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EUROPEAN HOSPITAL

EUROPEAN FORUM FOR THOSE IN THE BUSINESS OF MAKING HEALTHCARE WORK

Including EuroMedLab highlights!

One third of German hospitals are in the red

Government grants €1.1 billion to help finance rising personnel costs and increase nurses specialists in infection prevention and control

Report: Brigitte Dinkloh

The closure and consolidation of German hospitals over the past few years was a politically endorsed and necessary act to cut back on over-capacities and inefficiencies in the healthcare sector.

Hospitals were confronted with an ever increasing number of cuts and limitations, to an extent where even university hospitals and formerly profitable clinics are now sliding deeper and deeper into the red, without being able to do anything about it.

Thus, for quite some time, there has been resistance from German hospitals and among their 1.1 million employees against that policy.

The German Hospital Federation (DKG) is vehemently fighting developments – with one campaign under the banner All of us are the Hospital. 'When around 700 out of 2,000 national hospitals treating around six million patients and with 300,000 employees affected, are in the red, then this is a problem of national importance, which does not permit further cuts and must be addressed quickly,' Alfred Dänzer, President of the German Hospital Federation, emphasises.

Structural underfunding

Mark Schreiner, head of European Politics and Healthcare Industry at the DKG, sees several specific factors that place a financial strain on hospitals. 'There's a problem with structural under-funding, such as the coupling of cost increases in the hospital sector being linked to the cost orientation rate, insufficient financial investment in hospital infrastructure on the part of the Bundesländer, increasing bureaucratic expenditure, and legal cutbacks,' he explains.

During the 16th legislative period (2005-2009) the German legislator decided to replace the basic wage with a cost-oriented rate, but this change of paradigm, envisaged for 2013, has yet again been postponed.

The cost-orientation rate is determined by the Federal Statistical Office and shows what general cost increases are on the horizon, while the basic wage rate shows the average increase in agreed wages. Although 60% of hospital costs are personnel related, there are further cost drivers, such as increasing energy costs resulting from the German Renewable Energy Act contribution and also the increased bureaucratic expense caused by documentation obligations, along with increased expenditure on liability and investments. 'These costs exceed the maximum level of cost increases that the hospitals were allowed, based on the cost orientation rate by far,' Mark Schreiner points out.

The DKG's message in a campaign poster

Because the way in which diagnosis related groups (DRGs) are financed does not cover all costs, right from the word go there are funding gaps that hospitals must offset through more efficient economic operation and an increase in the volume of individual services provided. Mark Schreiner is optimistic that, with the help of a revised cost orientation rate, in the future it will be possible to show more realistically the price increases that must be set with health insurers. 'We expect an improvement in the financial situation and are optimistic that the revised cost orientation rate will soon be set. The reserves of around €30 billion built up by the statutory health insurers are unlikely to be structurally affected by this,' he points out.

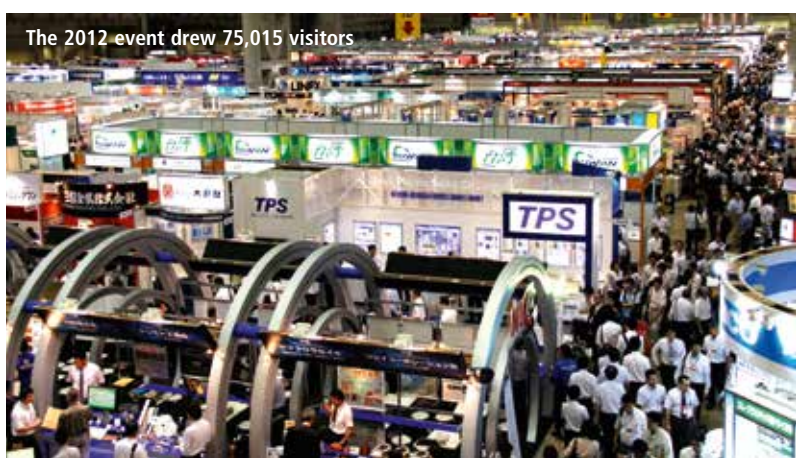
He sees the Bundesländer's lack of investment as far more severe. With Germany's dual financing system, where health insurers finance treatment costs and the Bundesländer finance infrastructure costs, an investment backlog runs to billions of euros – certainly a double-digit figure. Comparison: Whilst the national rate of investment is 18.2%, the figure is only 4.4% for the hospital sector. 'This is demonstrably

Mark Schreiner, DKG

Continued on page 3

19-21 June 2013 – Tokyo, Japan

Manufacturing World Japan 2013



The 2012 event drew 75,015 visitors

Manufacturing World Japan 2013, one of the world's largest manufacturing exhibitions, is a collective name for four different shows – the 17th Mechanical Components & Materials Technology Expo (M-Tech), 4th Medical Device Development & Manufacturing Expo (MEDIX), 24th Design Engineering & Manufacturing Solutions Expo (DMS), and the 21st 3-D & Virtual Reality Expo (IVR).

With such a broad range of manufacturing technologies and virtual reality products, this event has been attracting, year-by-year, increasing numbers of end-users and professionals. In June last year the show received 75,015 international visitors. This year, with 2,000 exhibitors booked, 77,000 visitors are expected.

Reflecting trends, the 7th Mechanical Components & Materials Technology Expo 7th Mechanical Components & Materials Technology Expo (M-Tech) and the 24th Design Engineering & Manufacturing Solutions Expo (DMS) will have new fairs and zones – another strong attraction this year, according to the organiser Reed Exhibitions Japan Ltd.

www.european-hospital.com

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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 ☒ in the relevant boxes.

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☐ General hospital ☐ Outpatient clinic ☐ University hospital

Specialised hospital/type

Other institution (eg medical school)

2.YOUR JOB

☐ Director of administration ☐ Chief medical director ☐ Technical director

Chief of medical department/type

Medical practitioner/type

Other/department

3. HOW MANY BEDS DOES YOUR HOSPITAL PROVIDE

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

☐ None, (not a hospital/clinic)

4 . WHAT SUBJECTS INTEREST YOU IN YOUR WORK?

☐ Surgical innovations/surgical equipment
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☐ Ambulance and rescue equipment
☐ Physiotherapy updates/equipment
☐ Nursing: new aids/techniques
☐ Hospital furnishings: beds, lights, etc.
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☐ Linens & laundry
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ESPECIALLY FOR DOCTORS:
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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

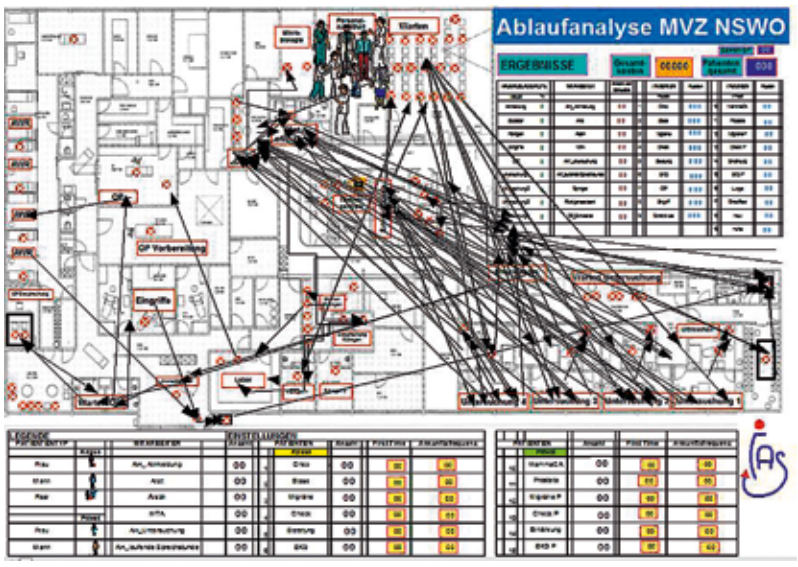
Do you attend congresses or similar meetings for your speciality? ☐ Yes ☐ No

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 2/13

Econometric 5-D hospital modelling optimises workflow

Multi-dimensional planning is the future



Visualisation of geometric structures as the basis of the actual data simulation

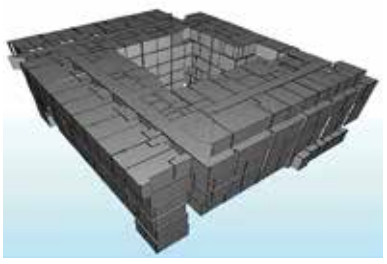
Hospital refurbishment or new buildings can quickly run into several million euros. Thus financial managers first need to assess whether theoretical plans realistically marry with future practical needs in daily hospital life, such as best patient care, resources and utilisation, avoidance of down and waiting times, under and over capacities, and whether the project will pay off. 'With all these considerations, a simulation of treatment processes, using a virtual building model, can help,' says Dr Michael Küpper, MD of M+management GmbH in Munich, a firm offering this procedure. Computer modelling facilitates various models and opportunities being run through until the best solution is found.'

What if?

The computer simulation proceeds according to the VAO method: Visualising, Analysing, Optimising. Parameters such as patient and staff facilities, operating theatres, recovery and waiting rooms, beds, equipment etc. are modelled onto a scaled plan of the new building. Using special tools, the typical processes, times, durations and costs are defined and distances are traced in the model. External data, such as examination and surgery times, work rotas, appointment diaries, and more, can be accessed via an interface. These parameters are then animated and simulated using the hospital data. Initially, the result is a realistic evaluation of the status quo. Potential problem areas and weaknesses can be recognised and compared with reference data.

The procedure

1. Objectives and target figures are determined and processes analysed
2. The relevant patient groups and their movements are recorded with the corresponding data through talks with doctors and nurses
3. Data preparation (new data collation or adaptation of existing data through clustering for instance)
4. Visualising, verifying and validating of actual processes in flow diagrams
5. Creation of simulation models
   a. Animated simulation of actual situation
   b. Animated simulation of target situation with actual processes
6. Workshop on fine tuning of processes and results – identification of optimisation approaches
7. Data transfer into an abstract space and function programme
8. Adaptation/optimisation of layout planning
9. Creation of optimised simulation model in a 3-D building model
10. Animated simulation of the new target situation with target process to check spatial planning (of existing versions)
11. Animated simulation of different future scenarios, such as with increased patient numbers



A 3-D building model of the day clinic after process optimisation with building costs 15% lower compared to the original plan. Source: M+management GmbH

Example: Planning a day clinic construction

Patient processes are established in the shape of swim lane flowcharts, where the competencies and rooms are shown. Patients requiring the same type of procedures were clustered. The processes shown were transferred to the planned layout of the Day Clinic and entered into the simulation model (diagram 1). Evaluation of the simulation, based on the actual data, confirmed the real, existing waiting times for patients as well as the capacity of rooms on one working day.

Increasing resources did not result in further improvement. However, optimisation led to a significant increase in patient stays and waiting times. The average patient's stay in the clinic can be cut from almost three hours to 35 minutes. The new building should also be able to cope with patient numbers increasing by 15%, as seen in recent years. This is why the preferred type of planning was an approach where computer simulation ensured that the planned geometric structures, as well as the number of resources required, harmonised with the processes.

A simulation model with actual processes was designed based on a revised construction layout with the affected functional areas. (See diagram 2 for result of simulation run with the target data.) Thus it was possible to cut staff movements by around 50%, and running costs could be reduced due to cutting down on excess capacities.

Geometric and functional structures in the building data model

Changing target values (patient numbers, waiting times, room sizes, resources utilisation) results in prioritisation of the spatial allocation of floor space in the computer model. The objective: Reducing distances and staff movements, patient waiting times, increasing throughput and cutting down on facilities required. In this way, staff movements in the day clinic were cut from 85km a day to 40km a day, equipment utilisation was increased from 65% to 85% and the energy requirement was cut from 380kWh/m2 to 260kWh/m2 a year.

The implementation of the target result data (target values) and the surface space from the room and function programme into a digital building model facilitated the calculation of building costs required for planning and running costs. As a result of the optimised space and creation of efficient geometric structures, building costs for the current example were reduced by 15%. 'Planning a building on a digital, virtual model puts an end to half-knowledge and isolated solutions. Our solution is a central data set with all relevant data used to design and run a building holistically, economically and with a look to the future. Multi-dimensional planning is the future – and nothing is as sure as the future,' explains Dr Klaus Kühn of M+management GmbH the 5D Hospital model.

Details: www.mplusmanagement.de

After studying architecture in Stuttgart, **Dr Michael Küpper** became a planner in architecture practices in London, Hamburg and Munich.

Since the mid-1990s he has focused increasingly on hospital planning, initially as a freelancer for project management in hospital construction for a Munich engineering firm.

In 2000 he became a Managing Partner of M-management GmbH, which specialises in healthcare projects.

Whole-body ultrasound emerges in critical care and emergency medicine

Beyond FAST!

Loading high performance functions on highly portable ultrasound systems puts life-saving tools in the hands of trauma physicians, John Brosky reports.

Scanning the entire body of a trauma patient has proven critical for detecting unseen injuries and whole body CT scans are routinely performed in emergency departments – when available. Thus physicians are increasingly turning to the always-ready, easily accessible and more affordable ultrasound systems for a rapid, yet comprehensive assessment of injured patients. 'I'm a pre-hospital physician and ultrasound enables me to detect and even treat a patient on-site, in his apartment, even in the car at the accident scene,' explained Dr Tomislav Petrovic, from the Urgent Ambulatory Services 93 group (SAMU) 93, which covers the North-Eastern Paris suburb of Seine-Saint Denis from the Hôpital Avicenne in Bobigny.

'Looking at a patient you can see a particular area of concern, but ultrasound allows you to rapidly look beyond this to conduct a wider, holistic assessment of how the patient's system is reacting to the trauma,' he said, however adding that the examination does not replace a CT scan. Instead, 'the advantage of ultrasound is you can do it right now at the point of care.

'Physicians no longer consider ultrasound as complementary examination,' he pointed out. 'It is going to be completely integrated in the physical examination where physicians use their hands, ears and eyes to gather all signs on patient.' Ultrasound becomes an extension of the physician's eyes just as the stethoscope amplifies the observational power of the ears, and the ultrasound probe is becoming as familiar as the stethoscope in routine examinations.

'Ultrasound can change not only the diagnosis but also the treatment and final orientation of the patient,' he said. 'This is what we call Critical Ultrasound, and this is what we are increasingly doing in emergency departments today.'

Ultrasound won a valued role in emergency with the focused assessment with sonography for trauma (FAST) rapid exam to determine if there is blood or liquid around the heart or abdominal organs. Originally called focused abdominal sonography for trauma, the exam was upgraded as a fuller assessment as physicians recognised the probe could also visualise injuries in the thorax well before a CT scan, detecting inter alia an otherwise occult pneumothorax, a deadly complication if not treated immediately.

Dr Petrovic said that, thanks to advanced capabilities available on portable systems, ultrasound is now being applied beyond the extended FAST (eFAST) examination to cover the entire body. 'A patient is not just an abdomen or a thorax, and a physician's focus is not just the immediate disease but the whole patient,' he explained. 'In many cases, ultrasound allows the physician to instantly go from saying, I don't know what to do, to saying I know and I will do.'

A classic case, he said, is the patient who arrives in the emergency department complaining of chest pain. If a physical exam complemented by an electrocardiogram (ECG) shows there is an acute myocardial infarction, the patient is immediately selected for reperfusion, whether chemical (thrombolysis) or mechanical (angioplasty).

What happens more often, he said, is that neither the physical exam nor the ECG are conclusive. 'Here you do not know what is happening and an ultrasound exam can rule in or rule out a range of pathologies, whether cardiac, pulmonary, or forensic,' he said. 'We often see cases where a patient had a thorax injury (e.g. fall off his bicycle) several days before and simply does not remember to mention it,' he explained. 'Now he has a chest pain. With ultrasound we can visualise a fractured rib or sternum. We can see if there is any pneumothorax or pleural effusion, which are not always visible on a chest X-ray.'

There are ultrasound exams used to assess bone fractures, especially for long bones and flat bones, he said. More recently transcranial Doppler also became available to assess blood flow in the brain for cranial trauma 'immediately, while we can do things to improve the survival of the patient, rather than waiting three or six hours to insert a device to measure intra-cranial pressure. This is point-of-care ultrasound and it's not a one-shot image,' he emphasised, contrasting it with ultrasound performed in the radiology lab that he called 'out-of-care' imaging, where a patient is transported and left for a specialised examination.

