EUROPEAN HOSPITAL

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

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The real Russian revolution

The main causes of Russian mortality: cardiovascular disease (1,200 deaths annually), cancer (300,000) and trauma (200,000)

Two serious new laws were passed at the end of 2010, one regarding obligatory medical insurance the other the '83 Federal Law', which changes the rules of state regulation of the social sector. Some experts believe that the 83 FL will be the death warrant for accessible education and healthcare in Russia. This law suggests a division into three parts of all social services – schools, universities, hospitals and cultural institutions must become Government (funded by the State), Budgetary (funded by the state and patients) or Autonomous (with economic and organisational freedom).

Russian patients worry that physicians will not help them without additional payment

The law's authors try to create a system in which money follows the person – a good physician, for example, will have many patients, whilst a bad doctor will run out of patients; a good, modern hospital will gain many patients, an out-dated one will close.

'Thus the State seeks to optimise the social accounts,' experts point out, 'but there is a huge danger that Russia will have many ruined hospitals because many people's health is bad and income is low. As a result, many Russians could find themselves without healthcare assistance, especially in rural areas.'

Unfortunately this very important law provides no instructions as to how an actual institution could decide the shape of its future. However, 83 FL came into force on 1st January this year and the process has begun.

It occurred in Russia's medical world at the end of 2010, some experts say, but then they add 'It's only a paper revolution'. EH Correspondent *Olga Ostrovskaja* reports

Every region has reorganised according to how its leaders have understood their tasks. Altai has declared that every regional medical institution will remain Government. Tatarstan, on the contrary, announced the Republic's hospitals will be autonomous.

Additionally, the first order to be prepared by Ministry of Finance appeared only in January, after the New Year holidays. Also, the Ministry of Health and Social Affairs has prepared several small bills, one of which is about the statement of an order of definition of a payment for medical services concerning the principal aspect of a hospital's 'activity'. This is a most difficult and old problem: Every government medical institution has received patients' money but no law has ever been accepted by the Russian government about this!

Nevertheless, the second law – obligatory medical insurance – has raised medical tax from 3.1% to 5.1%, by which the government plans to gain an additional 230 billon roubles. These billions are to be spent on the modernisation of hospitals and clinics, the development of information technologies and the creation of medical standards. Though, these 'state dreams' could become reality if Russian business will be good and the enterprises will be able to pay all the tax.

However, what if the money for a hospital's development is absent? The new 83 FL permits the sale of equipment – and even buildings – to some private person. Thus a government institute could become a private clinic.

It looks like the non-apparent 'revolution' could become a serious reform of Russian medicine.

A not so healthy glance at EU health

More are obese, more are demented and more have HIV – but some things are looking up

More than doubling over the last 20 years in most EU Member States, obesity has considerable implications for health, health systems and the economy. Over half our adult population is now overweight or obese, according to the joint European Commission and OECD report *Health at a Glance: Europe 2010*.

The report presents key trends on health, health systems and health spending in the 27 EU Member States, plus the three European Free Trade Association countries (Iceland, Norway and Switzerland and Turkey).

Compiling data from the OECD, Eurostat and the WHO, the report shows that the prevalence of obesity alone ranges from less than 10% in Romania and Italy to over 20% in the UK, Ireland and Malta. On average, just over 15% of the EU adult population is obese.

Currently, 1 in 7 children in the EU are overweight or obese – and the figures are set to rise even further.

There are fewer heart disease deaths, but it still has the highest mortality rate, accounting for 40% of all deaths in Europe in 2008.

Newly-diagnosed cases of HIV more than doubled between 2000 and 2008. HIV prevalence estimates were highest in countries with high AIDS incidence rates, namely Estonia, Latvia, Portugal and Spain.

Inevitably, the link is strong between the prevalence of dementia and population ageing; the number of over 65-year-olds is

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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

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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 1/11

Proton therapy

The Curie Institute opens a new state-of-the-art centre. *Annick Chapoy* reports from Paris

As one of the most advanced forms of precision radiotherapy, proton therapy enables the irradiation of tumours located deep within the body, in the proximity of critical organs, such as the optic nerve or some brain areas.

The Institut Curie has renovated its proton therapy centre in Orsay near Paris. Since 1991, when the original centre opened, it has treated over 5,000 patients (4,000 for eye melanoma, which remains the main indication to this day). The institute is a national centre of excellence on eye melanoma. 'Traditional therapies are rather inefficient,' said **Dr Rémi Dandale**, medical manager of the new centre. 'Proton therapy has a great advantage because it conserves the eyeball and useful vision in 90 percent of cases.'

Every year the proton therapy centre also treats about a hundred adult or child patients with chordomas or chondrosarcomas of the cranial base – rare tumours known to be resistant to traditional radiotherapy and requiring high doses of radiation.

'Proton therapy is certainly most beneficial among children since it enables better protection of critical organs, and thus reduces complications and the risk of secondary tumours,' explained radiation oncologist **Dr Sylvie Heffre**. Although they are not frequent (0.5% of cancers) paediatric cancers remain the second cause of child mortality between ages one and 15 years. Each year, 1,500 new cases are diagnosed in France.

The centre's complete renovation was designed to increase the number of children treated. In 2006 the creation of an anaesthetics team already enabled treatment under general anaesthesia for children less than four years old. Prior to this, they had to be sent to Boston or Switzerland. Every year since 2006, between 25 and 30 children have benefited from proton therapy at the Centre.

Following a total, four-year renovation, the new centre has the capacity to treat 200 additional patients annually, including 120 children (out of 750 children who need radiation therapy annually in France). This Centre of national importance needed an investment of €50 million, made possible by a loan of €30 million and exceptional support from the Ministry of Health (The State's subsidy of €15 million and support to pay back the loan taken out by the Institut Curie).

The Proton Therapy Centre is part of the Institut Curie's Radiotherapy Department, the most complete in Europe where patients from all over the country and beyond are treated.

The centre has a new generation proton accelerator (230 MeV) and treatment room equipped with an isocentric arm – a 10-metre diameter metal structure weighing over 100 tons – which enables the beam to be aimed around a patient at all angles in order to treat new indications, which were previously not accessible – particularly in children.

A pilot centre in patient management

Renovation not only involved new equipment and technological developments. The work organisation was also completely reviewed using lean management methods. This approach for the continuous improvement of work practices focuses on patients' expectations and on providing staff with the necessary conditions to meet them.

'At first feedback from the entire staff was taken into account to identify the valuable steps – those that could be optimised to increase productivity and those that could be suppressed. By improving the design of control panels, upgrading to digital radiology (faster than traditional technology), or by repositioning some accessories, we have saved a few – very precious – minutes for each patient,' healthcare manager Hélène Colella-Fleury pointed out.

Improved control over technical steps also allows more time to support patients throughout their treatments.

A new consultation is now offered: Additional time for exchange, which enables patients to have all their questions answered. They are less stressed and thus cooperate better during their treatment.

'Optimising treatment preparation steps enables us to receive 19 patients per day, instead of 12. We would like to increase that number to 21 in the future,' said Hélène Colella-Fleury.

The Centre receives adults and young children with their families for periods that can last for several weeks. To stay close to their children during therapy, families can be accommodated at the Irène Joliot Curie Parents' House in central Paris. Also, there are warmly coloured personal and family areas at the centre itself, to maintain a homely atmosphere.

Proton beam therapy in the UK

Over the next four years, and with a budget of £43 million, the Department of Health plans to roll out proton beam therapy at a number of National Health Service centres in the United Kingdom. Hospital sites in London, Manchester and Birmingham being considered.

Meanwhile, the department has confirmed that the NHS will 'continue to send patients abroad for this treatment where clinically appropriate'.

Beckman Coulter sold

Danaher Corporation intend to integrate the IVD firm into its Medical Technologies division


H Lawrence Culp Jr

USA - Over the past couple of decades, due to acquisitions California-based Beckman Coulter Inc has became one of the world's largest manufacturers of *in vitro* diagnostics analysers and automation for clinical pathology laboratories. Now, in a US$6.8 billion transaction, including debt and cash acquired, the company itself been acquired by the Danaher Corporation of Washington, D.C.

In future, Beckman Coulter will be part of Danaher's Medical Technologies division, joining the firm's Leica, AB Sciex, Radiometer and Molecular Devices businesses.

This is divided into two areas: Dental, and Life Sciences and Diagnostics, which includes Radiometer, Leica, AB Sciex, and Molecular Devices.

Danaher offered US$83.50 per share to Beckman's shareholders. However, by 2014, the firm expects a 10% return on its invested capital. In all, the acquisition has been predicted to double the Washington firm's presence in life sciences and medical diagnostics arena. Larry Culp, President and CEO of Danaher, explained in a meeting with investors that cost is 'a very important part of the equation; there is a lot of discipline Danaher can bring to Beckman' to see US$250 million cost savings. 50% of this will come from 'more traditional operational synergies', he said – citing sourcing, procurement and productivity efforts 'on the shop floor or supply chain'. Streamlining the general administration could result in 25% of savings and improvements in various other areas, including IT, the other 25%.

However, customers of the *in vitro* device specialist Beckman Coulter are not expected to experience any changes. The firm, which ranked fourth in the global IVD market showed an annual revenue of US$3.7 bn (estimated full-year 2010), some 70% of this from consumables and services and 30% comes from analyser system sales. In the firm's portfolio, clinical chemistry products account for 33%, cellular systems 30%, immunoassays 25% and life sciences 12%. Larry Culp said Danaher intends to unlock Beckman's value using Danaher's processes and enhanced sales and marketing services. 'There is a whole host of opportunities for us to accelerate spending in high impact areas,' he said, referring to Beckman's immunoassay products and life sciences and Danaher's expertise in these.

Danaher already has a presence in markets beyond the USA, in international markets such as the EU and China. 25% of Beckman's 2010 revenue came from areas beyond the US. The acquisition will clearly augment Danaher's international business.

Why the sale of the company? In September 2010, as the Beckman Coulter share price fell below US$50 after some stagnation over a five-year period, its then CEO Scott Garret suddenly resigned. However, rumours regarding a possible sale of the firm had somewhat lifted the share value again.

Some reported problems with quality control, and another with a test to detect a cardiac attack, have been blamed for Beckman Coulter's woes. In addition, the USA's new medical device (not including lab equipment) excise tax of 2.3%, to come into effect in 2013, is attributed to some misgivings among IVD firms in terms of launching new hospital devices.

A diversified technology leader, Danaher designs, manufactures and markets products for professional, medical, industrial, and commercial customers. The firm has 48,000 associates serving customers in some 125 countries. Revenue in 2010: US$13.2 billion.

Danaher originated from 'Dana', a pre-700 BC Celtic word meaning swift flowing. The firm's reputation for sustained and accelerating growth plus profits are clear, along with its aims for acquisitions – as underlined by the takeover of Beckman Coulter.

Report: Brenda Marsh

The 360° view

For 170 years, the German firm seca has set worldwide standards for medical scales and measuring stations. Today, its products are used by medical teams in 110 countries, measuring a range of patients from tiny premature babies to adults weighing 300kg and basket ball players soaring to 7' 4" high. For the family run seca such a successful track record inspired its new generation – brothers Robert Vogel, CEO Sales & Marketing, and Frederik Vogel, CEO Development & Manufacturing – to continue the set a trend by changing the product portfolio.

The seca 360° wireless is not an individual product, it is a philosophy on which all seca scales and length measuring stations will be based. Curious about this concept, which was officially launched in November 2010, European Hospital visited Robert Vogel at the company's headquarters in the Hanseatic city of Hamburg, to hear more.

Explaining the focus of seca's innovation driven by the needs and circumstances experienced by seca product users, as well as cost pressures on the healthcare systems, Robert Vogel pointed out: 'The first to feel this pressure are the staff; however, at the same time, the demand for quality and efficiency increases. Therefore we wanted to offer a system that simplifies workflow and simultaneously is more effective.'

