determined with certainty whether the vitrification solution has really reached all areas of the brain and washed the blood out completely.

### A race against the clock

Marcus Beyer, computer scientist and chairman of the German Society for Applied Biostasis, put it this way: 'Necrotic brain cells definitely can't be repaired with present technologies, though people waiting in liquid nitrogen are usually not in hurry.' However, even for him, time is the biggest enemy. Vitrification should begin as soon as possible, which is why he wants to generate more understanding and tolerance among physicians, patients' relatives and among the legislator, regarding why patients choose today's premature cryonics procedures to be applied upon them.

Christoph Meissner, forensic physician at the University of Luebeck, explained: 'Only if reliable signs of death can be observed is a death certificate issued by a physician. And those signs occur at earliest 1 – 2 hours after death.' According to the German Code of Criminal Procedure, a public prosecutor must be called by law if there are any hints for an unnatural death. In the United Kingdom there an autopsy is always necessary; by contrast, in France this is very rare – and one physician is enough to sign a death certificate. 'We fight for the right to die because we want to live afterwards,' he said, summarising the problem.

The easiest way today to solve that time problem is an alternative route: staying during the last days of life close to the chosen cryonics provider. Alternatively, EuCrio, a



Ice bath with dummy, ventilation tube, and continuous compression CPR device. Because lengthy time might elapse between a patient's death and its official affirmation, the mechanical ventilator and continuous compression CPR are to keep blood flowing until vitrification can begin

Portuguese start-up company based in Braga, launched in October, and begins in November, the provision of Europe-wide standby support and transportation.

Pre- and peri-death support is particularly needed in the period between death and its official statement: blood must flow through vessels and organs to ensure the oxygen supply of organs until the extracorporeal circuit can be established and the vitrification solution can start.

**Robert C W Ettinger** – widely regarded as the father of cryonics – celebrated his 91st birthday in January 2010.

When he dies his body will be frozen and stored – just like the bodies of his mother Rhea and his two wives, Elaine and Mae, who have been 'put on ice' inside giant freezers stored at The Cryonics Institute's 7,000 sq. ft. warehouse, not far from his home in Clinton Township, Michigan. There, deeply frozen in liquid nitrogen and lying in sleeping bags within fibre-glass cylinders, all four will await future resurrection. They are not alone – about a hundred other humans as well as family pets are also on hold.

Born in 1918, Robert Ettinger had developed a love of science fiction well before his 10th birthday. When about 13 years old, he was affected by reading *The Jameson Satellite* by Neil R Jones, which featured a millionaire who, after death, sent his frozen body into outer space and, millions of years later, was revived by alien mechanical men who placed him in a robot body like themselves, to live forever.

Later, studying maths and physics, Robert Ettinger became a college teacher, but his interest in the concept of freezing a body for immortality continued. In 1962, when in his early 40s, he self-published *The Prospect of Immortality*, a non-fiction book that explained in detail the methods and rationale for cryonics. This helped to

The members of national cryonic clubs may help one another, for example existing teams of volunteers in UK, Finland and Germany. However, David Styles, CEO of EuCrio, believes the time is right for professional service, even if clients must calculate additional costs from €45,000 up to €119,000. Trained teams will then come to the client with a mechanical ventilator and a continuous compression CPR device, a full arsenal of drugs and a portable dry-ice tub. Thus prepared, any delay – for example due to the absence of a coroner – can be avoided and the dead client may well-cooled shipped to Ben Best's Cryonics Institute or any other provider of his prior choice, to be stored there at -196°C until the desired de-freezing day.

### Betting on the future

When that day comes, the cryonauts hope, with will be thawed out and brought back to life, and damages are so much less, the mind so clear that they know it and enjoy their new lives.

Actually, no proof of this concept yet exists, neither for human nor other animals who are not hibernators. Prof. Sames can only refer to a vitrified and then successfully transplanted rabbit kidneys, published by Gregory M Fahy in 2009 [Source: *Organogenesis* 5;3:167-75] but never repeated by other teams and, he adds: 'We know that the ideal vitrification solution has not yet been found'. The professor is counting on medical progress that will bring a solution as well as develop rejuvenation technologies – very important for all cryonauts because, of course, they won't come back as old people with all their age-related disabilities and diseases. Certainly they have nothing to lose – except a little money, if this never works – but might win everything.

And so ends the first scientific symposium on cryonics in Europe with the hope of most participants that it will not last a thousand years before this future arrives.

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The trade fair will be opened by Markus Söder, Bavarian State Minister of the Environment and Public Health.

The Hospital Build Europe trade fair and congress aims to provide exhibitors and visitors from across Europe with a new and engaging platform.

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'The event will definitely have an impact in the health care policies worldwide,' the IHF forecasts.

Details: <http://www.ihfdubai.ae>