'At point of care, at the bedside, in a hospital or at a trauma scene, we may look at the chest, then a cardiac exam, certainly some abdominal, perhaps lower limb veins,' he said, adding that systems offer functions such as TM mode, colour Doppler, pulsed wave or continuous wave Doppler. 'These are focused exams, designed by ER physicians, with a precise protocol to give actionable information in a few minutes. For example, I don't need to know which organ is bleeding in the abdomen; I need to know if there is haemorrhage.

'When I place the probe I get the information I need, telling me if I need to send the patient directly to the operating room or not, if there is time to send him for a CT scan, or some other test to know more precisely what is happening.'

Dr Tomislav Petrovic examines a patient in an ambulance. Using a laptop-size ultrasound device the pre-hospital physician can gain an inside view of how the patient's system is reacting to the trauma.

Tomislav Petrovic MD, emergency physician and specialist in pre-hospital critical care, is a passionate advocate of training and education to integrate ultrasound as a tool to assess and monitor the care of patients.

From 2011-2012 presided over WINFOCUS, the World Interactive Network Focused On Critical Ultrasound, a professional society dedicated to improving primary, emergency and critical care medicine with ultrasound. He is also a contributing editor for *Critical Ultrasound Journal* and a regular speaker at congresses worldwide.

German hospitals

Continued from page 1

not sufficient investment funding. Last year alone, expenditure fell by another 1.4% to €2.7 billion. We can see a political to and fro between the Federal government and the Länder, with both sides reminding each other of their responsibilities.'

Therefore, in many hospitals there is a trend to fund investments in infrastructure out of their own pockets, thus also increasingly saving on labour, which pushes the remaining staff to the limits of their capacities. 'An increasing number of hospitals have their backs against the wall. We need more financial means to invest in staff and we need reliable investment funds,' demands Mark Schreiner, speaking on behalf of the German Hospital Federation.

Government grants cash injection

This request appears to have been partly granted: On 7 April the Federal Cabinet decided on a cash injection of €1.1 billion for hospitals for this year and the coming year to help finance rising personnel costs and additional infection prevention and control nurses.

Deficits caused by hospitals treating more patients than agreed are due to be offset by a new allowance. However, Daniel Bahr, Federal Minister of Health, who continues to put the onus on the Länder governments, said: 'I appeal to the Länder to also meet their obligations to fund investments.'

19-13 May. Milan, Italy

EUROMEDLAB 2013

This May, the futuristic Milano Convention Centre MiCo will open its doors to participants in the 20th IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine (EuroMedLab), organised by the Italian Society of Clinical Biochemistry and Clinical Molecular Biology (SIBioC), along with the 45th Congress of the Italian Society of Clinical Biochemistry and Clinical Molecular Biology (SIBioC).

Congress President Professor Mauro Panteghini, from the biomedical sciences and clinics department at Milan University, has announced that the IFCC-EFLM Organising Committee has arranged seventy-two scientific sessions involving approximately 200 outstanding international speakers, for '…this prestigious event, which represents the most important European meeting in this field.

The Scientific Programme Committee, in cooperation with the International Scientific Advisory Board, took consierable care to prepare a high-quality and varied congress programme, which incorporates the latest developments and ideas in the field of Laboratory Medicine to be presented in the form of Plenary Lectures, Symposia, and Educational Workshops.

Additionally, seven pre- and post-congress Satellite Meetings will be organised in different beautiful venues, located in Italy and in the surrounding Countries. A large exhibition of diagnostic products will also be hosted at the congress location.'

Young scientists have been particularly encouraged to attend the IFCC-EFLM congress and present their research, he continued. There will be bursary programmes and several poster awards to further support their presence.


Mauro Panteghini

On a different note, music lovers are in for a treat: During the Opening Ceremony the Orchestra Sinfonica di Milano Giuseppe Verdi (Giuseppe Verdi Symphony Orchestra of Milan), which refers to itself as La Verdi, will be performing.

A further treat will be the Congress Party held in the unique Castello Sforzesco (Sforza Castle). Constructed in the 14th and 15th centuries, this impressive residence for the Duchy of Milan, which included 26 towns and a massive rural area. As such, the structure is one of the biggest citadels in Europe, and it not only houses several museums and art collections but also has ceilings painted by Leonardo Da Vinci.

Milan is justifiably proud of its city's offerings, with the addition of EuroMedLab Milano 2013.

Details: www.milan2013.org/

Point of care testing

Demand is increasing for point of care (POC) diagnostic testing, particularly for tests that help foster clinical decision-making within 30 minutes or less. Laboratory-quality test results (once only obtained via the central lab) are now available directly in doctor's surgeries, outpatient clinics and within hospital departments. Thus it's no surprise to see a significant expansion of POC testing utilisation in critical care and chronic disease management situations, *says Dr David Stein*

In critical care environments, POC tests are helping physicians to make life-saving decisions within minutes, not hours. The ability to quickly and accurately assess troponin levels, measure pleural fluid pH levels, or rule out pulmonary embolism are just a fraction of the critical care tests now available that can be conducted near the patient.

Another example is lactate testing for lactic acidosis (or abnormally high acidity in the blood). Frequently seen in critically ill patients, lactic acidosis has a number of potential causes, including shock, diabetes,

Strategic lab control

Aiming to set up ordering standards in the context of reasonable ICDs/DRGs

Report: Michael Reiter

Managing physicians' test requests is a key ingredient of modern lab management. However, doctors and nurses still do not provide the clinical reasons for orders to all labs. As Professor Ralf Lichtinghagen, specialist in Laboratory Medicine in the Department of Clinical Chemistry at Hannover Medical University, Germany (MHH) explained during the German Society for Clinical Chemistry and Laboratory Medicine (DGKL) congress, 'Communication that accompanies samples merely covers profiles for tests. However, by analysing ordering behaviour, hospital laboratory managers can identify whether certain tests make clinical and economic use for certain ICDs or DRGs.'

The data platform used for his research is data collected by hospitals for the Institut für das Entgeltsystem im Krankenhaus (InEK), a body driven by payers and care providers, which optimises German DRGs.


Ralf Lichtinghagen MBA heads the School for Medical Technical Assistants at the Clinical Chemistry and Laboratory Medicine Department, Hanover Medical University

This pool of transparent information includes the ordering physician, respective DRG, length of stay, etc., and enables retrospective analysis aimed at a multitude of relevant issues, such as optimising ordering behaviour. In a drive to benchmark ordering behaviour, Prof. Lichtinghagen's team examines average numbers of tests ordered for each ICD/DRG, and creates basic profiles: 'Our plans are to set up ordering standards in the context of reasonable ICDs/DRGs'. Such standards may well result in reduced time required for therapy and in improved patient outcomes in cases where suitable tests are not ordered, or where orders are initiated with a delay. They may also serve to reduce cost by care providers in cases where benchmarks show that tests are not required.

Implementing expertise

'Based on information we extract from InEK data, we plan to enter into discussions with our clinical peers. This collaborative approach, backed by top management, enables us to pass on expertise about the suitability of tests for individual cases. This,' the professor explained, 'supports visibility of lab staff in the hospital community and the prestige of laboratory medicine.' The subsequent phase includes change management with regard to long-term implementation of evidence-based expertise into workflows and pathways.

The PDCA cycle

'Plan, do, check, act' is the implementation approach Prof. Lichtinghagen envisages for MHH. The university hospital may not be a typical care provider due to the complexity of disciplines needing lab results – including virology, microbiology, clinical chemistry, haematology, immunology, etc.

Taking a first look

In an environment where, out of 60 ordering physicians 80% of test requisitions come from around 14 peers, examining ordering behaviour appears legitimate. Analyses help to answer questions such as *'Which of the many DRGs generate the largest number of tests?'* Prof. Lichtinghagen aims to create a platform for diagnostic pathways, which, for a given symptom such as thorax pain, will produce suggestions for a set of lab tests. 'We hope to turn this concept into reality in a few years,' Dr Lichtinghagen predicts. Medical controllers and the hospital's management show great interest in this project.

A DATE FOR THE DIARY

23-26 October 2013. Dresden, Germany

The German Society for Clinical Chemistry (DGKL) Congress

Details: www.dgkl2013.de

Swiss labs are pushe

Infectious

Switzerland treads softly when it comes to governing its 26 independent-minded *cantons*. Yet, when it comes to electronic medical records, the Ministry of Health holds a particular power, not to dare to direct policy inside any canton, but for the exchange of data between the cantons

A small point is taking on increasing importance for clinical laboratories.

Beginning in January 2014, the Ministry will continue to allow labs to send results in paper form from clinical tests of some 50 pathogens, but it has set a single format for the delivery of these results electronically based on HL7 messaging language and an interface defined by profiles developed by *Integrating the Healthcare Enterprise* (IHE).

Typical of the Swiss, it is a gentle push, but an insistent one, as the Ministry progressively moves the country to a national framework for the digital exchange of medical data.

liver disease and sepsis. Although generally considered a nonspecific biomarker, knowing lactate levels early in a patient's presentation can provide valuable information and open a critical window for intervention when treatment is most likely to be successful.[1] Lactate testing at the point of care can be particularly useful in intensive care and the emergency room, where the presentation of symptoms may be inconclusive.

For chronic disease management, POC tests are helping to save valuable time by consolidating patients' visits, because physicians can now immediately review results and discuss necessary adjustments to treatment plans for a number of chronic diseases, such as diabetes, hypertension and cardiovascular conditions.

Notably, in-office diabetes testing is expanding. While historically, HbA1c testing has been commonly used to manage diabetes patients, more recently the medical community has recognised its clinical utility in the disease's diagnosis, with convenience cited as a significant patient advantage.

For example, HbA1c testing can be conducted at any time and requires no patient preparation, unlike fasting plasma glucose (FPG) measurements, where it's necessary to fast at least eight hours prior to testing. Also, only a single measurement is needed during HbA1c testing, as opposed to blood glucose testing, which involves serial blood draws over several hours. Recognising the value to physicians and patients, Siemens recently made its DCA HbA1c test kit (#: 10698915. Not available in all countries), which has been used for years as an in-office tool for monitoring diabetics, available as an aid to diagnose diabetes and identify people at risk of developing diabetes.

As POC testing continues to evolve, physicians and POC coordinators are helping us identify additional areas where it can be applied, including chemistry, immunoassay, haematology, and, in particular, coagulation testing. The ability to quickly deliver lab-accurate PT/INR results to clinics and physician offices is an important component of optimal patient care, and we plan to offer a new and innovative handheld device later this year to help address this need.

But the value of laboratory-quality POC testing goes beyond clinical application. The growing prevalence of health networks – comprised of hospitals, clinics and physician offices – increases the need for standardisation of test results across different locations. For example, a urine test result needs to correlate across multiple sites within the health network, regardless of whether the test was administered via a portable device in the physician's office, semi-automated device in the clinic, or on a hospital's fully automated analyser in the core laboratory.

We also anticipate more demand for smaller, easier-to-use devices that provide seamless connectivity throughout hospitals and health networks. Clinicians and POC coordinators will increasingly want to work in a POC Ecosystem – an environment that enables the ability to remotely access and monitor patient status simply, quickly and securely while centrally managing multiple devices to help standardise procedures, facilitate compliance and improve risk management.

David Stein PhD is CEO of the Point of Care (POC) Business Unit for Siemens Healthcare Diagnostics. He is responsible for the long-term global strategy and business planning, strategic marketing, product and brand management and product development for all existing as well as new POC products and solutions.

ed to report digitally

s diseases

In 2012 there were 180 labs in Switzerland that conducted some 80,000 tests for the infectious diseases on the Ministry's watch list.

Electronic reporting, it argues, holds great advantages over the current system where paper reports are sent to both the canton health authorities as well as the Ministry. For example, a clinical lab that complies with the new interface for sending the report electronically needs only do so once. The Ministry will then share this report with the canton where the report was generated, thus saving manual transmission costs and streamlining the national alert in the event of a dangerous or new pathogen being identified.

The electronic system has the potential to greatly improve infectious disease surveillance in Switzerland, according to Tony Schaller, technical project manager with IHE Suisse.

This is a significant step toward standardisation, he said, effectively giving the new framework the force of law

Cancer has a smell and breathprint

Research: Scientists have developed the NA-NOSE cancer breath-test whilst others seek to pinpoint those most at risk of developing the disease

Doug Easton

Hossam Haick is Professor of Chemical Engineering and Nanotechnology and Head of the Laboratories for Nanomaterial-Based Devices (LNBD) and Volatile Biomarkers at Technion, Israel Institute of Technology

Ros Eeles

Paul Little is Professor of Primary Care Research at the University of Southampton. Previously a general practitioner for 20 years, he was the first GP to be awarded a Wellcome HSR training fellowship (for health promotion research) and the first to receive an MRC Clinician Scientist Fellowship (for common self-limiting illness research). His current focus includes enabling behaviour change for health professionals and empowering patients.

Harpal Kumar

Report: Mark Nicholls

Israel - Researchers are using breath-test technology to detect volatile organic compounds to tell whether a patient has stomach cancer. Although still in early development, and yet to be clinically tested on a wider scale with bigger studies, the test is showing early potential as a new cancer screening tool.

The breath-test technology relies on the idea that the biology of tumours can lead to the production of specific 'volatile organic compounds' (VOCs) – chemical combinations unlikely to be displayed in healthy person's breath.

Based on his successes in separate studies on lung and head and neck cancers, as well as kidney, Parkinson's and Alzheimer's diseases, Professor Hossam Haick from the Israel Institute of Technology – Technion – recently led the team that created a breath test designed to detect stomach cancer. 'The exact composition of the volatile molecules in the breath is different from person to person and contains a lot of information about the individual,' he explained. 'For example, there are differences between men and women, between people that exercise and those that don't, and between young and old people.

All cells, he added, whether healthy or cancerous, constantly emit such VOCs into the blood, and different cells emit different types and/or amounts of VOCs. 'Therefore cancer not only has a smell but, at least, different cancers have different breathprints.'

To detect those cancerous breathprints, the Technion team has developed NA-NOSE, an artificial electronic nose that mimics the canine sense of smell. 'In our electronic nose, the receptors are mimicked by an array of highly sensitive gas sensors,' Prof. Haick explained. 'Like the biological receptors in the mammalian nose, these sensors can each absorb a wide variety of gas or vapour molecules.

'The collective sensing signals are processed by a computer, using a pattern recognition algorithm. But we have to "teach" the electronic nose how to identify a particular smell by controlled exposures in the laboratory.'

The Technion NA-NOSE has high levels of accuracy, he added, with the device achieving 'excellent' discrimination between gastric cancer and benign gastric conditions (89% sensitivity; 90% specificity); and early stage gastric cancer and late stage among gastric cancer patients (89% sensitivity; 94% specificity).

The professor believes the Gastric Cancer breath test could be developed to 'precede and complement' conventional upper digestive endoscopy with biopsy, as a low-price, high-scale, screening tool to identify individuals who should be referred for an endoscopic examination. 'The NA-NOSE approach is totally different from conventional cancer diagnostics,' Professor Haick confirmed. 'It diagnoses cancer based on a change of the blood chemistry and metabolic activity, which is reflected in the chemical composition of the exhaled breath and not on the basis of tumour imaging, thus permitting earliest cancer detection before a tumour of detectable size has formed.'

Following the present study using a relatively small test population of 130, a larger multi-centre clinical trial with increased sample size is being staged to further develop the technique and confirm its potential. However, he is convinced: 'This has the potential to reduce cancer mortality by enabling widespread, trustworthy screening, especially suitable for high-risk populations. The ultimate goal of the NA-NOSE project is to identify cancer volatile biomarkers at the earliest stage possible, ideally at the level of a single cell.'

The technique can be used beyond specialist settings and also for immediate diagnosis of fresh cancer tissues in operating theatres, where a dichotomous diagnosis is crucial to guide surgeons.

Identifying higher cancer risk

United Kingdom - A countrywide major study aims to develop a way to predict which individuals have a higher cancer risk, and also to help improve the referral process patients go through before diagnosis.

Researchers will collect and analyse clinical data and blood samples from 20,000 patients with symptoms that could indicate lung or colon cancer, to try to determine which signs and symptoms are most predictive among those who go on to be diagnosed with the disease.

Co-ordinated and led by the University of Southampton, the study will use patient samples from the eight centres within National Institute for Health Research (NIHR) School for Primary Care Research (NIHR SPCR).

