



SPECIAL ISSUE: MEDICAL, TECHNICAL, PHARMACEUTICAL, INDUSTRIAL NEWS

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Hardly any topic has been discussed as broadly as personalised medicine, with countless stakeholders, ministries and organisations involved. That's good news, says Professor Angela Brand, Professorial Fellow at the Maastricht Economic and Social Research Institute on Innovation and Technology (MERIT) and Professor at the Department of Health, Medicine and Life Sciences at Maastricht University. 'We should use this attention. Right now, many activities come together and move in the right direction. That is a huge success.' Although she was enthusiastic about the current developments, when EH met with her at the European Health Forum in Gastein, she also demanded a profound change in approaches and a reorientation of orthodox medicine.

Identified challenges

- 1 – Developing awareness and empowerment
- 2 – Integrating big data and ICT solutions
- 3 – Translating basic to clinical research and beyond
- 4 – Bringing innovation to the market
- 5 – Shaping sustainable healthcare

Personalised Health has turned into a buzzword and there are many parties interested in the subject,' Professor Brand points out. 'However, there is considerable confusion about the terminology and tasks of public health and personalised medicine. I strongly recommend using the terms personalised health and care because that is what personalised medicine and the reorientation of public health are all about.'

Orthodox medicine is coming of age

One feature that characterises personalised medicine is the use of tools and apps that work hand in hand and allow certain analyses. 'In the past, physicians treated their patients with therapies that were based on comprehensive studies but were not adjusted to the individual patient. This latter approach is entirely new,' Professor Brand points out. While traditional medicine, with its thousands of years of experience, has always had a holistic view and an individual perspective, Western orthodox medicine focused on evidence-based medicine, with evidence culled from large populations. 'Today, we see a turn towards a higher degree of individuality, albeit in a different context and with adjusted methods,' she underlines.

For the first time there seems to be a rapprochement of orthodox and traditional medicine. 'The advantage of these old, non-orthodox approaches is the fact they have always taken into account the dynamics of highly complex and interdependent environmental and genomic factors on the individual level, for example, when we are looking at cancer. In my opinion the highest hurdle is the integration of this dynamics into Western orthodox medicine.'

'We need to answer the question regarding what we will do when results cannot be reproduced across population-based clinical studies because of the individuality of the disease and the patient,' Professor Brand urges.

Politics is prepared to move – physicians are stalling

Over the past two years a consortium of ministries and funding bodies, funded by the EU and headed by German experts, has been working on 'Shaping Europe's Vision for Personalised Medicine'*. The team developed a roadmap to define the five major challenges (see box). 'The role of the individual – patient and citizen – must take centre stage, particularly in view of Big Data and of information and communication technologies. Moreover, issues around access and sustainable healthcare systems have to be clarified,' Brand stresses.

However, many physicians appear to be apprehensive. The implementation of a project in Malta, which was fully defined, failed because the GPs opposed it, as she explains: 'A discussion with the ministry in Malta quickly revealed that the health data cooperative was grounded because the physicians thought it created too much transparency.'

Physicians deal with best available evidence

Brand does not consider tightening the laws or EU rules to be a solution. 'Quite the contrary, we should try to decrease regulation and to offer guidance and support, so that we can think about how the challenges should be approached. Tightening the rules will have the exact opposite effect.' For Brand issues such as 'drug development, reimbursement of prescription drugs, evaluations and health technology assessment, are but parts of the overall challenge. As physicians we have to deal with "best available evidence", which might differ considerably from the results of the large randomised controlled studies. These issues have to be advanced.'

Brand clearly states the shortcomings and demands; she has great confidence in the future: 'For physicians this is not about power games;

Many issues must be resolved

The route to personalised medicine is lengthy

it's about how we define our role going forward. In the future the informed patients and citizens will be the master of their data in the cloud and they will be very careful whom they are going to trust. We should consider this an opportunity, not a threat.'

'IBM's analysis tool Watson is quite controversial among physicians,' Brand explains. 'That's why we asked an IBM representative to join us on the consortium and help us to optimise the system. I am convinced that, in the future, we will have many more such support tools.'

* PerMed: Shaping Europe's Vision for Personalised Medicine. Strategic Research and Innovation Agenda (SRIA) www.permed2020.eu



Having worked in clinics, at various academic institutions and in governmental bodies in the USA and Germany, today **Angela Brand MD PhD MPH (USA)** is Full Professor at the Faculty of Health, Medicine and Life Sciences (FHML) and Professorial

Fellow at Maastricht Economic and Social Research Institute on Innovation and Technology (MERIT), Maastricht Graduate School of Governance, Faculty of Humanities and Sciences (FHS), Maastricht University, The Netherlands. The professor is paediatrician, specialist in Public Health Medicine, holds a PhD in pathology, a Master of Public Health (MPH) from Johns Hopkins University, USA, and received her habilitation focusing on Health Technology Assessment. Brand also directs the European Centre for Public Health Genomics (ECPHG) and is the Dr T M Pai Endowed Chair on Public Health Genomics and Adjunct Professor at the School of Life Sciences at Manipal University, India.

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Cardiac

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Anemia

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Bone Metabolism

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Kidney Function

β₂-MG, Albumin

Immunoglobulin

IgM, IgA, IgE, IgG

Infectious Disease

HBsAg, Anti-HBs, HBeAg, Anti-HBe, Anti-HBc, Anti-HCV, Syphilis, Chagas, HTLV III, Anti-HAV, HAV IgM, HIV p24 Ag, HIV Ab/Ag combi

Prenatal Screening

cAFP, free β-HCG, PAPPA

Drug Monitoring

Cyclosporine A, Tacrolimus, FK 506, Digoxin

Inflammation Monitoring

CRP, PCT

Others

GH, IGF-1, Cortisol, ACTH

Audio-visual teleconferencing with advanced remote robotics

Long distance ultrasound is not so distant

The future of medicine lies at a distance, underlined in our EH interview with Professor Michel Claudon, head of Radiology at the Regional University Hospital, Nancy, France, whose particular interest is ultrasound. Advances in IT and telecommunications have driven expert healthcare provision even into the most remote rural areas – underlined by this notable test in ultrasound

The Melody System is the world's first remote ultrasound imaging system. Produced by French company AdEchoTech, and developed by radiologists for radiologists, the system has evolved to meet the real needs of an ultrasound examination. Recognising that the necessary precision would be impossible using only a voice-controlled robot, the system incorporates the most recent audio-visual teleconference technology with advanced remote robotics similar to those used in space exploration.

The lead radiologist controls the entire examination from a central workstation, where the video link enables the patient, operator and ultrasound images to be seen on high-resolution computer screens throughout the examination. The



highly sensitive audio-link also enables the expert radiologist to instruct the operator and discuss with the patient throughout the procedure.

However, most importantly, it is the use of a 'dummy' probe by the expert that drives the robot and therefore, ensures exam qual-

ity. and activation of various ultrasound modes, such as Colour Doppler and Pulse Wave Doppler.

Is the system as good as it seems? Claudon's team organised a test to find out. The Melody system was set-up in the Lunéville Hospital centre, over 30 km away from the specialist centre in Nancy.

The equipment was very easy to set-up – within a day it was completely operational in the Lunéville ultrasound room with the secure audio-video link picking-up the images in Nancy.

Over the next three days approximately 30 different abdominal ultrasound examinations were performed with the system. Following instructions from Nancy, the patients placed themselves on the couch and operator positioned the robot over their



body and applied gel. The probe on the robot, inclined at 45° then followed the movements of the expert's dummy probe to perform the examination.

The team were quite surprised at how quickly they adapted to using the system, within two-three examinations 'to use a dummy probe honestly became completely natural'.

While watching the images, the expert moves the dummy probe as they would if physically at the patient's side.

Currently used primarily for abdominal ultrasound examinations, the lead radiologist has complete control over the set-up parameters of the images, such as gain control, depth control, frequency change



Michel Claudon, Professor of Radiology, head of the Radiology Department at the Brabois Adult Hospital, and a past President of WFUMB – the World Federation of Ultrasound in Medicine and Biology, carries out an examination remotely, using a 'dummy' probe that drives the robot. The operators, like the one here, said they quickly adapted to using the Melody System

Also the images provided are completely compatible with the hospital's PACS, so they could be automatically archived for future reference.

What about the patient? In this series of tests, patients were completely relaxed and compliant and had absolutely no difficulty with the concept of having the specialist at a distance. For them the end result of the examination is the same but without the loss of time and other potential difficulties of having to travel to the specialist centre.

Are there limitations? The system is as good as the internet connection for the specialist to feel that they are present at the examination. It has to be performed in real time, with no pauses and screen break-up. While fibre-optic cable will produce the best results, for longer distances satellite connections may add up to a millisecond of difference, which nevertheless should be imperceptible to the radiologists concerned.

There is also the ergonomic question of probe depth because the pressure exerted by the robotically controlled probe is not the exact equivalent of the radiologist's hand but, as with robotic surgery, future developments and greater use of such systems will overcome.

The team in Nancy are unanimous in praising the system and can see advantages far outweigh the minor disadvantages. They consider it could enable specialist radiologists to intervene earlier in diagnoses, reduce travel for frail patients, training of junior radiologists and a host of other applications.

* European Hospital would like to acknowledge the help of Dr Alix Martin-Betaux, Dr Frédéric LeFevre (CHRU Nancy) and Dr Eric LeFevre (AdEchoTec) in producing this article.

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Government support technology innovation

Representatives from various German authorities and institutions of are at Medica to explain and discuss the country's Government support measures aimed specifically at small and medium-size enterprises (SME).

The Government's aim is to support SMEs through the risks involved in research and development to the transfer of scientific research findings into the industry through its various initiatives, for example KMU-innovativ: Medizintechnik, or the Central Innovation Programme for the Mid-size Sector (ZIM).

The government, represented by the Federal Ministry of Education and

Optimising the use of devices cuts costs and boosts output

Philips: New tools clearly map workflow

A new server-based suite of tools from Philips can help change the way hospitals and imaging centres operate, the company reports. 'OmniSphere offers several applications designed to increase business efficiency and optimise operations by gathering and presenting utilisation data for administrators, radiologists, imaging technicians, and hospital IT teams to assess, analyse, and put into action.