Direct data transmission via radio

In this case, functioning particularly relates to functioning in the hospital. The main attraction of the seca 360° wireless is that, in future, the scales and measuring stations will simply and safely transfer data directly to the patient data management system via radio signal. As electronic recording of measurements is increasingly mandatory in many countries, Robert Vogel is convinced that this is where the future of medical technology lies: 'It is not only in the US where the reforms in the healthcare system have stimulated discussion around Electronic Medical Records (EMR) but also in Europe. That's why we are already fitting all our seca products with a WLAN chip suitable for radio transmission without charge, so that even customers who are not yet active in EMR are equipped for the future.' Thus at a later stage, all customers have to do is acquire a receiver stick for the computer and the radio transmission software *seca emr flash 101*. Adaptation to the different HL7 and GDT standards is possible without a problem.

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A not so healthy glance at EU health

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expected to double between 1995 and 2050.

The shortage of doctors is a cause for concern in many European countries.

Health spending has risen in all EU Member States, often increasing at a faster rate than economic growth. In 2008, EU Member States spent, on average, 8.3% of their GDP on health, up from 7.3% in 1998.

Now the good news:

In the UK the number of doctors per capita rose by 30% between 2000-2008 (from 2.0 per 1,000 population to 2.6). Ireland saw a 50% rise. Why? Partly due to increased recruitment of foreign-trained doctors.

Life expectancy at birth in the EU increased from 72 years in 1980 to 78 years in 2007.

On average, women spend 75% of their life without disabilities, for men it is 80%.

The number of premature deaths has reduced dramatically. Mortality rates in Estonia, the Czech Republic, Hungary and Poland have fallen by over 30%, a decline greater than the EU average. Ireland's mortality rates have fallen by over 50%.

EC and OECD conclusion: 'There is no better or worse health system; each system has strengths and weaknesses. The aim of providing comparable data is to give countries the possibility to learn from each other, to gain efficiency and to improve the health of their populations.'

Details: http://ec.europa.eu/health/reports/european
www.oecd.org/health/healthataglance/europe

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Getting to the heart of measurements

seca takes this a step further. For those already working with digital patient files, seca analytics 105 software already facilitates quick, precise interpretation of vital functions. 'seca analytics 105 offers a type of interface where different data converges,' he explained. 'The software links the measurements on size and weight with other parameters from the digital patient file, such as blood count, and merges all data into an overall picture. The individual modules allow an insight into the energy balance, growth curves and cardiometabolic risk of individual patients. The doctor therefore receives informative support to make his diagnosis.'

seca products are used in hospitals in 110 countries

seca 360° wireless – benefits at a glance

- Wireless communication instead of cable connections
- System components can be set up anywhere
- seca's own secure wireless protocol for simple, quick recognition of devices in the seca 360° wireless network
- Paperless and error-free transmission of measurements
- Software seca analytics 105 for diagnostic assistance based on highly qualified analysis and assessment of health status and nutritional condition of the patient
- Graphic presentation of measurements and their comparison to standard values – digital display or hard copy printout (DIN A4)
- All measurements are EMR integrated for inclusion in electronic medical records.

Service and simplicity

The modular concept of the seca 360° wireless product range is based on expandability, which means seca is centred in a metamorphosis from product to systems provider. Robert Vogel takes this responsibility very seriously: 'We knew from the beginning that this new orientation for the company would have to be based on three columns – products, software and service. Even the best technology is of no use if the provider does not offer help before, during and after purchase of the product. This is why our service technicians advise and look after our customers on site to ensure the products work faultlessly. And the customers are mostly surprised how simply everything works.'

Ergonomic design in medical technology

Siemens' Touchpanel

It's not just an industrial designer's buzzword. This concept brings added value to patients, staff and manufacturers, *Anja Behringer* reports

The application of ergonomic principles can enhance product design and, more importantly, the usability of medical devices. Ideally the operation of the product is adaptable to the individual user's preferences and to different workflows, for example when safe handling is ensured in routine as well as in emergency situations.

One of the objectives of ergonomic design is minimising user errors and thus patient safety since incidents and damages caused by user errors most frequently impact the patient. However, healthcare staff is also exposed to danger when a medical device is electrically operated, when it contains harmful substances or ionised radiation. While technical safety standards aim at managing these obvious risks, proper product design can help reduce many other risks that are frequently not considered outright dangerous, such as unhealthy posture, crush and puncture injuries or cuts.

Ergonomic design is still often considered a superfluous marketing gimmick that only drives up acquisition costs. A close look at the figures, however, tells a different story: Additional costs accumulated in the course of the useful life of a product often significantly exceed the price difference between the cheap and expensive product. Over time the ergonomically designed medical product is often less expensive than the product with the same technical features but a lower price tag.

Self-explanatory, easy and clear operation of a medical device creates more space for medical and nursing care. It reduces training times and increases user acceptance. If users feel comfortable working with a device the error rate will drop – another cost-saving factor. Whenever a job description is modified or expanded a review of the tasks and processes is recommended as well as their comparison to the original needs regarding workplace set-up. Test phases for new equipment are useful and taking a look at the sheer size of a user manual can be telling. For purposes of cost-benefit analyses the mandatory manufacturer's notes on training requirements are also helpful.

Ergonomic design that saves time and costs has many more – seemingly mundane – aspects. Is the surface of the device dirt-resistant; the display easy to clean, and the colour selection appropriate for the product's functions? Noise

2-D building navigation

People are confronted daily with finding their way in new buildings and building complexes. Generally these are intricate, have numerous sections distributed among different houses and/or floors. Whether in hospitals, rehabilitation clinics, airports, or other large building complexes, finding the way to a particular destination can be an extremely difficult or even an impossible undertaking.

Paradoxically, it's the visitor, customer or patient who generally pose the first barrier to reach his/her destination. He or she arrives at the building in haste and is emotionally and cognitively diverted. In this situation, site plans, information signs and even electronic displays put too high a demand on the first-time visitor. Stress levels increase, with a patient losing orientation and the way to his/her destination, thus arriving late for the appointment or therapeutic session.

Günther Ortmann embarked on a search for an effective solution to this problem, which soon enough proved a real challenge: no single solution available today on the market could fulfil the primary requisites of the intended application: a practical – easy on the user and the system operator – and safe solution for hospitals and large medical facilities.

He identified the requisites clearly for such a system after extensive discussions with customers and users: the intended system should require no technical know-how whatsoever on the user's side (patient, visitor, customer, etc.); its operation should be as simple as possible for people of all ages, with particular consideration for the demographic group '60 plus', which is of constantly growing in importance.

With these initial insights, definitions and ideas for the development of an innovative building navigation system, he approached the Fraunhofer Institute for Photonic Microsystems in Dresden, Germany. There, engineers **Hans-Jürgen Holland** and **Dr Nicolas Gay** quickly grasped the actual demand and huge potential of the idea, leading to a collaboration between Günther Ortmann, as project leader with focus on acquisition and distribution, and the Fraunhofer Institute for Photonic Microsystems, as system developer and supplier.

After detailed examination of the undertaking, which included a feasibility study, followed technical development that led to the 2-Dimensional Building Navigation System – or 2D-GN (German short form). The 2D-GN system not only fulfils the accessibility and usability requirements detailed above but also constitutes an extendable platform for innumerable future applications.

The actual operation of the 2D-GN system is remarkably simple: When the first-time visitor, for instance a patient, arrives at a hospital or medical facility, he/she receives a 2D-GN mobile unit at the reception desk. After patient registration, the receptionist types in the 2D-GN mobile unit information regarding the attending physician and destination within the building complex. The 2D-GN mobile unit then employs signals from a wireless local-area network (WLAN) infrastructure to compute its exact position, leading the patient quickly and exactly to the desired destination.

2D-GN is based on robust mobile navigation units for in- and outdoor use. A 2D-GN mobile unit describes the way to a given destination via spoken and written multilingual instructions, 2-D graphics, plus visual and acoustic cues. To compute a route, the system also takes into account factors such as barrier-free and accessibility constraints, shortest or easiest route, forbidden and restricted areas, intermediate destinations and appointment times, to name but a few considerations.

A mobile unit displays its current position by means of a map with varying degrees of detail (as much as the user requires/demands). Furthermore, the user can always establish a direct link to a central operator for further assistance. A dynamic guidance feature enables the user to find additional points-of-interest (POI): pressing the

The EU Cross-border Directive

Pan-European cooperation on HTA – good; eHealth – a missed opportunity, says COCIR

When the European Parliament voted in favour of the EU Directive on Patients' Rights in Cross-border Healthcare, Health Commissioner John Dalli, explained that this is an important step forward for all EU patients – i.e. by gaining easier access to good quality and reimbursed treatment across EU borders. Meanwhile, Europe's healthcare systems will need to deliver 'more for less'.

In this context, the non-profit trade organisation COCIR (Coordination Committee of the Radiological and Electromedical Industries) has welcomed the decision to have pan-European cooperation on Health Technology Assessment (HTA) involving all relevant actors – including industry – in the discussions. COCIR has pointed out that HTA when properly used '… will help ensure better use of healthcare resources, accelerate the uptake of innovative technologies and reduce inequalities between EU citizens with regards to their access to healthcare.'

However, COCIR expresses disappointment about '… the weak compromise reached on eHealth (Article 13) as we believe this is a missed opportunity to leverage its considerable potential for European prosperity. It is obvious that eHealth could bring enormous benefits while we continue to face a number of barriers preventing its effective deployment.'

COCIR Secretary General, **Nicole Denjoy**, said: 'HTA is instrumental to achieve a favourable environment to foster better use of new technologies in an integrated care approach. eHealth is a great enabler to improve access, quality and continuity of care of citizens, while contributing to rationalisation of costs. We hope that this Directive, which provides for the first time a legal basis for eHealth, will encourage Member States and the European Commission to continue their joint efforts, especially through the eHealth Governance Initiative and the European Innovation Partnership for an effective deployment of eHealth across Europe.'

Oxford's new centre for science entrepreneurs

UK – A partly refurbished building in central Oxford is opening to provide space for science entrepreneurs. Science Oxford, a charity that supports education and business in the city, ultimately aims to demolish the building to create a science-focused public building to showcase new technological innovation from the Oxford area.

Last year, the renowned architectural firm Foster + Partners won a £30 million commission for the five-year project, which will see the 0.2 hectare site emerge to provide rentable space for start-up scientific businesses, conference facilities, as well as a digital planetarium, public plaza, café and shop.

Among the first tenants expected to move to the existing building is Pennsylvania and Oxford based Mirada Medical Limited, the software firm that focuses on medical software for advanced oncology imaging, launching its latest software fusion technologies, MR-PET Fusion, to support MR-PET and MR-CT-PET imaging at the 2010 RSNA, and recently its XD3 multi-modality image fusion analysis package as an option to users of Sectra PACS.

Designs for the centre are at a preliminary stage, said Chris Connell of Foster & Partners 'Our intention is to create a striking contemporary addition to the city's rich architectural heritage that symbolises and embodies the possibilities of science and the future of technology.'

Trumpf's TruPort ceiling-mounted supply unit. All four sides and the entire length of the support heads can be easily equipped with supply modules, components and accessories

design can also be an important issue if, for example, equipment is used in intensive care units. Noise level and the alarm sound should be considered: a device should also have a unique sound to distinguish it from other devices.

Alarms with soft audio sequences offer better recognition than single shrill tones. In studies, the recognition rate of the single shrill sounds was below 50% and staff and patients felt extremely annoyed by loud and unpleasant noises.