The CANcer DIagnosis Decision rules (CANDID) study will also see genetic testing carried out after the recruitment phase, to establish how much extra information genetics provides over and above clinical information.

Under current NHS targets, family doctors must refer urgent cases within two weeks and within 62 days for other cases. However, there is evidence within the NHS that some patients wait much longer and visit their GPs more than once before being referred.

University of Southampton Professor of Primary Care Research, Paul Little said that while clinicians have a 'reasonable idea' of predictive symptoms from retrospective and smaller studies, until now there have not been any large prospective studies looking at how predictive particular symptoms are for developing cancer. 'We need to improve both the early referral rates for cancer but, at the same time, we don't want to overload the system with lots of people who are at a low risk of having cancer and may have negative side-effects of being over-investigated… Our research aims to aid the patient pathway and help medical professionals, so every patient is dealt with in the most appropriate way and in a timely fashion.'

Results from the £2 million study - funded by the NIHR SPCR - will be available in five years' time and could not only identify high-risk cancer patients but also mean lower risk patients are not over-investigated.

Hospitals and health systems will also benefit from better targeting of referrals reducing unnecessary use of resources.

The genetic causes of cancers

UK researchers have also identified multiple genetic variations that raise the risk of breast, prostate or ovarian cancer in a development that could lead to new treatments and more targeted screening of the conditions

In the largest study of its kind, more than 80 regions of the genome that can increase an individual's risk of breast, prostate or ovarian cancer have been found through international collaborative research. Funded by the European Union, Cancer Research UK and the US National Institutes for Health, the research involved scientists looking for genetic variations called single nucleotide polymorphisms (SNPs), which are linked to an increased cancer risk.

They studied the DNA make-up of more than 100,000 people with cancer and 100,000 people from the general population and found alterations that were more common in people with prostate, breast or ovarian cancers.

While each alteration raises cancer risk by a small amount, the 1% of people who have had a significant number of these alterations could see their risk of developing prostate cancer rise by almost 50% and breast cancer to around 30%.

Study author Professor Doug Easton, from the University of Cambridge, said: 'We're on the verge of being able to use our knowledge of these genetic variations to develop tests that could complement breast cancer screening and take us a step closer to having an effective prostate cancer screening programme.

'By looking for people who carry most of these variations we will be able to identify those who are at the greatest risk of getting these cancers and then targeting screening tests to these individuals.'

Many of the SNPs were near to areas of the genome that control how certain genes behave and researchers say that understanding how these genes are involved in cancer could provide new understanding of how cancers develop and how to treat them.

For breast cancer, the researchers found 49 SNPs, more than doubling the number previously identified and for ovarian cancer, 11 new regions were found, while in prostate cancer, 23 of these genetic variations were identified.

Faults in the BRCA genes increase breast cancer risk

As well as looking for the variations that raise the risk of these cancers, the researchers also looked for the SNPs that may influence how different breast cancers behave and regions that influence the cancer risk of people with faults in the BRCA genes. Carriers of BRCA gene faults are known to be at greater risk of developing breast and ovarian cancers, but it remains unclear which women will go on to develop cancer.

The researchers found that the 5% of women who have a BRCA1 fault, and carry most of the genetic variants linked to BRCA1, have an over 80% chance of developing breast cancer by aged 80 years. Women with few of these variants and a BRCA1 fault have a 50% risk of developing the disease.

Paul Pharaoh, Professor of Cancer Epidemiology at Cambridge University, said that an understanding of risks in individuals who carry the BRCA1 and BRCA2 fault will 'almost certainly' have a clinical significance. He believes that common variant genetic testing will be standard practice in genetic clinics counselling people with mutations in known high-risk genes within 2-5 years.

'Women at very high risk of breast cancer may opt for interventions, such as mastectomy, to reduce the risk, but if we were able to test them and show them that they were at much lower risk, they may choose not to have a mastectomy,' he explained.

Professor Pharaoh said that gaining greater understanding of the inherited genetics for these cancers offers scientists better information about the biology of why people get cancer. 'That's likely in the long-term to lead to improvements in the way we treat cancers. We are beginning to identify molecular pathways that had previously not been indicated, for example in ovarian cancers, that may well provide drug targets.'

Dr Julie Sharp, Cancer Research UK's senior science information manager, described the discovery from the study as a 'really important step forward' and one that provides a wealth of information that experts can start to use immediately. 'It's really important to note that actually one of the first applications of this information will be those people who already have some kind of family history of cancer, and it's those people where we really might start to apply this work first of all, before we start looking at the wider population.'

Professor Ros Eeles, professor of oncogenetics at The Institute of Cancer Research (ICR), added: 'These results are the single biggest leap forward in finding the genetic causes of prostate cancer yet made.'

Cancer Research UK chief executive Dr Harpal Kumar said: 'By understanding why some people seem to be at a greater risk of developing cancer, we can look towards an era where we can identify them and take steps to reduce their chances of getting cancer or pick up the disease in its earliest stages.'

Denmark's top-class robot technology

The world's utmost automated hospital laboratory system is operational

Report: Mark Nicholls

Copenhagen's Hilleroed Hospital now has the world's most advanced medical laboratory system, providing full automation from the point of drawing a blood sample to results delivery. Using world-class robot technology, the system was designed to meet the specific requirements of clinical and laboratory staff to analyse blood samples and deliver results as quickly as possible.

In seeking inspiration for their fully-automated laboratory system, the team from the Department of Clinical Biology visited hospitals in Scandinavia and Japan, where they saw excellent solutions but also noted potential for improvements.

After drawing up quality specifications about the functions they required for their proposed laboratory system, the Hilleroed team invited five major companies to give a presentation on creating a system.

Dr Georg Sölétormos, Medical Director of the Department of Clinical Biochemistry at North Zealand Hospital, which incorporates Hilleroed Hospital, explained: 'We chose Siemens because they offered a flexible and fully-automated system and one that was very user-friendly.'

Prior to installing the Siemens system, he explained, the 6.8 million analyses conducted annually were performed in different hospital areas, wasting time transporting samples, which prompted the department to upgrade its ageing system with the latest robot automisation.

Installed last autumn (opened in January), the system features a blood sample-receiving module connected to two tube transportation systems from the emergency department and the ambulatorium. When a blood sample is taken, it is barcoded, scanned with a handheld computer and sent to the lab via tube, where it is lifted onto a transportation track that registers the sample arrival.

From the output, track samples go to centrifuges, are de-capped and transported to a Centaur XP system, which runs immunological analysis, two Siemens coagulation systems and to three Dimension Vista 1500 Intelligent Lab systems. There is also a tracking aliquoter for samples that need allocation for further analysis. This, the most automated system performs chemical, bio-chemical and immune-analysis, Dr Sölétormos pointed out.

Hourly capacities for each part of the system are: input/output module (800 tubes), receiver unit (1,000 tubes), centrifuge (300 samples an hour if centrifuging for 10 minutes), de-capper (800 tubes), aliquoter (500 tubes). The transportation track can handle 3,600 tubes an hour, each Centaur XP can conduct 240 tests an hour and the Dimension Vista performs up to 500 tests an hour.

In an area with a population of 380,000 people this, the largest lab in Copenhagen, serves the seventeen clinical wards at Hilleroed Hospital, eight wards at a neighbouring hospital, the 'health house' in Copenhagen and 200 general practices in the area.

'What is especially new is that the analytical equipment is all covered in the same system but integrated with different IT solutions, so the results are directly delivered to the clinical ward or general practitioner through the IT system,' Dr Sölétormos added.

Full automation, from sample taking to results delivery, cutting time by at least 50%, means quicker patient treatment, also with fewer faults through greater automisation and integration with the IT system. 'Our goal is for 85-90% of our production to be delivered within an hour,' he said. 'Earlier diagnosis means a decision can be taken sooner on whether the patient should go into a hospital bed, be managed by the GP or be seen in the ambulatorium the day after.'

No staff numbers were lost through the implementation. 'We implemented a function called the "diagnostic partner", where these staff are integrated within the daily work of the clinical ward to give advice on laboratory-related questions and help manage laboratory IT systems,' he explained. The hospital's investment will see greater efficiency in sample analysis, and savings with significantly lower numbers of blood sample tubes used, less use of reagents, and reduced hospitalisation.

A new hospital is planned for Hilleroed in 2020, with the Department of Clinical Biochemistry continuing the evolution of its automated lab processes to hold its ranking as 'the most automated lab in the world.'

Dr Georg Sölétormos, Medical Director of the Department of Clinical Biochemistry, North Zealand Hospital.

Two new lab launches

A bench-top haematology analyser for mid- to high-volume labs and new software to bring confidence in the use of flow cytometry

Beckman Coulter, Inc. has released a new bench-top haematology analyser for mid- to high-volume laboratories, and upgraded software for HematoFlow.

Building on proven cellular analysis technology, the company's new UniCel DxH 600 Coulter cellular analysis system – complete with FDA-cleared advanced software – provides laboratories with exceptional quality results, improved first-pass accuracy and automatic re-run and reflex testing, thereby reducing overall manual review rates and processes, the firm reports.

The haematology laboratory's single most important step, and most time consuming, is the manual review. By reducing manual differential rates, the new analyser frees mid- to high-volume labs to focus time on quickly and accurately reporting patient results, improving patient health and reducing the overall cost of care.

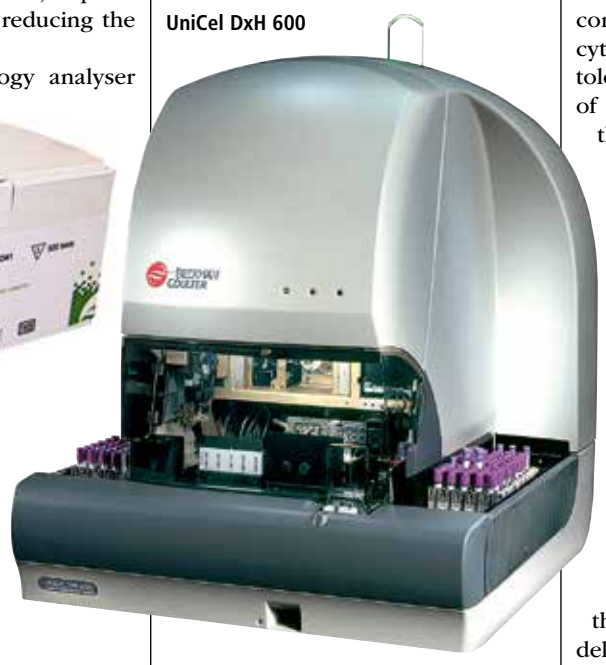
'This new haematology analyser has the ability to transform the haematology lab with unparalleled efficiency, revolutionary scalability and quality of results,' said John Blackwood, the company's senior Vice-President for Product Management at Beckman Coulter Diagnostics. 'The UniCel DxH 600 advances the technology that made Coulter systems the worldwide market leader in haematology and will change how labs manage their cellular analysis process.'

CytoDiff Panel Kit

The software provides new features, enhancements and research-use parameters to improve laboratory efficiency, reliability and quality, the firm adds. 'The software saves time by allowing labs to partially release patient results manually or automatically via decision rules and offers users the ability to create and edit decision rules during instrument operation and offers pre-defined decision rules using Cell Population Data.'

In addition, the firm reports, other software features include '…the ability to track workload by the day, hour and test, as well as providing automatic notification of STAT samples that have neither been processed nor released within an expected time frame, helping users to report STAT results in a timely and efficient manner.

UniCel DxH 600



'With the same technology, user interface and consumables as the UniCel DxH 800 Coulter cellular analysis system, the UniCel DxH 600 brings true standardisation of results and process to the haematology lab, reducing lab personnel training and simplifying consumable inventory management. To further enhance standardisation, all new DxH 800 analysers will be installed with the advanced software; and current DxH 800 customers will be upgraded.'

Upgraded CytoDiff CXP software for HematoFlow

Also launched in April was the advanced version of the CytoDiff CXP Autogating Software. This new software is an integral part of Beckman Coulter's unique HematoFlow solution, which combines diagnostic reagent, haematology and flow cytometry hardware and IT expertise.

Version 2 CytoDiff CXP Autogating software was designed to bring confidence in the use of flow cytometry in the routine haematology lab for the auto-validation of abnormal samples. Easy-to-use, the advanced Version 2 software further improves sub-population classifications, the manufacturer reports. 'It adds new features, such as greater precision in the removal of potential interference and metrics that provide a new "confidence level" on population classification. The new software simplifies the review process making it easier to validate results with greater certainty.'

HematoFlow with the CytoDiff five-colour antibody cocktail and CXP Autogating Software make it possible to use the precision of flow cytometry to deliver extended white blood cell (WBC) differential results with far greater consistency than manual microscopic assessment, Beckman Coulter adds. 'The five-colour antibody cocktail, the CytoDiff, uses six monoclonal antibodies to establish the differential.

'HematoFlow with CytoDiff CX Autogating Software offers enhanced performance by delivering flow cytometry expertise alongside cutting edge image analysis technology applied to each of the multiple population classifiers,' explains Dr Josee Naegelen, haematology marketing manager for Beckman Coulter Diagnostics Global Product Management and Strategy. 'The routine use of flow cytometry for validating abnormal samples can improve workflow and turnaround time as well as providing access to additional diagnostic information for patients. This has a significant impact on the lab, enabling it to handle increasing workloads with greater confidence.'

European laboratories are already working with Beckman Coulter to increase confidence in the routine use of flow cytometry in the haematology process for validating abnormal samples. According to the firm, hospitals including University Hospital, Rennes and Bordeaux in France, Erasme University Hospital, Brussels, Belgium and several private labs are successfully adopting this approach: 'They are using our FC 500 flow cytometer and the CytoDiff reagent to establish the extended flow WBC differential, detecting and quantifying normal and abnormal population subsets.'

Strategic a

Automation software will enhance medical IT services

Big Iron meets Big

Major players in laboratory instruments will meet in Chicago in January 2014 for the final tests of a new framework for pushing results to middleware platforms

Report: John Brosky

Lab instruments are marvels of modern technology able to dice, splice and analyse microscopic specimens. Yet pushing the results into modern medical reporting systems is as slow, and often as painful, as pulling teeth.

It took a concerted, coordinated industry effort to break the bottleneck in reporting by bring connectivity for lab instrument into the new century. (See EH03 2012, *'Upgrading 'Big Iron' for the digital century'*)

The breakthrough came last year in Berne, Switzerland when the major instrument makers tested a common interface at the European Connectathon, a marathon of IT system connectivity organised by the Integrating the Healthcare Enterprise (IHE). As a result of these first exchanges between platforms, the industry partners in the IVD Industry Connectivity Consortium (IICC), decided to refine specifications for a system integration profile called Lab Analytical Workflow (LAW) developed through IHE.

The instrument makers also asked to extend the scope of the LAW to include microbiology, according to François Macary with ASIP-Santé in Paris, which sponsors the IHE Lab domain. The first version of the lab interface dealt primarily with results from chemistry analysers.

'The big rendezvous is now set for Chicago in January, 2014,' he said when the refined and extended LAW 2.0 will be put to the test at the North American Connectathon.

By using the collaborative process of IHE, the major players have created a neutral ground where they can cooperate on a shared framework. The IHE Lab profiles create a level playing field for vendors of both the instruments that analyse specimens and the software that manages and communicates the results. As one

Özen Akyürek (left) General Manager at Ventura/Egesoft, welcomes a common platform for developing lab reporting software for customers

cquisition

Canadian firm Labotix Automation Inc. has been acquired by the Cerner Corporation based in Kansas City, Missouri, USA, amid predictions that the combination of the Labotix' solution with *Cerner Millennium and Cerner Copath* will create the most comprehensive set of capabilities on the market to support high volume testing.

With 20 year's experience and installations around the world, Labotix Automation is an open automation solution, meaning it will work with all best of breed devices currently on the market.

Established some 30 years ago, today Cerner offers a highly comprehensive array of information software, professional services, medical device integration, remote hosting and employer health and wellness services. The firm plans to immediately offer Labotix Automation solutions to clients internationally and expects to drive increased value for laboratories through integration with Cerner's platforms.

As a Cerner representative outlined for our *European Hospital* representative: 'The joining of Labotix automation to Cerner's laboratory software solution family provides Cerner with a unique advantage in the management of laboratory business.

'This benefits Labotix as well. Since Cerner can offer a large global distribution channel, we will be able to harvest and grow the business quickly.

'With Cerner's ability to offer a wide global distribution channel combined with our solid solution family, we have now become the largest publicly traded company in the world with and open automation platform.

