VOL 26 ISSUE 3/16 • JULY/AUGUST 2016

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Britain and Brexit

A largely stunned nation now asks what will happen to its beloved NHS and the EU medical professionals who are here to support it

Report: Brenda Marsh

No doubt about it, Brexit – the majority vote cast by just over 52% of citizens for Britain to leave the European Union – has thrown the nation into political and emotional turmoil and, yes, ordinary people are at last asking more questions than many among them did prior to pencilling in their X to march their country down the separatist lane.

Many of those people simplistically believed what the Vote to Leave campaigners erroneously claimed to be £350 million per week, contributed by Britain to the EU coffers, could be brought home to fund the financially stressed National Health Service (NHS) – the nation's 'love child', of which most are proud and determined to protect.

Phew! Now the realisation is sinking in regarding many facets of the country's extraordinary public organisation the NHS, Europe's largest employer, and fifth biggest employer in the world – 1.7 million people – are NHS workers (ironically, in terms of health, McDonald's employs .2 million above this and Walmart employs .4 above this!)

Inevitably, Britain's NHS not only employs nationals but internationals, as needs must. Now the focus begins to sharpen – even though each of our four countries, England, Scotland, Wales and Northern Ireland, runs it own NHS – as a whole we directly employ over 640,000 professionally qualified clinical workers, including 110,000 doctors and over 315,000 nurses.

So, the big question arises: when all the aspects and chaos created by Brexit are addressed and hopefully sorted out, what will happen to our existing EU employees and future migrant employees? Some very confident people proclaim there will be no problem for existing employees. Others, sensibly to my mind, say 'We don't know, yet.'

Employing foreign nationals is fraught with uncertainties anyway. There's the burning question of training and language competency, for which would-be migrant doctors are tested. However, the case of the EU doctor, employed at huge cost for weekend work, to lower waiting lists (flying in from Europe on a Friday night, operating for two days, and taking home £-thousands) ended, in his case, with prosecution for incorrectly reading and administering the wrong dosage and killing a patient – claimed to be caused by a language glitch. Hmm.

Surmounting that case, 11% of all staff estimated to work for the NHS and in community health services are not British – they are foreign nationals from more than 200 countries.

Among them we are also blessed with the presence of 3.6% clinically qualified EU doctors, nurses and therapists, among others (but a percentage that excludes general practitioners and those working in administration on the NHS staff list). Just topping this percentage is the 4% of NHS medical people who come from Commonwealth countries.

The percentage, within the English NHS alone, represents 55,000 EU nationals out of its 1.2 million healthcare employees (Source: the English Health Service's Electronic Staff Record). That number includes doctors, nurses, other professionals e.g. paramedics and pharmacists, support carers, and administrative staff.

In terms of the highest numbers of people from specific EU countries who work for NHS England alone, here are a few figures:

7,170 Poland
4,517 Portugal
4,174 Spain
3,278 Germany
2,929 Italy
3,076 Greece

The move to cut migration

Britain's present need of migrant workers for the NHS can only increase. A member of the Institute for Public Policy Research think-tank, Tim Finch, pointed out that statistics held lessons for immigration policy. 'If the single thread of immigration policy is just to get the overall figure down, by any means, you've got to look at the consequences of that on the NHS.'

Speaking at the International Festival of Public Health held in Manchester, the Medical Director of NHS England, Sir Bruce Keogh, also predicted that the already stretched NHS will face very tough times in the coming year due to the uncertainties caused by Brexit on top of its financial settlement. Brexit, he warned, could lead to lower-quality services, longer waiting lists and the need for 'unsavory questions about which services we can afford and which services we cannot'. (Ah! Little imagination is needed to forecast the outcry from certain members of the British public – particularly those who believed healthcare could improve through leaving the EU community.)

Sadly, some of our much-valued EU medical care contributors have also been unnerved by reports of the extraordinary xenophobia that raised its ugly head during and after referendum voting – even resulting in the murder of a 42-year-old woman MP. Such incidents also distressed most of the rest of our countrymen – including a surprising number of those who voted for Brexit.

Referendum result is not binding

Fortunately, it appears we have time to pull ourselves together and at some distant stage sort out whether we are in or out of the EU – because, legally, the referendum result is not binding.

As most of us have now learned, the only way to even begin Britain's exit is to trigger Article 50 (1) of the Treaty on the European Union for withdrawal from the EU, but only then 'in accordance with its own constitutional requirements'. In the UK, those requirements include parliamentary approval – but, the

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Needed: an umbrella organisatio

Robots will never replace

As the number of patients and people requiring care increases, exacerbating the shortage of care staff for in- and out-patients, care robots might solve the problem. For menial tasks, many devices can contribute well; however, at the complex interactive human level of care, the idea that advancing technologies could replace human caregivers to alleviate staff shortages is clearly simplistic. Overview: Melanie Günther

Robots that perform cleaning or transport tasks, or distribute medication or meals, are now often indispensable in hospitals and clinics, contributing significantly to smooth operations behind the scenes. A robot offered by medical technology provider Xenex, for example, disinfects the environment with UV rays. According to the manufacturer the device can handle 64 rooms a day, calculating its route carefully so as to cover every nook and cranny. The robot is an important aid in the on-going battle against hospital-acquired infections (HAIs) by helping to contain infections caused by pathogens such as Clostridium difficile or MRSA.

Japan's technology research

For the past few years Japanese companies, such as Panasonic and Toyota, and many research institutes have driven the development of care robots, due to the rise in the country's aged population and the shortage of care staff, which is even more pronounced than in Germany, for example.