In radiology and nuclear medicine, the conflict between the priorities image quality and radiation dose is a crucial issue. The higher the image quality, the higher is the dose. To ensure patient and operator safety, manufacturers and physicians alike follow the ALARA principle (As Low As Reasonably Achievable). For their radiology equipment that operates with X-rays or radioactive tracers Siemens, for example, developed several technologies – the so-called Combined Applications to Reduce Exposure (Care) – that allow a significant dose reduction while maintaining high image quality. The system issues a warning as soon as a certain dose threshold is reached. The examination reports can be analysed according to certain criteria and processes and workflows can be optimised – another innovation that saves time and money.

symbol 'WC', for example, suspends the current route and leads the user to the nearest toilet, after which the mobile unit proceeds to the original destination.

The system is basically made up of WiFi-enabled mobile navigation units, a monitoring station and WLAN hotspots, used as beacons by the positioning algorithm and for the exchange of on-demand information.

The 2D-GN system was developed under strict compliance with the German and European EMC regulations in medical facilities, thus qualifying its use for numerous other private and public application areas. Every mobile unit counts with detailed plans of the building, which, combined with a built-in real-time location algorithm, enables the accurate positioning of the mobile unit.

Because 2D-GN relies for its operation on an unmodified WLAN infrastructure, it is possible to offer the user additional services, such as Internet access, mobile telephony, on-demand music streaming, e-mail, mobile unit-to-mobile communication, VoIP, instant messaging and other data transfer services. For instance, large cruise liners could offer passengers not only regular mobile telephone services (cell phones are useless where a mobile telephony infrastructure is unavailable), but also event lists, coming attractions, restaurant menus, individual and group games, special offers, day excursions and other personalised services. Moreover, 2D-GN can prove very useful when quick communication of safety-relevant information and indications become necessary.

From its initial conception, 2D-GN was developed around a proven software architecture. So the system, depending on the mobile unit of choice, relies upon Google's Android or Apple's iOS operating systems, both robust descendants of Unix, an extremely reliable operating system used in critical applications. For the system owner this translates into additional reliability, safety, data security and the possibility of performing remote maintenance with minimal operation expenses. The system was conceived with the consideration of a continuous development of the underlying infrastructure (hospitals, buildings, cruise liners, airports etc.). Modifications on the facility architecture, changes or improvements on the wireless networks and the addition of novel, enhanced, or newer services can be easily incorporated in a 2D-GN system thanks to its versatile concept.

2D-GN systems also offer effective mechanisms for theft protection and against mobile unit manipulation – welcome features in open facilities and/or when stringent control of mobile units is not feasible. To this extent, the monitoring station is equipped with tracking capabilities, permitting the exact localisation of individual mobile units. These become unusable as soon as they are beyond the wireless network for which they were intended. In addition, every unit has safety features that render them unusable if manipulation is attempted.

Inevitably, this article has included a limited number of applications for 2D-GN systems, focusing on hospitals, rehabilitation centres and other healthcare facilities. Many other large buildings etc. could benefit from their use, for first-time visitors to make their way to their final destinations without frustration. Should this first-time experience of prospective customers, patients or visitors begin this way? The answer is a clear and categorical NO: the 2D-GN 2-Dimensional Building Navigation system can be an integral part of this experience and thus turn it into a very positive event.

Details: www.2D-GN.de
Source: The Fraunhofer Institute for Photonic Microsystems IPMS. Günther Ortmann, 2D-GN Project Manager, Marketing. Dr.-Ing. Nicolas Gay, 2D-GN Research and Development. Institute Head: Prof. Dr.-Ing. Hubert Lackner. International contact: Dipl.-Ing. Hans-Jürgen Holland, Assistant Head of WMS Business Sector. hans-juergen.holland@ipms.fraunhofer.de

While other industries race towards an all-digital world, healthcare remains frozen in the Analogue Age.

However, the success of established, world-leading e-health programmes in Denmark, Andalusia and Lombardy, have built confidence in secure patient data exchanges. This April, France will be the first among Europe's large population states to introduce a national system for sharing patient record sharing by bringing online the *dossier medical personnel.*

In the short history of cross-border e-health, the interconnection of so many countries to share health records has never been tried. For epSOS, the Bratislava Projectathon also enabled determination of which countries were ready to participate in a year-long pilot programme beginning later this year. This will involve over 30,000 healthcare professionals at 183 hospitals, 2,149 pharmacies and 1,113 point-of- care or general practice clinics. (*See EH issue 02, 2010: 'Crossing frontiers in e-health'*)

According to epSOS Coordinator Fredrik Linden, the importance of the Bratislava Projectathon was that 'we successfully introduced end-to-end testing for healthcare professionals and contributed to advancing the global interoperability work. It is now proven the technology is there to support interoperable patient summaries and ePrescriptions. Now it's clear which steps need to be taken next regarding the technical and organisational level to make the pilot operation successful.'

Beyond computer interfaces, it took a year just for 10 different epSOS work groups to sort out legal and technical challenges among Member States for transferring electronic patient data. 'There are many difficult issues to be solved to fulfil the vision of e-health as an enabler for a continuity of care both within Member States and across borders between the Member States,' said Fredrik Linden. 'For the epSOS pilot we picked only two small issues out of this context, basic patient summaries and e-prescriptions, yet they are proving to be a world-class challenge.'

Hard-wiring e-health

Europe moves digital records closer to patients in large-scale pilot

To speed up and take e-health to the next level, health records will need to follow Europe's highly mobile citizens when they cross national borders. Following three years of study, connecting Europe's wildly diverse national systems is at last shifting from project managers into the field.

The first bold step into this operational phase was the marathon testing event 'Projectathon', organised by Smart Open Services for European Patients (epSOS) in Bratislava in November, which drew in over 140 engineers from nine countries (Austria, the Czech Republic, Denmark, Spain, France, Greece, Italy, Sweden and Slovakia) to interconnect for the first time multiple independently developed systems. 146 of 165 tests were successfully completed, and a second Projectathon will take place in Pisa, Italy (11-15 April 2011), expecting more countries and health information system developers to attend.

After years of talking, suddenly European e-health is moving out of conference rooms and onto the computers of healthcare professionals, *John Brosky* reports

The protocols for linking the disparate national systems were specified by epSOS based heavily on integration profiles developed by Integrating the Healthcare Enterprise (IHE), an international open source method for the coordinated use of established standards, such as DICOM (Digital Imaging in Communications and Medicine) and HL7 (Health Language Seven).

Key to the success of the event was the use by epSOS of IHE profile specifications and the unique Gazelle Test Management Tool. Participants registered their systems through Gazelle prior to the Projectathon and used simulators and validation tools for the execution of lab testing. During the event, the same set of tools and simulators was used to assist testers and monitors in their tasks: A team of eight Connectathon veterans led by IHE-Europe served as monitors for the Projectathon, assisting engineers in test set ups and verifying tests results.

Germany's international medical travel card

NEW

Wolfram-Arnim Candidus, President of DGVP (German society for the insured and patients), Prof. Michael Nobel, Chair of World Medical Centre Holding SA, Dr Albrecht Hauff, Publisher of Thieme Publishing and Tomas Jelinek MD, Scientific Director of CRM

The Swiss-based World Medical Centre Holding SA and German Centre for Travel Ltd. medicine have launched an international personal medical record system – the CRM travel.CARD – for travellers to keep their essential medical data with them at all times. Representatives of the two firms, both specialised in travel medicine, presented the CRM travel.CARD at a press conference this January in Berlin.

The system provides a simple paper-chart with basic data for the pocket, a mobile phone application and web portal with personal access. After a customer subscribes, he/she enters their medical data on a personalised web portal called onWeb – and can edit the data as necessary. onWeb can also digitally collect documents, e.g. a vaccination card or X-ray.

These web-based medical data also can be downloaded to the customer's mobile phone (onMobile), which can translate them into 20 languages.

Tomas Jelinek

Albrecht Hauff

The basic tool, onCard, a small, sealed plastic card the size of a credit card, will be sent to the customer after his/her manual data input, to keep with his ID-card.

The basic medical data on the card, e.g. allergies, diagnoses, medications and blood type, is in clear text and in the international medical code set by the WHO, ICD-code (International Classification of Diseases). Access code and pin for the mobile application and web-portal is provided inside onCard and is easily accessible to attending medical staff abroad. According to its makers, all communication pathways – web-based or via the mobile phone – meet the highest security standards.

Issued for the German market, the CRM travel.CARD is technically the same as the well-advanced, technically matured, globally operating World Medical Card distributed by the World Medical Centre Holding SA (WMC) since 2004.

Due to the nationwide network of the German Centre for Travel Medicine (CRM), owned by Thieme Publishing Group, the cooperation looks promising. 'In over 20 years of activities the CRM has established a network of more than 6,000 physicians and chemists. Hopefully, this network will offer the CRM travel.CARD to patients,' said Albrecht Hauff, Thieme's CEO.

Ideally, a family physician or chemist, to whom CRM will offer an expense allowance of €10 annually, will help the patient to coordinate and verify his/her data. For patients the card, including all services, costs €34.50.

Tomas Jelinek, scientific director of CRM, conceded that a residual risk of data miss-entry will remain, but argued: 'The risk of being harmed by false data is considerably less than coming to grief due to the lack of information.'

The 31st ISICEM

Jean-Louis Vincent, Chairman of the Dept of Intensive Care, Erasme Hospital, Université Libre de Bruxelles, welcomes visitors to this year's International Symposium on Intensive Care and Emergency Medicine

22-25 March 2011 Brussels, Belgium


Jean-Louis Vincent

The 31st ISICEM will open its doors early on March 22 2011 for four exciting days packed full of all the latest developments and news in the world of intensive care and emergency medicine. Housed in Square, the new meeting centre right in the heart of Brussels, this annual event will welcome more than 6,000 participants from around the globe. With standard presentations, tutorials, pro-con debates, round tables, meet-the-expert sessions, and interactive quizzes, faculty and participants will have plenty to keep them busy!

One of the important aspects of any large meeting of this kind is the rapid transmission and dispersion of results of new clinical trials. As a brief taster of this year's meeting, I would like to highlight some of the recently completed important clinical trials, the results of which will be presented for the very first time during this symposium.

One study that is certain to generate some heated discussion and controversy is the multicentre French study of stress-dose hydrocortisone in patients with severe trauma. Moderate dose corticosteroids have been suggested as being beneficial in patients with severe septic shock, and some data suggest they may reduce the incidence of hospital-acquired pneumonia in patients with acute respiratory distress syndrome. But an earlier study in patients with traumatic brain injury, methylprednisolone administration did not affect nosocomial infection rates and *increased* mortality. So what did *this* study reveal?

Staying with trauma, we will also see results from the Australasian study randomising patients with severe traumatic brain injury to management with or without decompressive craniectomy. This technique decreases the high intracranial pressures often seen in patients with severe brain injury, but does it improve neurological outcomes?

Severe sepsis and septic shock are still associated with unacceptably high mortality rates and the search continues for effective immunomodulatory therapies. Eritoran blocks Toll-like receptor 4 (TLR-4), which is involved in early sepsis signalling. In a large multicentre study of 2,000 patients, the effects of eritoran administration on 28-day mortality were compared with those of placebo; but did the drug live up to expectation? Also in patients with septic shock, the results of a French multicentre study comparing the effects of albumin versus normal saline on outcomes will be presented.

Optimal nutrition in critically ill patients has been a subject of some debate for many years, with the only real agreement being that enteral feeding should be started as early as possible once a patient is hemodynamically stable. How best to ensure adequate calorie intake has yet to be determined. A multicentre study in Belgium, in which patients were randomised to enteral nutrition only for the first week of intensive care or enteral nutrition with additional parenteral nutrition from day three, aimed to provide some answers. Sedation is another hot topic and the results of a large randomised controlled trial comparing dexmedetomidine with propofol and midazolam for sedation (> 24 hours) in critically ill mechanically ventilated patients are certain to be of interest.