Open automation is an affordable possibility

'This growth will make it more affordable for smaller labs to automate and allow for existing closed-loop labs to effectively and affordably customise their systems. This is something long needed, as the shortage of qualified individuals grows in the laboratory sector.

'Delivering automation to any size lab provides benefits such as high-speed turnaround times, it improves workflow coverage and makes the process safer.

'People make mistakes - no matter how well trained. Labotix will help to mitigate this risk,' he said. 'There is a growing demand for laboratory automation and Labotix is poised to be the bridge that makes open-automation an affordable possibility.

'The reason is quite simple: Labotix has a proven strong growth potential in its current global market. A market that is wide open for one basic reason, the ability to connect multiple-vendor devices together into one line of operation. Benefits of this are custom built workflow, expansion of current closed-loop automation, reduce turnaround time, improved workflow coverage and integration into any LIS on the market.'

The acquisition is not expected to have a material impact on Cerner's 2013 financial results.

Data

company spokesman put it, 'On IHE we collaborate, on everything else we compete.'

Founding members of the IICC include Abbott Diagnostics, Beckman Coulter, Becton Dickinson, bioMérieux, Data Innovations, Orchard Software, Ortho Clinical Diagnostics, Roche Diagnostics, Siemens Healthcare Diagnostics, and Systelab Technologies.

Preparing for Chicago, Systelab/Isasa participated in April 2013 at the IHE Europe Connectathon in Istanbul. Daniel Nesbot said the Barcelona-based group was testing LAW as it prepares to integrate the profile across a line of instruments over the coming year.

Smaller vendors are also seizing the chance to play on the neutral ground.

Ventura/Egesoft from Ankara was testing the overarching LAW interface, as well as others among the IHE Lab profiles that include data management for tasks such as ordering and performing in-vitro diagnostic tests inside a healthcare institution, managing the content of an electronic clinical laboratory report, integrating robotic laboratory equipment, performing and collecting the results of in-vitro testing at the point of care or patient's bedside.

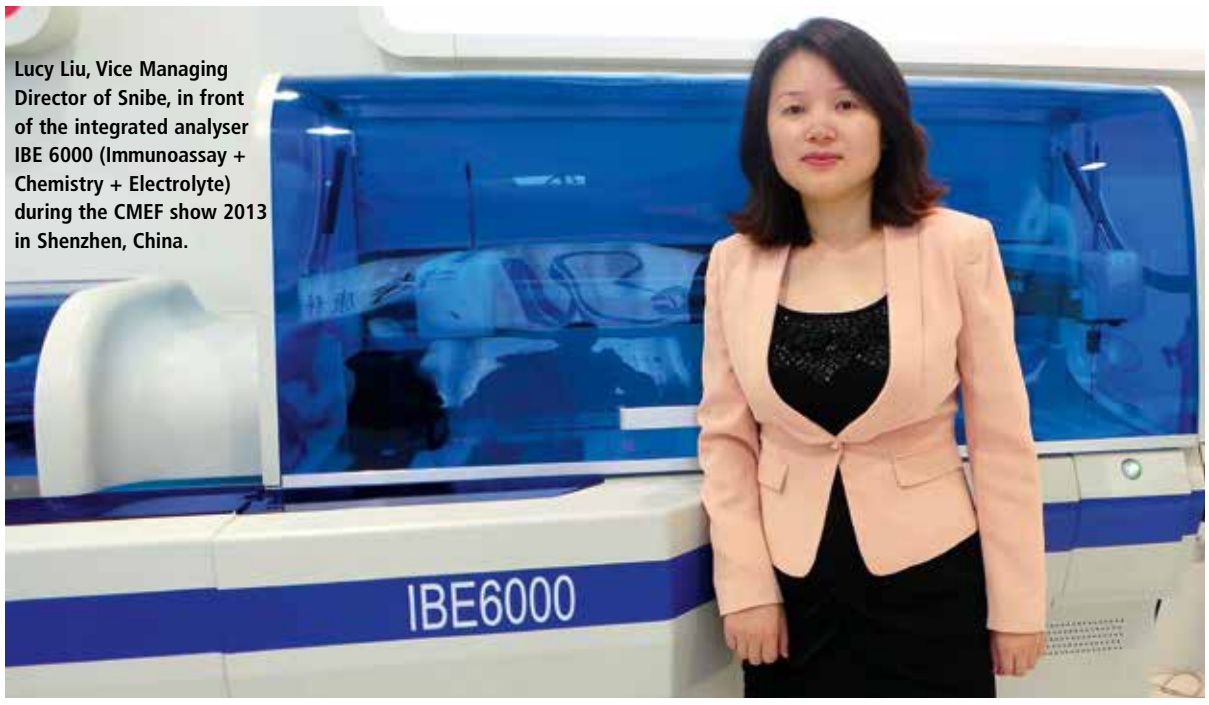
'We are creating new capabilities for new customers, primarily in Turkey,' said Özen Akyürek, general manager of Ventura/Egesoft. 'Regulations in Turkey are forcing our customers to do this, to assure the quality of lab data, to help consolidate the number of labs nationwide, and lower costs.

'In data exchanges there has always been just one common language for lab reporting, which is HL7,' he added, 'and now there's one common framework for exchanges, which is the IHE.'

En route to win over Europe

Immunoassay-focused IVD firm Snibe makes an entry at EuroMedLab

Snibe, Shenzhen New Industries Biomedical Engineering Co., Ltd., is a leading Chinese biomedical technology company dedicated to developing and manufacturing clinical laboratory equipment and reagents. Snibe was founded 18 years ago and is a growing force in the Chinese market. The firm is based in Shenzhen, China's fourth largest city, situated in Guangdong Province. Driven by subsidies as part of healthcare reform, Snibe's domestic market includes hospitals in all categories, and includes III-A hospitals in Beijing and Shanghai, for example Peking Union Medical College Hospital, General Hospital of Beijing Military Region, Shanghai Ruijin Hospital etc. Currently, 2,000 of the firm's installations are operating in over 70 countries, explained by Vice Managing Director Lucy Liu, when at the recent China International Medical Equipment Fair (CMEF), the large semi-annual tradeshow that presents innovative products from and for China. Snibe, she explained, is now placing an increasing emphasis on the further internationalisation; EuroMedLab will play a key role in that strategy. In Shenzhen, *Michael Reiter* of *European Hospital* asked Lucy Liu to describe the company and range of products.



Lucy Liu, Vice Managing Director of Snibe, in front of the integrated analyser IBE 6000 (Immunoassay + Chemistry + Electrolyte) during the CMEF show 2013 in Shenzhen, China.

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

'Our line of reagents covers more than a hundred parameters, most of them developed based on need from customer communicated to us – including kidney function, hepatitis, thyroid, drug detection, infectious diseases, tumours and many more. Every year we produce approximately 1,000,000 reagent kits and 1,500 automated immunoassay units.

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

Chemiluminescent Immunoassay (CLIA)

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

Products offered in Europe

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

'At EuroMedLab in Milan this year, we will present our brand new products-Maglumi 600 and Maglumi 4000. Maglumi 600 is what we call a Super POCT – it lets you perform tests with roughly 100 parameters on this compact machine. It's perfectly suited, for example, for emergency departments, small hospitals and small labs.

Snibe milestones

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

R&D team achievements

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

In the pipeline

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

The company mission

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

*** EuroMedLab: Snibe's products will be on show at booth 093**

The 16th Workshop on Image Processing in Medicine

The route from algorithm to clinical application

Report: Ralf Buchholz

The panel agreed: IT and medical specialists share common objectives – close cooperation between universities and industry plus interdisciplinary approaches will bring good results

'Radiologists and clinicians continue to evaluate 2-D images on the workstation even though the very same images are available in 3-D and my students are already doing research in 4-D. This fact tells me that we computer scientists are not particularly successful in taking our research results to the clinical front,' declares Professor Hans-Peter Meinzer, based at the Medical and Biological Informatics Department in the German Cancer Research Centre (DKFZ), Heidelberg. Problem seen, problem solved? Not quite, although there are some promising approaches for a solution.

The participants of the 16th Workshop on Image Processing in Medicine passionately discussed the challenges surrounding the transformation of research results into products. Going beyond the presentation of current research results in digital image processing the medical IT specialists looked at the relevance of these results in clinical practice.

Image processing is of paramount medical importance as complexity increases on all levels: patient care, technology and management. The modalities provide more data and larger data volumes – as in, for example, functional magnetic resonance imaging (fMRI), molecular imaging or 4-D ultrasound, not to mention the increasing applications in diagnostics and therapy.

Joint development platform paves the way

'For a long time it had been a real problem that universities and institutes all did their own isolated research. Consequently the results were non-standardised, not comparable and moreover non-transparent because they remained in their institution of origin,' Professor Meinzer explained. Today, however, young scientists use joint development platforms. In Heidelberg the Medical Imaging Interaction Toolkit (MITK) was established, along similar lines as its counterpart 3-D Slicer from Harvard Medical School.

Both are open source solutions and support translation from innovative algorithms to clinical research applications. Currently, the participating institutions are even in the process of developing a new supra-platform, the Common Toolkit (CTK). As far as Professor Meinzer is concerned CTK may well provide a platform that is competing with the industry's research efforts. 'If we succeed in using CTK to develop algorithms and tools to market maturity we will also be able to take them to the clinical application stage. This will provide us with a certain degree of independence from the device and software industry.'

However, in Germany the regulatory obstacles continue to impede swift translation from research to applications. For example, the Medical Devices Act requires drawn-out and resource-intensive studies. Nevertheless, translation can be successful. So, what could be the secret of success? 'Two things,' says Professor Meinzer pragmatically, 'a figure showing that the application to be developed will generate income for the physician, and a proof of efficiency that it will support the users in their daily work.'

Canon Europe

Launching over a dozen new digital radiology tools.

Adora DR

When Yoshiyuki Masuko, Senior Director of the Medical Imaging Group at Canon Europe, said, 'We're dedicated to providing the right combination of diagnostic imaging technology for any circumstances', this was no underestimation. Canon Europe launched nine DelftDI digital radiography (DR) modalities, four new Canon flat panel DR detectors and several healthcare IT solutions, all during ECR 2013.

DelftDI, now a Canon Group company, showed a range of new DR modalities '…designed to allow radiographers to create bespoke solutions that can be adapted to examine all patients, while delivering high quality imaging under all circumstances'. At the event, highlights included the Adora RF and D2RS hybrid solutions for fluoroscopy and radiography, as well as Xsense DR for freedom in static imaging and a variety of mobile, field and paediatric applications. The four new flat panel detectors CXDI-701 and CXDI-801 Wireless series expand the firm's existing range. 'With a reduced image preview time of only one second for higher throughput and the auto detection feature, they will increase the flexibility for easy retrofit and system integration,' Canon reports. 'All the new DR devices are equipped with Canon's CXDI Control Software NE, enabling medical staff to reduce patient examination times by decreasing the number of steps needed to capture an X-ray.' The company's new range of software solutions enable quick and secure access and management of hospital images. 'Canon's Radiology Information Systems (RIS) and Picture Archiving Communication Systems (PACS) ensure optimal workflow and high patient throughput' the firm reports. 'With the advanced Cross Enterprise Document Sharing (XDS-i) solution healthcare institutions can exchange documents and information more easily

Mobile DaRt

Vital parts

IAE's rotating anode tubes: playing a valuable role in X-ray diagnoses

Products include inserts and housing for CT scanners, digital angiography and cardiac apps as well as complete units for mammography

Italy – In 1950, Industria Applicazioni Elettroniche – IAE – began life making high-power electronic valves. 15 years later, due to already advanced technology in high vacuum and special metals, the firm produced X-ray tubes. A major ownership change in 1973 ended valve production as the firm advanced into medical X-ray tube applications, focusing on rotating anode tubes for general purpose diagnostic systems.

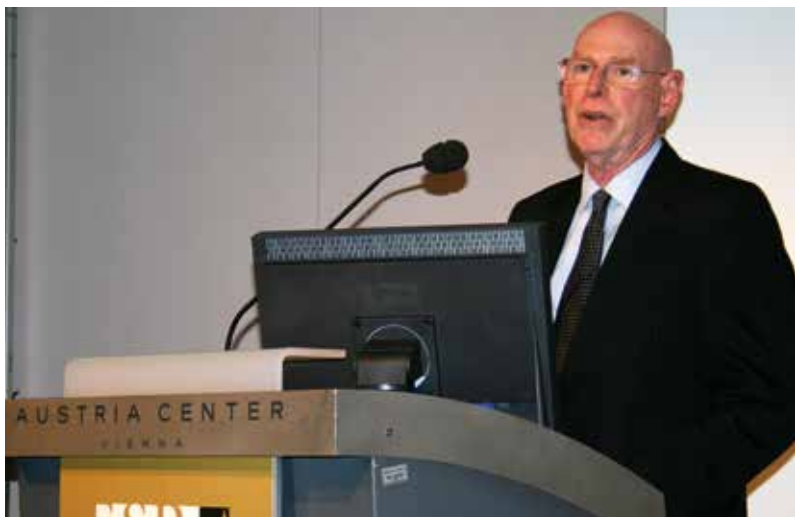
In 1988, a strategic investment in people and resources enabled more sophisticated technological applications development and thus to CT tube production. In 2002 IAE opened a new logistic and reloading station nearby – and production surged. Around that time, the firm also opened IAE France at Etampes, near Paris. Today, IAE is Europe's biggest standalone X-ray tube manufacturer for rotating anode tubes. With a wide range of products (over 100 insert/housing combinations) the firm supplies the world's leading equipment manufacturers. 'With the addition of more than 30 different competitors' unit reloadings (all CE marked), IAE is sure to satisfy at the highest level in the market of service,' the firm reports.

Products include special application tubes (for monoblocks, mobile systems and C-arms) inserts and housings for medium and high duty radiological systems; inserts and housings for digital angiography and cardiac applications; complete units for mammography; inserts for CT scanners. Also recently launched is a rotating anode X-ray unit specifically designed for mobile X-ray equipment film and digital detectors.

'New technologies may well sneak up on you and put you out of business before you know it'

Management in Radiology ESR MIR European Society of Radiology

Innovation management and the future of radiology



Report: Michael Reiter

Dedicated to management topics, developments in e-health and major trends in the discipline, the ESR subcommittee Management in Radiology (MIR) is chaired by Professors Yves Menu and Peter Mildenberger. The subcommittee organises MIR sessions at ECR as well as a scientific meeting on related topics, to be held between 9-11 October in Barcelona, Spain.

The renowned panel of speakers included Bruce Hillman, Professor of Medical Imaging and Public Health at the University of Virginia in Charlottesville

At this year's ECR the first of two *Management in Radiology* (MIR) sessions addressed the issue of innovation management and future challenges. According to key speaker Bruce Hillman, Professor of Medical Imaging and Public Health at the University of Virginia, 'accessed innovation' has proved a remarkable success story during the past forty years. 'It has brought radiology up from a specialty hidden in basements … to being one of the premier specialties in all of medicine,' he said. 'What we need now is innovation that will carry us into the future, responding to the major paradigmatic changes in medicine.' This includes innovations geared at enabling 'P4', precision medicine – at affordable cost.

Investors are more cautious

Innovations have typically come from independent individuals in academia to be translated into clinically viable technologies by the industry, the expert continued. 'This cycle has brought us technologies such as ultrasound, CT, MRI, and PET. Today, however, there is a highly disadvantageous milieu for this – due to the overall emphasis on cost and further pressures, such as a general bias against medical imaging. 'These factors are making companies cautious about investments in innovation,' Prof. Hillman believes. Thus firms will approach innovations rather strategically, with an eye towards the cost and the potential return on investment.

Care providers need to be careful about the technologies that may interest them, in terms of when they purchase and what the actual value will be to patients as well as their individual institution. This really holds true for technological innovations in all medical fields including radiology.

'Today, new technologies tend to be disruptive,' Prof. Hillman concluded: radiologists may tend to be rather satisfied about how their business is progressing and not worry too much about innovation. 'But new technologies may well sneak up on you and put you out of business before you know it.'

To ensure they can continue being the provider, radiologists therefore need to 'put their feet into waters', while continuing their conventional work, even if emerging technologies may appear to be crude and costly.

Information about innovations will increasingly come from social networks and further online sources.