Panasonic developed the RoboticBed, which not only lifts a patient but can also transform into a wheelchair. From the same firm comes the Hospi-Rimo, a tele-presence robot enabling communication between patient and physician. In hospital trials 'Hospi' also distributed medication.

Toyota Motor launched the Care Assist Robot, which lifts hospital and care home patients from the bed or takes them to the toilet.

Riken, another Japan-based company, follows a similar approach with Robear.

Drawback: Currently, none of these technologies is marketable because the development and acquisition costs are prohibitive.

Care-O-bot shows how to handle the haemodynamometer

Robots – a very distant switch from human caregivers

There is no mass market yet for electronic patient care and the use of robots in clinical routine is still pie in the sky, since none of the high-tech devices recognises emotions or responds to them.

While humanoid robots can indeed simulate emotions, they lack the 'social skills' to interact with patients. This is a major issue, as Professor Birgit Wilkes, Head of the Institute of Facility Telematics at the Technical University Wildau, Germany, points out: 'In my opinion, the use of care robots can contribute greatly to facilitate lifting actions. However, it is incredibly difficult to programme sensitivity into robots so they don't hurt patients. They simply lack empathy and this is where today's robots clearly hit the wall.'

Technical assist systems support care staff

Technical assist systems are quite a different story: they can improve difficult working conditions in in-patient care, be it in hospital or geri-

Britain and Brexit

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argument goes, withholding that would end our precious respect for democracy!

Some diehards among the 'remainers' also speak of a renegotiation of Britain's EU membership terms (despite what other EU countries might petulantly think); others are simply stiffening upper lips and proclaiming 'We've done it; now we must just get on with it'

What those in British healthcare are focused on is further renegotiation to ensure the free movement of qualified EU medical workers to take up British NHS employment. It has been said that this could prove difficult in the future – but not for some time.

Much is already afoot: The present chief executive of the General Medical Council, Niall Dickson, commented: 'Withdrawing from Europe will have implications for the way we regulate doctors but we understand that the vote to leave the EU will have no impact on the registration status of any doctor already on the register.

'We will now explore how doctors from the EU will be granted access to the UK medical register and how any concerns about those doctors will be shared between us and other countries.

'We will also seek to understand the implications for UK doctors wishing to work in the EU once the UK is no longer a member state.'

How to achieve 'leave'

The process of a EU exit runs in several stages. First, the European Council - without the UK - must agree guidelines for negotiations and then the European Commission is to negotiate an agreement on behalf of the EU. The agreement would need to be approved by Britain as well as 20 of the 27 remaining member states, representing 65% of those states' population. (Why did we not adopt that before the referendum?!)

The European Parliament (EP) then would need to approve the agreement with a simple majority. British Members of the EP could vote.

Not surprisingly, the process needs two years to complete – after Article 50 is initiated, unless surprisingly Britain repeals the European Communities Act of 1972, but that would breach treaty obligations under international law.

Leaving could, according to the UK government, take 'up to a decade or more' just to negotiate exit from the EU, the trade deals, and more.

Even then a state that has left the EU could request re-joining.

In a nutshell, for now Britain has its EU healthcare staff, and we need to do all we can to show our gratitude and to retain them – as well as, in the interim period before an actual Brexit, to encourage others to work alongside us. We also need to influence whatever future government and medical institution leaders we have, to exercise their greatest efforts to ensure freedom of movement of qualified medical professional EU and other healthcare migrants.

So far, a laudable number of parliamentarians are calling for guarantees to cover EU nationals' employment in British healthcare.

An independent and transparent event

The first Spanish oncology forum

When two Spanish oncologists launched the first independent Spanish oncology forum this May in Madrid, European Hospital's correspondent spoke with Dr Javier Cortés, co-organiser of the event, to find out more about its expected impact in their field

Report: Mélisande Rouger

There are many oncology meetings in Spain, including the annual meeting of the Spanish Society of Oncology Medicine. What's different about your event?

'All these meetings are financed by the pharmaceutical industry. The forum is not; it is a completely independent and transparent event, organised by and for oncologists.

'We wanted to offer frankly objective information on the most frequent tumours without being conditioned by industry-related aspects. Our speakers are free to present what they think are the most appropriate aspects of cancer therapy.

'There is neither industry symposium nor technical exhibits at the conference, but the industry is more than welcome to participate and attend sessions.

'We had around 350 registrations, mainly oncology physicians but also nurses, pharmacists and people from the oncology industry. The forum is open to anyone interested in oncology. We'll try to make it an annual event.'

Did the programme tackle every aspect of oncology?

'Yes. We aimed to review cancer management over three days, by presenting the latest advances in diagnosis and treatment of all kinds of tumours. With Dr Enrique Grande, who co-organised the event, we invited over 60 oncologists as speakers and moderators to ensure we covered every aspect of tumour management.

What about the two slots dedicated to lung cancer?

'Lung cancer, one of the most common cancers, is the leading cause of cancer death in Spain and incidence is rising. 26,715 people were diagnosed with the disease in 2012 and experts predict it will affect over 40,000 individuals by 2035 in our country, according to the Spanish Association Against Cancer.

'We presented all the newest developments – in personalised medicine, knowledge of mutations in risk factors, molecular biology and immunotherapy – in both localised and advanced lung cancer.'

Is oncology care good in Spain, particularly regarding personalised medicine?

'The field is doing very well here. The national level is very high, also in personalised medicine.

'Cutting-edge centres include Vall d'Hebron Hospital in Barcelona, Clínico Hospital in Valencia and Ramon y Cajal Hospital in Madrid, among others. They all need more resources to continue to do things properly.

'Spanish oncologists are involved in numerous international studies; for instance at Ramon y Cajal Hospital we participate in various studies on immunotherapy drugs and targeted therapy.'