Finally, for the purposes of this brief appetiser, the Canadian Critical Care Trials Group conducted a study comparing the effects of low molecular weight heparin versus unfractionated heparin on prophylaxis of thromboembolic events in critically ill patients. Deep vein thrombosis is a recognised and important complication of critical illness, but again the optimal means of preventing it is uncertain, so this large study was designed to clarify the role of these two commonly used thromboprophylactic agents.

Whatever the results of these studies, they provide important additions to the evidence base in critical care and emergency medicine, and I am sure will be the topic of heated discussion both in and out of the meeting arena during our 31st ISICEM.

Details: www.intensive.org

Electrical impedance tomography

A new respiratory monitor visualises lung activity in real-time

This March, Dräger Medical will bring to the bedside of respiratory patients an innovative new monitor that vividly shows, breath-by-breath, their response to treatment. After shifting a patient's position, or adjusting the respirator setting, or delivering a drug to open airways, physicians and nurses will be able to watch in real-time the response inside the patient's lungs.

The images created by this novel technology, called electrical impedance tomography (EIT), are stunning. The cross section view of the patient's lung on the new Dräger monitor looks like weather maps used on TV, with regions changing from dark blue to powder blue as warm air masses flow in. Where the lung remains closed to the passage of air, the region remains dark.

Gently move the patient and the change to lung capacity can be immediately seen on the monitor.

'It's a giant step forward in the handling of ventilator patients,' according to **Professor Ola Stenqvist** at the Sahlgrenska University Hospital in Göteborg, Sweden, who over the past five years has conducted research using EIT. 'This technology will bring a new clarity into handling patients with uneven lung disease,' he added, providing continuous bedside monitoring of effective recruitment and indicating the optimum PEEP (positive end-expiratory pressure) settings on respirators.

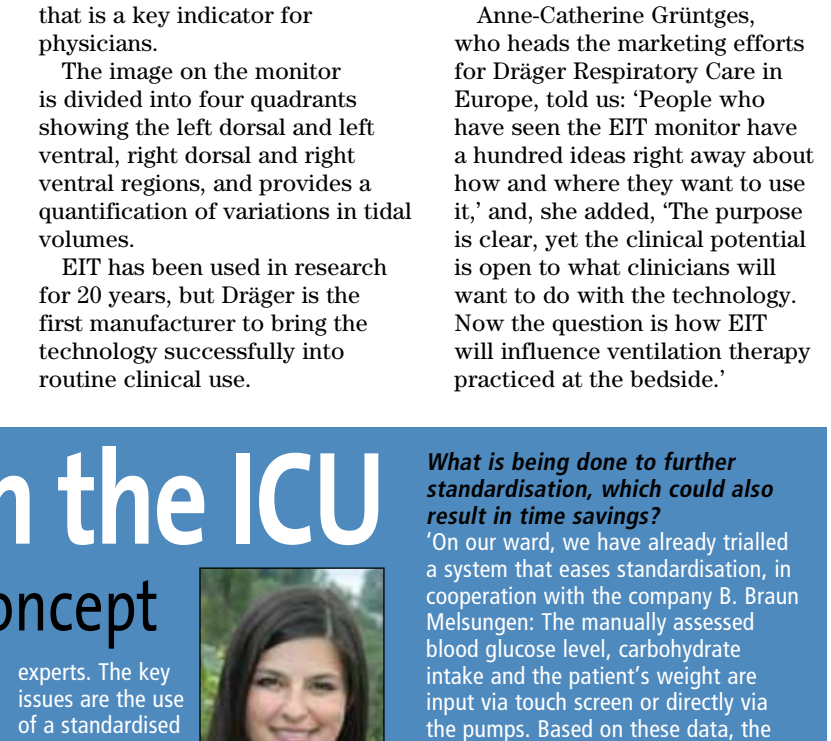
EIT provides a functional image of breathing that is a complement to the structural images provided by computed tomography or chest X-rays.

Non-invasive, radiation free, and portable, the bedside EIT monitor means these fragile patient's will not need to be transported as often to the radiology department to evaluate changes in their condition.

The video-like EIT images of the lung are constructed from data collected by 16 pairs of electrodes on a belt that circles the patient's thorax. The electrodes rest gently against the skin and no gel is required to enhance conductivity.

In sequence, each emitter on the ring sends a low-energy electrical pulse, using the same voltage as an electrocardiogram, which is captured by the ring of detectors.

The impedance of the signal passing through body tissue is filtered, a complex challenge considering the number of cross currents of electricity in the human body, and more so for patients attached to ventilators.



By sequentially firing the emitters in a rotational pattern around the patient's chest 208 data sets are collected to construct a single image. Up to 50 images can be acquired each second, creating the video motion that depicts the patient's breathing patterns with the regional ventilation distribution and, significantly, the end-lung expiratory impedance that is a key indicator for physicians.

The image on the monitor is divided into four quadrants showing the left dorsal and left ventral, right dorsal and right ventral regions, and provides a quantification of variations in tidal volumes.

EIT has been used in research for 20 years, but Dräger is the first manufacturer to bring the technology successfully into routine clinical use.

The new model, which the company estimates is the fifth generation evolution of the EIT technology, was demonstrated for the first time at Medica in 2007.

Dräger has not released the name of the new EIT monitor that it previewed at Medica 2010, but told European Hospital that the final product will be introduced to hospitals at the end of March.

Anne-Catherine Grüntges, who heads the marketing efforts for Dräger Respiratory Care in Europe, told us: 'People who have seen the EIT monitor have a hundred ideas right away about how and where they want to use it,' and, she added, 'The purpose is clear, yet the clinical potential is open to what clinicians will want to do with the technology. Now the question is how EIT will influence ventilation therapy practiced at the bedside.'

Blood glucose monitoring in the ICU

An important puzzle piece within the overall concept

Although there is still disagreement as to 'how', when it comes to the question of whether the glucose level affects the prognosis for intensive care patients, the answer is a definite 'yes'. 'We know now that glucose levels that are too high, as well as those that are too low, are predictive for the mortality of intensive care patients, for the risk of infection, wound healing and length of hospital stay. But the function of different organs and the neurological outcome is also strongly impacted,' says **Dr Karin Amrein**, Specialist Registrar at the University Hospital Graz, Austria. In her lecture *Glucose Monitoring today and tomorrow*, at this year's International Symposium for Intensive Care and Emergency Medicine (ISICEM) Dr Amrein will report on current knowledge and on procedures to simplify regular monitoring in ICUs – giving European Hospital an overview in advance

Karin Amrein: 'Basically, even sceptics now acknowledge the relevance of the blood glucose level for the outcome of intensive care patients. After all, around every third severely ill intensive care patient with multi-organ failure or sepsis has an impaired blood glucose tolerance, which coincides with increased blood glucose levels. This problem with the body's own glucose control is a sign of the severe illness and normally readjusts itself once the patient recovers. However, opinions on the importance of blood glucose monitoring, the target range and resulting therapeutic steps to be taken, vary considerably and strongly depend on the individual points of focus on the respective ward. Even within our own hospital, which has about ten intensive care wards, there are big differences between the individual wards. Each ward certainly measures blood glucose levels fairly efficiently, but at what stage and from what kind of glucose level action is taken, and how strictly the resulting insulin therapy is regulated, is currently discretionary. Although there are now some guidelines for orientation, we are currently still a far cry from standardisation.'

What do those guidelines state?

'Critical Care (Carole Ichai et al) recently published a brand new summary of recommendations by international experts. The key issues are the use of a standardised protocol, a target value of <180mg/dl and standardisation of measuring procedures. The important early studies carried out by the working group led by Greet van den Berge, from Leuven, show a significant decrease of the mortality rate with blood glucose levels between 80 and 110 mg/dl. However, these strict levels more frequently tend to result in increased rates of hypoglycaemia. Therefore the current recommendations tend towards a moderate target range of between 80 – 180 or 80 – 150mg/dl.

Karin Amrein

What is being done to further standardisation, which could also result in time savings?

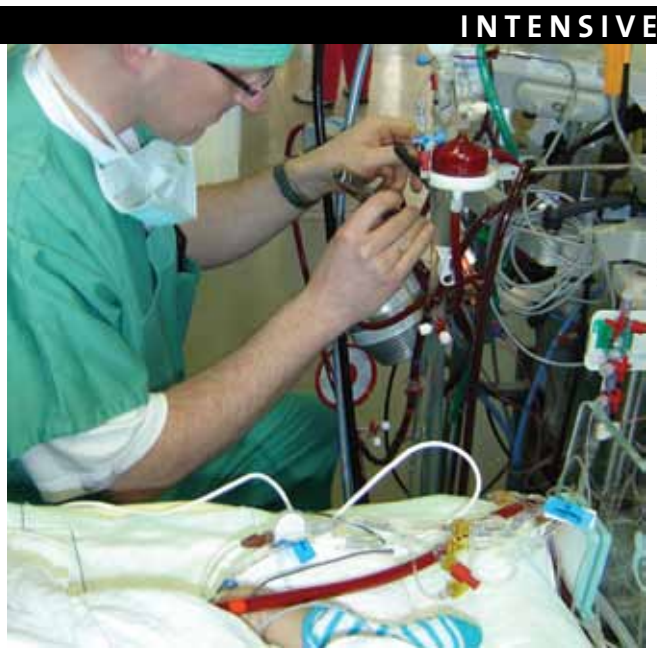
'On our ward, we have already trialled a system that eases standardisation, in cooperation with the company B. Braun Melsungen: The manually assessed blood glucose level, carbohydrate intake and the patient's weight are input via touch screen or directly via the pumps. Based on these data, the system calculates how much insulin the patient is likely to require and suggests an insulin dose and measuring interval of between half an hour and four hours. Through the integration into the pumps the systems can communicate with one another and automatically transfer the information.

'Particularly against the background of limited staff resources and lack of time, this type of automation has advantages for patient management as it relieves the nursing staff or important tasks. Full automation of measuring and insulin administration would be desirable; however, we are currently still a far cry from this.'

Easy breathe

New tools for prolonged lung support

Almost 40 years old, the idea of temporary lung assist device has reached a level where it works not only in anecdotal cases, *Holger Zorn* reports

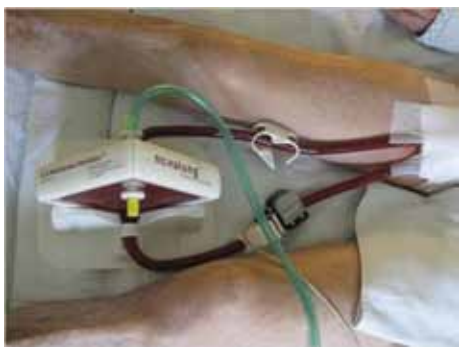


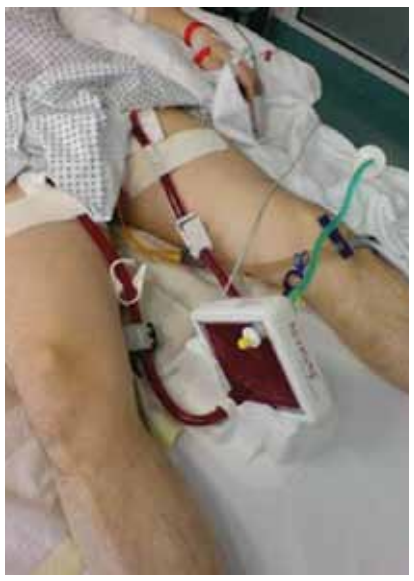
COURTESY: JUSTUS LIEBIG UNIVERSITY HOSPITAL

Perfusionist Johannes Gehron examines a newborn-ECMO for clots and sediments. Many lab tests are also performed, he emphasised, e.g. for fibrin degradation products

Often a life-saving intervention, mechanical ventilation also has some serious drawbacks: the need for sedation, the risk of ventilator associated pneumonia, intubation or tracheostomy related complications. In 1972, Donald Hill from Pacific Medical Centre, Los Angeles, reported the first successful long-term mechanical lung assist device with extracorporeal membrane oxygenation (ECMO). After 75 hours of support of a 24-year-old multiple trauma patient with aortic rupture, the shock-lung syndrome was reversed and the patient recovered *[Source: NEJM 286:629-634]*.