Software combats insidious X-ray radiation hazards

Real-time reassurance from the new cloud-based dose management system RaySafe S1

X-rays are medically invaluable. However, it is common knowledge that inadvertent radiation exposure can be harmful – and undesired exposure can raise the risk of cancer, have unwanted genetic effects and more. Yet, as Magnus Kristoferson, CEO of Unfors RaySafe underlined during ECR 2013 in Vienna, in the last 30 years the number of X-ray examinations, and therefore exposures, more than doubled in the USA. For instance, in Florida the Department of Health registered over 18,000 facilities – including hospitals, doctors' surgeries, universities and corporations – that operate more than 50,000 X-ray machines.

Today stricter legislation secures better usage of X-ray equipment. Still there is a strong international requirement for more advanced methods of monitoring exposure levels in medical facilities.

At the ECR, Magnus Kristoferson, also highlighted international studies of real-time dose monitoring. 'What is significant,' he concluded, 'is that every single study has shown dose reduction after a change in behaviour, due to the use of the real-time dose monitoring system (as high as 45% according to one of the studies).'

Among other systems to ensure that radiation dose is monitored, and controlled, are products manufactured by this Swedish firm Unfors RaySafe, a leading specialist in radiation measurement solutions: 'Like canaries in a coalmine, Unfors RaySafe offers a range of solutions that provide relevant information about dose exposure, so that people can take action to reduce their personal dose. Unfors RaySafe strategy focuses on raising awareness of unnecessary radiation exposure among the different target groups and enables working according to the radiation safety principles of ALARA (As Low As Reasonably Achievable).'

RaySafe S1 Dose Management **software can be introduced smoothly into radiology departments with X-ray equipment from different manufacturers that support the DICOM standard**

After introducing the real-time dose monitoring system *RaySafe i2* in early 2012, and following the successful introduction of the company's cloud-based solution *RaySafe S1* in the USA and Canada during the RSNA in Chicago, this new software solution was introduced to the European market at the ECR in March this year.

The cloud-based solution enables efficient dose management in hospitals within the diagnostic imaging process. By providing accurate and easy-to-use radiologic information, RaySafe S1 helps healthcare workers in order to avoid unnecessary radiation to their patients. The software can be implemented smoothly into radiology departments with X-ray equipment from different manufacturers that support the DICOM standard. 'The software also helps to reduce faulty images and contributes to long-term reduction in costs by improved process quality,' the company adds.

Quality assurance for diagnostic X-ray

Unfors RaySafe had also successfully launched the measurement device *RaySafe X2* in Chicago last November. 'This solution was designed specially for quality assurance of radiographic and fluoroscopic X-ray equipment and is characterised by advanced sensor technology paired with intelligent signal processing as well as intuitive user guidance,' explained Mats Alm, Vice President for diagnostic X-ray. 'The sensor of RaySafe X2 captures all relevant parameters and provides the user with easy-to-read information, such as dose, dose rate and waveforms on the touch sensitive display.'

Magnus Kristoferson concluded: 'Having dose reduction solutions for equipment, staff and patient, we aim to minimise hazards for hospital staff and patients and to optimise the technical performance. With the introduction of RaySafe S1, we are the only company worldwide able to provide clinics and hospitals with effective solutions for the complete X-ray room to measure, monitor and manage dose.'

Up to now, Unfors RaySafe holds ISO 13485, ISO 14001, ISO IEC 17025 and ISO 9001 quality management standards certifications.

With a team of 150 employees, in the fiscal year 2011/2012 the company generated a revenue of around €20 million.

Complete vision for interventional radiology

Taking a comprehensive approach to reducing dose, each link in the imaging chain was reengineered to deliver a superior clinical image with Ziehm Vision mobile C-arms

Report: John Brosky

The importance of imaging for interventional radiologists is clear the moment you step into the operating theatre.

Hovering above the patient, directly in front of the surgeon, the display screen becomes critical to the procedure, a window at once presenting a precise view of disease pathology, a map for navigating anatomical landmarks and a path for arriving at the targeted site to repair or restore function.

Yet the price of a high quality intra-operative imaging is the risk of a dangerously high exposure to radiation for both the patient and surgical team.

As a result surgeons must compromise image quality during the procedure to keep radiation dose to safe levels.

Thanks to innovative engineering, Ziehm Imaging has broken this traditional trade-off, delivering superior imaging quality while dramatically reducing radiation exposure. 'We actually started out to reduce dose and ended up with both: less dose and a better image,' explained Martin Herzmann who leads Global Marketing for Ziehm Imaging.

Specialised in C-arms for interventional radiology and surgeons, the company has introduced a series of enhancements across its line of Ziehm Vision systems with SmartDose, a comprehensive approach to reducing radiation exposure. SmartDose presents a rethinking of the imaging chain for the Ziehm Vision line of mobile C-arms that includes novel features, such as laser cross-hair positioning to precisely target the region of interest, organ specific protocols and automatic down-pulsing to avoid continuous fluoroscopy with a strobe effect.

The Object Detected Dose Control (ODDC) is unique to Ziehm Vision systems, software that detects motion in the target area and adjusts accordingly. Another software enhancement is Ziehm Adaptive Image Processing (ZAIP) that sharpens the image with optimal noise reduction and edge enhancement while enabling up to 20% dose reductions for flat-panel C-arms.

'When you start to speak about dose you find there are a lot of calculations out there,' Martin Herzmann explained. 'At Ziehm Imaging the dose is measured, so we prefer to speak about numbers that are measurable as dosage levels.'

With a slim profile and minimal footprint the Ziehm Vision line offers maximum mobility with minimum space requirement serving as an all-around system for general surgery, orthopaedics, traumatology and vascular applications.

With more than 1,300 Ziehm Vision systems already used in operating rooms worldwide, Martin Herzmann said the new generation Vision C-arms would open a new chapter, creating new opportunities for the company. Until recently many believed that only a hybrid operating room with a fixed imaging system could accommodate interventional radiology procedures, he added. Yet the growth in minimally invasive procedures, combined with the high cost of building dedicated surgery suites has brought more and more hospitals to Ziehm Imaging with its reputation for high-performance and highly mobile C-arms. Ziehm Imaging technology is known to be robust and solid with the image quality surgeons need, motorised systems to enhance flexibility and liquid cooling to support complex procedures.

'Ultimately, healthcare professionals make their decision based on image quality and the quality of the company's image,' he pointed out. 'We are well positioned with both.'

Madrid gains GE's new CT

The Discovery CT750 HD with spectral imaging

Madrid, Spain - General Electric Healthcare's new Discovery CT750 HD with spectral imaging was presented in April, with details regarding its provision of high image quality and multiple dose reduction features on one platform.

Report: Dr Eduardo de la Sota

ASiR (Adaptive Statistical Iterative Reconstruction) dose reduction technology may enable reduction in pixel noise standard deviation. The ASiR reconstruction algorithm may allow for reduced mA in the acquisition of diagnostic images, thereby reducing the dose required – and with high-definition image quality across anatomies — the Discovery CT750 HD can reach any part of the body of virtually any patient, and perform both generalised and specialised clinical applications, including:

1. Gemstone Spectral Imaging – the first quantitative dual-energy CT on the market
2. Cardiac imaging – highest spatial resolution in the industry at 18.2 lp/cm2
3. Neuro-imaging – the Discovery CT750 HD is reported to ensure ample coverage to perform perfusion studies of the entire brain.

GE reports the main advances of CT750:

- High Definition – high level resolution; low dose
- Cardiac CT – The Discovery CT750 HD FREEdom Edition designed to address the foremost challenges in Cardiac CT'
- Spectral Imaging – the Gemstone Spectral Imaging feature
- Veo Imaging under 1mSv with profound clarity.

In the Beata María Hospital in Madrid (Spain), in the presence of Antonio Burgueño Carbonell, General Director for the Hospitals of Madrid, Luzia Pereira, Director for CTs, GE Healthcare, explained the technical issues.

Additionally, Jorge Gómez, Assia Litcheva, Jose Vicente Monmeneu and Elvira Conde (Doctors from the Beata María Hospital) delivered an extensive presentation of preliminary results from using the CT. The Beata María Hospital, which belongs to the Congregation of the Hospitaller Sisters of the Sacred Heart of Jesus, and is present in the healthcare and mental healthcare sectors in 34 countries, is the first to offer this advanced technology in Madrid (it is already available in the Valencia and Catalonia regions).

According to Joaquim Luzia, with GE Healthcare in Spain, '…this CT system is the first in the world with high resolution. It reduces radiation doses up to ninety percent, at the same time improving resolution by fifty percent.'

Dr Belloch, radiologist and Director for Research and Development with the ERESA group, added: 'We are starting a new era for CT. We will now be able to identify the chemical and functional characteristics of different pathologies, so the patients will benefit from safe, less invasive, less costly and more effective diagnostic solutions.'

From left: Radiologist Dr Jorge Gómez, Cardiologist Dr Jose Vicente Monmeneu, Medical Director Dra Elvira Conde, Radiologist Dra Assia Litcheva and Joaquim Luzia, GE Healtcare Spain Manager of TC

Dr Gómez, from the Beata María Hospital, stressed, '…in cancer patients we can identify tumours by characterising tissues. In vascular examinations we can differentiate stenosis from occlusion…'

As we have seen in recent decades, probably the most radical healthcare advances come via diagnostic technologies. In those decades, surgical exploratory and diagnostic procedures became prevalent, involving suffering, risks and high costs for many patients.

* With thanks to Albert Concepción, at GE Healthcare in Spain, for this interesting information.

Stem cell therapy

Routine clinical use will take another decade

A tissue plaster for the infarction scar

Report: Axel Viola

Numerous cardiac muscle cells die following myocardial infarction, due to reduced blood flow in the affected muscle areas. What remains is a scar, which also mechanically affects cardiac pumping. The muscle itself has no, or hardly any, capacity to regenerate itself. Speaking at the Annual Meeting of the German Cardiac Society in Mannheim this April, Professor Gerd Hasenfuss, head of the Göttingen Heart Research Centre, explained, 'At best, the heart has a capacity of around 1% to regenerate itself.' Although this means that the heart completely renews itself once throughout a person's entire lifetime, this capacity is not nearly strong enough to counteract any damage occurred during acute events.

There have therefore been – and still are – high hopes placed on potential stem cell therapy. Pluripotent cells are to replace damaged tissue. The initial phase, when expectations of this therapy were rather exuberant, appears to have passed for now, although the first case studies of catheter-supported application of stem cells from the bone marrow for patients who have just suffered heart attacks were still being hailed as recently as 2000. Meta-analysis, Prof. Hasenfuss pointed out, has shown that, although the application of bone marrow stem cells after a myocardial infarction results in a slight improvement of cardiac function, the effect could later no longer be verified. 'The stem cells cannot differentiate. So it's assumed that what can initially be seen is in fact a slight "pharmacological" effect of the bone marrow stem cells - they may be secreting messenger substances with a supportive impact on tissue regeneration.'

New opportunities for stem cell therapy are therefore the object of much research. One option being more extensively examined is the use of cardiac progenitor cells. 'Small amounts of these cells can be found in the heart,' explained the Göttingen cardiologist. These stem cells are harvested via biopsy. Because only few cells are naturally available, the cells have to be grown in vitro, making this approach unsuitable to treat acute infarctions. Moreover, clinical studies confirming the effectiveness of the procedure are lacking.

Based solely on his looks, **Professor Gerd Hasenfuss** could be classed as an eternal youth among cardiologists. However, he can in fact look back on an impressive career, having taken on outstanding leadership roles early in his medical career. The professor studied medicine and specialised in cardiology in Freiburg, Germany. Following research in the USA he wrote his habilitation in 1989.
In 1993 he became a consultant and in 1996 was awarded an extraordinary professorship. He was awarded a C-4 professorship at Göttingen University and then appointed Director of the Cardiology and Pulmonology Departments at the Centre for Internal Medicine.
Since 2001 he has also chaired the Göttingen Heart Research Centre and, since 2005, been head of Internal Medicine at the Lippoldsberg Rehabilitation Centre.

Based on today's level of knowledge, Prof. Hasenfuss sees the best chances for stem cell therapy in the use of induced pluripotent stem cells. In 2012, Japanese doctor and scientist Shin'ya Yamanaka and British researcher Sir John B Gurdon received the Nobel Prize for their discovery that mature cells can be changed into stem cells. Prof. Hasenfuss: 'Practically every cell in the body is interconvertible.'

This means, for example, heart or liver cells can be grown from skin or blood cells. The mature cells are basically reprogrammed back to the stage of stem cells and are then differentiated into heart muscle cells, for instance. The objective is to grow heart tissue using induced pluripotent stem cells, which can then be transplanted to areas affected by post-myocardial infarction scarring. This tissue plaster, so goes the idea, can then stabilise the infarction scar as well as improve the contractility of the myocardium. 'This tissue engineering approach also facilitates better control of tumour growth,' Prof Hasenfuss explains, highlighting another advantage compared to previous approaches in stem cell therapy. In addition, the new heart tissue would be grown in the laboratory under controlled conditions.

However, it will be a while before this procedure will become part of clinical routine. It is now possible to create cell layers. Whether or not these will have the desired characteristics is currently being trialled in animal experiments. The first human studies could, he estimates, take place in five years' time. Based on a positive progression of studies and trials it will take at least another decade for the procedure to be ready for clinical use.

Why ECMO? Why an airbag?

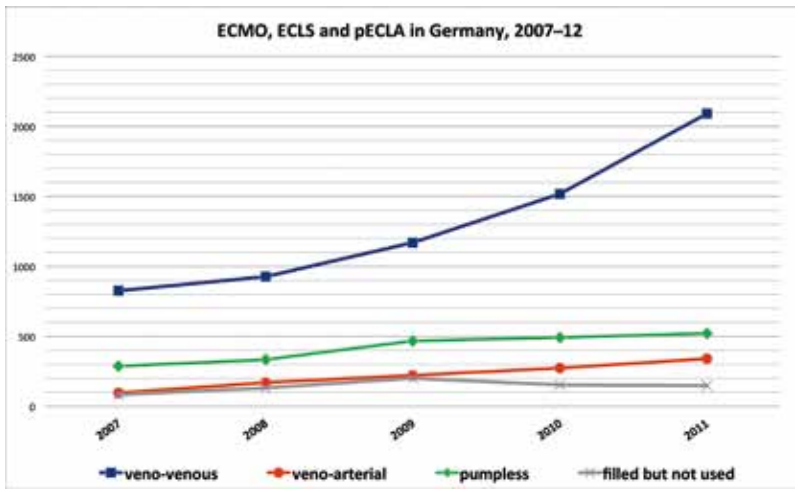
Extracorporeal membrane oxygenation

Report: Holger Zorn

There is little evidence on respiratory support with extracorporeal systems – enough of an argument for most of those doubting the procedure not to use it, or even make it available. However, the requested prospective, randomised – and ideally double-blind studies involving large numbers of patients – are unlikely ever to be carried out. And why should they? After all, no one ever requested these types of studies for air bag use – yet they are still being fitted.

ECMO, i.e. extracorporeal membrane oxygenation, takes the strain off a patient's own lungs for a few hours or days, and in exceptional cases even weeks, by supplying pre-oxygenated blood. A catheter is inserted into a hollow vein close to the heart and transports blood along a gas exchange membrane, filters out carbon dioxide and enriches it with oxygen and, most often powered through a centrifugal pump, transports it back to a venous vessel near the heart.

The procedure became possible through the development of the membrane lung by Dr Theodore Kolobow, and first used successfully in an adult in 1972 by Dr Donald Hill. Even the first large, prospective randomised study, published in 1979, appeared to point towards the end for this then relatively new type of treatment. Out of 90 adult patients with arterial hypoxia, 48 were exclusively treated with mechanical ventilation and 42 patients additionally with veno-arterial ECMO. In both groups, four patients survived (8.3% vs. 9.5%). Due to the lack of survival benefit patient recruitment for the study stopped early. 'ECMO can support respiratory gas exchange but did not increase the probability of long-term survival in patients with severe acute respiratory failure,' the authors concluded [JAMA. 1979 Nov 16;242(20):2193-6].