Precision medicine is another important trend. Is this the case in Spain?

'We've been talking about precision medicine for many years because we've been trying to treat patients more precisely, according to the nature of their disease, to improve both diagnosis and treatment.

'However, to do so, we need more and better-designed clinical studies. These must be carried out everywhere, because cancer is a worldwide disease, but especially in centres of excellence, which have all the latest available therapies.

n to link path, lab and IT experts

human beings

atric care, by supporting staff and relieving strain on the caregivers. In 2015, Germany's Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) developed a prototype of an intelligent care trolley. This can be summoned, contain care material and documents material use, and thus supports care staff on a physical and information level.

Such a system, Professor Wilkes concedes, is indeed promising: 'I don't see robots alleviating the care staff shortage. What we do need, though, is the same amount of care staff, but being supported by technical assist systems – this would give staff more time for patients; but robots will never be able to replace human beings.'

Rehab and pre-care assist systems: the future of robotics

The service robot Care-O-bot, another Fraunhofer Institute development, has a different focus: as a pre-care assist system this is suitable for home care and provides a communication interface. 'Particularly in rural areas, tele-presence robots can help alleviate the physician shortage. Particularly elderly people, who are less mobile, will benefit from such systems. Wounds, for example, can be reviewed in a tele-conference,' Professor Wilkes explains, 'the robot can actively address people, that is if a patient falls and does not react, the robot will trigger an emergency call.'

The rehabilitation sector is also set to profit from robotics. Founded in 1894, the Technical University Illmenau, a German public research university has five academic departments (faculties) and about 7,200 students. The focus is sharply on computer and systems engineering and one team there is developing a robot that supports walking and orientation training of stroke patients and offers guidance to improve mobility and spatial orientation.

Complex tasks: functionality and development

Care robots and assist systems are not welcomed everywhere. On one hand lies the fear that the use of robots will weaken the human relationship between caregiver and care recipient. On the other, caregivers are worried that robots will lead to a further commercialisation of the care industry, since wards equipped with assist systems can take on ten rather than eight patients. And last, but not least, not all patients are enthused by the idea of being carried or washed by a robot.

Amid all the hype, one thing is clear: care is an area that poses very special and complex challenges for developers and proves that not everything is technically feasible. So far, none of the prototypes is fully functional and, as long as the development and acquisition costs are prohibitive, care robots won't prevail.

Therefore, most European research projects focus on relieving the strain on caregivers - although it is clear that the robots could never completely replace the input of a human nurse.

Javier Cortés MD is a member of the Spanish, European and American Societies of Medical Oncology (SEOM, ESMO, ASCO), and a member of the Scientific Committee of the European Society of Medical Oncology, and leads breast cancer and gynaecological tumour care at Ramón y Cajal University Hospital, Madrid. He is also clinical investigator in the Breast Cancer Research Programme at Vall d'Hebron Institute of Oncology, Barcelona. Author of more than 140 publications, mainly on breast tumours and new drugs, he also helps to develop national and international clinical investigations, particularly of drugs against molecular targets and new chemotherapy agents.

'Spain is doing well in clinical practice, but investigation is another thing. There's a lot of good and leading research here, but too little knowledge of precision medicine, even though the concept is old and has been applied to cancer management for a long time.'

The future

'Clinical trials must be designed in a more intelligent way. I think liquid biopsy and immunotherapy will play an important role in the future in many types of cancer.'

Transplants: Beating organ rejection

Cell-free DNA offers several

As part of a national, joint research project in cooperation with Chronix Biomedical (San Jose, CA/USA/ Göttingen/Germany), Professor Michael Oellerich MD is on new biomarkers in organ transplantation, aiming to develop personalised immunosuppression for patients. This also entails the development of molecular test procedures, among others for the early detection of rejection. The keyword here is cell-free DNA (cfDNA).

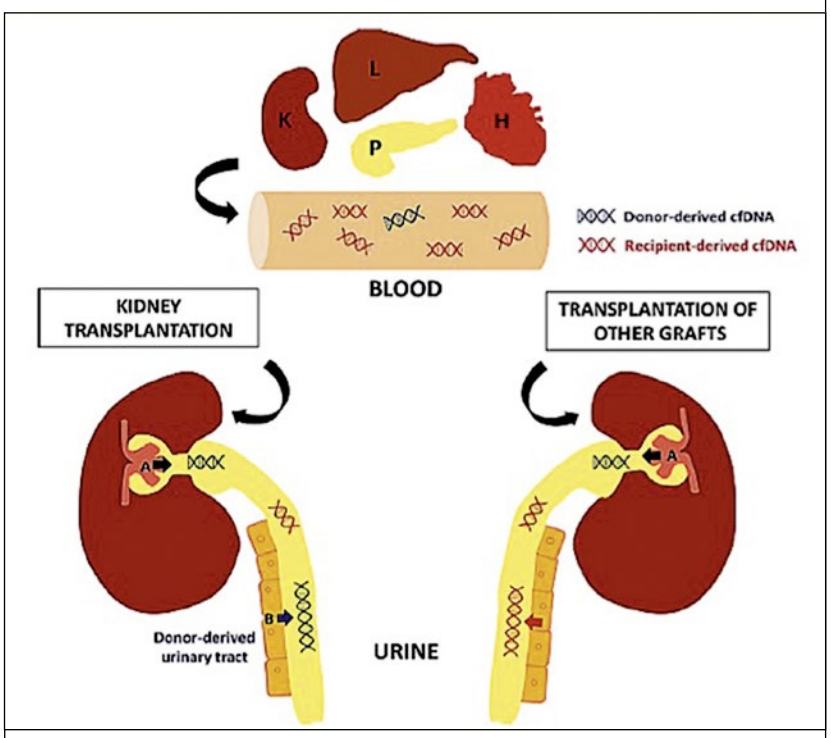
The worldwide problem for transplantation is the lack of donor organs. 'Therefore,' Professor Michael Oellerich explains, 'we have to expand the range of donors in transplant medicine and must also use organs from marginal donors under considerations of the risks involved.