'In an increasingly consolidated healthcare environment, efficiency and workflow optimisation are vital for hospitals and imaging centres. Traditionally, it has been overly tedious and labour intensive to run detailed reports that allow for in-depth analysis of how an organisation's ultrasound systems are being used across a site, or a networked system. Due to this, the staff often works around inefficiencies on a daily basis, without addressing the root cause, resulting in lost time and increased costs. Driven by customer insights, Philips OmniSphere's Utilisation Optimiser and Remote Technical Connect applications are designed to make it easier to optimise equipment utilisation for reduced costs and increased productivity.'

'OmniSphere's Utilisation Optimiser gives ultrasound managers a clear view into workflow, staffing, and equipment utilisation and downtime. The platform provides easy access to deep levels of data through an intuitive interface and can help users customise the level of reporting based on their needs.

'Based on the existing landscape, easy access to staffing and equipment usage reports has the potential to increase productivity and recapture lost revenue,' Philips continues. 'For example, if an hour of downtime for an ultrasound costs \$175/€161 in potential revenue, a lost eight-hour day of downtime can cost \$1,400/€1,285. The OmniSphere Utilisation Optimiser allows users to filter and manipulate data to guide more informed decision-making for purchasing, staffing, training and workflow.

'The Remote Technical Connect application delivers quick, easy, and secure access to ultrasound systems to help Biomed and IT teams gain insights that allow them to increase their productivity and uptime. There are many scenarios that cause frustration and setbacks when Biomed are

out in the field, such as bringing the incorrect equipment or wasting travel time. Enabling Biomed to provide first response remotely, and be more prepared when they arrive to service equipment, can save labour hours and associated costs, not only freeing

them up to service other needs but also increasing equipment uptime.

'Further, if Biomed employees earn a median of \$41.45/€38.04 an hour, reducing inefficient travel time and unnecessary repair trips can quickly add up to meaningful cost savings.'

Vitor Rocha, CEO of Philips Ultrasound, adds: 'The healthcare landscape is changing. With larger networked systems and more consolidation, it will be more important than ever for leaders to get a clear picture of their operations through data analysis. The Philips OmniSphere suite makes evaluating efficiency quick and easy so professionals can build it into their regular routine and start confidently making choices backed by

data.' Philips is dedicated to improving both the patient and provider experience with tools that make a difference, the company points out. 'Driving better business models and workflow efficiency leads to less wait time and a better patient experience. Every manager wants to make smart decisions based on data, and Philips OmniSphere can uncover inefficiencies to help administrators make more informed business decisions. Philips believes that meaningful solutions – those that make a real difference – are developed in partnership with customers, with an understanding that quality patient care extends outside the hospital walls.'



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Support for medical innovations

Research (BMBF), and the Federal Ministry for Economic Affairs and Energy (BMWi), will present those initiatives and activities to support medical technology innovations.

Government tenders

The promotion of R&D will also be covered by experts on site: Representatives from the BMBF project sponsor for health science and the ZIM project sponsor at the BMWi will provide information on current government tenders and how to bid for them.

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Ultrasound can reveal different types of shock in trauma

Resuscitation: E-FAST or CT?

Ultrasound examinations are considered cost-efficient, fast and effective. The E-FAST (Extended-Focused Assessment with Sonography for Trauma) is a standardised examination used in accident & emergency medicine worldwide. The procedure helps to diagnose internal bleeding and organ damage in severely injured patients in the resuscitation room and, in some regions, even during emergency transport to the hospital, gaining valuable time for the primary care of these patients. [AWMF Register No. 012/019].

'Apart from haemorrhagic shock there are other forms of traumatic shock which are just as life-threatening,' explains Dr Dieter von Ow, Assistant Director of the Central Accident & Emergency Department at the Cantonal Hospital St. Gallen.

Although haemorrhagic shock is common, there are also non-haemorrhagic types of shock, such as tension pneumothorax, cardiac tamponade or severe paraplegia with neurogenic shock.

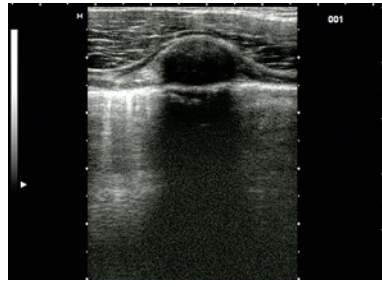
With tension pneumothorax, a valve mechanism, particularly during artificial ventilation, increases pressure in the pleural cavity so much that the venous return to the heart is impaired, resulting in circulatory shock.

A cardiac tamponade leads to direct compression of the cardiac chamber and thus a reduction of the stroke volume. Cardiac tamponade is relatively rare, but fatal if not diagnosed. These two types of shock are not caused by blood loss,' von Ow explains, 'but by the aforementioned, direct increases in pressure in the mediastinum or the pericardium. Not rarely do the latter two types of shock also occur combined with blood loss, which leads to severe impairment of the patient's circulation and requires fast treatment.'

Each patient with potential multiple injuries or uncertain injuries



Tension/pneumothorax: (lack of lung sliding in the moving image), lack of comet tail artefacts and distinct reverberations ('lines')



Normal findings: (lung sliding, moving image), comet tail artefacts (on the left in the image)



(Massive) haemothorax: Fluid (blood, hypoechoic) between diaphragm and thoracic wall, with an atelectatic lung section (half moon) 'swimming' inside



Pericardial effusion: Fluid (blood, hypoechoic) between the pericardial sac and the heart suggested compression of the right ventricle (tamponade)



Haematoperitoneum: Fluid (blood, hypoechoic) between kidney and liver, i.e. in the Morison's pouch



Haematoperitoneum: Fluid (blood, hypoechoic) in the lesser pelvis, with the uterus and full bladder, separated by the bladder wall (on the right in image) 'swimming' inside

admitted to the Central Accident and Emergency Department at the Cantonal Hospital St. Gallen is examined with the E-FAST procedure. 'This involves assessing the thoracic cavity, or the pleural cavity respectively, in so-called sectional planes, ventrally and from the side towards the armpits. This provides clues as to the potential presence of tension pneumothorax or haemothorax.

The subcostal plane makes it possible to diagnose a cardiac tamponade. A tension pneumothorax, a massive haemothorax or a cardiac tamponade require immediate release of air, or blood respectively, by the insertion of the appropriate drainage in the resuscitation room.'

The peritoneal cavity is also examined for the presence of free fluid

via sectional planes from the sides, toward the abdomen and in planes directed towards the lesser pelvis. Finding shocking and potentially fatal bleeding in the lesser pelvis is not always easy because rupturing aneurysms are not always easy to detect retroperitoneally. Severely injured patients in persistent shock, i.e. so-called 'non-responders' defined by unchanged blood pressure readings below 80mmHg, despite the administration of fluid, who have large blood loss in the thorax, abdomen or pelvis diagnosed via the E-FAST procedure must undergo emergency surgery without delay.

Multiple trauma patients who need to be stabilised in the resuscitation room – the so-called 'responders' or 'transient responders' – are immediately

given a polytrauma CT scan and, depending on the results of this scan, the further (surgical) strategy is then determined,' von Ow explains. [klinikarzt 2012; 41 (1): 26-30]

This point-of-care ultrasound is handled in a very similar way in many trauma centres and is always carried out at the beginning of treatment. It is conducted by specialists in emergency medicine, traumatologists, anaesthetists or radiologists in the resuscitation room, requires six sectional planes to ensure a safe diagnosis and takes only a few minutes.

It answers a small number of specific questions: Is it a tension pneumothorax? A cardiac tamponade? Is there fluid – i.e. blood – in one of the three large cavities, i.e. the tho-



Internal medicine and intensive care specialist **Dieter von Ow** is also qualified in clinical emergency medicine at SGNOR (Swiss Society for Accident and Emergency Medicine). He is a course instructor and tutor for abdominal ultrasound and point-of-care ultrasound (basic emergency ultrasound, echocardiography, thoracic and musculoskeletal ultrasound), as well as course director/instructor for Advanced Trauma Life Support (ATLS) American College of Surgeons and Advanced Cardiovascular Life Support (ACLS), American Heart Association. He has worked in the Central Accident and Emergency Department at the Cantonal Hospital St. Gallen for 15 years, where he is currently Assistant Director. This is Eastern Switzerland's main hospital providing maximum care for around 40,000 patients annually. As one of the Swiss Trauma Centres it is included in the national trauma register.

rax, abdomen or pelvis? (The ability to differentiate between these types of shock requires conducting 50-100 such bedside examinations under supervision).

The results of the examination either lead to life-saving intervention in the resuscitation room, or they support the life-saving triage decision 'Emergency surgery or poly-trauma CT'.

In other words, 'E-FAST can save lives,' von Ow is convinced. Current data from large trauma registers confirm this statement. When multiple trauma patients are given a CT scan without being assessed via this system beforehand, this does not improve their chances of survival [The Lancet 2016; 388: 673-83]

The parenchymal organs, the liver, spleen and kidneys can also be assessed via contrast medium ultrasound instead of CT, he explains. However, there are only few radiographers experienced enough to carry out the procedure on trauma patients.

Nevertheless, it does significantly reduce the potentially carcinogenic radiation exposure from CT scans and other radiological examinations, particularly for children and adolescents, given that the radiation exposure following relevant trauma exceeds the average annual terrestrial exposure per patient 15-30 times.

Medica very best

MEDICA 2016 has attracted a high level of British healthcare companies keen to develop and nurture worldwide trade links post Brexit. The organiser, the Association of British Healthcare Industries (ABHI) reports that the UK Pavilion is demonstrating cutting edge technologies and world-class UK innovations. It is also

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Sensing and communicating our ups/downs and many needs

There's sanity in embedded computing

Report: Cornelia Wels-Maug

The power of computing grows more pervasive as it is increasingly integrated into everyday items within our immediate environment, as in smart toothbrushes, for example, or a vortex whistle for managing chronic lung function via smartphones. This September, scientists, developers and designers from around the world met in Heidelberg, Germany, for two parallel events: ACM International Joint Conference on Pervasive and Ubiquitous Computing (UBICOMP) and the International Symposium on Wearable Computers (ISCW) 2016. What was their aim? To compare notes on how computing can be embedded into daily life

Sensors everywhere?