Extracorporeal techniques are used increasingly beyond cardiac surgery. Classical extracorporeal membrane oxidation (ECMO) techniques (veno-venous) used for respiratory support account for the largest portion of these methods. Techniques used for cardiac support (veno-arterial) are also referred to as extracorporeal life support (ECLS), or mini heart-lung machine (mini-HLM). Pumpless extracorporeal lung assist (pECLA) is a special case used less for oxygenation of the blood than for decarbonation. The number of systems filled but not used is a measure of 'standby' procedures (usually in heart catheter laboratories). Source: The Federal Statistical Office (Destatis)

However, ECMO therapy for infants is different. First successfully used in 1975 by Dr Robert

Continued on page 18

Celebrating the 60th birthday of a fabulous lifesaver

This May it will be exactly 60 years since the first extracorporeal circulation device to temporarily replace heart/lung function was successfully used in a clinical setting. High time for a big cheer, says EH correspondent Holger Zorn, who recalls the anguish and excitement, high hopes and shattered dreams in medical history

'Block aorta! Maximum vent!' The tension in the operating theatre (OT) is on high voltage as surgeons, nurses and perfusionists approach the first critical moment in cardiac surgery. Terse commands fly about: 'Cardioplegia on!' The aorta is clamped, blood is drained from the heart and a solution is pumped into the coronary arteries. The heartbeat slows, flutters, and then lies entirely silent. It is also still. However, that flat green line on the monitor does not mean death, but hope. Bypasses are inserted, holes are closed and valves are repaired. The contraption that makes all this surgical wizardry possible is exactly 60 years old. On 6 May 1953, John Heysham Gibbon, a surgeon at Pennsylvania University in Philadelphia, repaired an atrial septum defect in 18-year-old Cecelia Bavolek using a heart-lung machine (HLM).

John Gibbons had taken almost a quarter of a century to develop the method and construct an apparatus to siphon venous blood from the large veins, remove the dioxide, enrich the blood with oxygen and return it, clean and filtered, to the human aorta. Up to six litres per minute, unfailingly, for hours. The saga began on 3 October 1930, when Dr Gibbon, then a young assistant physician, was asked by his boss to stay on night watch with a patient who suffered from severe pulmonary embolism. Without doubt, she was dying. It was impossible to simply cut open her heart and remove the thrombi. That night the young doctor had the idea to replace the heart, a muscle pump, with a mechanical pump for just a few hours, as long as the surgery would take.

Yes, huge! A first generation heart-lung machine used at Düsseldorf University Hospital in 1964. Courtesy of Josef Güttler (BVK)

Cat and fish

John Gibbon's boss wouldn't have any of it. But his assistant, Mary Hopkinson, was to become one of the young surgeon's most important partners in research – and in real life. After their March 1931wedding, they began their experiments, first using cats lured off the street with fish. They occluded the pulmonary arteries and pumped the blood through a mechanical lung. On 10 May 1935 the first cat survived. It had been without its own heart function and kept alive by extracorporeal circulation. Mary and John prance about the lab, elated. World War II interrupted their work but, after the war, IBM supported their research and deployed engineers to construct three heart-lung machines. Model II brought success.

A biker's life saved

1972, barely twenty years after Dr Gibbon's pioneering feat, a 24-year-old man rode his motorbike through Santa Barbara, California, fell and suffered a closed thorax trauma. The lungs were compressed, aorta damaged. Four days after surgery his lungs failed. By that time Donald Hill and team, at the Pacific Medical Centre in Los Angeles, had significantly improved the heart-lung machine, particularly replacing the rotating discs of the gas exchanger by a membrane lung.

Photo: Frank Born

Transporting a circulatory collapse patient, whose blood flows through the cylindrical oxygenator (transparent housing with green gas tube).

They transported the device to Santa Barbara, connected it to the patient and supported his circulation for three days. With an extracorporeal blood supply of 3.0 to 3.6 litres per minute, oxygen tension in the blood increased from 38 to 75 mmHg, oxygen in the tidal air was reduced from 100 to 60 percent and peak airway pressure was reduced from 60 to 35 cm H2O. Respiratory distress was relieved; the patient recovered.

Three years later, in 1975, a baby girl was born at the Orange County Medical Centre. Something was wrong. Her small lungs would not work properly. Despite the ventilation system, oxygen tension fell to 12 mmHg. Robert Bartlett, pulmonary surgeon and co-developer of the membrane lung, brought a machine that had never before been used for a baby. The child's mother tried to understand what she was hearing, signed the patient consent form with an X and disappeared, never to be seen again. Being an illegal immigrant from Mexico, staying in the hospital would have meant arrest and deportation. After three days of blood oxygenation the baby's lungs were strong enough to work without mechanical support. The nurses had named the girl Esperanza - hope...

HLM going mobile

In 1997, again almost 25 years later, a 55-year-old surgeon collapsed in his own practice in Germany. The emergency physician arrived on the scene within minutes, but too late. He was the surgeon's friend. If he had had an HLM, Georg Matheis was convinced he could have saved the surgeon. As a result, he founded a company to develop the world's first really mobile heart-lung machine. Dr Matheis wanted the device to weigh only ten percent of a normal HLM – less than 20 kg. Whilst he quit the company he founded to pursue other goals, in 2007 the *Lifebridge B2T* proved its worth at the German Heart Institute in Berlin. In 2008 the machine received Europe-wide approval; FDA clearance followed in 2010.

Today, millions of people worldwide live on thanks to a heart-lung machine. However, it could not save its inventor. In 1973, during a tennis match, John Heysham Gibbon died of a heart attack. Recently Lifebridge Medizintechnik AG also needed reanimation and was acquired by ZOLL Medical.

Pacemakers, defibrillators and MRI

Scans are possible for some implant patients

Report: Axel Viola

Not such a rare situation: A patient is due for an MRI scan to clarify a diagnosis. However, it transpires that this patient is fitted with an implant, say an implantable cardioverter defibrillator (ICD), which is contraindicated for MRI examinations. The strong magnetic fields of the MRI scanner can trigger malfunctions in the ICD, or increase or heat up the tip of the probes positioned in the cardiac muscle.

Manufacturers have acknowledged this problem and are now developing devices that do not incur any damage during MRI exams and do not impact on the patient.

Annually, the number of patients who need ICDs increases between 10% and 15%. At the same time, the number of MRI scans worldwide is increasing by around 10% each year. Between 2006 and 2010 alone, the number of MRI examinations increased from around 30 million to 50 million. 'The probability that a patient with an ICD may require an MRI examination based on these figures increases up to 75%,' explained Professor Wolfgang Rudolf Bauer, cardiologist, physicist and consultant at the Medical Clinic and Polyclinic I, at Würzburg University Hospital, Germany. Speaking during a press event held by Biotronik in Mannheim this April, he added: 'The main problem is the high frequency field of the MRI scanner.'

Biotronik's Iforia is the world's first DF4 ICD/CRT-D series approved for MRI

With colleagues, Prof. Bauer was involved in the development of the Biotronik ProMRI system, which enables, under certain conditions, examination of patients fitted with pacemakers or defibrillators.

At the end of March the firm received CE certification for its *Iforia* product range (ICD and implants for cardiac resynchronisation therapy (CRT-D), which, combined with ProMRI technology, is also licensed for MRI. However, it should be noted that certain conditions must be met and monitored before an MRI scan can be performed. The implants were only tested for certain MRI scanners, namely 1.5-Tesla devices. Furthermore, no changes must be carried out to the tomograph, such as the addition of more local transmission coils. Prior to an MRI scan the implant has to be programmed into a certain MRI mode. Therefore, not all treatment functions are available during the exam – in the case of the ICD, for instance, the MRI programming mode disables the defibrillation function.

Advice: A specialist cardiologist should be consulted as a matter of principle prior to any impending MRI examination of a patient with cardiac implants.

Source: Morgan Stanley, ICD market 1996 – 2009

The future of endoscopy and imaging procedures

Art meets science

Report: Anja Behringer

The future will be aesthetic or, put another way, *Art meets Science*. With this motto, the 43rd Congress of the German Society for Endoscopy and Imaging Procedures e.V., jointly held in Munich with six other specialist associations, demonstrated that aesthetic means the brilliance of images generated by the latest generation of X-ray, CT, MRI and ultrasound equipment. Whilst those images have so far been of high-resolution, but mostly black and white, static and two-dimensional, this is increasingly changing. Visualisation from inside the body with panoramic functions, 3-D reconstruction, video films, functional and molecular-genetic imaging, marker-guided procedures and, finally, the interaction of the different visualisation procedures, open up new insights into as yet unknown perspectives that sometimes can be reminiscent of modern art.

Christian Jennsen et al. write in their *Thoughts on interfaces between Art and Science* (Endoscopy Today 1/13): 'With the help of high-resolution video-endoscopes it is now possible to visualise the finest mucosal structures of the embryo-genetically uniform aero-digestive tract in HD quality. Real and virtual colouring procedures highlight the finest structural characteristics of mucosal surfaces ingeniously. Confocal laser technology facilitates an insight into vital cell structures. Colour coded duplex and triplex ultrasound, as well as contrast-enhanced ultrasound procedures, show vessels and blood flow in organs and tumours in real-time. 3-D imaging allows fascinating insights into normal perfusion and tumour-associated neovascularisation.

'Multiplanary reconstructed and fused US, CT, SPECT and MRI images give a plastic impression of topographic relationships between organs, vascular structures and skeletal structures and their relation to pathological processes. This can, for instance turn them into three-dimensional pointers for surgeons and interventionists for complicated procedures and also facilitates robot-associated surgical procedures and interventions.'

Colour is an essential contributor towards the current aesthetics in diagnosis because it adds to images another level of information. This in turn triggers emotions that are particularly well remembered in connection with what has been viewed. Guidelines on contrast-enhanced ultrasound procedures are now also available.

In the case of elastography, tissue elasticity levels are shown in colour. Harder tissue is shown in red, softer tissue in blue - if the equipment was manufactured in Asia. For cultural reasons, in the rest of the world this is the other way round. However, the user can adapt colour coding individually.

Between 1981-85, **Professor Christoph F Dietrich MD**, now head physician at the Caritas Hospital in Bad Mergentheim, Germany, was a medical student at the Medizinische Hochschule in Hanover. In 1986-86, gastroenterology study followed in Seville, Spain, and at New York Medical College, USA. From 1988 to 89, following his German medical exam he received the ECFMG Certification, USA. He then specialised in Internal Medicine (1997), Gastroenterology and Hepatology (2000) and Pneumology (2002). In 1999 he joined Frankfurt University as an Assistant Professor and was appointed a full professor in 2005. He became a haematology and oncology specialist in 2008, in Palliative Care Medicine, and in Geriatric Medicine and Proctology in 2009 In 2010-12 he was a member of Frankfurt School of Finance & Management. For 2011-13 EFSUMB elected him President, and from 2012-13 he has been president of DGE-BV.

With these technologies, information is not only obtained but also creatively presented to benefit of insight. This in turn promotes the recognition of patterns, and training in this recognition process gives hospital practitioners the necessary reassurance, because demands on doctors' capabilities are continuously on the increase. In endoscopic ultrasound both procedures are utilised and must be mastered at the highest level, and an excellent 3-D orientation, as well as knowledge on the clinical context of an indication, are required. To that end, cooperating endoscopy societies offer constructive and certified courses.

Congress President Professor Christoph F Dietrich, of the Caritas Hospital in Bad Mergentheim, Germany, emphasised that the technological development will lead to an amalgamation between diagnosis and treatment. 'In many cases the results of endoscopic ultrasound examinations are of significant importance for prognostic assessments and the further diagnostic and therapeutic management. Training of doctors who carry out endoscopic ultrasound examinations in different fields of medicine must keep up with – and do justice to – the increasing importance and technological developments of this procedure.'

Doctors working in oncology, gastroenterology, pulmonology, thoracic and visceral surgery are also calling for more cooperation as contrast-enhanced endoscopic ultrasound (CE-EUS) and real-time elastography (RTE) will improve differential diagnostics in these areas.

The change of EUS, only 25 years after its introduction from a purely diagnostic procedure into an increasingly interventional, lies is in the new ability to guide a high-resolution ultrasound instrument close to structures in the body that were previously inaccessible. This enables precise application of needle systems as transportation media for different instruments and substances. The good rate of success so far will lead to new applications and further technical developments that cannot yet be foreseen.

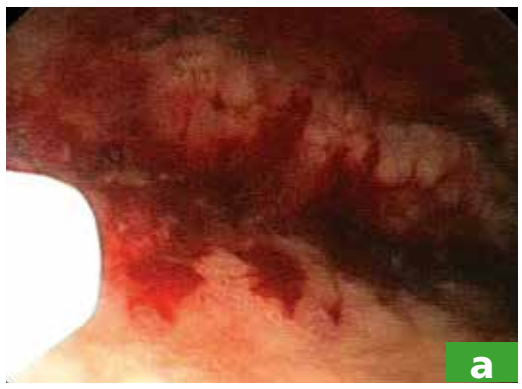
Professor Ralf Kiesslich, at St. Marien Hospital in Frankfurt, hazarded a forecast for the year 2025. Known as the 'Endoscopy Pope' amongst colleagues because he brought this medical specialty to the medical forefront, he also emphasised the importance of interdisciplinary cooperation. Among others, this has previously been affected by data protection restrictions between hospitals, but these are due to be lifted.

Amongst technological innovations is nanotechnology, which provides new opportunities to guide light within the body using LED-illuminated instruments and a periscope with three cameras, which show round structures as flat. On the other hand, the professor does not give the controllable magnet capsule much of a chance – too much expense for too low a detection rate.

Finally, the latest news: Colon cancer might actually develop as a result of an infection.

Study proves Hemospray is effective and safe

Endoscopic Hemostat stems bleeding



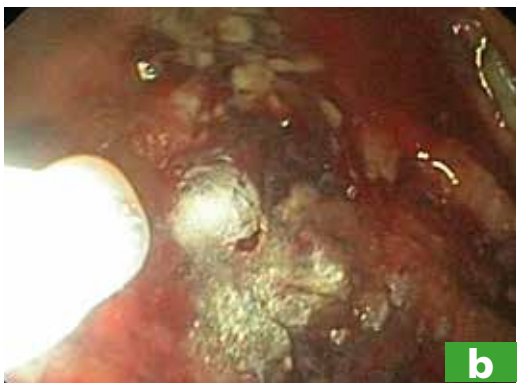


Image a is the bleeding site pre treatment. Image b is mid treatment with Hemospray. Image c is the bleeding site covered with Hemospray and the bleeding has been stopped successfully.

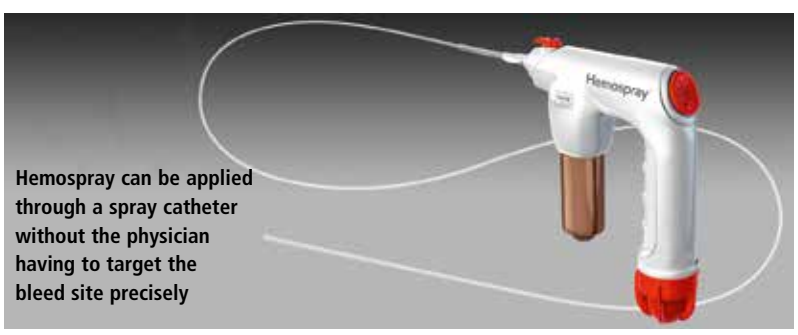
A few years ago the American forces succeeded in dramatically lowering the mortality of soldiers from gunshot wounds with the help of a new, haemostatic powder. These silicate crystals, which attach to a wound, not only stem external bleeding but also internal bleeding resulting from stomach or duodenal ulcers, tumours or rare types of vascular deformities.

Named Hemospray, Cook Medical will introduce this new type of endoscopic haemostatic agent to Europe this year. Over the last few months this product was tested for effectiveness and safety within the context of a European and multi-centric registry, the SEAL study.

The Medical Clinic at St. Marien Hospital in Frankfurt, under Professor Ralf Kiesslich, was the first centre in Germany to use the spray, with very promising results, he emphasises. 'Hemospray is an additional option for haemostatis not previously available to us. The endoscopic haemostatis guidelines in principle recommend the combination of different procedures. First data from the study points towards Hemospray on its own being just as effective as the combined procedures,' Prof. Kiesslich explains.

Previously, the options for haemostatis in the gastrointestinal tract extended to under-injecting the specific area of the bleed with medication, mainly with diluted adrenalin solution, or to seal the bleeding vessel mechanically with titanium clips. Often, however, this is not easily possible due to the lack of an overview of the bleeding area, and some bleeds are in such anatomically awkward positions that both procedures combined can only be used with great difficulty.