The rate of transplant rejection within the first year is up to 20% for liver transplants, 27% for lung transplants and 29% for heart transplants. For the latter, 11% of deaths within the first three years are due to rejection, which therefore poses a significant risk.

'The survival time of transplants is important for long-term outcome. For the liver and kidney the average is 13 years. The average survival of patients with heart transplants is 11 years. If we could extend the half-life many more people would benefit from a new transplant and the general shortage could be overcome, not to mention the costs.

'The limiting factors are the irreversible chronic rejection on one hand and, on the other, side effects, such as nephrotoxicity, cardiovascular disease, infections and malignant tumours. Secondary complications are also dangerous and clearly contribute to the difficult prognosis. The problem we continue to deal with is over- and under-immunosuppression.

'Measuring the cell-free DNA allows us to continuously monitor the integrity of the transplanted organ and so to reduce the number of rejections whilst lowering the side effects through optimisation of immunosuppression,' Oellerich explains.



Graft-derived cell-free DNA (GcfDNA) is released from kidney, liver, heart or pancreas transplants into the recipient's blood. It accounts for a small fraction of total circulating cfDNA. Small cell-free DNA fragments from the recipient's blood circulation can be filtered through the glomerular barrier and appear in the urine. (Reprinted from Gielis EM et al, Am J Transplant 2015; 15: 2541-2551)

The procedure

'If a patient has been under-immunosuppressed after a kidney transplant, for a period of time, for instance, he can develop donor-specific antibodies, which will destroy the organ in the course of time. Drug monitoring allows us to detect the toxicity better, i.e. the over-immunosuppression. However, the procedure is less suitable to assessment of immunosuppression effectiveness, meaning the minimum exposure required cannot be safely predicted.

'To escape this dilemma we need a parameter that can reveal something about the state of the transplant at any given time. There are no reliable conventional markers for rejection as yet: liver enzymes are not sufficiently specific, there are no suitable non-invasive markers for the heart and lungs and the kidneys can already be affected by a fifty percent loss of function before a rise in creatinine can be detected.

'In other words, we'd like to improve and personalise immunosuppression through early detection of rejection so that we can also diagnose slow, continuous damage to the transplant at the subclinical stage and prevent chronic loss. We need a test that's practicable and can be quickly carried out at a reasonable cost.

'Cell-free DNA is extremely suitable for this. The cell nucleus of a damaged cell releases DNA into the blood which can be used as a marker for cell necrosis or apoptosis; it is a marker which indicates the destruction of the tissue. If, for instance, a liver cell dies and the cell nucleus is destroyed, the nucleosomes are flushed into the blood. In the case of necrosis these show up as large fragments and as smaller ones in apoptosis.

'Against the background that organ transplants are always also genome transplants, i.e. that the donor and recipient genomes are different, there is a fantastic opportunity to detect the genomic DNA of the donor in the recipient's blood, even though it is present in much smaller quantities. If we detect an increased amount of cell-free donor DNA in the blood we know that the transplanted organ is not doing well.'

How the test works

'Circulating cell-free DNA in the blood has a very short half-life of four to 30 minutes. In studies, we have examined patients' stable phases to determine a ratio as to how high the fraction of the circulating donor DNA can be. We then use this as a threshold above which it indicated that the organ becomes damaged.

'The fraction of donor DNA is very high immediately after a transplantation because of the ischemia/reperfusion damage, but it quickly decreases. If the values rise significantly again over time this is a sign of rejection or other damage to the organ (severe ischemia, for instance).

'A method has been developed based on droplet digital PCR, which allows cost-effective monitoring of graft-derived circulating cell-free DNA with same-day turnaround. Donor- and recipient DNA are amplified in the droplets and quantified in a flow cytometer via the emission of different fluorescence signals. This procedure has quickly proved itself of value in molecular diagnostics.

'The particular advantage is that we require no donor material for our test. We use e.g. Streck Cell-Free DNA BCT tubes for the blood test, which keep the sample stable for up to seven days at room temperature through stabilisers. The donor DNA can then be extracted from the sample and the recipient DNA is determined via the white blood cells. Using preselected single nucleotide polymorphisms (SNPs) it is possible to obtain respectively heterologous, homozy-

Professional and ethical challenges

No shortage of labs in Malta

Report: Moira Mizzi

Nowadays, the variety of clinical laboratories in a hospital setting is endless, especially due to the constant advent of new technology and scientific discovery; this places a cutting-edge professional and ethical challenge on both the clinician and the laboratory specialist to give the best service to the patient in the realm of diagnosis and prevention. Despite its minuscule size, Malta still boasts of a hub of state owned laboratories and a number of much smaller private enterprises in the field.

Virologist Dr Christopher Barbara, chairman of the Pathology Department at Mater Dei hospital, describes the particular challenges of the only state-owned laboratory service on the island. 'We cater for a large number of tests, almost 22,000 in a single day, coming from different sectors in the hospital, other public hospitals and clinics around the island and even from private labs that use our services in certain circumstances,' he explains. 'We offer these services on a 24/7 basis irrespective of the cost.'

The labs are also a national focal point that forms part of an international network (ECDC, WHO) focusing on disease surveillance and prevention.