The two conferences showed that, next to smartphones, sensors embedded in watches, glasses, fabric and jewellery, the most common objects, permit new ways of collecting and exchanging data. By bringing artificial intelligence (AI), cognitive computing and deep learning into the mix, this development allows healthcare and wellness industries not only to monitor individuals with more sophistication but also to predict behaviour patterns and trajectories of diseases, among other things. Research in the overall healthcare field featured highly in both events.

Whereas some solutions were clearly in early development stages others were closer to market launch, European Hospital was intrigued by innovations such as:

- Technology enabling users to make up for physical disabilities when communicating with the outside world. For example, 'mood lenses' are glasses that offer people with a neurodegenerative disease who have lost control of facial muscles, to express their emotions via physiological signals integrated into wearable technology. This tool enables individuals to restore non-verbal communication with the help of an in-lens fibre optic display.
- Improving note taking during surgical procedures. As operations need to be documented,



Google glass is a wearable computer

surgeons struggle to find the most accurate and time-efficient way to do so. To wait until the procedure is over risks inaccuracy that can be fortified by inconsistencies in note taking, because there is no standardised way for paper-based systems. With the surgeon's hand busy, documenting during a procedure is difficult. Developments are under way to establish whether Google glasses can help and what the best input modalities are – perhaps speech, head movement or discrete head gestures?

- Advancing the measurement of body and mental functions. This covers a wide array of development and research efforts, resulting, for example, in the design of a non-invasive blood screening system. Using the optical properties of blood and applying machine learning algorithms, the blood's haemoglobin concentration can possibly be estimated based on the blood's colour when illuminating a finger with the help of a smartphone camera.
- Predicting patient behaviour: Hospitals have a vital interest in cutting re-admission rates to avoid penalty payments. Based on the positive correlation between the physical activities of cancer

patients after surgical procedures and the likelihood of not being re-admitted, how about using a step counter or a wireless-enabled wearable technology device to document patients' mobility as an indicator of their likely re-admission? This would then help to introduce timely interventions such as changes in medication or arranging for home monitoring.

- Another fascinating application is work on predicting the onset of depression by using a person's wearable and smartphone data along with data generated in social networks and geo-location information and combine all data with machine learning analysis. The outcome is then fed back to the individual, who is often not aware of any mood changes. However, by making the person aware of those factors it is hoped to prevent depression or even suicide.

Outlook

Considerable work will still need to go into measuring and modifying user experience. Work presented at the Heidelberg events made it clear that just monitoring is a welcome first step, but by no means enough. More intelligence is asked for. Individuals not only want to be able to read their vital signs or their blood glucose levels by, for

well as their circumstances.

And, yes, these are all projects in the making, shining a light on what might be possible. It will take years before some of it will be eventually mature enough to become an actual product – like that electronic toothbrush, equipped with a water-resistant camera to inform the user on the level of plaque on her teeth, using different sounds as feedback. There is just one little drawback – it does not work well with toothpaste!

example, holding their smartphones still in their hands, but also want to obtain advice on how to stay healthy or become healthy faster, based on the current readings. User experience and design will become more important. Consumers increasingly, expect more customised interactions that take into account their personal preferences for communication as



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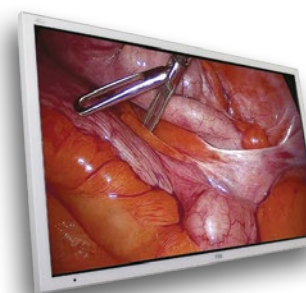
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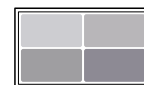
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Paul Benton, International Director of the ABHI, said: 'We are extremely excited to be at Medica to showcase the high level of expertise that the United Kingdom has to offer. The UK is open for business and is keen to forge global healthcare links and Medica offers the perfect platform to do this. Leading British businesses are

bringing solutions to healthcare challenges that will transform the way care is provided in the future and will have the power to radically improve outcomes for patients, globally.'

The ABHI adds: 'The UK has incredible depth and breadth of expertise across the life sciences and healthcare industries. Renowned for its creativity, research, and outstanding talent, the British medical technology industry is at Medica to share, learn and find new global partners.'



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Now available with full HD camera optional

A highly versatile surgical LED lamp

StarLED3 NX, a lamp produced by ACEM Medical Company, is based on the next generation LED technology '... assuring cold light, long life and low energy consumption,' the manufacturer reports. 'Its suitability for countless applications both for surgery and the operating theatre – it is ideal for diagnosis, gynaecology, dermatology, general medicine and surgery. 'StarLED3 NX grants a homogeneous and shadow-less light thanks to its special LED optics created by

ACEM that directs light beams at best according to the needs,' the firm continues. 'The visual area is perfectly illuminated assuring both excellent visual comfort and working conditions. Its next generation LEDs produce an unparalleled quality of light with a colour temperature (CCT) of 4.500 K and a colour rendering index (CRI) of 95.' With light intensity of 130.000 lux the lamp also has a low energy consumption of 69W. 'The life cycle of its LEDs is about 50,000 hours.' ACEM points out. Composed of three reflectors, these produce a well-blended and intense cone of light focusable through the automatic adjustment of the light spot diameter. The firm also points to assets in the lamp's slim, practical

and compact and ergonomic design and suitability for the laminar flows of the operating theatre. Now available with full HD camera optional The ENDO function (light for endoscopy) also adds the value of using this lamp for minimally invasive surgery. 'Functions are adjusted by its innovative easy-to-read, ergonomic and easy-to-clean I-SENSE control panel,' the manufacturer confirms, and lists attributes that include light intensity adjustment; DoF – depth of field – for a deep light; Endo – for endoscopy; Size – light spot diameter adjustment to focus the operating area; Sync – an optional function to synchronise controls of the combined lamps: StarLED3 NX double (twin dome configuration) and StarLED3 NX with StarLED5 NX or StarLED7 NX. The lamp also can be ceiling, wall or trolley mounted (ABPS battery on demand). www.acem.it

ACEM is at Medica Hall 10 / Stand E31

Textile and flexible

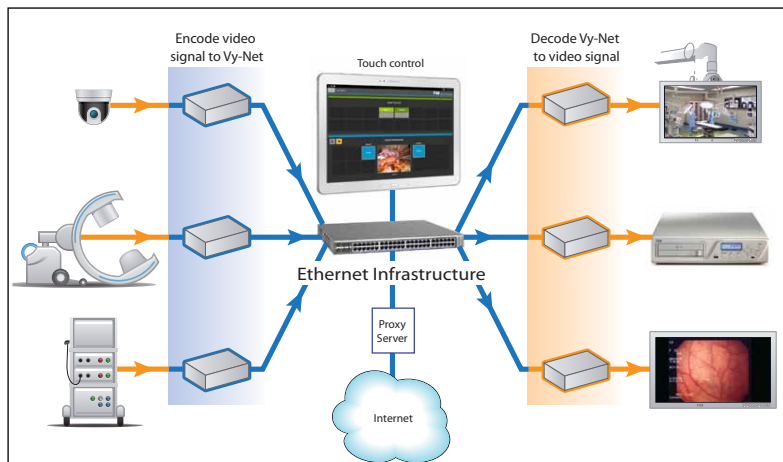


Techtera is an innovation cluster dedicated to textiles and flexible materials in the Auvergne-Rhône-Alpes region, the French leader in the textiles and composites fields. This sector offers many medical applications (implants, bandages, PPE), which represent a growing market for the French textile companies (+1,9%, 2014). 'We support our 120 members in the emergence, structuring and implementation of their collaborative R&D projects. 'Since 2005, we have approved and supported 182 R&D projects. Among them, the global R&D budget for medical projects only represents more than €120 million. 'These projects are under development or finalised, with innova-

tions already available on the medical market. 'Our members offer textile and flexible medical materials, three of which we are presenting at this year's Medica trade fair. The BiliCocoon pad from NeoMedLight treats neonatal jaundice; the silicone yarns and dyed covered yarns for medical use, from Masseur and, from Bertheas, for orthopaedics etc. the 3-D elastic grip belt, plain elastic fabric or open ribbed fabric with Airtex microfibre.' www.techtera.org

Techtera is at Medica Hall 17 / Stand A24

Easing medical video networking



With a straightforward design, Vy-Net, a video over IP network solution for surgical and other departments, 'deploys quickly, integrates smoothly, and can be updated remotely,' the supplier reports. 'The Vy-Net system utilises existing Ethernet infrastructure, and keeps new hardware requirements to a

minimum.' Within its straightforward design, video source signals from medical imaging equipment are received into small Vy-Net converter boxes, set up as encoders. These transform video into an Ethernet/network-compatible signal, and supply a format compatible with display monitors or other medical visualisation components. On the touchscreen interface, video



sources and end-point destinations are clearly shown. 'Simply select a source, and then select a destination to automatically route the video signal,' the firm explains. Additionally, a live preview can be displayed on the touchscreen. The interface also has options for naming equipment, reorganising the touchscreen dashboard, and saving personal preferences for later use. Benefits of Vy-Net include very low latency (under 200ms glass to glass). www.foreseeson.com

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The single-use cervical rotating biopsy punch



Award-winning United Kingdom manufacturer DTR Medical produces innovative, high quality single-use instruments. At Medica this year the firm is showing a new Cervical Rotating Biopsy Punch featuring a low profile jaw. In busy clinics, the single-use punch is valuable because the metal jaw ensures a sharp, clean, 3.0 x 7.5 mm cut that delivers consistent results. Hilda Dunsmore, gynaecologist & colposcopist at the UK's Victoria Infirmary, echoes the benefits of this product saying '...it gives me an accurate biopsy as it has sharp edges so I know I will get a good sample.'



The Cervical Rotating Biopsy Punch has been designed with a low profile jaw to ensure better access to the transformation zone. With a rotating head, the tool facilitates positioning and enables increased visibility, making it an instrument of choice.