Hemospray on the other hand can be applied via spray catheter and the physician does not have to target the location of the bleed precisely. 'The crystals spread very finely and quickly lead to a mechanical barrier that stops blood flowing out. Therefore, bleeding can be stemmed without contact or manipulation of the mucous membrane. In the SEAL study, Hemospray was used in three different scenarios: It was either sprayed directly onto the bleed leading to haemostatis, or used additionally where haemostasis with conventional procedures, such as under-injection and clipping, could not be achieved.



Hemospray can be applied through a spray catheter without the physician having to target the bleed site precisely

Conversely, in cases where the primary application of Hemospray did not lead to haemostasis, under-injection and/or clipping were used. The physicians in charge were free to choose the procedures as well as where and in which order they were being used. Afterwards it was observed how successful the respective procedure was.

'The study results are very satisfactory,' the gastroenterologist confirmed. 'The use of Hemospray for active bleeds did not lead to any undesired side effects and, particularly pleasing, Hemospray lead to a very high rate of haemostatis, i.e. it was successful in 90% of applications.' In particularly dangerous situations, i.e. active bleeds during endoscopy, situations that can be life-threatening for patients can, in most cases, be avoided simply through the use of the new spray.

Therefore, there is no reason to stop the introduction of Hemospray to Europe to treat active bleeds in the upper gastrointestinal tract. However, Hemospray has not yet been licensed to treat oesophageal varices bleeds. These can also be life-threatening events diagnosed with the help of endoscopy. Hemospray is not licensed for this because there is concern that the silicate crystals applied to those oesophageal varicose veins might be carried to the lungs, leading to a pulmonary embolism. 'However, some centres have actually also used Hemospray successfully in the con-

Anaesthesiology

Accidental awareness under general anaesthesia

Professor Jaideep Pandit is a consultant anaesthetist at Oxford University Hospitals and the lead author of the NAP5 study *Accidental Awareness under General Anaesthesia*. In 1998-99 he was Assistant Professor of Anaesthesiology at the University of Michigan, Ann Arbor, USA, and in the latter year appointed to his present consultancy post. In 2000 he was elected to St John's College, Oxford. The professor's research interests include respiratory physiology, anaesthesia and critical care, health economics and operating theatre management. He is an editor of the journal *Anaesthesia*, and of *Surgery* and the *British Journal of Cardiology*. He is also on the Board of the National Institute of Academic Anaesthesia and is Scientific Officer of the national Difficult Airway Society.

Report: Mark Nicholls

A UK study has highlighted the issue of patients waking up from a general anaesthetic while undergoing surgery. The research, which questioned more than 7,100 consultant anaesthetists, revealed that there was about one episode of accidental awareness in every 15,000 general anaesthetics cases in the three million UK operations in 2011.

This equated to 153 reported cases, with 46 patients conscious throughout the operation, according to the interim report of the study *Accidental Awareness during General Anaesthesia in the UK*. This compares with previous studies, which suggested the figure was as high as about one in 500 general anaesthetics cases. Yet, the survey, to which 82% of all senior anaesthetists in National Health Service (NHS) hospitals responded, also revealed the very low use of brain monitoring technology: only 2% of anaesthetists routinely use this. Further research will be conducted to discover the reasons why.

This on-going study, by the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland, aims to identify and quantify the issues and ensure improvements continue. It is part of the major 5th National Audit Project (NAP5), thought to be the largest study of its kind, and follows on from previous research by UK anaesthetists' bodies that focused on areas such as airway management and regional anaesthesia complications.

Most episodes are brief and cause no pain

Professor Jaideep Pandit, Consultant Anaesthetist at Oxford University Hospitals NHS Foundation Trust and lead author, said: 'Anaesthesia is a medical speciality very much focused on safety and patient experience. We identified accidental awareness during anaesthesia as something that concerns patients and the profession. The profession is therefore undertaking this major study so that we can better understand the problem and work to reduce the likelihood of it happening to patients.

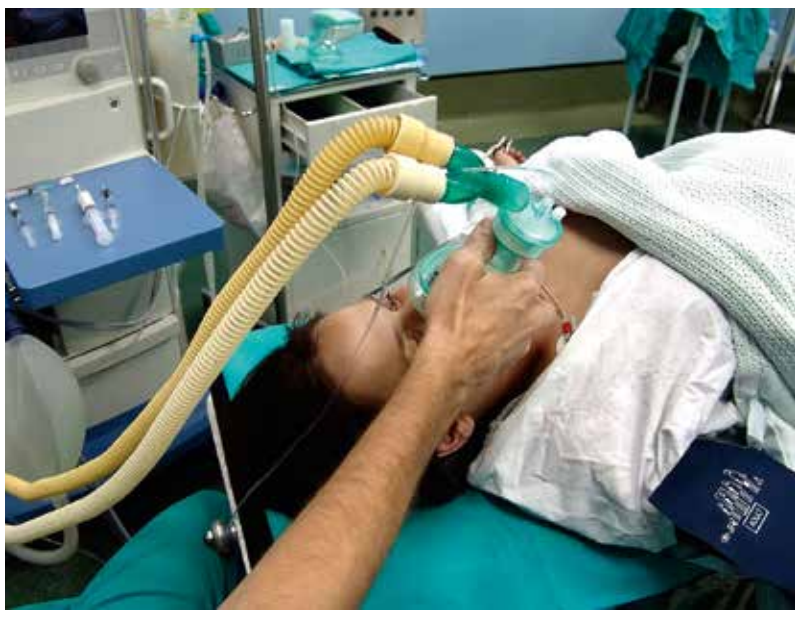
'We are particularly interested in patient experiences of awareness. Although we know that some patients do suffer distress after these episodes, our survey has found that the vast majority of episodes are brief and do not cause pain or distress.'

The study will continue to explore the reasons for the differences between the latest figures and previous reports, Prof. Pandit said. These could include the fact that anaesthesia is a consultant-led service in the UK, compared to the use of nurse anaesthetists elsewhere, possible differences in patient sensitivity to anaesthetic drugs, or different detection rates influencing the reported numbers.

Findings in previous studies, showing higher incidence of accidental awareness, came from research in which patients were asked about their experiences after surgery, following informed consent before the operation, while the current study details reports directly from anaesthetists.

Researchers say that patients who experience accidental awareness can remember events taking place just before or during their surgery and while most recall only noise or touch, a smaller number describe feeling unpleasant sensations, such as suffocation, inability to move or even the pain of surgery. Each case will be examined in depth. Professor Pandit said: 'We know that two thirds of episodes occurred during the dynamic phase – during induction or emergence - and because those phases are brief, it follows that the awareness may have been brief.'

'Overall, patients should be heartened by fact that cases of accidental awareness are one in 15,000, and in two-thirds of those the experience was brief, with no pain,' Prof. Pandit concluded.



Leaving the Johannes Gutenberg University in Mainz in 1996, with his medical degree and doctorate, **Professor Ralf Kiesslich MD** took specialist training in internal medicine and gastroenterology and, in 2004, received particular acclaim for his description of endomicroscopy. He became an international expert on innovative and low-impact endoscopic procedures and has received numerous awards. The professor wrote his habilitation in 2008 on *Chromo, magnifying and confocal laser endoscopy for the early diagnosis of gastrointestinal tumours and their preliminary stages.* In 2008 he was appointed Professor for Gastrointestinal Endoscopy at the University of Mainz, founded by Pentax Europe GmbH and aimed at developing new endoscopic procedures for the early detection of tumours in the gastrointestinal system. Up to November 2012 he headed the internationally renowned Department of when he was appointed senior consultant for the Medical Clinic of St. Marien Hospital in Frankfurt. He is also a Section Editor of the publications *Gastroenterology* and *Gastroenterologie*.

text of off-label-use for this indication in patients where bleeding from oesophageal varices could not be stemmed with conventional procedures.

'These publications show that, even in this critical emergency situation for gastroenterology, bleeding could be stopped with the help of Hemospray,' Prof. Kiesslich points out.

Lighting

Starled3 Evo Plus suits countless applications

Completely digital and microprocessor controlled, the Starled3 Evo Plus, with new I-Sense control panel '… grants an extremely simple and ergonomic way of adjusting and visualising light intensity, ENDO function (light up) as well as the selection of its three reflectors that can be separately used according to the different needs,' the Italian manufacturer ACEM Medical Company reports.

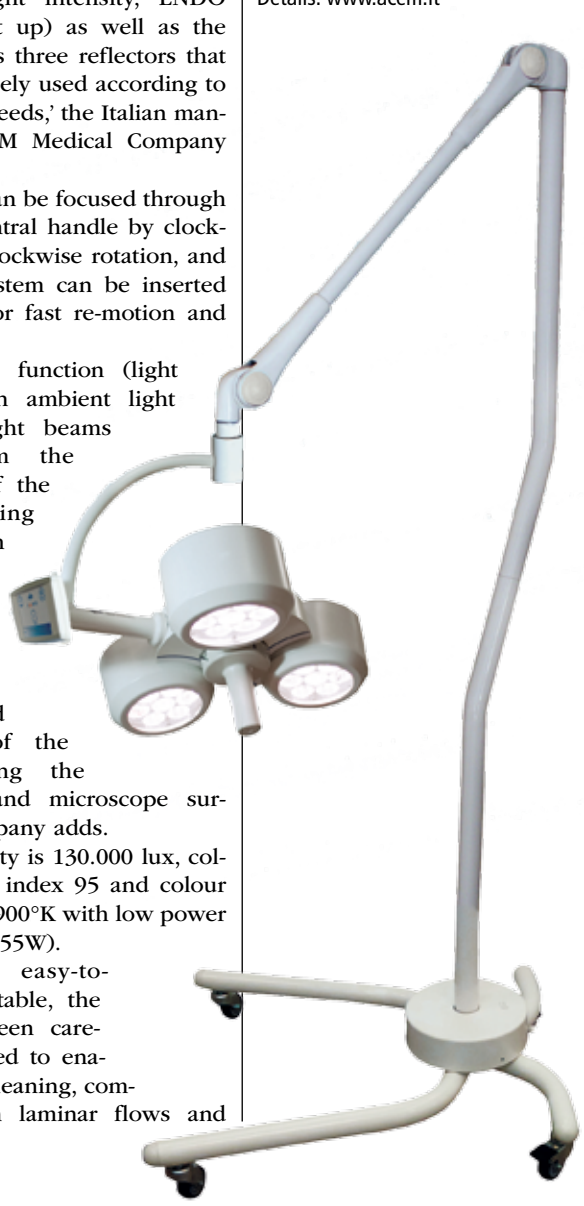
The beam can be focused through the lamp's central handle by clockwise or anti-clockwise rotation, and the simple system can be inserted or removed for fast re-motion and sterilisation.

'The ENDO function (light up) grants an ambient light thanks to light beams coming from the upper part of the lamp allowing the regulation of light levels particularly fit for the preparation, assistance and monitoring of the patient during the intervention and microscope surgery,' the company adds.

Light intensity is 130.000 lux, colour rendering index 95 and colour temperature 4900°K with low power consumption (55W).

Compact, easy-to-handle and stable, the design has been carefully considered to enable speed in cleaning, compatibility with laminar flows and simplicity of use. The Starled3 Evo Plus is available for trolley, wall or ceiling mounting in single or double configuration, and can be supplied with battery.

Details: www.acem.it



Nutrition and Health — Sponsored by seca Precision for health

Treating type 2 diabetes mellitus

Type 2 diabetes mellitus often involves overweight. However, emphasising reduced calorie intake and increased exercise can result in weight stagnation or even increased weight – but, it can be successful if fat decreases and muscle increases.

Using the medical Body Composition Analyzer seca mBCA 515, a diabetologist can determine a patient's fat/muscle mass development with precision, as shown in four international studies. The device from seca gmbh & co. kg, Hamburg, was compared with gold standards (current status: www.seca.com/studies).

In less than 20 seconds a non-invasive bio-electrical impedance measurement of fat mass, water and skeletal muscle mass are determined and the data is presented in a user-friendly form.

Using this device for fat mass measurements, energy stores can be calculated and a patient's personal energy expenditure per day determined. A weight loss plan is then based on the figures.

Whether therapy leads to fat mass reduction with a simultaneous increase in muscle mass can be seen in seca's Body Composition Chart (BCC) – a further development of the Body-Mass-Index (BMI). Two indices are generated for the BCC: fat-free mass index and fat mass index. As with the BMI, values are related to a patient's height and plotted in a system of coordinates, and represented in percentiles. The level in low muscle mass, obesity, chronic lack of energy and high muscle mass categories can be seen instantly, as can whether the goal – fat reduction and muscle increase – has been reached. Even though his weight is not changing, a diabetic can become motivated because his body composition is developing positively.

Analysis of fat-free mass using Bioelectric Impedance Analysis (BIVA) facilitates early detection of other diseases, such as ischaemic oedema due to circulatory disorders.

Details: mbca.seca.com

Body Composition Analyzer seca mBCA 515

Vital research recommences at the Erasmus Medical Centre

Investigating the HFN1 virus

Report: Sabine Spatzek

Dutch virologist Ron Fouchier and his colleagues around the world stopped their research into the bird flu virus H5N1 for a whole year to allow an international debate surrounding the benefits and risks of their work. Since mid-February, Dr Fouchier and team, who work in the high security laboratories at the Erasmus Medical Centre in Rotterdam, have resumed their research into the transferability of the virus to mammals.

The international influenza research community is agreed that these studies are rightful and important, he emphasised during the 23rd Annual Meeting of the Society for Virology in Kiel, Germany. During this meeting in early March 2013, around 1,000 participants, mostly from Germany, Austria and Switzerland, discussed current findings and developments in the diagnosis, prevention and treatment of viral infectious diseases.

Dr Fouchier's research was among the key topics. The hosting Society for Virology, the largest scientific society in Europe in this field, supported the re-uptake of research into the transferability of the H5N1 virus in principle, confirmed the society's President Professor Thomas Mertens, medical director at the Institute of Virology, University Hospital Ulm. 'We are convinced that the scientific findings and social benefit of such studies outweigh the risk of danger, assuming adherence to the appropriate safety precautions are adhered.'

By introducing the H5N1 bird-flu virus to lab ferrets, the Dutch team studied which mutations need to be present in order for mammals (or humans) to contract the virus.

Unlike the swine flu virus H1N1, which caused a worldwide pandemic in 2009, H5N1 is not transferable from human to human. However, there is no guarantee that it will remain so: 'We know that flu viruses jump from animal species to humans on average every 20 years,' Dr Fouchier said, during a *European Hospital* discussion. 'And, every time this happens they acquire the ability to become airborne.'

Precisely how that change – which is decisive for transmission – occurs as yet is completely unclear. This knowledge would be a prerequisite for the ability to identify dangerous types of viruses and to fight their transmission systematically. These findings would also be valuable for the development of vaccines and medication – making the respective studies also of great importance for hospitals, Dr Fouchier pointed out. 'If we ever see a pandemic with a virus like H5N1, clinical management will rely on laboratory experiments like those we did.'

Incidentally, the question is not if but when the next pandemic will occur and how severe it could be, said the scientist, who is considered to be one of the world's leading experts on highly pathogenic influenza viruses. 'Maybe next time we are not as lucky as we were in 2009.'

The trigger for the controversy that caused Dr Fouchier and colleagues to interrupt their research into the H5N1 virus early in 2012 was an evaluation by the US National Science Advisory Board for Biosecurity (NSABB), which advised Science magazine against publishing Dr Fouchier's research findings in their entirety.

Allegedly, there was a danger that terrorists could use this knowledge to create a 'killer virus' for use as a biological weapon. This then unique event alarmed the media as well as the political world.

Dr Fouchier himself has often explained that he considers the NSABB's position on this matter wrong. On one hand the 'reproduction' of an H5N1 virus, which may possibly be able to reproduce in human hosts, and to trigger a pandemic, would require solid, specialist knowledge.

On the other hand, numerous viruses occur naturally and they could lead to fatalities at a higher rate of transmission. The lack of publication led to the controversy, which has not always been professionally handled. 'Since we were not allowed to disclose details of our work and explain the benefits, the only thing left to discuss was risk.' Meanwhile, the findings have now been published.

The safety of the laboratories at the Erasmus Medical Centre in Rotterdam was never officially doubted, Dr Fouchier pointed out. Therefore, there was also no need for any changes before research in to the H5N1 virus resumed. 'Our laboratories were specifically designed for this work; they were already extremely safe and well secured. Scientists working there have very extensive training and are re-evaluated for their knowledge and ability to respond to incidents every year.' In addition to the license from the responsible Dutch ministry, the safety of the facilities is also checked by the US government, which finances the research.