Having to cater for such a large number of samples from different sources puts to test service quality, particularly where blood collection and transport are concerned. 'Quality has been a major priority for me during the seven years I've been in charge of the labs,' Barbara says. 'Thus I insist on having a clear visibility of things to ensure accountability and efficiency.'

In his opinion this must start at a pre-analytical level so that the accuracy of the result is not jeopardised. In fact, the pathology department at Mater Dei has gone through major quality-centred changes for this purpose, with the aim to gain a much coveted ISO certification; these include the installation of a harmonised Lab Information System (LIS) software that ensures the acquisition of 'clean data' from sampling to result, putting in place standard operating procedures and quality manuals, the setting up of a coagulation clinic at all the outside clinics with a point of care (POC) testing facility, connected through the latest software to the haematology department, and the use of sample bottles with gel separators.

Paul Sultana is Head of Medical Laboratory Services at St. James Hospital, Sliema

Phlebotomy was also relegated to staff members on a lower salary scale, who were specifically trained for the job to avoid sampling problems – usually rampant with junior medical staff. This shift in tasks also allowed a parallel shift of funds, which could then be used in the acquisition of necessary state-of-the-art equipment.

Malta has a hub of state owned laboratories and a number of much smaller private enterprises

Capital expenditure is in fact another major challenge faced by labs every day. Barbara believes much can be done if unnecessary cost is curbed and funds are then used in a more profitable way. 'At the moment we are planning to get an automatic sorter from the money saved from vetting unnecessary tests,' he explains, excitedly. 'In turn, this will save on human resources and extra wages, improve turn-around times, which then can be used to acquire other analysers, such as the Guthrie test. Although the challenges and demands are never ending, there'is a lot we can do to give the best service to the patient.'

For a private lab, giving the best service to patients is not just an exercise in quality control and cost-effectiveness but also having to contend with the ever-looming shadow of reputability, especially in a small market where competition is tight and patients have been accustomed to free medical service for decades.

Paul Sultana, head of Medical Laboratory Services (MLS), the private laboratory at St. James Hospital, in Sliema, describes how this focus on quality of service, especially where timing and reliability of results and availability of a wide range of tests is concerned, put his lab among the forerunners in diagnostics for patients and clinicians. 'The advantage of running a private lab is the paucity of the bureaucracy that often limits state-owned labs,' he observes. 'For example, we immediately introduced liquid based cytology five years ago, whilst at Mater Dei, there

advantages

gous SNPs, i.e. SNPs which are different in the donor and recipient.

'With the help of droplet digital PCR it is then possible to determine the percentage of cell-free donor DNA.'

Trials held

'Ten studies have already been published by different centres on the use of graft-derived cell-free DNA in kidney, liver, heart and lung transplantation. We have finished the first multicentre study on liver transplants in 115 patients. The transplant centres at the Hamburg-Eppendorf University Medical Centre, the Charité Berlin and the University Göttingen Medical Centre took part in the study.

'Most rejections recorded in this study occurred between day 20 and 40 after transplantation, making this period particularly suitable for the early detection of looming rejection through serial determination.

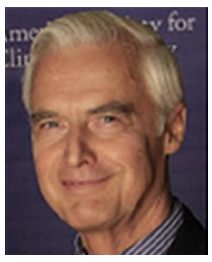
'Patients with rejection had ten times higher values of cfDNA than stable patients, and an increase in cfDNA was already detectable 8-15 days before rejection. The diagnostic sensitivity of cfDNA was 90% and the specificity was 95%.

'cfDNA allows a considerably improved identification of acute rejection compared to conventional liver function tests. We have also seen that under-immunosuppression in the first weeks after liver transplantation leads to a significant increase of cfDNA, which can possibly result in negative aspects for long-term survival of the organs. Further comprehensive prospective clinical trials for heart transplants are being carried out with the Bad Oeynhausen Heart and Diabetes Centre NRW and for kidney transplants with the Klinikum Stuttgart.

'Cell-free DNA offers a number of advantages: It facilitates the detection of subclinical and clinical rejection episodes at an actionable stage, the detection of slow, continuous transplant damage which can lead to chronic dysfunction, the detection of compliance problems with the administration of immunosuppressives and better personalisation of immunosuppression.

'Based on our experience so far, cfDNA can make a valuable contribution towards shifting the focus from reaction to prevention and saving costs through the avoidance of complications due to improved identification of complications after transplantation.

'After all, the objective is to improve the outcome based on the maxim 'value for outcome' and to use this as guidance for clinical decision making.'



Chemical pathologist **Michael Oellerich** earned a string of credits to his name: MD, HonMD, FACB, FAMM, FFPath (RCPI), FRCPath. Since 2012 he has been a Lower Saxony Distinguished Professor of Clinical Chemistry at the Department of Clinical Pharmacology, Medical Faculty (UMG), at George-August University, Göttingen. At UMG he also chaired the Clinical Chemistry Department/Central Laboratory, and was Dean of the Faculty of Medicine. Presidencies of national and international professional organisations include IATDMCT, DGLM, DGKL, WASPaLM, and from 2003 he has been Editor-in-Chief of Therapeutic Drug Monitoring, since his current research lies in that field, particularly focusing on endogenous biomarkers to achieve personalised immunosuppression in transplantation (e.g. graft-derived circulating cell-free DNA as 'liquid biopsy'), as well as pharmacogenetics. He has authored over 400 publications and received the Ludolf-Krehl Award, IATDMCT Charles Pippenger Award, WASPaLM Medal of Honour, and WASPaLM Gold-Headed Cane) etc.

is still a struggle to start up. Twenty-five years after being set up, MLS caters for both centres of St.James Hospital (Sliema and Zabbar), their respective out-patients departments and four immediate medical care units, two of which are located in each of the hospitals and the other two in the north and central parts of Malta, respectively.