DTR is at Medica Hall 16 / Stand F4

Not automatically universal for every facility

Hybrid operating theatres

The hybrid operating theatre is among the most innovative developments in the surgical sector, Melanie Günther reports. 'The combination of interventional and minimally invasive surgical procedures is exciting for many clinical disciplines. The room design, intraoperative imaging techniques, as well as interdisciplinary collaboration, play a pivotal role in this.'

Clinical trials have already shown that image-guided interventions produce better clinical results and also enable the treatment of new patient groups. Hybrid operating rooms (ORs) are used in cardiac surgery, vascular and endovascular surgery as well as in neurological and spinal surgery. Intraoperative imaging to perform and assure the quality in complex surgeries plays a central role in this. Next to a few highly specialised operating rooms equipped with MRI and CT scans, intraoperative angiography with mobile C-arms is now standard.

Dr Lars Kock, Head of the Department for Vascular and Endovascular Surgery, knows about the potential of hybrid operating rooms, based on the clinical practice at the Albertinen Hospital in Hamburg, Germany. 'The hybrid OR is suited to interventions that require intraoperative imaging, for instance in the form of completion angiography. Another application is interventions where one part is open surgery and the other is a minimally invasive procedure.' With the help of the C-arm, 2-D or 3-D images are generated during surgery that can be merged with preoperative CT scans, thus delivering an accurate presentation of the intervention. This cuts down on nephrotoxic contrast agents and reduces the radiation dose for patients and staff.



From planning to implementation

The planning phase is an important determinant of the success or failure of a hybrid OR. 'To start with it is crucial to decide which specialty is intended to use the hybrid OR. Is it exclusively to be used by cardiologists, or vascular surgeons, or by both disciplines? Both of these specialties have a very diverging requirement profile that needs to be considered during the planning process.'

This decision is a significant factor in choosing an operating table, for instance. 'Cardiologists are used to working with a floating tabletop that is common in angiography suites. A floating operating table is a huge disadvantage when surgeries are performed in a half-sitting position. In this case, a conventional operating table system with a stationary column, where several operating tables can be installed, is a better fit. This increases flexibility,' Kock explains.

Cardiologists and vascular surgeons also have different preferences when it comes to the size of the flat detector system. Cardiologists, whose focus is primarily on the heart, prefer a smaller detector, since it is easier to achieve steeper beam projection angles. Vascular surgeons, who provide endovascular treatment of aortas and peripheral blood vessels, prefer to work with a bigger detector since it allows you to map larger sections of the vascular system.

A hybrid operating room is not equally well suited for all hospitals. The type of intended intervention determines the additional benefit of this technology. In particular, hybrid procedures that combine catheter techniques with an open surgical procedure benefit from this. Everything else is a waste of resources, according to Kock. He adds that open surgery can be just as well performed in a traditional operating theatre.

Layout avoids collisions

Setting up a hybrid operating room is not an easy task. You need to decide whether an existing OR should be newly constructed or remodelled. The availability of adequate space is crucial. 'You should allow for 1000 square feet including a central control and equipment room when planning a hybrid OR so that ultimately 750 square feet are allotted to the actual operating room. It must not be any smaller than this since this only increases the risk of potential collisions.'

Cardiology and vascular medicine particularly require materials such as stents, stent grafts, wires, catheters or balloons that need space. Therefore infrastructure is another factor that needs to be considered when outfitting a hybrid operating room. Short routes make workflow easier. Storage cabinets with glass doors in the hybrid OR provide better orientation.

Workflow optimisation on a broad scale

Even the processes that take place in a hybrid operating room need to be integrated into the planning process from the beginning. That most notably applies to the positioning and arrangement of the individual devices. This is the only way to ensure a smooth workflow. The decision to use a laminar airflow system impacts how the X-ray equipment is being installed, for example. Ceiling mounted equipment frequently obstructs the ventilation system that subsequently is no longer able to work as efficiently as it should; an effect that impacts negatively on infection risk. Kock also suggests 'considering whether a unit with several smaller monitors or a large display is more conducive to an optimal workflow when choosing screens'.



Dr Lars Kock, Albertinen Hospital in Hamburg (Germany) works in a hybrid-OR

Hype or real benefit?

Hybrid operating rooms are frequently downplayed as mere marketing tools for hospitals and clinics. This much is clear: not every facility needs a hybrid operating room, only those that perform complex surgeries. This particularly applies to large heart and vascular centres that regularly perform endovascular interventions for aortic and mitral valves or offer complex endovascular and aortic surgical procedures. At the same time, a reimbursement process also needs to be in place. Ultimately, the acquisition and maintenance of a hybrid operating room are a financial decision since investment costs and maintenance expenses still remain high.

Additionally, other specialties increasingly discover the benefits of hybrid ORs. The required system components for preoperative, intraoperative and postoperative imaging, patient positioning, visualisation and data integration, as well as the adherence to strict hygiene regulations, are already available.

Kock is confident that further improvements will increase the benefits of hybrid operating rooms. 'The existing technology is great and continues to advance. X-ray technology, for instance, continues to improve: the image quality increases while exposure rates decrease. Various manufacturers also provide the relevant software and programmes to combine preoperatively and intraoperatively generated images.'

evolution

colposcopy punch with low profile jaw



Made of 20-37% renewable material, the handle utilises a renewably sourced propanediol (PDO) made from technical starch, the Cervical Rotating Biopsy Punch is also environmentally friendly.

DTR Medical reports that it understands the importance of a cost-effective solution for a high demand clinic such as colposcopy potentially could help save up to £31,500 per annum, 'allowing clinicians to carry out more resourceful procedures'.

Established for over ten years, DTR Medical is a leading supplier of single-use surgical instruments for ENT/max-fax, general surgery, gynaecology, neurosurgical, ophthalmic and orthopaedics. Its collaboration with healthcare professionals and academics at leading hospitals worldwide has enabled the company to develop innovative single-use alternatives to re-usable instruments. The company's new products are on show at Medica 2016. www.dtrmedical.com

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The IVDR will bring about extremely significant changes

IVDs under the microscope

New EU legislation gives manufacturers five years to meet strict standards. That may not be enough time, John Brosky reports



European regulators have turned the world of *in vitro diagnostics* (IVDs) upside down with new legislation that will come into effect at the end of this year.

The stricter rules are especially tougher for advanced molecular diagnostics and lab-on-chip assays used in the clinic to help identify a patient's pathology. But also coming under scrutiny for the first time will be DIY pregnancy kits or at-home nutrigenetic tests that have not been covered by the current regulations.

Outraged by the scandal over breast implants that fraudulently used industrial-grade silicon and with on-going concerns for metal-on-metal hip implants, the European Parliament launched a total overhaul

of the directives for awarding the CE Mark for medical devices and *in vitro diagnostics* (IVDS) devices.

The reform movement in Brussels has resulted in nothing less than an upheaval of the landscape for manufacturers.

For example, all IVDs will need to be recertified, including products already on the market. And where the current EU directives allowed a self-certification of the vast majority of tests, the new IVDR now requires 80 percent of all assays and reagents to undergo a strict level of independent scrutiny that runs up the supply chain to include subcontractors and software associated with the product.

While there is a five-year transi-

tion period provided in the new laws, that may not be enough for many manufacturers, according to Gert Bos, the Executive Director at Qserve Group, a medical device consulting firm based in Amsterdam. He also is the past-President of the European Association of Notified Bodies for Medical Devices.

The notified bodies are the gatekeepers for access to the EU market, independent companies accredited by a Member State to assess whether a product to be placed on the market meets the preordained standards.

'Most manufacturers will have to revisit all technical files and the quality systems for all their devices, they will need to generate additional clinical and performance evidence,' Bos

wrote in a detailed guide entitled, *Dos and Don'ts: How to prepare for and implement the upcoming In Vitro Diagnostic Regulations (IVDR)*.

The white paper was co-authored by Erik Vollebregt, a partner at Axon Lawyers in Amsterdam, an expert on EU regulation and the author of the widely followed blog, *Medical Device Legal*.

With permission of the authors, this article extracts highlights from the white paper.

'The IVDR will bring about extremely significant changes. Most critical is the full revision of the classification system into a rule-based risk classification matrix. In contrast to the current situation, this means the vast majority of products will need to be evaluated by the notified bodies.'

As the result of greater scrutiny since 2013, the number of notified bodies has been dramatically reduced, a critical issue for manufacturers. Bos estimates that, by the end of 2016, there will be from 40 to 45 certified notified bodies remaining from approximately 80 before the 2011 breast implant scandals that provoked the reform movement for EU regulations.

'Manufacturers must be aware that they may need to change a notified body as a result of this development, and act accordingly if their current notified body is not able to support the manufacturer anymore,' he cautions.

In addition, he said that the administrative burden will increase substantially for manufacturers as a result of registration requirements and the implementation of a Unique Device Identification (UDI) system. 'Consequently,' he wrote, 'manufacturers must take a proactive approach to the new regulation, plan and budget for the transition of existing devices in a timely and detailed way, and allocate resources for this



Gert Bos PhD is an influential voice for European regulatory issues. For many years he served as the President of the Notified Body association TEAM- NB, and as Vice Chair of the Medical Notified Body Forum. Until 2016 he was the Head of Regulatory and Clinical Affairs of British Standards Institute for Medtech. Currently he is the Executive Director and Partner at Qserve consultancy.

effort.' IVDR shares many new features with the upcoming EU Medical Devices Regulation (MDR) proposal, such as new supply chain requirements and the implementation of a central database (EUDAMED)

Here are the four major developments specific to the IVDR field highlighted by Bos and Vollebregt.

1. Extension of the concept of *in vitro* diagnostic devices to include tests of 'indirect medical purpose' and 'prediction' to include nutrigenetic tests and lifestyle tests, which are not covered by the current IVD Directive.

2. IVDs will no longer be subject to the list-based system currently in the IVD Directive, but to the risk classes developed by the Global Harmonisation Task Force (GHTF), dividing the landscape of IVDs into risk classes from A (low-risk) to D (high public and high patient risk) with seven classification rules.

With notified bodies having to perform conformity assessment on all but class A devices, the landscape is dramatically changing in terms of files to be reviewed and audits to be performed pre- and post-market.