Three years later, a Mexican woman who believed her unborn child would have a better life in the USA, journeyed to Los Angeles. En route, when her membranes ruptured she arrived at Orange County Medical Centre. The child was born but her lungs could not supply enough oxygen. Despite turning up the ventilator to the highest settings, oxygen tension dropped to 12 mm of mercury.





Involved in developing the membrane lung, thoracic surgeon Robert Bartlett brought in a machine from the laboratory. About 150 severe respiratory failure patients had already been treated with the device; 10-15% survived. However, all were adults, not infants, not newborns. In a strict sense probably without informed consent, he explained what they were going to attempt. Without English and being illiterate, the mother signed with an X and disappeared, perhaps fearing her baby's outcome as well as her own of deportation. After three days of bypass, Esperanza – the name nurses gave the baby — completely recovered.

How ECMO works

Back then, three days of support was an incredible success. Today, a three-day treatment is likely to be regarded as short-term therapy. ECMO acts temporarily as a patient's lung while recovering from an underlying condition. After cannulation of the femoral or neck vessels, a portion of the patient's blood flows through to an extracorporeal membrane oxygenator, where carbon dioxide is removed and blood is oxygenated and then pumped back into the vascular system.

Cannulation, homeostasis and coagulation management are the critical points. Johannes Gehron, head perfusionist at the Justus Liebig University Hospital Giessen explained: 'I must consider not only the current state but also the coming days. The patient interacts with the ECMO system. Any change in his clinical situation may result in ECMO adjustment for optimum performance, but currently there is no simple clinical measurement method to detect such a change.'

From ECMO to ECLS

In 2009, the Mater Public Hospital in Dublin established a veno-venous ECMO programme using the PLS system by Maquet Cardiovascular AG, Hirrlingen. Actually, due to the results, indications for the use of extracorporeal lung assist no longer rely solely on respiratory failure. Today, the combined, circulatory and respiratory, veno-arterial support has become routine practice; even so, it typically bears higher risks than the isolated veno-venous ECMO. The hospital has switched from PLS to HLS system (Cardiohelp) and carries out national and even international patient transport. Its approval of both ground and air transport stems from the idea to stabilise patients with severe respiratory failure and to subsequently transfer them to a specialised hospital. In particular, swine flu has led to the rise of such transfers.

Cardiohelp offers continuous monitoring of venous blood parameters and is designed to meet the increasing demands for convenient management of both long-term ECMO application and patient transport, called Extra-corporeal life support (ECLS).

MAQUET also envisions a new therapy approach for protective ventilation combined with Extracorporeal Life Support (ECLS) and Neurally Adjusted Ventilatory Assist (NAVA). According to a recent publication from Karagiannidis at Regensburg University Hospital, effects are as follows: Less sedation allows earlier mobilisation and better functional results, precise monitoring and adjustment of gas exchange led to faster and easier weaning from the ventilator, and combined therapy can minimise ventilator-induced diaphragmatic dysfunction *[Source: Int Care Med 2010;36(12):2038-44]*.

continued on page 8

Device	iLA Membrane Ventilator		Hemolung	PLS System	HLS Advance (Cardiohelp)	Lifebridge B2T
Manufacturer	Novalung GmbH, Heilbronn, Germany		ALung Technologies, Pittsburgh, USA	Maquet Cardiopulmonary	AG, Hirrlingen, Germany	Lifebridge Medizintechnik AG, Ampfing, Germany
marketed since Approval sold units	2003 CE, FDA (510k) > 5,000		2012 expected CE in trial none	2006 CE > 7,000	2010 CE, FDA (510k) pending < 1,000	2008 CE, FDA (510k) > 400
Intended type of assist	pulmonary				cardiopulmonary	
longest treatment time	150 days		7 days	> 40 days	30 days	50 hours
Oxygenation CO2 removal	low complete	full complete	low sufficient	full complete	full complete	full complete
Flow generated by	arterial pressure	additional pump	pump		suction and pump	
Typical cannulation	arterio-venous	veno-venous			veno-arterial	
arterial cannula size venous cannula size Cannulas provided	13-15 French 15-17 French no	none 15-17 French no	none 15 Fr double-lumen yes	15-21 French 19-29 French HLS Set		13-18 French 16-23 French no
Blood flow Oxygen flow	0.8-1.5 l/min 10 l/min		0.3-0.5 l/min n/a	0.5-7 l/min 15 l/min	0.5-5(7) l/min	1-6.5 l/min depending on the in-built oxygenator
Oxygen transfer Carbon dioxide removal	~ 50 ml/min 150-180 ml/min	150-180 ml/min	n/a 100-120 ml/min	30-425 ml/min 20-420 ml/min		
Weight	n/a		n/a	15 kg	10 kg	18 kg

Artificial lungs at a glance: The table contains systems for both lung and heart and lung support. A-V systems as well as V-A systems may also be used V-V. Except columns 5-6, the given performance data are typical clinical data and not manufacturer's instructions. (Own compilation.)

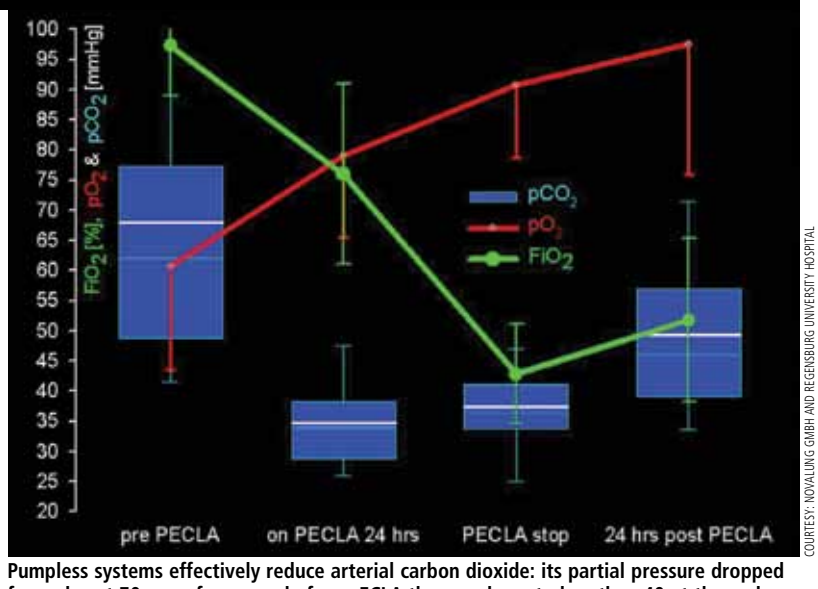
continued from page 7

From ECMO to pECLA

In 1996, a group of perfusionists, intensivists and cardiac surgeons at the University Hospital Regensburg, developed a complementary method: the pumpless extracorporeal lung assist (pECLA) device, an arterio-venous bypass system without a pumping unit. The patient's mean arterial pressure is responsible for blood flow through a low-resistance gas exchange module.

With the arteriovenous, pumpless mode, the extracorporeal blood flow is limited; as a result, oxygenation capacity from extracorporeal gas exchange is lower compared to venovenous ECLA employing higher blood flows. For that reason, pECLA focuses on treatment of predominately hypercapnic patients. The use of a smaller cannula for arterial access (13-15Fr) allows appropriate blood flows to decarboxylate the blood.

'The procedure is reserved for patients without severe functional impairment of cardiac pump function,' explained Alois Philipp, one of the inventors and chief perfusionist at the Regensburg University Hospital. For pumpless use, the mean arterial blood pressure should at least be 60 mmHg. Due to a lower risk of bleeding and the associated decrease in transfusion requirements, patients with abnormal clotting particularly profit from pump-free therapy. In principle, PECLA can be used in all forms of respiratory failure.



COURTESY: NOVALUNG GMBH AND REGENSBURG UNIVERSITY HOSPITAL

Pumpless systems effectively reduce arterial carbon dioxide: its partial pressure dropped from almost 70 mm of mercury before pECLA therapy down to less than 40 at the end, while the fraction of inspired oxygen reduced from 100% to 40%

The iLA Mechanical Ventilator

Developed in cooperation with Jostra AG, this technology is currently sold as the iLA Mechanical Ventilator by Novalung GmbH, Heilbronn, and has two major indications: Pulmonary lung failure (Acute Respiratory Distress Syndrome – ARDS) and breathing pump failure (exacerbated Chronic Obstructive Pulmonary disease – COPD). Depending on the clinical needs of the patient, and extracorporeal blood flows required to support gas exchange appropriately, the iLA can be used in pumpless, arteriovenous and pump driven venovenous modes within the approved ranges for blood flow of 0.5-4.5 L/min.

Dr Torsten Rinne, Medical Director at Novalung, said: 'With arteriovenous use, nearly complete carbon dioxide removal is achieved at gentle flow rates in range of 0.8-1.5 L/min, allowing reduction of aggressive mechanical ventilation in ARDS patients. In acute hypercapnic lung failure, such as exacerbated COPD, the device is increasingly used to avoid intubation and to support spontaneous breathing. New technologies like the upcoming Novalung veno-venous lung assist device will also aim to support the patient's mobilisation better.'

Hemolung respiratory dialysis

Not yet on sale is the Hemolung, developed by Dr W J Federspiel, Professor of Chemical Engineering, Surgery and Bioengineering at the McGowan Institute of Regenerative Medicine, and founder of ALung Technologies, a Pittsburgh-based medical start-up company. The Hemolung is expected to allow patients in acute respiratory failure to avoid intubation and mechanical ventilation or, as an adjunct, shorten the time spent on the ventilator in an ICU. The dialysis-like system effectively supplements lung function through a single, 15-French small, double-lumen cannula, preferably inserted via jugular vein and removing up to 50% of retained carbon dioxide from the blood while administering up to 25% of oxygen.

A pilot study of the Hemolung device is currently underway in German clinics (including Essen, Goettingen and Bonn) to demonstrate the safety and performance of the device. Actually, 12 out of 20 patients are enrolled. A US-based pivotal trial to gain FDA clearance will follow. 'We are very excited about the early results from our clinical trial in Germany,' said Nicholas Kuhn, Chief Operating Officer at ALung. 'We look forward to completing our clinical trial and introducing the Hemolung to physicians and patients in the near future.'

The time seems ripe for new devices: In Germany, for example, the number of ECMO rose from 719 in 2005 up to 2057 in 2009 – an increase of 286% in five years! How? Just before the rally started, the therapy was reimbursed in the DRG system. Depending on the hospital's negotiating skills, an ECMO or ECLA generates revenue of €600 via €6,800 up to €32,000.

Another reason for the start-up companies' hope: in 2010 the UK National Institute for Health Research (NIHR) published the *Conventional Ventilator Support versus ECMO for Severe Adult Respiratory Failure* (CESAR) trial, the first randomised controlled trial with parallel economic evaluation. 180 patients (90 in each arm), aged 18–65 years with severe, but potentially reversible, respiratory failure, were randomised from 68 centres to either conventional management (CM) in referring hospitals throughout the UK, or to consideration of interventional treatment at the ECMO centre at Glenfield Hospital, Leicester. Of the 90 patients randomised to the ECMO arm, 68 received that treatment. In the ECMO arm, 33 of 90 patients (36.7%) died or were severely disabled six months after randomisation, compared with 46 of 87 (52.9%) in the CM arm [Source: Health Technology Assessment 2010; Vol.14: Nr.35]. This equated to one extra survivor for every six patients treated and is promising compared to the 10-15% survival rate at the early beginning in Orange County in the 1970s.