The main labs are housed in the Sliema hospital, while smaller hubs are also found in both the Zabbar hospital. All these centres are natural sources of clinical samples, together with private general practitioners and specialists.

According to Sultana, these sources pose particular challenges, for example in the quality of the sampling and the cost-effectiveness of tests requested. 'The labs must obviously run at a profit, so minimising cost is a must. As a result certain tests uncommonly requests are at times analysed in batches, or sent abroad; in most cases, however, we try our utmost to accommodate most patient and clinician requests especially the latter's need to have the latest diagnostic tests at their fingertips.'

The biggest challenge that clinical laboratories face nowadays is balancing the responsibility and commitment to give the best service to patients against the scourge of the ever-rising running costs and hurdles to maintain high levels of quality assurance, especially since the miniutest break in the chain can spell the loss of human life.

Paediatric laboratory medicine

The Orphan

Paediatric laboratory medicine plays a minor role in the large clinical laboratory field. This may be due to the low incidence of rare diseases, which are a major task of paediatric medicine, but also to the small number of paediatric samples in routine laboratory medicine overall. Since most diagnostic laboratories do receive paediatric samples now and then, it is essential that there are primary sources of information and networks to answer questions arising around paediatric laboratory medicine, explains Professor Martin Hersberger, Head of the Division of Clinical Chemistry and Biochemistry at the Children's University Hospital in Zurich, Switzerland

Hossam Haick is a professor in the Department of Chemical Engineering and Russell Berrie Nanotechnology Institute in Haifa, Israel

Paediatric laboratory medicine plays a minor role in the large clinical laboratory field. This may be due to the low incidence of rare diseases, which are a major task of paediatric medicine, but also to the small number paediatric samples in routine laboratory medicine overall. Since most diagnostic laboratories do receive paediatric samples, now and then, it is essential that there are primary sources of information and networks to answer questions arising around paediatric laboratory medicine.

The challenge in paediatric laboratory medicine starts in pre-analytics: the small blood collection tubes with capillary blood samples are not compatible with automated tube handling of pre-analytical solutions in high throughput core laboratories. In view of the fact that pre-term neonates can have a total blood volume of less than 80 ml, it is understandable that neonatologists are reluctant to draw more blood than absolutely necessary. Thus, the paediatric laboratory has to collect manually even the last drop of plasma for diagnostic purposes to prevent a transfusion of erythrocytes.

Among the main challenges in paediatric laboratory medicine are inborn diseases, which individually are rare but, in their multitude, lead to a large number of paediatric patients. The wide field of inborn errors of metabolism, inborn endocrine disorders, and inborn immunological defects mainly pertains to the paediatric population.

For these diseases paediatric laboratory medicine offers many analyses to support diagnosis and follow-up. For example, paediatric laboratories offer several targeted metabolomic profile analyses that may lead to the investigation of a specific enzyme defect, followed by genetic confirmation of the rare monogenic disease. Whilst most paediatric laboratories offer targeted metabolomic profile analysis, enzymatic and genetic analysis are available only in specialised centres for inborn errors of metabolism that have the necessary diagnostic experience for a limited number of diseases.

Communication between the paediatric laboratories and the specialised centres enables the diagnosis of many rare or orphan diseases. Networking support is provided by orphanet (www.orpha.net), an initiative that allows searching for orphan diseases and directly lists the specialised paediatric laboratories offering the appropriate diagnostic procedures. However, the current list of orphan diseases is incomplete and novel orphan diseases are discovered every week.

Thus, paediatric laboratories need to adapt their metabolomics profile analyses constantly in order to cover all newly discovered diseases. It is reasonable to assume that these metabolomic profile analyses will become crucial also for adult patients since life expectancy of paediatric patients with inborn errors of metabolism is increasing and more of these patients will reach adulthood due to new drugs and better treatment in general

Even routine paediatric laboratory medicine can be challenging because children are not just small adults but have a distinct physiology that moreover changes during development from neonate to young adult. This is particularly obvious in analytes such as alkaline phosphatase during growth and in sex hormones during puberty, which require interpretation and reference intervals.

Due to the rapid changes of reference intervals during development, paediatric laboratories would prefer implementing continuous reference intervals rather than displaying the categorical age groups that most laboratory information systems support today.

In order to be able to develop continuous reference intervals, we need solid reference data over the entire developmental period from the neonate to the young adult. While these data were not available in the past, several working groups within the IFCC in Northern Europe and in Canada have contributed recently to the establishment of solid reference intervals in the paediatric and adolescent age range. For example, the large children and adolescent health study (Kinder- und Jugend-Gesundheitsstudie – www.kiggs.de) in Germany established reference intervals for routine clinical chemistry and haematology; in addition, the Canadian CALIPER study (www.caliperdatabase.com) provided reference intervals for endocrinology.

Those studies now allow the diagnosis of orphan diseases detected with routine diagnostics such as hypophosphatasia or hypoalphalipoproteinemia, which both need lower reference levels for alkaline phosphatase and HDL cholesterol, respectively.

These initiatives for the establishment of solid reference intervals are supported and coordinated by the Task Force for Paediatric Laboratory Medicine of the IFCC. This Task Force also organises the triannual 'International Congress on Paediatric Laboratory Medicine' (ICPLM) as a satellite meeting of the IFCC WorldLab. * The next ICPLM will take place on 20 to 22 October 2017 in Durban, South Africa.