3. The conformity assessment routes for IVDs are amended to fit the new classification logic. IVDs that do not fit any of the other classification rules fall into class B and have to be certified by a notified body. This is a major change compared to the IVD Directive, which allows such IVDs to be self-certified. As a consequence 80 percent of all IVDs will need to be certified by a notified body under the IVDR, as compared to 20 percent currently under the IVD Directive.

4. Clinical performance studies will be required to support the CE mark under the IVDR. As a consequence IVD manufacturers will need to produce significantly more clinical evidence. The IVDR will contain rules for interventional clinical performance studies and other clinical performance studies that largely overlap with the clinical studies regime in the MDR proposal.

It is crucial for manufacturers of IVDs currently on the market to plan the generation of additional clinical evidence well, and timely assess what clinical evidence will likely be required, how long it will take to generate this and plan ahead for notified body slots for conformity assessment.

In short, the clinical performance evaluation will include not only the classic clinical performance and analytical performance, but also scientific validity. With this change, the first steps towards manufacturers becoming fully responsible for the clinical utility of their devices are initiated.

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The capillary blood collection system not only benefits geriatric patients, or those who need regular blood sampling, but also burns victims and others, including the youngest patients. All need a gentle approach. To that end, Austrian firm Greiner Bio-One has developed and optimised its MiniCollect system.

No more tubes and funnels

The cumbersome process of transferring the drop of blood using capillary tubes or funnels is in the past, thanks

to this system because the blood collection scoop is integrated into the wide tube opening. 'The sample comes into contact with the additive immediately,' the manufacturer reports. 'The caps are completely sealed, meet the highest standards and can easily be sent via pneumatic dispatch or other transport systems without losing any sample material.'

Carrier tubes and combined filling volumes simplify use

'For centrifugation, the MiniCollect tubes can be inserted into a premium carrier tube using a simple rotational movement. When combined, the dimensions correspond to a standard 13 x 75 mm tube format and can easily be placed in a standard rack or standard centrifuge.'

Two easily visible filling marks on the tube provide greater flexibility for use.

The new MiniCollect capillary blood collection system is on show here at Medica. www.gbo.com



The MiniCollect capillary blood collection system

Greiner Bio-one is at Medica Hall 03 / Stand F72

Emergency POCT

Point-of-care testing can play an influential role in reducing overcrowding in hospital emergency departments, Mark Nicholls observes

Emergency medicine consultant Ulf Martin Schilling MD, based in Linköping, Sweden, believes that the strategic use of POCT can improve patient flow through departments and in some cases initially avoid the need for patients to attend.

In a recent symposium Dr Schilling posed the question: 'POCT in the Overcrowded Emergency Department - Can It Make a Difference?' during the AACC (American Association for Clinical Chemistry) conference, held in Denmark this September.

The use of point-of-care tests (POCT) in various patient care settings was examined, with a focus on clinical decision-making and improved patient outcomes.

Speaking to European Hospital after the event, he said that, although emergency departments (ED) with increasing public demand are becoming ever more overcrowded, on the spot tests can be used to help alleviate this.

Improvements in the survival rate of critically ill patients in the ED are directly related to the advancement of early recognition and treatment though frequent episodes of overcrowding.

With prolonged waiting times forcing EDs to operate beyond their capacity and threaten to impact upon patient care, he suggested point of care testing can be brought into play at every stage. 'We have good evidence, for example that, if you empower GPs with POCT analysis, the number of unnecessary referrals can be reduced because GPs can reliably rule out disease and do not need to refer some patients,' he explained. 'And if you use POCT in the ambulance, you can improve the overall process for the patients because you are winning time at the ED.'

Once in the emergency department, POCT can be used at the triage stage to safely identify urgent cases, and save more time as well in the diagnostic and treatment stages. As a result, the process towards one of the main goals of the emergency department will be speeded-up: the decision on whether a patient is admitted, discharged or referred elsewhere.

'At every different step of the

emergency process and on every single patient's process you can be losing time,' Schilling emphasised. 'If this happens for a team caring for 6-8 patients, all the different delays in the patient process will accumulate to a critical level. As a result, your team will not be as effective and you find your department in an overcrowding situation.'

'Overcrowding is not so much about how much space or how many beds you have but mostly about when emergency department staff cannot work efficiently any more in processing patients. But, if you reduce the delays at the front end, you will have faster processes and you gain time on each patient. Even

small earnings in time will give the emergency team the possibility to work efficiently. The key is to have a more efficient process that will reduce the effect of overcrowding and this can be achieved with point of care testing.

'In recent years, particularly during the last decade, POCT has evolved due to new technology, and the range and accuracy of many tests has become better as well as the quality.'

POCT in the ED can include virtually all relevant testing in emergencies, urgent and acute care, he said.

'To be approved by the authorities, POCTs have to follow the same regulations as the core laboratories, which means the major producers must maintain very high standards of quality,' he added.

However, in the use of on the

spot tests in emergency departments there is inconsistency across Europe in the use of such testing in emergency departments, often due to factors such as the remuneration system, a limited analysis of front-end investment towards cost-return in the overall process, and the policy of the local hospital and trust.

To profit from the potential of point of care testing at the pre-hospital, hospital and post-hospital level, he suggests, a knowledge-based change of culture among local staff and management is essential. Training and knowledge about the possibilities – and limitations – of POCT is crucial for efficient implementation of new systems and tests. 'If you can process patients in a much smoother way, it improves flow and reduces the crowding problem.'

'Point of care testing,' he concluded, 'can make a difference in the overcrowded emergency department and can contribute to alleviating the effects of overcrowding.'



Dr Ulf Martin Schilling is head of the clinical education and simulation department Clinicum East Sweden and the unit of testing, innovation and technology assessment. A consultant in emergency medicine and specialist in Internal medicine, he is also a consultant in simulation and implementation at the University hospital of Linköping, Linköping, Sweden. His research interests include patient flow, POCT, the economics of the emergency department, and point-of-care ultrasound.



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The quiet force to optimise existing resources

The value of point-of-care

Some significant changes in the European hospital sector have occurred over the last 20 years. 'The necessity to contain the exploding costs in particular has led to a reduction in the number of hospitals and hospital beds, and staffing levels have also been affected by the many cost cutting measures. This has not been without its consequences, as we now know,' writes **Ludwig F Rutten**.

Whilst objects such as beds, medical devices or other materials may be easy to acquire, lease or hire, the situation is different when it comes to human resources. There is a lack of nurses, doctors, medical engineers and IT specialists, across the entire European employment market. Nothing damages a hospital's reputation more than a rating that states it does not provide adequate patient care. There has been no getting away from it: Long waiting times and deteriorating care caused by a lack of staff on the wards are standard in many hospitals. This is particularly frustrating for all concerned when the respective budget is actually in place but suitable staff cannot be found.

There are obviously various ways to solve these problems. The easiest, but not necessarily most effective solution is to put the blame and responsibility on the 'system' and to wait until the system solves the problem. Actually, this tends to be the most common approach!

A much more successful line is to utilise improve productivity in existing

resources more efficiently. A closer look at workflows repeatedly reveals a multitude of activities that originated in the past, but the necessity of which has never since been questioned.

One of the factors that could lead to a significant improvement in the situation is the handling of laboratory tests beyond the laboratory. A look at the entire process for some essential laboratory tests shows, without a doubt, that some tests could benefit



Equipment advances according to needs. POCTs can increasingly be carried out beyond a centralised service provider, easing pressures on hospital or external laboratories

from substantial improvements if the analysis was carried out on site, i.e. via a point-of-care test (POCT), rather than by a centralised service provider – the laboratory.

Some excellent examples of POCT can be found in the A&E department. Nowadays, to determine a troponin level via a POCT, within 15 minutes, is no longer a problem. However, the majority of A&E departments still send samples to the central laboratory. This results in long waiting times, unnecessary additional work for nurses and doctors and in patients spending far too much time in treatment rooms. What applied in the past is still relevant today: time is money. A solid analysis of the current situation and the willingness of all those involved to

allow changes can lead to considerable increases in efficiency.

Naturally, it would be wrong to say that POC does not exist in European hospitals at all; it is already in practice in many places. The most important examples are blood glucose measuring systems and blood gas analysis. The question is, whether the right systems are being used. Finding systems that actually worsen a situation, instead of improving it, is not uncommon. Systems must fit into the workflow. In other words: When the decision is taken to establish POC, the optimum work process must be defined before the required systems are chosen. Whether or not a POC concept supports workflows in a meaningful way depends to a large part on the performance of the IT systems used. Modern systems specifically developed for POC offer the user many opportunities to make working with the systems as easy and safe as possible. However, for this, an IT system that supports the different opportunities offered by POCT systems is a prerequisite. The latest systems make the use of pen and paper completely redundant. It makes no sense to make laboratory test results available more quickly if old, standard forms are then used to document patients' results, or for the obligatory quality control documentation still required in some countries. A combination of 'modern'



Currently co-owner of POCT medconsult GmbH, in Germany, **Ludwig Rutten** has more than 10 years' experience in marketing Point of Care (POC) products. In a previous role, for example, he initiated several studies and workshops on process optimisation and POC.

with 'stone age' would be counterproductive in this case. What we would like to tell the observant reader with this contribution is that the integration of POC can only be successful if thorough preparation takes place beforehand. The change to POC is more than a discussion as to whether a system is technologically suitable to carry out certain types of analyses or not.

As the resulting profitability of a POC project directly depends on the increase in efficiency expected, all those involved should take enough time for a detailed analysis of the current situation and the results to be expected. If everything has been done properly POC will be the quiet force that helps to utilise the existing resources in the best possible way for a long time to come. ■

German biobank develops standards for European Research Association

Frozen samples are scientists

Our knowledge of causes and mechanisms of current and future diseases is on ice – not the perpetual ice of the polar caps but artificial ice. It is stored in biobanks at -80 to -160 °C. One of Europe's leading biobanks is the Interdisciplinary Bank of Biomaterials and Data Würzburg (ibdw), Germany. Since 2013, biomaterials

collected at Würzburg University Hospital are stored centrally for research purposes in a state-of-the-art facility. Any discipline can make use of the quality-assured bank content. ibdw is one of the first biobanks to implement the concept of 'broad consent' and to almost fully automate its processes. Availability of



With a medical degree from the University of Würzburg, **Professor Roland Jahns** became a CEA Fellow in Sophia Antipolis (France) and DFG Fellow at the Institute of Pharmacology and Toxicology in Würzburg. He specialised in cardiology in 2002 and received the GoBio Award of the German Federal Ministry of Education and Research (BMBF) in 2006. In that year he also became chair of the Working Group at Rudolf Virchow Centre for Experimental Biomedicine. He became a professor in 2008 and, since 2011, has been in charge of implementing the University Hospital Würzburg central biobank, becoming its director in 2013.

biomaterials will allow research on issues and diseases that are not even known today.