ECMO economics

UK patients allocated to ECMO incurred average total costs of £73,979 compared with £33,435 for those undergoing conventional management (UK prices, 2005). A lifetime model predicted the cost per quality-adjusted life-year (QALY) of ECMO to be £19,252 (95% confidence interval £7622 to £59,200) at a discount rate of 3.5%. Lifetime QALYs gained were 10.75 for the ECMO group compared to 7.31 for the conventional group. Costs to patients and their relatives, including out of pocket and time costs, were higher for patients allocated to ECMO.

The importance of medical teamwork

More 'we' less 'me'

Peter G Brindley

By **Peter G Brindley**, Critical Care Medicine, University of Alberta, Canada

In 1935, following the spectacular crash of the much-heralded Boeing B-17 bomber, it was concluded that the 'modern plane was too much for one man to fly'. Similarly, given the complexity of modern healthcare, medicine is rarely a solo pursuit. In 1977, following the largest commercial aviation crash to date, flight investigators concluded the crew had 'failed to take the time to become a team'. Similarly, increasing evidence shows that human errors are the greatest cause of medical errors, and that suboptimal teamwork and inadequate team communication are our greatest shortcomings. However, in stark contrast to aviation, medical curricula typically focus on individual aptitudes such as factual knowledge or procedural dexterity. Instead, by borrowing strategies from other high-risk professions, we could address how to function as a team, as well as how to develop our 'verbal dexterity'. The airline industry felt compelled because lives and profits were at stake. Similarly, medical errors are believed to result in several hundred thousand annual deaths and to squander vast resources. As such, we should be similarly motivated. Moreover, given the importance of teamwork we need to make a 'science of team performance' and a 'science of controlling complexity'. This also means creating a culture that empowers subordinates to speak up and compels leaders to listen.

The origin of the word 'communication' means to 'share, unite, or make understanding common'. As a result, much of what it means to function as a team equates with good communication, and our curricula should mirror this. High-functioning teams also need to establish a 'shared mental model', which means ensuring team members are on the 'same page', working towards the same goal, and aware of the issues and resources. A shared mental model also creates a structure to prioritise and coordinate tasks, control the flow of information, and stabilise emotions. If time allows, the leader should share mental models. In time-critical situations, the leader needs the confidence and experience to create a model that the team can share. Regardless, without a shared mental model, the cognitive resources of the team cannot be fully leveraged. This requires regular practice.

Interestingly, fewer planes crash when the co-pilot is flying! Aircraft are likely safer with subordinates at the controls because, firstly, the senior pilot is unafraid to speak up, and, secondly, the co-pilot is actively engaged. As a result, crisis management becomes a shared goal, and a team is created. In contrast, during crises, physicians often fail to share what they are thinking or doing. When they do, it is often only to other physicians, not the whole team. With nurses, there may be lengthy delays between when a problem is first identified and when this is shared with the team. Fortunately, other high-stakes professions have shown how much can be achieved by focusing on team development. These professions have also shown that regular simulation incorporating all team members, and not just the most junior, is likely the safest way to do so.

In short, there are exciting opportunities to optimise the medical team. It remains to be seen if medicine has the insight, humility, and determination.

Obesity from the lab point of view

Over the last 25 years overweight and obesity have become a global epidemic. According to WHO figures, at least 400 million adults are obese worldwide. Part of this phenomenon relates to lifestyle changes – lack of exercise, wrong eating habits – whereas genetic factors also play a role (according to twin studies, the determination of obesity is 70% nature and 30% nurture). The increasing prevalence of overweight and obesity is associated with many chronic diseases, including diabetes mellitus, cardiovascular disease, stroke, hypertension and certain cancers. As a result, general practitioners and internists are increasingly confronted with this medical condition – and so are laboratory physicians


Joao Tiago Guimaraes

Obesity is a diagnosis without science – it doesn't even need a healthcare professional to detect whether someone is obese. The simple measurement of weight and height with the calculation of body mass index (BMI) quickly indicates whether a patient is overweight (BMI between 25 kg/m2 and 30 kg/m2) or obese (BMI over than 30 kg/m2). However, this simple diagnosis opens the door to further testing to detect the risks of further complications and increased risks in a patent's health. Here the laboratory can render much assistance, according to **Professor Joao Tiago Guimaraes**, Head of the Clinical Pathology Service in São João Hospital and Professor of Biochemistry in the Faculty of Medicine, University of Porto, Portugal: 'There are many parameters, such as hormones or proteins, that are typically changed in obese patients. Excluding the endocrinological causes of obesity that are rare, research in the last few years have found new lab markers to classify the pathophysiological progresses of the disease. To these belong adipokines, like adiponectin or resistin C-Reactive Protein (CRP) and the hormone leptin, which normally inhibits the sensation of hunger.'

Adipocytes (fat cells) are very important in the regulation of metabolism, but the proteins and hormones that they produce also have an effect on the immune system. 'Adipocytes are bigger and more numerous in the obese, producing more pro-inflammatory cytokines with which more macrophages infiltrate the adipose tissue. The immune system reacts to metabolic changes in a way similar to the response to infection and there is an increased production of tumour necrosis factor (TNF-alpha) and interleukin-6 (IL-6),' Prof. Guimaraes explains. 'For example, the abnormal production of TNF-alpha, IL-6 and CRP are associated with a chronic systemic state of inflammation that can lead to the development of insulin resistance, metabolic syndrome and diabetes mellitus type 2.' This also has consequences in terms of laboratory results, with impaired glucose tolerance and dyslipidaemia.

All these complex biochemical mechanisms are translated as information in the central nervous system where the regulation of appetite, energy consumption, hormone level and growth takes place. Thus a huge branch of laboratory research concentrates on the study of the CNS.

Another matter of particular interest is the rather new research discipline of lipidomics, which contains all studies around lipids in biological systems. Due to technical progress in mass spectrometry and chromatography lipidomics has advanced in the recent years. However, expression profiles of lipid-associated genes and the determination of regulatory networks are necessary to receive a holistic picture of lipid associated metabolic processes.

Sometimes, the only alternative to weight reduction in morbid obesity is surgery, in form of gastric banding, gastric bypass or gastric sleeve. Numerous studies document that these procedures induce the reduction of insulin resistance as well as improvement of liver function and liver histology. 'The increasing number of bariatric surgery also brings up a whole new catalogue of questions to our labs. These patients have to be monitored after surgery, because valuable substances such as proteins, vitamin and mineral levels can go down after the surgical intervention,' he points out. 'So, it's fair to say that the tasks of the laboratory team in the companionship of obese patients really range from screening and detection to monitoring of obesity and the constellation of diseases that come with this medical condition.'

Pre-analytical quality improvement


Sverre Sandberg

From dream to reality

1-2 April 2011 – time for lab and clinical staff to be in Parma, Italy, at the 1st European Conference on Pre-analytical Phase. Organised by the European Federation of Clinical Chemistry and Laboratory Medicine (EFCC), the meeting will present a range of events to launch a platform for continuous knowledge and idea exchanges regarding pre-analytical aspects of lab medicine. The spotlight is on two increasingly important topics: patient safety and the uptake of total quality management practices in clinical laboratories

'The time for a European Conference on Pre-analytical Phase is now,' says Scientific Committee Member Dr Sverre Sandberg, Head of the Laboratory of Clinical Biochemistry, Haukeland University Hospital, in Bergen, Norway, and Chair of the Scientific Division in the European Federation of Clinical Chemistry and Laboratory Medicine. 'While in the past a lot of efforts were expanded to improve the quality of analytical phase of laboratory practices, for example by the technical optimisation of test instruments, today it's increasingly realised that about 70% of errors in laboratory diagnostics happen before the samples hit the analysers at all.'

Standardisation processes will play a big role at the Parma conference. Sources for errors lurk all around the lab department, from receipt up to final sample analysis. They range from wrong preparation to even a swapped specimen. Patient identification shows a big failure rate, but the actual figures can only be estimated. 'Before the era of computerisation about 2-3 % of samples were mixed up. Manual work is simply fault-prone. But still, even with barcode systems and automated technologies, specimen interchange can happen if samples are not correctly tagged. Hence the only way to prevent confusion of patient samples is to have strict workflow routines.'

Another question occupying lab experts is how to acquire proper samples. Obtaining the basic state of samples before analysis is the basic requisite for correct testing results, so the correct transport of substances plays a key role. For example, wintry cold spells substances can inadvertently freeze during transport and thus falsify test results. Furthermore, many errors in the pre-analytical phase originate at bedside, Prof. Sandberg emphasised: 'One of the most important things is to request the correct analytes to a certain question. If physicians are not educated right and take the wrong kind of test, they will not obtain the answers they were looking for.'

Thus, education and interdisciplinary communication are most important in order to avoid test errors. Consequently Dr Sandberg and colleagues hold regular meetings with clinical colleagues to discuss what tests to perform for which indications and how to interpret the results correctly. The latter cannot be taken for granted, he points out. Although clinicians have broad knowledge in their subject, it is not clear if they are familiar with suitable testing procedures.

In Parma, Dr Sandberg will lecture on *The impact of biological variability on laboratory testing*, to approach this problem. Biological variability occurs in 'between subject variation' as well as 'within subject variation'. The first means, for example, that haemoglobin has different concentrations in different patient groups, depending on factors such as gender or age. This is well known and held on in reference intervals. The 'within subject variation' is a more complicated and crucial factor. It describes the variation of haemoglobin concentration in the blood of an individual patient. Some variation constituents depend on the season, or time of day, others are more individual and due to unknown causes This means that haemoglobin can vary between + / 5-10 % independent of the analytical imprecision. 'It means that we first have to draw the physician's attention to when would be the best point in time to perform the test, the best sample to take – for example capillary vs. venous samples – and then, after delivering test results to them, we must clarify what the variations in haemoglobin values in a patient really mean and what variations in test results can be expected from within-subject and analytical variation.'

Further details: www.preanalytical-phase.org

Anything but standard

The desperate need for reference values in the paediatric lab

Although paediatric laboratory medicine and clinical chemistry is a well and long established scientific field, it is still a challenging one with its own special problems, as **Dr Massimiliano Cantinotti**, Paediatric Cardiologist Consultant at Fondazione G Monasterio, National Research Institute, Massa, Italy, well knows. As a speaker* at the forthcoming IFCC WorldLab and EuroMedLab international congress for clinical chemistry and laboratory medicine, here he presents an overview about organisational and scientific hurdles that need to be overcome in his field


Massimiliano Cantinotti

"There exist characteristic differences in the organisational structures of European paediatric labs. The main difference is that, in some countries, the paediatric lab is separated from the adult laboratory, whereas somewhere else they are joined together. In my opinion, it is essential to separate the two disciplines from each other in order to create dedicated teams. These teams should be multidisciplinary and combine the different professional skills of clinicians, biologists and dedicated technicians. Moreover, such specialised paediatric labs allow for the use of separate testing kits and to save economic resources.

Due to the scant samples in the paediatric lab (at least 0.25 ml EDTA blood) there is an ongoing need to optimise every single test. For example, every paediatrician would want micro-samples for children, especially in the neonatal age. Therefore, there is a growing demand to use blood analytic kits and systems that may potentiate the use of capillary samples. Capillary samples taken with a finger stitch may avoid multiple samples in children who are particularly stressful, especially for neonates and which may cause iatrogenic anaemia. Moreover, genetic examination and screening tests for metabolic disorders are relatively new and a growing field of work in the paediatric lab.