Congresses such as ICPLM allow networking between professionals in paediatric laboratories and provide clinical and scientific further education for these professionals. In addition, these events offer laboratory professionals who handle paediatric samples now and then insights into paediatric laboratory medicine and serve as a communication forum with professionals in paediatric laboratory medicine.

Stoppi device

The European Parliament, the Council and t a compromise draft regulation covering me following more than 42 months of negotiati

Interview: Walter Depner

According to Dr Peter Liese (CDU), speaker for health issues for the European People's Party (EPP Group), the largest parliamentary group, this is an important step for Europeans who have long awaited appropriate consequences to follow scandals such as poor quality breast implants, stents or unsafe HIV tests. Due to extremely complex issues, it took several years to reach an agreement, according to Liese, who suggested that certain ministers in some countries obviously did not consider this a top priority issue. EH asked the healthcare speaker to outline the draft regulation and expected effects

The VDGH, the association representing the IvD industry in Germany, expects – or rather fears – that EU law will once again place a high financial and time burden on manufacturers, mainly due to the increased administrative requirements. Is this fear justified?

Peter Liese: 'I do understand the concerns of VDGH. The Council's position, as defined last year, indeed overshoots the mark. Pressured by the European Parliament, we revised the text. After long negotiations the Council finally agreed to reduce overly bureaucratic requirements in many areas. I'm confident, that we will have a good compromise.'

Company banishes white from medical interiors

Colour up your lab!

This January, KUGEL medical, from Regensburg, Germany, announced an interesting new venture. Although a leading manufacturer of equipment for pathology, histology and the laboratory for over 20 years, the firm launched its new Colour up your Lab design service.

A month later, at the German Pavilion at ARAB LAB 2016 in Dubai, the firm was presenting lab personnel with this concept and reports: 'We received a lot of questions: What's high pressure laminate? What makes it eco-friendly? What kind of laboratory furniture can be colour matched? Why is it antibacterial?'

Along with a 'Colour up your lab' leaflet, the company showed its histo-pathology equipment, e.g. grossing tables, staining tables, preparation cabinets, stainless steel furniture and more, and also presented a new brochure about exhaust systems for histo-pathologies.

However, KUGEL medical was keen to point out that it not only manufactures this equipment but also provides planning. 'No matter if you're looking for a partner for a sophisticated furnishing of an entire building complex or a partial fit out, we are your point of contact concerning designing, developing and planning.'

KUGEL medical is encouraging medical personnel to leave those traditional sterile white worlds behind, stating that the 'design possibilities are almost endless. The combination of different materials like wood with granite or the mixture of cold and warm tones gives your laboratory design that little extra something.

'We do not limit ourselves to laboratory furniture and laboratory table plates, but rather we also colour match our preparation cabinets with the corporate identity of your laboratory. All woods and raw materials that we use for our eco-friendly high pressure laminate solution come from sustainable managed forests with PEFC and FSC certificates.

'Additionally, daily adjustments of production processes guarantee that 10 times less water and 40% less energy are used and 75 % of the waste is recycled or recovered.

Color concepts in laboratories instead of sterile white

'During production of high-pressure laminate, fine paper layers as well as a thin eco-friendly melamine resin film are applied on top and bottom of a wooden base plate. Then, the different layers are pressed together under high pressure of 75 kg/cm² and temperature of approximately 150°C, making the

Medical devices and in vitro diagnostics face EU regulation

ng unsafe medical production

the European Commission have agreed on dical devices and in vitro diagnostics (IVD), ions.

A core issue are the so-called notified bodies, the certifying institutions. In Germany, these bodies are fairly well defined with TÜV, DEKRA, etc. But what is the situation in other countries? Are there comparable institutions?

'Yes, there are comparable institutions – notified bodies – in almost all Member States. However, the quality differs.'

How and by whom are these notified bodies controlled?

'Following inter alia the scandal regarding non-authentic breast implants the notified bodies have been controlled more tightly over the past few years. However, this is a purely voluntary measure in the Member States. The new regulation aims to make stricter controls mandatory. Moreover, the notified bodies can control each other across borders, for example German and French notified bodies can check whether their counterparts in Eastern European countries work properly. And in the future, these institutions have to employ healthcare professionals.'

In the past we saw a number of – not necessarily 'scandalous' – cases where the quality of IVD products was questioned, for example, test kits. Due to the common market, these kits can obviously be sold all over the EU. Probably everyone remembers the case of breast implants made from cheap industrial silicone, clearly a scandal. There was also an HIV test that, as the Paul Ehrlich Institute discovered, produced a high number of false negative results.

'The new regulation will at least make fraudulent actions much more difficult. The notified bodies will be able to make unannounced visits to companies after a market launch of

Continued on page 8

From left: Dr Martin Walger (VDGH), Dr Matthias Dettloff (German Health Insurance) and Dr Peter Liese of the European People's Party (EPP) in a discussion on European Union plans.