In the Netherlands the study's publication will have legal repercussions. A court will investigate whether the work could indeed be perceived as an instruction for the creation of biological weapons. If the judges share this view, each individual EU government would be given the option to censor scientific work at will, Dr Fouchier fears.

In 2012, Time Magazine listed **Dr Ron Fouchier** among the 100 most influential people. In the Department of Virology at Erasmus Medical Centre in Rotterdam his research focuses on the evolution and molecular biology of respiratory viruses in humans and animals, with special emphasis on influenza virus zoonoses and pandemics and hMPV. In 1995, Dr Fouchier received his PhD in Medicine at the University of Amsterdam for his studies on molecular determinants of HIV-1 phenotype variability at the Department of Clinical Viro-immunology, Sanquin Research. From 1995-1998 he was a post-doctoral fellow at the Howard Hughes Medical Institute, University of Pennsylvania School of Medicine in Philadelphia, where he studied the function of the HIV-1 Vif protein and nuclear transport of HIV-1 pre-integration complexes. Subsequently he set up a new group at Erasmus MC to study the molecular biology of respiratory viruses, particularly the influenza A virus. As a fellow of The Royal Netherlands Academy of Arts and Sciences, he studied influenza virus zoonoses and pathogenicity. Recent achievements of his team include the identification and characterisation of several 'new' viruses; the human metapneumovirus (hMPV), a human coronavirus (hCoV-NL), the SARS coronavirus (SARS-CoV) and a new influenza A virus subtype (H16).

Membrane oxygenation

Continued from page 15

Bartlett, in 1991 the Extracorporeal Life Support Organisation (ELSO) reported that out of 3,528 infants with predicted mortality of 83%, 80% in fact survived thanks to ECMO.

The lack of real options to treat acute, progressive lung failure on the one hand and advances in membrane technology on the other, have continued to maintain interest in ECMO. Continuously increasing cases leave us with no choice. Consider the H1N1 pandemic of 2009 and 2010, with talk of 18,500 dead worldwide. Epidemiologists now estimate there were in fact 284,500 victims, 80% of them aged under 65 and 51% in Southeast Asia and Africa [Lancet Infect Dis. 2012 Sep;12(9):687-95].

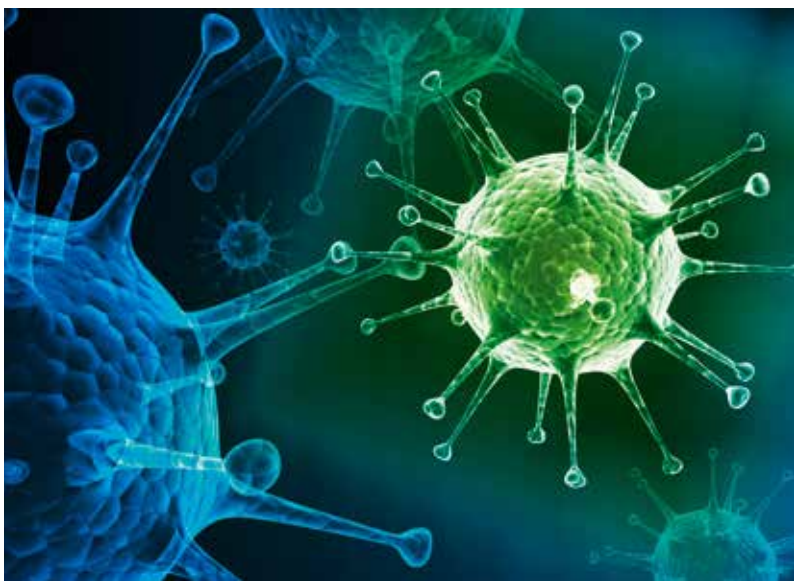
At the time, researchers from Australia and New Zealand collected data on frequency, clinical characteristics, complications and survival of patients with severe influenza-associated ARDS. 15 out of 187 intensive care wards treated 68 patients with ECMO. The average age was 34.4 years, the length of ECMO support a median of 10 days, and mortality was 21% [JAMA 2009 Nov 4;302(17):1888-1895].

Sceptics view the fact that these patients cannot be compared to those who – being less severely ill – were not given ECMO, as further proof of a lack of evidence. They also similarly view the results of the CESAR trials published in 2009. Out of 790 patients examined, 180 were admitted and randomised 1:1. 90 patients were to receive conventional treatment, the other 90 via ECMO. Ultimately 68 patients (75%) were given ECMO, 57 (63%) were still alive after six months – compared to 41 out of 87 (47%) in the conventional group [Lancet. 2009 Oct 17;374(9698):1351-6].Although this result is significant, with a relative risk of 0.69, a 95% confidence interval of 0.05-0.97 and p=0.03, critics claim that only one patient made the difference between a significant and non-significant result.

So, what would help to convince the critics? Maybe take a look at medical history. All it took to establish vitamin C as a valid treatment of scurvy among sailors were a few lemons, a keen eye and conviction. Nobody then had the idea to randomise sailing crews before they set off on months-long journeys. Or let's take a trip in the car: Nobody these days would seriously request that only every other new car should be fitted with airbags and then to check, a year on, in which group more passengers survived accidents …

Shunning the flu vaccine

France experiences its longest flu epidemic in 30 years



Report: Annick Chapoy

Although receding since late March, the 2012-13 seasonal flu epidemic in metropolitan France, appears to be the longest in some 30 years, even if it did not strike the highest numbers, according to the monitoring network Sentinelles-Inserm.

The epidemic affected 3,563,000 persons – who had 39°C+ fever and had to see a doctor – over a 13-week period, according to Sentinelle's head Dr Thierry Blanchon. 'In some 30 years it's the longest epidemic episode, since our network began to monitor the influenza impact.' However, although a major seasonal epidemic episode, some previous outbreaks have affected more people – in 1998-89 3.5 millions cases were recorded, and in 1989-1990 flu affected 4.6 million people in 11 weeks.'

All the figures do not take into account the pandemic A/H 1N1 flu, which had its own characteristics, among which an exceptional length of 16 weeks, and specific monitoring procedures.The Sentinelle doctors record flu symptoms such as a sudden fever peak to 39° C+, together with muscle stiffness and respiratory discomfort.

The Grog (regional groups for flu monitoring) stressed that, although the flu epidemic was weakening in mid-March, the flu virus remained 'active'. 'Since the outbreak, the A and B flu viruses (H1N1 and H3N2) have been circulating in a quasi-equal fashion', Grog observed. The groups measure the flu varieties with fevers including those under than 39°C. It estimated that this year more than 10 million persons had to visit a GP or a paediatrician since the outbreak of the flu epidemic.

Since November 2012, according to Grog, 664 very severe cases put patients in hospital intensive care units. 98 patients died (from five months to 88 years old) according to the national Institut de Veille Sanitaire (InVS). 72% of these patients had been infected by the A virus.

Disaffection grows against seasonal flu vaccine

'We need to save the seasonal flu vaccine'… it could be a message from the GEIG (Groupe d'expertise et d'information sur la grippe), which recently held its 25th congress. Experts expressed dismay at the insufficient and declining flu vaccine uptake, especially among people at high-risk, as well as healthcare workers, two groups receiving the vaccine free. In winter 2011-12 uptake dropped significantly among pregnant women, people over 65, and those suffering chronic diseases such as respiratory, cardiac or kidney pathologies, blood and hepatic pathologies, diabetes or immunodeficiency. Specifically, only 43 % of people below 65 suffering from chronic obstructive bronchopneumopathy had the flu vaccination last year as opposed to 68% the year before.

A 75 % uptake among over 65-year-olds and high-risk patients would be needed to reduce the flu impact significantly on this particular population. The GEIG stresses that '…last winter, the mortality rate was especially important during the cold wave and the flu epidemic' with a low vaccination rate in the background. 'Almost 6,000 died between February 6 and March 18, a toll 3% higher than the year before'.

As for healthcare workers, in 2011 only 25% were vaccinated, 7% less than in 2010. Moreover, 24% who had received vaccination before, stopped doing it, and 51% of healthcare staff have never been immunised against influenza. They mention 'apprehension about injections' and are also sceptical about the vaccine's efficiency and safety.

In October 2012, Novartis flu vaccines were temporarily suspended in several countries, pending tests for possible side-effects. This was a 'precautionary measure', but it came after the disastrous scam of the swine flU vaccination in 2010, when 94 million Tamiflu doses were uselessly ordered by the then Minister of Health Roselyne Bachelot.

A leading periodontologist calls for multidisciplinary collaboration

From bad breath to cardiac infarction

Report: Michael Reiter

More than half of Germany's population aged between 18 and 74 years cannot show off a gapless set of teeth, and that's similar in France and worse only in Poland, according to a 2012 study, which also investigated oral hygiene. At the recent German Federation of Dentists FVDZ meeting, Professor Thomas Hoffmann, Director of the Department of Dental Medicine at Dresden University Hospital, emphasised that periodontitis, which causes bad breath, can result in serious health consequences, such as cardiac infarction. Enhanced collaboration between medical disciplines is needed to contain this problem, he urged.

Periodontitis is a polybacterial oral infection defined by host reactivity, he explained. 'Its progress is influenced by risk factors such as behaviour, genetics, morbidities and age. They include smoking habits and diabetes as well as osteoporosis, viral infections, gender, as well as socio-psychological aspects.' Periodontitis, he underlined, can induce the risks for chronic ischaemic cardiovascular disease (CVD), diabetes, premature births, osteoporosis and COPD.

Periodontitis micro-organisms can be transported from mouth into bloodstream while chewing, or during diagnostic and therapeutic activities. Periodontal pathogens have been found in atheromatous plaques. Pro-inflammatory proteins, such as cytokines in the serum of periodontitis patients, also function as markers for CVD; increased formation of special proteins, such as HSP and CRP in periodontitis cases, increases the risk of CVD; the plasma fibrinogen titre is increased in periodontitis; add to this the overall risk factors mentioned.

A multi-gene model

Host reactivity in the context of chronic inflammation is determined by a complex set of gene-gene and gene-environment interactions, the professor pointed out. Individual susceptibility can result from various genetic variations of pro-inflammatory proteins and their receptors, from components of the immune system as well as proteins that are involved in tissue reformation, such as matrix-metallo proteinases, cathepsines, and the vitamin D receptor.

The systemic effect of periodontitis therapy demonstrates these complex interactions and points to the key role of this therapy as medically required. It leads to improved endothelial dysfunction in cases of severe periodontitis. The therapy reduces CRP titres, and – combined with antibiotics – of IL 6 and TNF[a] titres, as well as total and LDL cho-

Thomas Hoffmann

lesterol. Interventional studies on Par therapy demonstrate that HbA1c is reduced significantly.

Collaboration to improve outcomes

Interaction between dentists and physicians from other specialties is not common practice, Prof. Hoffmann explained. 'In a significant number of cases, information exchange about a patient would enable precise diagnosis and help define suitable holistic therapies.' This would support the best possible outcome for a patient. 'Oral health,' he stressed, 'is an important part of the whole picture and combined therapies help reduce severe risks.

New Zealand's collaboration and IT data exchange system could benefit Europe

The earthquake that shook up healthcare

In recent years the Canterbury District Health Board (CDHB), which organises and funds the healthcare of over 500,000 citizens in a remote region of New Zealand, has raised the quality of care and access to care – and the country's major earthquake contributed largely to CDHB's IT-supported approach.

Using the control unit for the Orion Health online information portal

A few years ago, although primary care was well coordinated, CDHB's single tertiary hospital was in serious trouble. Due to overload, Gridlocks occurred regularly; surgery targets lagged seriously behind. 'In winter, bed shortages were frequent and staff satisfaction was low,' explained Dr Nigel Millar, Chief Medical Officer of the Canterbury District Health Board. Financial challenges added stress. 'These drivers initiated a major transformation at the hospital.'

Today, gridlocks are virtually abolished and surgical procedures are generally ahead of targets. The average time a patient spends in A&E is down to two hours and a programme to reduce hospitalisations has been extended to roughly 24,000 patient events annually. Based on patient pathways, processes were streamlined to coordinate hospital care, Dr Millar added. The financial situation was amended and an engagement survey documented a high degree of staff commitment.

During the major 2011 earthquake, improved hospital processes, linked up with coordinated primary care, helped the CDHB to cope with the surge in demand for medical services. Due to damages to facilities and losses in resources, part of the acute services had to be moved off-site. 'We had an absolute imperative to accelerate things, and staff embraced the notion that something had to be done.' The aim was to provide consistent, reliable care during recovery, and ensure a more reliable, safer and more efficient health system.

Approaches discussed before the earthquake included the *Crest* programme – a 'hospital in the home', or early discharge. After the disaster, it became clear that this concept would greatly improve bed shortages and it became a reality within three weeks.

The acute admission rate adjusted by population is a measure of effectiveness and reflects quality provided in the care chain. 'The CDHB admits only around 70% of the number of patients compared with the rest of New Zealand,' the CMO pointed out. 'The treatment pathway for COPD patients, engineered by GPs together with clinicians, is a perfect example of creative approaches.'

IT uptake

The IT uptake in primary care, with GP systems including electronic patient records (EPRs) and a digital flow of information, has been very high. An electronic referral system helps streamline planning with the hospital. To improve processes, the hospital implemented Emendo software to analyse all activity data from previous years. 'This provided a predictive model, which allowed us to look ahead with regard to the number and types of cases. It turns out that demand for acute services in acute care is entirely predictable, which helps us to respond early to predicted bed crunches', Dr Millar explained.

Nigel Millar

The earthquake caused a loss of conventional records for some care providers; the CDHB realised the need to share electronic files when patients are relocated and data is not readily available from GPs. 'We created the *eSCRV,* the shared summarised care record viewing platform.' This brings together data from the community pharmacy, nursing, primary care, and hospital and specialist services, presenting it in the Concerto Portal from Orion Health –*Health Connect South*. 'This became the essential strategy of the overall recovery effort,' he added.

The system, which makes patient's overall medical data available to GPs 24/7, is secure and permissive, with access by providers audited. GP's soon accepted that their patients would receive better care due to this collaboration.

The Canterbury, West Coast and South Canterbury district health boards now use a unified version of this portal, 'and within about a year, all of New Zealand's South Island will be able to exchange information about patients who relocate', Dr Millar predicted. The country's unique patient identifier system and secure health information network support this integration. 'During the next few years, regional versions of the portal will be implemented across the country.'

Dr Millar is part of the National Health IT Board. 'Its strategy is not to control, but to provide direction about what is required and enable innovation,' he said. 'This leadership has provided a major stimulus over the past years. European health systems face similar challenges regarding cost and access. We invite Europeans to enter into a dialogue with New Zealand about our solutions that provide appropriate information flow in order to improve healthcare.

(mr)

Highlights from Barco on show at ECR 2013

Launched: The new 6-MP display

Report: Michael Reiter

Here comes a new, aesthetic look and feel of display systems, advanced LED technology, and cranked up luminance enhancing image quality: imaging specialists from Barco are taking their displays to the 21st century. At ECR 2013 product announcements included the Eonis 22' model available in black or white, 'with the latter offering a fully cleanable front gorilla glass panel to prevent infection', business development manager Jurgen De Backer pointed out.

The Coronis Fusion 6 MP DL – launched and gaining considerable attention: 'It presents images to physicians in a way that will not be achieved by dual-head 3 MP systems,' explained Bjorn Belpaeme, Product Manager of Barco's Healthcare Division. 'Initial results of an on-going study at the Montefiori Medical Centre in New York show that shortened read times and reduced eye strain can be achieved.'

Bjorn Belpaeme at the Vienna congress

Robust and with a protective cover, key features include anti-reflective coating, more luminance emitted – 450 candelas – thanks to edge-lit, energy-saving LED technology and an optimised viewing angle, e.g. for groups. I-Guard integrated sensor technology measures, triggers and calibrates luminance correlated with the centre of the screen, conforming to regulations. Control of ambient light and just notable differences (JND) as well as automatic correction depending on the lookup table (ULT), based on the MediCal QAWeb cloud-based tool, are further benefits of the system.

The display is brighter, shows more details, and requires less zooming, panning, and window levelling, Bjorn Belpaeme added. 'It comes with 50 percent more calibrated luminance, 50 percent more guaranteed lifetime, and 25 percent less power consumption, as well as nought percent mercury – an eco-friendly approach.'

* Price and product release: March.

The new display is already in routine use at Keio University Hospital in Japan

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