Broad consent

Since 2010, the German Federal Ministry of Education and Research (BMBF) has supported the establishment of centralised structures at five selected German locations to systematically collect liquid and solid human biomaterials. The University Hospitals in Aachen, Kiel, Heidelberg, Berlin und Würzburg were the first to

implement centralised biobanks and the umbrella organisation 'German Biobank Nodes', founded in late 2013, will continue to develop the concept.

The purpose of a biobank is storage of patient tissue, blood and DNA samples donated for research. Prior to participating in a study, a patient signs a detailed consent form describing the research and the future use of the donated samples. 'This broad consent is unique,' says Professor R Jahns MD, cardiologist and director of the Interdisciplinary Bank of Biomaterials. 'Drawing on our experience, a working group of the German Ethics Commission drafted a text template for non-specified storage and use of donor material for medical research purposes, since we don't know today what research might be necessary 20 years down the road. The consent survives the death of the donor.'

Ethically and legally this is a balancing act that requires numerous accompanying measures. For example, the donor can withdraw consent at any time, research results must be presented to the donor and the public in a transparent and comprehensible way and, prior to the release of material that is not tied to a specific purpose, an Ethics Committee must approve the research project for which the material was requested.

Automation makes reproducibility

A further unique feature of the Würzburg biobank is the high degree of automation. It facilitates quality assurance and makes processes and results reproducible and comparable across locations. The OECD



standard that defines handling of human biomaterials requires end-to-end documentation of the sample path, from sample taking to storage. 'We document each and every step with a timestamp,' Jahns explains. 'On average we have ten to twelve timestamps per sample – completely automated. We are pioneering this process in Germany.'

The lack of reproducibility of research results prompted the Federal Ministry to intensify funding of centralised biobanks. Healthcare facilities have long been collecting blood and tissue samples in refrigerators. Any graduate student can take a frozen sample, thaw it, remove whatever he or she needs and refreeze it. In a modern biobank, a blood sample is separated into smaller 300 ml units prior to storage. These subsamples

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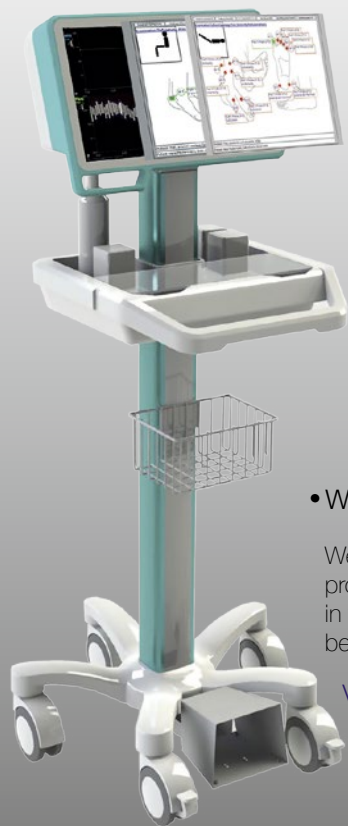
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Interdisciplinary Bank's of Biomaterials and Data Würzburg (ibdw) Bio II Lab for automated processing of liquid biosamples

are usually sufficient to perform a triple assay that conforms to academic standards.

'Such a smaller sample will usually allow serial triplets. Thus one blood sample will generate 10 subsamples. When a researcher requests a sample, only one sub-sample will be removed, the others remain at -80°C. It is a basic principle of a biobank to turn one large sample into several smaller ones.'

Keen protection

Currently, close to 200,000 liquid samples and 3,500 tissue samples are stored in Würzburg, allowing



1.2 million aliquots and 16,000 tissue sub-samples. Each sample tube is identified by an engraved unique barcode. 96 tubes fit on a rack, which is scanned prior to storage. The data are transmitted to the lab information system, which records the location of each tube.

Every piece of information is double-coded which means only the system itself knows where a certain sample is. 'We can request a sample by entering a code. A virtual server and a double firewall make unauthorised access from outside pretty much impossible. The biobank is close to 100 percent safe.'

Biomarkers and molecular signature

The Würzburg biobank aims to support the research projects of the university's medical school. Therefore, it collects a broad range of samples for oncology, cardio-vascular diseases and endocrinology.

Samples from cancer patients usually encompass tumour core tissue, tumour margin tissue and non-tumour tissue. These samples are the basis for personalised therapies, since they allow examination of different tumour-specific molecular changes on the genetic level and molecular

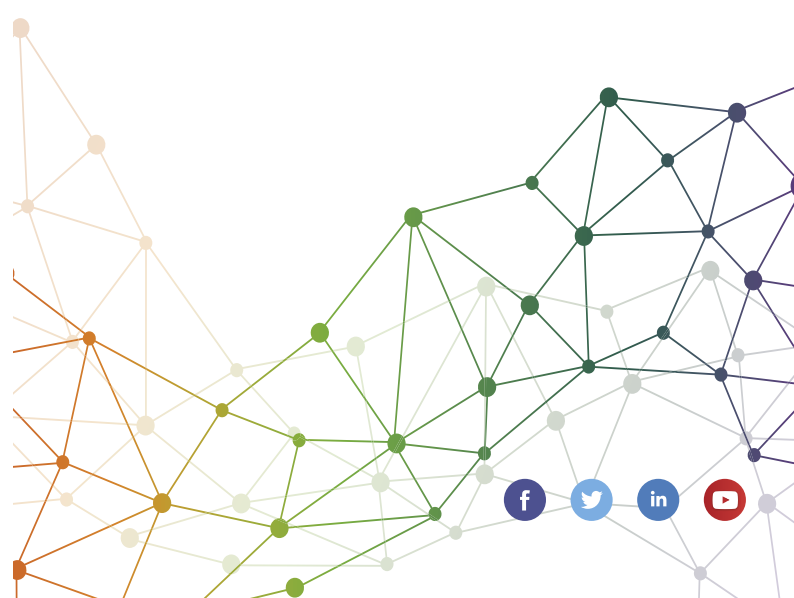
tumour signatures may be decoded.

Today, different mutations can be treated in a highly specific manner. Certain tumour DNA can be detected very early in blood - via a liquid biopsy - which can act as biomarker. 'Biomarkers are also interesting for cardiologists. We take different samples over time from a patient with poor cardiac pump function and compare them looking for biomarkers that tell us how the heart will recover after a myocardial infarction.

'The interesting point is that we collect prospectively but do the research retrospectively and still obtain valid results. Thus the samples are the scientists' gold,' Jahns explains.

Going forward, the number of biobanks to be funded in the context of the German Biobank Alliance will be doubled.

The aim is for Germany to improve integration on the European level in the Biobanking and BioMolecular Resources Research Infrastructure (BBMRI) to be able to contribute significantly to research on rare and widespread diseases such as diabetes, hypertension or cancer.



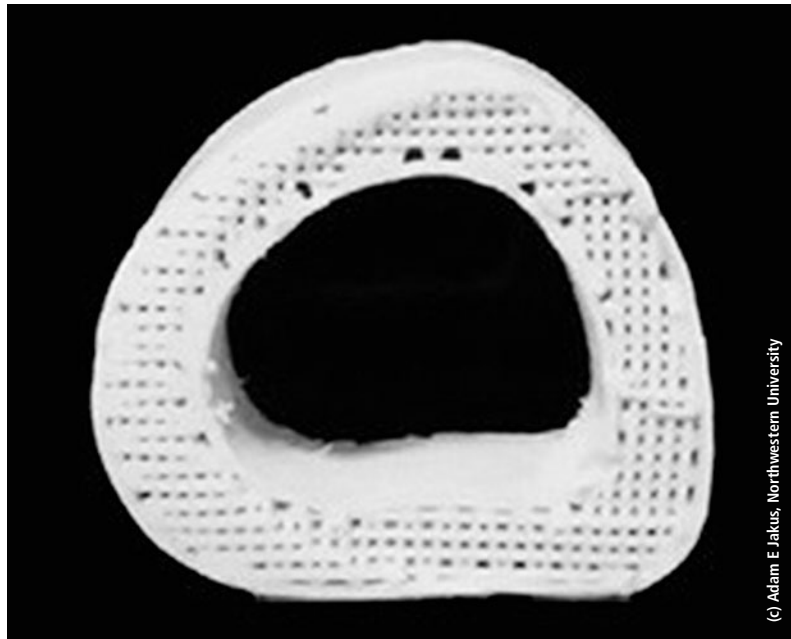
Implants printed while you wait

A promising biomaterial to build better bones

A Northwestern University research team has developed 3-D printable ink that produces a synthetic bone implant that rapidly induces bone regeneration and growth. This hyper-elastic 'bone' material, whose shape can be easily customised, one day could be especially useful to treat bone defects in children.

Bone implantation surgery is never an easy process, but is particularly painful and complicated for children. With both adults and children, often times bone is harvested from elsewhere in the body to replace the missing bone, which can lead to other complications and pain. Metallic implants are sometimes used, but this is not a permanent fix for growing children. 'Adults have more options when it comes to implants,' said Ramille N Shah, an assistant professor of materials science and engineering in Northwestern's McCormick School of Engineering and of surgery in the Northwestern University Feinberg School of Medicine, who led the research. 'Paediatric patients do not. If you give them a permanent implant, you have to do more surgeries in the future as they grow. They might face years of difficulty.'