One of the major concerns that paediatric labs worldwide are occupied with is the establishment of age-related references values. These references values are defined as standard values in healthy probands. They do not mean a single standard value but that a certain range within all values is classified as normal. In contrast to adults, the humoral values in children heavily vary in age and gender, which is especially true in neonates within the first weeks of life. The problem is that it still lacks a valuation data basis in children containing a wide population of healthy subjects to reflect what is statistically normal in what stage of life.

Furthermore, these new references values would also be especially helpful for the application of new testing kits and metabolites, respectively the analysis of new specific markers.

Additionally, another issue is that references values are strongly method dependent. Which means that, on the one hand, different methods often have different reference ranges and, on the other, with many labour parameters it is impossible to repeat an analysis of a probe truly and exactly. Therefore it is difficult to compare values of different labs with one another.

Nevertheless, I do believe that the establishment of references values is not only a crucial field for basic research, but would also be a crucial field of future activity for European collaboration projects, e.g. to create joint blood banks."

**As an international expert and speaker at the IFCC WorldLab session 'Current challenges in the paediatric laboratory', Dr Cantinotti will discuss 'Diagnostic accuracy of BNP in children with congenital heart disease' on 19th May. The IFCC WorldLab meeting is held every three years; the 2011 congress will take place on 15-19 May, in Berlin, Germany.*

Bacterial or viral? – Name it! Beat it!

Laboratory markers in paediatric febrile infections

The smaller the child, the more defenceless it is against viral and bacterial attacks. That is why infection accompanied by the symptom of a high temperature is the most common illness in children. So, when a child has a runny nose and fever an infection is clear. The more elemental question is: *Should it be treated with antibiotics?* Laboratory markers are a useful diagnostic tool to separate febrile infection into viral and bacterial pathogens. 'Only a differential diagnosis can lead to differential treatment', says Professor Nikolay Mayanskiy, Head of the Laboratory Department at the Scientific Centre for Children's Health in Moscow, Russia.* 'About 70-75% of febrile infections are viral, so only 20-25% is bacterial and needs to be treated with antibiotics. The biggest problem in a clinical approach is fever without a source. Therefore, laboratory markers are a great help for differential diagnosis, prognosis and follow-up.'

A lesson in paediatric laboratory medicine to be learned is that children are not small adults. In a medical sense, this means they are more unpredictable patients than adults. They can either recover from an infectious disease much faster than grown-ups, or develop severe complications more suddenly and unexpectedly, with only a few prognostic symptoms. This is also true in testing for laboratory markers. The fluctuations in these markers, such as C-reactive protein (CRP) and Procalcitonin (PCT), are much higher in children, so the specificity is sometimes not very high in this patient group. 'That's why we need additional markers,' Prof. Nicholay Mayanskiy points out. 'The use of a complex of different markers to estimate several different parameters appears to be the best way to gain the whole picture of information leading to certainty in the diagnosis of a febrile infection condition. In our institute, we are presently evaluating such a laboratory score. We have already developed a database from several hundred paediatric patients. I hope to present the first results of our study analysis at IFCC WorldLab 2011.'


Nikolay Mayanskiy

Prof. Mayanskiy and team are also trying to find new differential markers for bacterial and viral infections. 'With advanced haematological analysers we can test for additional information in complete blood count (CBC). An increase in lymphocytes as an indicator for viral infection, or neutrophil granulocytes as an indicator for bacterial infection, are not very specific markers alone. Sensitive additional tools analysed by modern technologies can measure, for instance, the concentration of haemoglobin in reticulocytes (erythrocyte precursors).' The technical development of better analysers is also beneficial to paediatric lab testing, especially in the neonatal field because it takes smaller blood samples to screen for more parameters.

Another challenge in paediatric laboratory testing is the different physiological processes in children. To interpret their results adequately, specific age and gender haematologic and biochemical references intervals are needed. Particularly for emerging markers there is only scarce data available in paediatrics. However, because this references range can only be characterised among healthy children's blood serum, it is difficult to collect data for ethical reasons.

Prof. Mayanskiy's institute is collaborating with the Canadian Laboratory Initiative on Paediatric Reference Interval Database (CALIPER) to establish reference intervals according to CLSI/IFCC C28-P3 guidelines by the Robust statistical method.

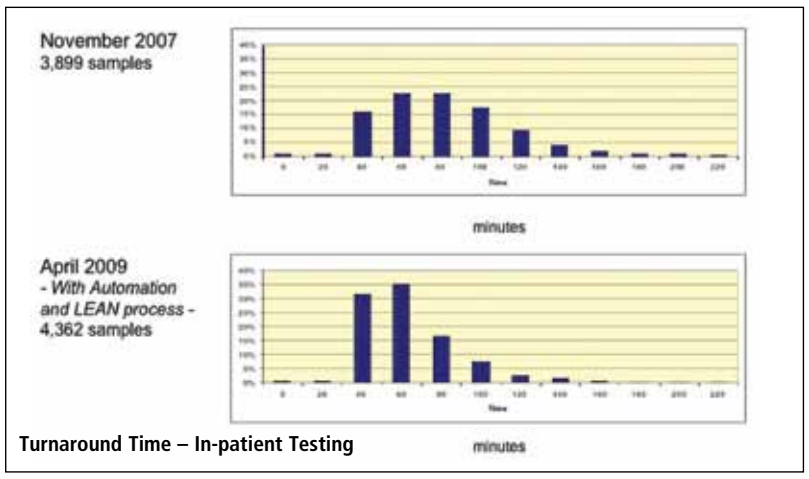
** As an international expert at the IFCC WorldLab session 'Current challenges in the paediatric laboratory', Prof. Mayanskiy will discuss 'Laboratory markers for differential diagnosis of febrile infections in children' on 19th May, in Berlin.*

Partnership delivers

Dr John Wood, Head of Pathology, Southampton University Hospitals NHS Trust, UK, describes how the hospital boosted productivity by 97% after automating its entire laboratory process – and is now part of an expanding NHS network

Southampton University Hospitals' Department of Laboratory Medicine has recently transformed the way it delivers its pathology service, becoming one of the largest automation installations in the National Health Service to operate under a managed service contract. This has contributed significantly to the development of a strengthened and expanded pathology network across Southern England.

As well as serving the community of 500,000 people in Southampton and South West Hampshire, the 1,300-bed hospital is also a tertiary referral centre — providing specialised services such as cardiac surgery, oncology and neurosciences for 3 million people in Southern England and the Channel Islands. Mainstream NHS work is split evenly between outpatients, general practitioners (GPs) and in-patient testing requirements. Our workload in the laboratory includes a mix of referral work, forensic toxicology and clinical trials.



Turnaround Time – In-patient Testing

Over the last few years, workload has increased by 65 percent. However, in the same period, our productivity has risen by more than 97 percent — in spite of budget and staffing constraints. This improvement has been particularly apparent since the hospital partnered with Beckman Coulter in 2007 to automate the laboratory fully. The entire lab process – from sample receipt to reporting of results – is now completely automated, with access to instruments and results from one central workstation. The laboratory operates on a 24-hour basis, handling more than 700,000 samples per annum and delivering a total of 6.5 million biochemistry tests results. The peak period begins at 2 p.m. and continues unabated until the early evening.

Focus on predictability of results

For Southampton, the right automation choice, as well as utilising LEAN process improvements (which eliminate waste from business processes), has driven hourly success rates for turnaround time (TAT) to 95 percent. But more significantly, the lab consistently exceeds them. We have set ourselves the challenge of an on-going strategy to focus more on sustaining the predictability of the results reporting, as well as continuing to improve TAT.

Already, these changes to our pathology service have had a dramatic impact on both outreach customers, as well as all hospital departments. For the GPs, a fast and predictable TAT means that results flagging up life-threatening conditions can be processed and returned before GP surgeries close, with results from more routine tests returned within the day.

The impact on Southampton's emergency department (ED) has been equally significant; for example, prior to automation, the ED staff was frustrated because they did not know when laboratory results would be available. This unpredictability was hindering the ED from meeting its critical four-hour targets set by the Department of Health. Before the automation track was installed, only 12 percent of test results were delivered to the emergency department within 46 minutes and 22 percent were taking as long as 90 minutes. The current situation is completely different, with 70 percent of test results returned to the ED within 30 minutes and a further 20 percent returned within 46 minutes.

Inefficient workflow practices, bottlenecks and duplicated processing streams — these were the driving factors that led us to search for process and automation solutions. However, as a first step, we carried out a detailed process analysis of how the existing laboratory functioned. This identified two key issues that needed resolving:

- Turnaround time had to commence from the moment the samples arrived and should not end until their automated archiving. The target was to deliver results within an hour with minimal staff involvement
- The ability to handle future workload growth was critical if the laboratory was to sustain the targeted service delivery improvements.

Our team now constantly seeks to outperform our targets, all the while providing customers with consistent, timely results. We process approximately 3,500 samples per day and operate on a daily basis with no more than three people needed for system maintenance, reagent loading, calibration, validation and looking after the help desk. In addition, the pre-analytical stage has significantly improved, eliminating four hours of non-valued-added work and the total time in sample reception has been reduced to less than 50 minutes.

None of these achievements would have been possible without the teamwork and cooperation of staff at all levels, investment by hospital management and the on-going partnership the laboratory has established with Beckman Coulter.

Success through partnership

Our now-streamlined lab operates very much as a business partnership, setting service delivery for customers at the top of the agenda. A regular dialogue is maintained — whether it is with the GPs, the emergency department or the hospital medical oncology teams. This strategy allows us to identify needs and constantly adjust the service accordingly, to match and even exceed expectations — and to do that on a sustained basis.

Our business model of partnership is a continuation of the close collabo-

improvements in pathology services

ration we developed with our automation provider. Beckman Coulter's active involvement to help establish and improve the laboratory's workflow has enabled us to:

- Consolidate and streamline the whole of the laboratory testing service
- Sustain improvements
- Handle increasing workloads with existing staff numbers
- Reduce variation time in turnaround times
- Simplify the entire process, not just the analytical phase.

The decision to automate was taken as part of an innovative tendering process in collaboration with four other NHS trusts. Our joint goal was to improve service delivery and maintain its consistency – both now and for the future. Beckman Coulter's total laboratory automation solution was chosen for its flexibility and streamlined approach. Once we decided to go forward with a provider, the four trusts chose to collaborate under a managed service contract.

Previously, the Southampton laboratory operated with three clinical chemistry and two immunoassay standalone systems. In order to meet our current requirements and create solutions that would meet long-term needs, we built a system that included

The Department of Laboratory Medicine at Southampton, part of the Southampton University Hospitals NHS Trust, operates one of the flagship in vitro diagnostic testing services in the United Kingdom. Dr John Wood, head of pathology, has been a recent finalist in the NHS Healthcare Scientist of the Year – and is a member of the Clinical Pathology Accreditation (CPA) training and education group. He is an expert in information management.

Beckman Coulter's Power Processor, which has extensive tracking, linking automated centrifuges and aliquotter. We now have four UniCel DxC 800 clinical chemistry analysers (running up to 1,440 tests an hour), two DxI 800 immunoassay systems (up to 400 tests an hour), and a stockyard with the capacity for storing 3,060 samples. We also decided the laboratory needed a fifth DxC 800 to operate as a standalone unit for additional testing to handle the specific requirements from the hospital's paediatric department.

The redesigned layout of the lab is very space efficient with two lines of tracking and linked analysers running up and down the length of one section of the laboratory. Samples are monitored using the REMISOL Advance data management system, which automatically highlights abnormal results and samples that require additional attention, such as dilution.

Staff motivation vital to 'sustainability'

Partnership was key to our success, demonstrated not only by Beckman Coulter's ability to deliver the right solutions – but the willingness of colleagues in other laboratories to collaborate with us. However, ultimately it will be the active involvement and cooperation of staff that makes it possible for us to sustain and build upon these process improvements.