Shah and her team aim to change the nature of bone implants, and they particularly want to help paediatric patients. Their 3-D printed biomaterial is a mix of hydroxyapatite (a calcium mineral found naturally in human bone) and a biocompatible, biodegradable polymer used in many medical applications, including sutures. Shah's hyper-elastic 'bone' material shows great promise in in vivo animal models; this success lies in the printed structure's unique



Cross-section of an adult human femur, 3-D printed using ink developed at Northwestern University

properties. The material is majority hydroxyapatite, yet it is hyper-elastic, robust and porous at the nano, micro and macro levels.

'Porosity is huge when it comes to tissue regeneration, because you want cells and blood vessels to infiltrate the scaffold,' Shah pointed out. 'Our 3-D structure has different levels of porosity that is advantageous for its physical and biological properties.'

While hydroxyapatite has been proven to induce bone regeneration, working with it is also notoriously tricky. Clinical products that use hydroxyapatite, or other calcium phosphate ceramics, are hard and brittle. To compensate for that, previous researchers created structures composed mostly of polymers, but

this shields the activity of the bio ceramic. Shah's bone biomaterial, however, is 90 percent by weight hydroxyapatite and just 10 percent by weight polymer, and it still maintains elasticity because of the way its structure is designed and printed. The high concentration of hydroxyapatite creates an environment that induces rapid bone regeneration.

'Cells can sense the hydroxyapatite and respond to its bioactivity,' Shah said. 'When you put stem cells on our scaffolds, they turn into bone cells and start to up-regulate their expression of bone-specific genes. This is in the absence of any other osteo-inducing substances. It's just the interaction between the cells and the material itself.'

This is not to say that other substances couldn't be combined into the ink. Because the 3-D printing process is performed at room temperature, Shah's team could incorporate other elements, such as antibiotics, into the ink. 'We can incorporate antibiotics to reduce the possibility of infection after surgery,' Shah explained. 'We also can combine the ink with different types of growth factors, if needed, to further enhance regeneration. It's really a multi-functional material.'

One of the biggest advantages, however, is that the end product can be customised to the patient. In traditional bone transplant surgeries, the bone -- after it is taken from another part of the body -- has to be shaped and molded to exactly fit the area where it is needed. Using Shah's synthetic material, physicians would be able to scan the patient's body and 3-D print a personalised product.

Alternatively, due to its mechanical properties, the biomaterial also can be easily trimmed and cut to size and shape during a procedure. Not only is this faster, but also less painful compared to using autograft material.

Shah imagines that hospitals may one day have 3-D printers, where customised implants can be printed while the patient waits. 'The turn-around time for an implant that's specialised for a customer could be within 24 hours,' Shah pointed out. 'That could change the world of craniofacial and orthopaedic surgery, and, I hope, will improve patient outcomes.'

Source: Northwestern University

Malta takes a closer look at 3-D printing

A radical

21st century technology has outpaced our expectations. One such example is the invention of advanced digital manufacturing techniques, better known as 3-D printing. Patients and the medical community are yet to see the full implementation of this technology within healthcare, Moira Mizzi reports

One of the biggest challenges of our existence is the possibility of our technological dreams actually becoming a reality. For surgeons, one such dilemma is the introduction of 3-D printing.

The possibility of manufacturing tissues and organs is especially exciting due to the lack of transplant organs



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Change for surgeons

The 3-D printing concept arrived more than 30 years ago when Chuck Hull filed his patent, 3-D printing – the mechanical process in which solid objects are created by ‘printing’ layers of material to replicate a shape that was modelled by a computer programme. However, despite undying enthusiasm and rigorous research, its use in surgery has been very limited – partly due to cost, lack of expertise and the paucity of suitable materials for manufacture.

Actively seeking experience in this novel skill

Despite its minuscule size and limited resources, Malta is still attempting to explore uses for this technology in surgery. Jeffrey Dalli, Higher Specialist Trainee in General Surgery, attends conferences and collaborates in a number of research projects



Jeffrey Dalli is a senior surgical trainee at the Mater Dei Hospital in Malta. He has a research interest in 3-D printing and fat grafting.

that include 3-D printing techniques. ‘At the moment I’m mostly attending conferences to expose myself to training simulation, both for regular and complex surgery, and to get the latest information on current uses such as stencils and prosthesis,’ he explains.

One of the most ambitious goals of 3-D printing is that of manufacturing tissues and organs, better known as bio-printing. ‘This is a truly exciting prospect for surgeons, especially for the Maltese surgical community, which has to deal with limited organ donors for transplantation,’ he points out, ‘as great as this may sound, we still have the technical challenge of manipulating the cells to survive and thrive within a given engineered environment. It’s here that we have met a stumbling block for the time

being. At this stage, what I predict is the possibility of the use of bio-printing in the manufacture of tissue grafts such as skin, liver or veins, for example the liver tissue produced by the American company Organovo, for drug testing.’

Other less futuristic uses of 3-D printing include the printing of prosthesis and stencils. In orthopaedic surgery, 3-D printed hip and knee replacements are already a reality, for example those manufactured by DiSanto Technologies. Other firms are manufacturing computer-generated stencils from radiological images. These offer ‘join the dots’ operations, diminishing the need for surgeons to manually manipulate the fractures. Such devices require less operative skills than conventional methods, thus increasing the chance of roboticisation and in turn possible ‘de-professionalisation’ of surgical specialties.

Other less futuristic uses of 3-D printing include producing prosthesis and stencils. Orthopaedic surgery, especially where complex fractures are concerned, has gained greatly from this new technology. Presently, custom-made joint and hip replacements are on the market and licensed in Europe, the USA and China, and has been replaced by computer-generated stencils. Such fractures require much less skill to fix, thus increasing the risk of de-professionalisation or roboticisation of the surgical specialties in the near future.

We need a new class of surgeon

Dalli, however, predicts a difficult path to full implementation of these new technologies because surgeons are not currently trained to bridge the gap between 3-D images and surgical procedures. On the other hand, he foresees a greater role for computer systems in the planning stage



There’s a stumbling block in the technical challenge of manipulating the cells to survive and thrive within a given engineered environment

and a diminishing role for surgeons as decision makers. In fact, surgical planning may take place remotely, by technicians, or even automatically on the cloud. ‘This means we need a change in medical curricula, more specifically, the creation of a new class of surgeons,’ he muses. ‘As surgeons, we’re still dependent on other professions, such as engineering, to bridge the gap between the technological and clinical aspects. My generation of specialists are still not ready to fully capitalise from 3-D printing technologies.’

Regulatory issues will take time to resolve

From a medical perspective, those patients who stand to gain most from this technology are those who suffer from rare and complex surgical pathologies. 3-D printing is currently adapted for tailor-made procedures, as mass production manufacturing techniques provide better economies of scale. This brings about a socio-economic problem for state funded healthcare systems, where single complex cases will consume larger portions of the healthcare budget. On the other hand, this poses less of an issue in countries where individuals self-fund their care.

From a local perspective, the medical community is eagerly watching this technology, anticipating more involvement as it becomes more available. However, it may take some time before the regulatory problems are ironed-out and may take even longer for local surgeons to assimilate this new identity as advanced manufacturing techniques empower them to operate on more complex cases with the possible trade-off of having a smaller say in the planning and decision making.

There are a multitude of challenges ahead even before this revolutionary technique has seen the light of day. The training of medical personnel in this scenario goes beyond the learning of new techniques, it involves a complete change of perception and identity of what a medical professional is, resulting in uncertainty and fear.

Regulations and ethical issues will also need to be reassessed. Last but not least the patient, who ultimately is the key stakeholder in this endeavour, needs to be adequately educated and prepared, keeping in mind that ultimately no scientific discovery no matter how exciting can ever surpass the dignity and integrity of human life.



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Seeking the gateway towards deeper computer intelligence

Cognition-guided surgery

Surgery will change – with all the challenges that developments such as Big Data create there are no two ways about it. However, how deep those changes run remains to be seen. In a rather young field of research, scientists look at the ways all components used during surgery can be interlinked. Professor Beat Müller, co-initiator of the project ‘Cognition-Guided Surgery’, explains results achieved so far and coming challenges

Report: Marcel Rasch

Cognition-guided surgery aims to enable surgeons to make knowledge-based computer-aided decisions during surgery – with the help of computers. This requires the creation of a database that is filled with factual and practical knowledge that a machine can process and use.

The underlying idea is for a surgeon to be able to call up suitable actions when planning or performing an intervention. ‘You can compare it to a cognitive vehicle. While we are in the car driving along the road we often don’t notice that there are technologies in the background that control traction or chassis or whatever.

‘When problems occur, a warning is displayed. As an advanced development, the cognitive car is autonomous, entirely disconnected from the human driver,’ MIS and bariatric surgery expert Professor Beat Müller explains.

The human brain can process or access a maximum of about seven pieces of information at a time. However, large amounts of data are not a problem for a computer. The challenge for the machine is not data volume but data interpretation. ‘In surgery we are dealing with massive data volumes. Every day, new knowledge is published in thousands of books and articles, new insights are culled from diagnostics, which is an increasingly complex discipline. A few decades ago X-ray images were all we had; today we are looking at CT and endoscopy images, at lab and histology parameters previously unknown.

‘To collect these data and channel them into a sound decision – that’s the complex art of medicine. Unfortunately humans do make poor decisions every once in a while. Thus cognition-guided surgery wants to create a system that helps to make good decisions.’

Initial results

That’s a long way to go. It won’t suffice for scientists to access Big Data and to design analytical tools; they must consider a very special factor, as Müller points out: ‘The ability to learn is a crucial feature of the machine. The computer must be able

to process not only factual knowledge, or book knowledge, but also practical knowledge gathered over time in the course of our everyday work. All these types of knowledge are input for the knowledge base. What we are aiming at is a system that does not suggest certain procedures anymore, because of the negative outcomes this procedure yielded in the past. Instead the system suggests only procedures with a higher probability of success.’

Such a system might indeed work, as was demonstrated by an initiative funded by the German Research Fund (DFG) between 2012 and 2016. ‘In the special research area Cognition-Guided Surgery, teams from a consortium of researchers, including the German Cancer Research Centre and the Karlsruhe Institute of Technology, looked at several key aspects of this idea,’ Müller reports. In the course of the project an adaptive autonomous

camera-guidance robot was developed. ‘When the computer correctly guided the camera during an intervention, this experience was stored as “positive”.