Automation requires a fundamental change in the way a laboratory operates, causing the staff anxiety and concern, even when they know it might improve their daily work routine. However, once staff members can rely on an automated system to function consistently, without their input, they are able to concentrate on more challenging diagnostic work (much of which may be income-generating). As one of the biomedical support workers said: 'It's great that no work is left over. Otherwise, we would be starting the next day with yesterday's work yet to do.'

It is a measure of the dedication of the staff at Southampton — and the way they bought into the modernisation programme as individuals — that has made the transformation possible. The challenge, however, is to sustain improvements and maintain the standardisation of processes. To help achieve this, Southampton utilises LEAN process improvement principles so that quality control indicators are implemented and are easily accessed and understood by staff.

One of the ways we maintain these process improvements is to publish regular bulletins and spreadsheets demonstrating lab operating performance by quantifying the consistency of process improvements. This enables laboratory staff to see the benefits to patients and colleagues of continuing to implement new processes and maintain production standards. This 'visual management' technique is the key to sustainability.

Delivering a consistently high level of service

To gauge the effect of these changes, we carried out a survey asking colleagues, in confidence, how each felt about the changes and the impact on their work life. The results showed that:

- Every staff member agreed or strongly agreed that workflow had improved
- Everyone said they were delivering an improved service
- Most reported significantly less time spent solving problems
- In the main, all confirmed that work is finished more quickly.

The Department of Laboratory Medicine at Southampton is determined to provide a consistently high level of service to all customers – and to be able to accomplish those goals in the most time and cost efficient manner. By combining high-specification instrumentation with strategies to deliver a sustained level of process excellence, the laboratory will continue to meet and increasingly exceed the level of service required by today's NHS, and most importantly by our patients.

Source: The case study on Beckman Coulter's laboratory automation solution for Southampton University Hospitals' Department of Laboratory Medicine first appeared in Hospital Healthcare Europe 2011, published by Campden Media.

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Integration to combat diabetes

The German Centre for Diabetes Research joins five highly specialised partners

To face the national and worldwide increase in diabetes mellitus cases, the German Federal Ministry of Education and Research initiated the foundation of the German Centre for Diabetes Research (DZD), aiming to improve basic research, prevention, diagnostic and therapy of diabetes. Inaugurated in Berlin a few months ago, the centre has five strategic partners

In 2009, the Federal Ministry of Education and Research decided to explore new pathways in health research and planned to establish six new centres of health research to cope with widespread diseases, diseases with a high mortality rate and emerging diseases, such as diabetes. In the same year as the establishment of the Centre for Neurodegenerative Diseases the German Centre for Diabetes Research (DZD) followed, inaugurated on 9 November 2010 by the Parliamentary State Secretary Helge Braun. The remaining four centres that will pool resources and energies in the field of infectious, pulmonary and cardiovascular diseases and cancer are scheduled to open in 2011.

The DZD comprises three non-university partners – the Helmholtz Centre in Munich, German Diabetes Centre in Dusseldorf and the German Institute of Human Nutrition Potsdam-Rehbrücke and the two universities of Tübingen and Dresden. The cooperation of the five – with registered office in Munich – is generously supported by the Republic. The Federal Ministry of Education and Research will provide €8 million for the start-up because, from 2015, the Ministry and the Federal States will provide a projected annual funding of €33 million.

A wide range of different aspects in diabetes research will be the focus at DZD. During its inauguration in Berlin, five panel speakers, representing each partner, introduced their specialisations and discussed their potential contribution to DZD.

Professor Hans-Georg Joost, from the German Institute of Human Nutrition in Potsdam-Rehbrücke, emphasised the high quantity of data that his institute brings in – the so-called Potsdamer cohort of around 27,500 people. The German Diabetes (type 2) Risk Score, for example, was compiled via that cohort.

Professor Hans-Ulrich Häring, representing the University in Tübingen, which contributes a well characterised cohort of pre-diabetics, also quoted the Tübingen Lifestyle Intervention Programme (TULIP). This project involves the transfer of cross-sectional data relating to the Tübingen Family Study into a longitudinal study for the prevention of type 2 diabetes mellitus and its vascular complications.

Professor Michael Roden, from the German Diabetes Centre in Dusseldorf, presented the Centre's study that examines the natural course of the disease in the long run, to identify the factors that induce long-term complications. The study also will be conducted at the other sites, one of the big advantages of a consortium, the Professor emphasised.

The Helmhotz Centre in Munich attaches utmost importance to basic-research, as Professor Martin Hrabé de Angelis explained. He quoted inter alia the characterisation of mouse diabetes models, in collaboration with the German Mouse Clinic in Munich, to understand the molecular mechanisms of the disease better and to develop new therapies.

The Helmholtz Centre also develops a vaccination-strategy for type 1 diabetics in partnership with the University Clinic Carl Gustav Carus of Dresden, the latter being represented by Professor Michele Solimena. Collaborating with both the Helmholtz Centre and the German Diabetes Centre, he and his colleagues examine how to differentiate embryonic stem-cells into insulin-producing cells. The team is also trying to transplant pancreatic islets.

All in all this is a promising scheme. Whether, as the Parliamentary State Secretary Helge Braun hopes, the dream of preventing and curing diabetes will come true in the near future, is more than uncertain. However, the consortium will present its first jointly achieved results in three years.


Michael Roden


Hans-Ulrich Häring


Hans-Georg Joost


Martin Hrabé de Angelis


Helge Braun


Michele Solimena

Keeping everything under control in the ICU

During intensive care, hyperglycaemia and insulin resistance are widespread in diabetics as well as non-diabetics. However, whether the normalisation of blood glucose levels with insulin therapy improves the prognosis of such patients is still debated. Adequate clinical studies and sufficient personnel resources to cover glucose monitoring and control in all hospital departments is missing, says Professor Christophe De Block, at the Department Endocrinology and Diabetology, University of Antwerp, Belgium. However, he believes that a strict glycaemic control does have beneficial effects on patient's outcome

The Leuven I Study in 2001 (van den Berghe et al), the first randomised trial on intensive insulin therapy in critically ill patients, showed an improvement on the morbidity and mortality of surgical intensive care unit (ICU) patients, when blood glucose was maintained ≤ 110 mg/dl. In recent times, a couple of other studies refute that intensive glucose control reduces mortality. Instead, in the NICE-SUGAR trial (2009), for example, intensive glucose control in critically ill adult patients increased the number of hypoglycaemic events and even the mortality risk by 10%.

'The conclusions of those current studies must be handled with caution,' Prof. De Block advises. No decent study design has yet been designed that evaluates the outcome of strict glycaemic control over a long period of time, he points out. 'Usually, strict glycaemic control is applied only during 3-5 day stay in ICUs or coronary care units, then the outcome is evaluated later, after 90 days – so no one knows what happens between day five and day 90. Therefore, it's difficult to make a firm recommendation on an effective glucose control management.'

In this regard, another problem is that, while in the ICU, a patient's blood sugar levels are monitored on a frequent basis, following transfer to a hospital ward, glucose monitoring loses priority. And, there are no trials investigating the influence of glucose control on patient groups moving from an ICU to a hospital ward. 'Whereas, in the ICU one nurse tends two patients, in other departments three nurses take care of 20 patients,' the professor points out. 'Achieving strict glycaemic control


Christophe De Block

requires extensive nursing efforts. A tight glucose control means that glycaemia has to be measured every two hours. The measuring itself takes 3-5 minutes. In other words, one hour a day would be reserved only for measuring glucose values and adapting insulin infusion.'

At Antwerp University Hospital, Prof. De Block and team have developed a peri-operative glucose management programme which takes three parameters into account:

- adoption of a safe target between 80 to 150 mg/dl
- a reliable administration route (preferred an Intravenous/IV Route)
- frequency of glucose monitoring.

A strict protocol must be observed to achieve an adequate frequency of glucose measurement. Preferred are computer-driven glycaemic control protocols taking into account the actual glucose value, rate of insulin infusion, and also the rate of change (increase/decrease) of glycaemia. In recent years, continuous glucose monitoring (CGM) systems have become available to measure interstitial glucose levels every five minutes, day and night.

In a 2010 study by Holzinger and colleagues showed that the use of real-time CGM technology reduced the number of hypoglycaemic events – the limiting factor to apply strict glucose control - significantly. 'But, because these systems measure glucose levels of interstitial fluid, instead of in arterial or venous blood, they have to be correctly calibrated and interpreted with the necessary caution,' Prof. De Block emphasises.

Thus, while it has been shown that continuous glucose monitoring technology can help to administer insulin infusion and avoid glucose variability, nonetheless the accuracy of CGM still must be improved.

'Several international researchers are working on a proper algorithm to add to the technical CGM tool – like our group, and the groups of Roman Hovorka, University of Cambridge, UK, Greet Van Den Berghe, Katholieke Universiteit Leuven, Belgium, and Professor Thomas Pieber at the Medical University Graz, Austria.'

England: Foot and limb losses must be cut

New data has highlighted wide variations in amputation rates for diabetics across hospitals, *Mark Nicholls* reports


Barbara Young


Gerry Rayman

Much of the newly revealed variation in amputation rates in England is due to many diabetics not receiving nine key care processes, including checks on weight, blood pressure, blood glucose, cholesterol, urine and, in particular, consistent foot care checks.

Figures contained in the NHS Health Atlas in Variation of Healthcare show how, in the south west of England, amputations are three in 1,000 diabetes patients, which is almost twice the level in the south east.

However, there are examples where hospitals have seen dramatic reductions in amputations by introducing simple and inexpensive foot care management clinics to offer patients support and advice.

The Health Atlas says that to reduce major amputations, more integrated multi-disciplinary specialist diabetes foot teams (MDT) need to be established.

At Ipswich Hospital, in the east of England, the amputation rate has fallen significantly since the MDT was established 11 years ago. At that time there were 36.4 amputations per 10,000 people with diabetes, now there are 6.7.

Dr Gerry Rayman, Head of the hospital's diabetes department, said that a key element of their success came through lesions being efficiently identified, assessed and patients prioritised as low, moderate or high risk and then treated accordingly. 'Patients with moderate risk can be given support in the community, but those at high risk need to be seen immediately by the knowledgeable Multi Disciplinary Foot Team,' added Dr Rayman, who is also the national diabetes lead for inpatient diabetes for the NHS in England.

Further liaison with interventional radiologists and vascular surgeons is then an important element in helping to avoid unnecessary amputation. And, he pointed out, preventative treatments also need to be put in place, such as identifying foot ulcers before they become serious or infected.

Diabetes can lead to a loss of sensation in the feet so minor injuries can become badly infected without the patient noticing. If the infection becomes too severe, amputation of a foot, or the leg below the knee, becomes the treatment of last resort.

As well as obvious benefits to the patients, he said there are clear cost savings to the health system by implementing prompt treatments to avoid amputations.

Across England, there are about 70 amputations a week on type 2 diabetes patients but the Health Atlas says that 80% of amputations could be prevented.

Diabetes UK is also concerned about amputation levels and the need for consistent foot checks after figures for 2007/2008 showed that 23% of people with diabetes did not have a foot check. The charity is now working with the Department of Health to address the regional differences in amputation levels.

Diabetes UK chief executive Barbara Young said the findings 'demonstrate that the NHS is failing to provide universally high quality care across the country and shows that diabetes care is still a postcode lottery'.

The charity says that with access to high quality care, patient education and effective diabetes management, there is no reason why people with diabetes should not live long and healthy lives, particularly because 95% of diabetes care is patient self-management. She added: 'Diabetes is the single most common cause of lower-limb amputation in the UK. Foot checks as part of the annual review should be a given and any injuries or ulcers that are detected need to be assessed as soon as possible by an expert team.'

The UK government has published the Health Atlas to try and improve care and eradicate regional variations in quality of care. The amputation difference is one of the most striking revealed in a series of 34 'maps', which also covers stroke, heart disease and asthma treatment.

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