‘But when the camera-guidance robot was corrected, it stored the correction,’ he explains. Thus the system learns the correct camera positions step by step.

The road ahead

However, many challenges lie ahead. ‘Don’t forget – we are at the very beginning of our research,’ says Müller, dampening unrealistic expectations. ‘On the one hand we have to make the required data available in a machine-compatible way. When, as trained physicians, we look at an X-ray image and can read it – we understand what we are seeing. The more X-ray images we read, the more we learn.

‘The computer must also go through this phase of gathering experience and knowledge.’ On the other hand, Müller explains, ‘a computer can easily do statistical analyses, but semantic assessments are a major obstacle. We are talking about model-based or pattern-based action. It’s not only about gathering data but about the way these data are perceived and evaluated.’

A third difficulty is system validation. ‘The computer has to show that its suggestions, which are based on the learning process, are indeed better. Human beings learn from success and failure.

‘Machine learning happens in smaller increments. If an error made by the system is not corrected, the system will store it as “positive”, no matter whether there might have been specific reasons for not correcting the error in this particular case. In short: We must ensure the system not only gathers knowledge but that it indeed improves.

‘Poor approaches to learning might very well lead to poor therapy

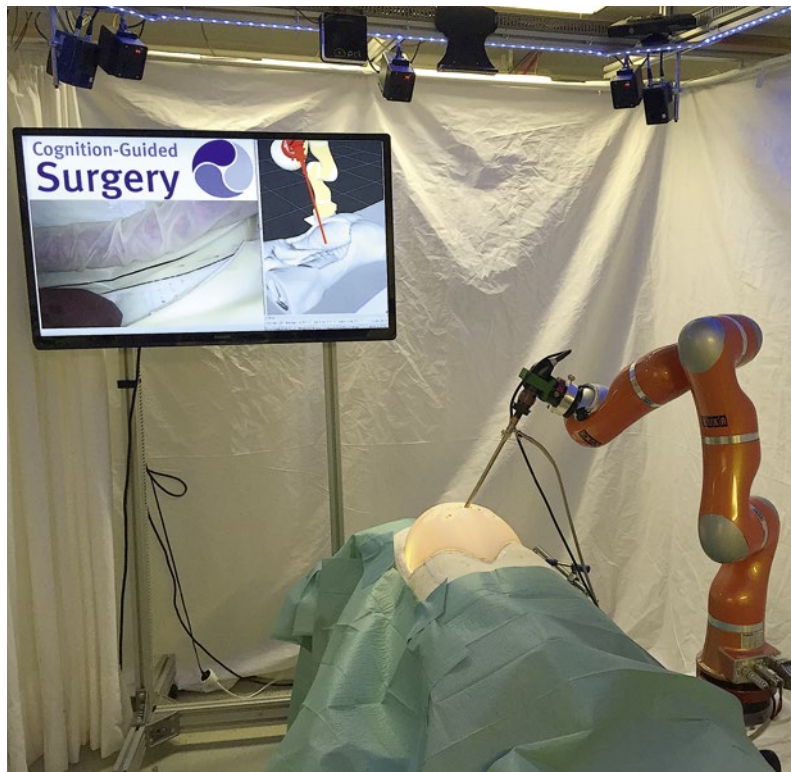


Leading senior physician **Professor Beat Müller MD**, Head of Section for Minimally Invasive and Bariatric Surgery at the Department for General, Visceral and Transplantation Surgery at Heidelberg University Hospital, also researches computer-based surgery. He has been lead investigator in several interdisciplinary and multi-partner research projects such as ‘Intelligent Surgery’ and ‘Cognition-Guided Surgery’ (both underpinned by the German Research Fund (DFG) until 2014 and 2016 respectively. Beat Müller is also a key participant in InnOPlan (Innovative, Data-driven Efficiency of Surgery-related Process Landscapes), a project funded in the framework of the technology programme ‘Smart Data – Innovations from data’ by the German Federal Ministry for Economic Affairs and Energy, and the EU-funded project COMBIOSCOPY (Computational biophotonics in endoscopic cancer diagnosis and therapy).

suggestions. And the worst-case scenario is that we don’t even realise that the surgeon performs worse with computer aid than without it,’ Müller warns.

Despite these caveats, the vision is alive. ‘There is enormous potential to make surgery safer and more efficient,’ Müller believes. However, today there are only a few isolated solutions and there are not enough research partners for large interdisciplinary research projects. ‘However, if we look at cognitive vehicles again, there are market-ready solutions claimed to be safer than human drivers. This is what I’d like to achieve for surgery.’

Details: www.cognitionguidedurgery.de
http://rob.ipr.kit.edu/837_1586.php



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Medical technology: a k in transition

Examining the business performance of the medical technology sector, consultancy firm Ernst & Young forecasts changes in this industry, as reported by Medizintechnologie.de, the national information platform for medical technology.

Last year, the global turnover in medical technology sales shrank for the first time, although the market value increased. Digitisation, cost pressures and increasing demand for patient oriented, complete solutions led to drastic changes, a transformation highlighted by Ernst & Young in ‘Pulse of the industry’, the firm’s current global medical technology report. After years of low growth, the medical technology turnover in 12 months from June 2015 shrank by 1.2% to US\$ 337 billion. Whilst the turnover in the USA decreased by 11%, sales in the European medical technology sector increased by 21% and, despite worldwide revenue losses, the market value of the industry increased by 13%.

The current key performance indicators paint a mixed picture of the med-tech performance and show

that the sector is in a transitional phase to a previously unseen extent. ‘The tradition of step-by-step innovations is no longer effective today,’ says Dr Siegfried Bialojan, head of Life Sciences at Ernst & Young (EY). ‘Big Data, enlightened patients and cost pressures call for fast, real innovations which offer breakthroughs and convince customers of the added value of development. Therefore, the industry is undergoing a transformation: whilst some companies’ strategy in this competitive sector is to focus on the size and depth of their portfolio, others try to meet customers and their requirements in a more wide-ranging manner.’

Springboard type innovations are urgently needed to make the medical technology sector grow again, the consultancy suggests. New business models are also required for

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the transformation to ‘Medicine 4.0’. Digitisation has created a need for additional services going ‘beyond the product’ and for patient orientated, complete solutions that link various competencies. ‘Cross-sectional cooperation could be a drive for innovation,’ says Bialojan.

An example of this is the joint venture between Johnson & Johnson and the Google parent company Alphabet Inc, which aims to try to revolutionise surgery with Big Data and intelligent robots. A partnership between Boehringer Ingelheim and Qualcomm aims to develop an

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Extending intra-operative radiotherapy to breast treatments

Dutch centre of excellence adopts dedicated device



Surgeon **Dr Yvonne van Riet** has worked at the Catharina Hospital since 2002. Following training as a general surgeon she specialized in cancer surgery, on a broad level. From 2005, she has focused on breast cancer. Along with colleagues she established the use of a small radioactive rod (125-iodine seed) on breast abnormalities so that, in just one procedure, a breast tumour can be removed. The technique is now used in the Netherlands. Van Riet also chairs the Mamma Centre at Catharina Hospital and is President of the hospital's Quality Commission for Oncology



After gaining a BSc in Medicine (Groningen Univ.) **Dr Jeltsje Cnossen**, trained as a radiation oncologist at the University Medical Centre Utrecht and gained a PhD at the University of Amsterdam, and MSc in Epidemiology at the EMGO Institute. Today, she is a radiotherapist at the Catharina Hospital in Eindhoven, focusing on gynaecological, oesophageal and colon tumours, intraoperative radiotherapy (IORT), brachytherapy and palliation.

the underlying ribs, lungs, and also the left side of the heart from the applied radiation. Then the mammary gland tissue to be irradiated is stuck together; the irradiation tube is positioned and coupled with the irradiation unit. In this way you can determine very precisely where you need to irradiate without affecting the surrounding tissue.'

New device choice

The old linear accelerator used for IORT needed replacement. 'The Mobetron meets all our requirements. It is user-friendly and safer because there is less radiation leakage into the environment. It's not only an investment in equipment, but also in the possibility to continue the treatment and help even more women,' said radiation oncologist Jeltsje Cnossen, explaining the institute's choice.

'For IORT you need specially equipped operating rooms with extra thick walls,' van Riet added. 'And, very important: you need a team of experienced specialists, surgeons and radiation oncologists who seamlessly respond to each other.'

Therefore intra-operative radiotherapy cannot be applied in every hospital. Currently, in the Netherlands, it is provided only in the Catharina Cancer Institute and Medical Centre Haaglanden, in The Hague.

Less harmful than regular radiation

IORT is meant for women of 60 years and older with diagnosed breast cancer and a tumour no more than 2 centimetres in size. In addition, it should be sensitive to female hormones and there should be no malignant cells detected in the sentinel lymph node.

'The treatment lasts one and a half hours,' van Riet said. 'After the tumour removal by surgeons the area is treated only once with a higher dose of radiation than in external radiation. The patient is discharged from hospital the same day and doesn't have to return for radiotherapy for three weeks, five days a week. This means less stress for the woman concerned.'

Effective

Figures from both hospitals show

of about 250 to 300 patients and review the longer-term results.'

'The general trend is that treatments for cancer are becoming more individual,' Cnossen pointed out. 'Meaning not to treat all patients with the same brush, but to look at what is possibly most effective and the least burdensome. The Mobetron will certainly contribute to that goal.'

Known for cancer and cardiovascular disease treatments, the Catherine Cancer Institute acts as a Centre of Excellence and last resort in terms of, inter alia, rectal cancer, breast cancer, peritoneal metastases of colorectal cancer, cardiac arrhythmias, valvular interventions and oesophageal disorders.



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internet-capable inhaler to improve the care of lung disease patients, and the cooperation between Medtronic and IBM's Watson aims to optimise diabetes care. 'The sector has always worked with "go-to-strategies", but now the network of alliances comes from different industry sectors, as

big data and digital or mobile technologies also open up new chances of growth for medical technology businesses,' Bialojan explains, adding: 'Companies that are not heading in the direction of Medicine 4.0 are in danger of being forced out of the market.'

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