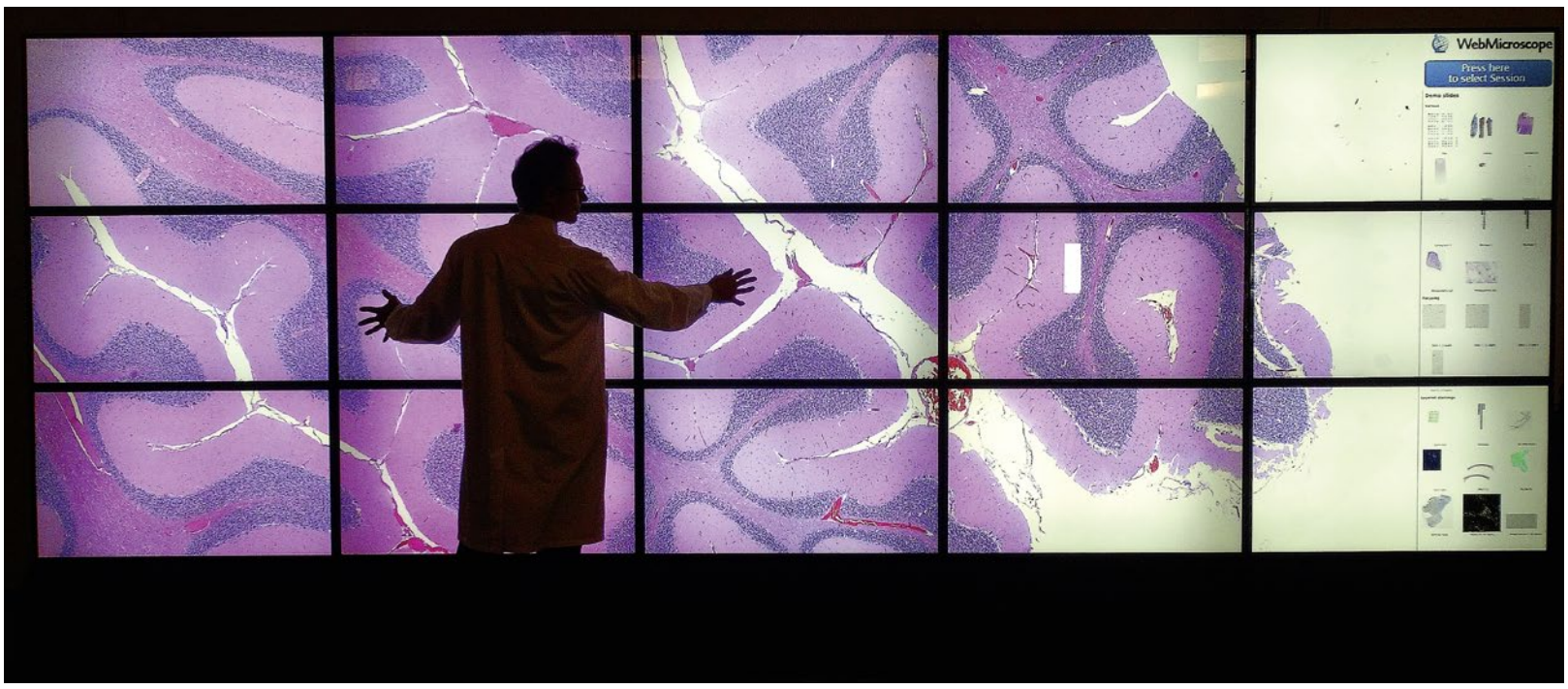
furnishings colour fast and light insensitive; moisture resistant and hence suitable for damp environments; resistant against high temperature and most chemicals; easy to clean and scratch and impact resistant.'

The firm also reports that its high-pressure laminate laboratory furniture 'is coated with the antimicrobial Sanitized coating, with silver ions, which kills 99.9% of bacteria within 24 hours'.

Mobile technology could enhance digital pathology

Mobile digital microscopes are in development

Mobile technology could prove an important catalyst in helping to raise digital pathology to a new level in delivering clinical diagnostics, Mark Nicholls reports



For many years pathology has moved more slowly than other fields that have embraced digitisation primarily due to costs and scale of the equipment, according to Professor Johan Lundin, Research Director of Finland's Institute for Molecular Medicine (FIMM), at the University of Helsinki.

An inability to take digital microscopy out of the laboratory as a portable tool has also been a consideration, which is about to change, however, with a number of mobile digital microscopes in development. Among these is Lundin's research group at FIMM and Karolinska Institute in Stockholm, which is pioneering the MoMic portable scanner, currently undergoing tests in Finland and Tanzania.

'Having the microscope closer to a patient, or where the samples are obtained, would improve the way you can perform diagnostics, making it more rapid and more accessible,' Lundin pointed out. It would improve the workflow of diagnostics, not just in pathology but also microbiology, cytology and forensic medicine.'

The low-cost, easily transported mobile microscope and scanner developed by the Finnish researchers, which enables the use of rapid, computer-assisted remote diagnostics, uses cheap components originally intended for mobile phones and connects wirelessly to a cloud server to which it transmits images for machine vision analysis.

'Digital pathology, and digital microbiology, can make much use of technology from the mobile phone industry if combined with the optical components you need for microscopy,' added Professor Lundin, who is chairing sessions at the 13th European Congress on Digital Pathology (Held in Berlin - 25-28 May 2016).

MoMic is still an academic study, but what differentiates it from similar mobile microscopy projects is the scanner facility it incorporates, which is vital because it enables the digitisation of the whole sample. 'If you cannot digitise the whole sample it's very difficult to use it for medical diagnostics because it's extremely difficult to control where the important part of the sample is on the slide,' Lundin explained.

The advantage of MoMic is that it becomes a point-of-care (POC) device and can attain laboratory-levels of microscopic resolution and scan a sufficient area of a sample to enable diagnosis. Once a sample is obtained it can facilitate faster digital diagnosis, or the ability to consult remotely.

Lundin said the MoMic project began with the goal of creating an instrument for low resource settings and currently five prototypes are being tested. Field studies are under way in a small hospital in a provincial area of Tanzania, a country where there are less than 20 pathologists among a population of 45 million people. In the three-year pilot programme, patient samples will be diagnosed both on location and remotely based on the digitised sample.

In such countries, he believes MoMic will impact on diagnoses of cancer, infectious diseases, including malaria, tuberculosis, and stool parasites.

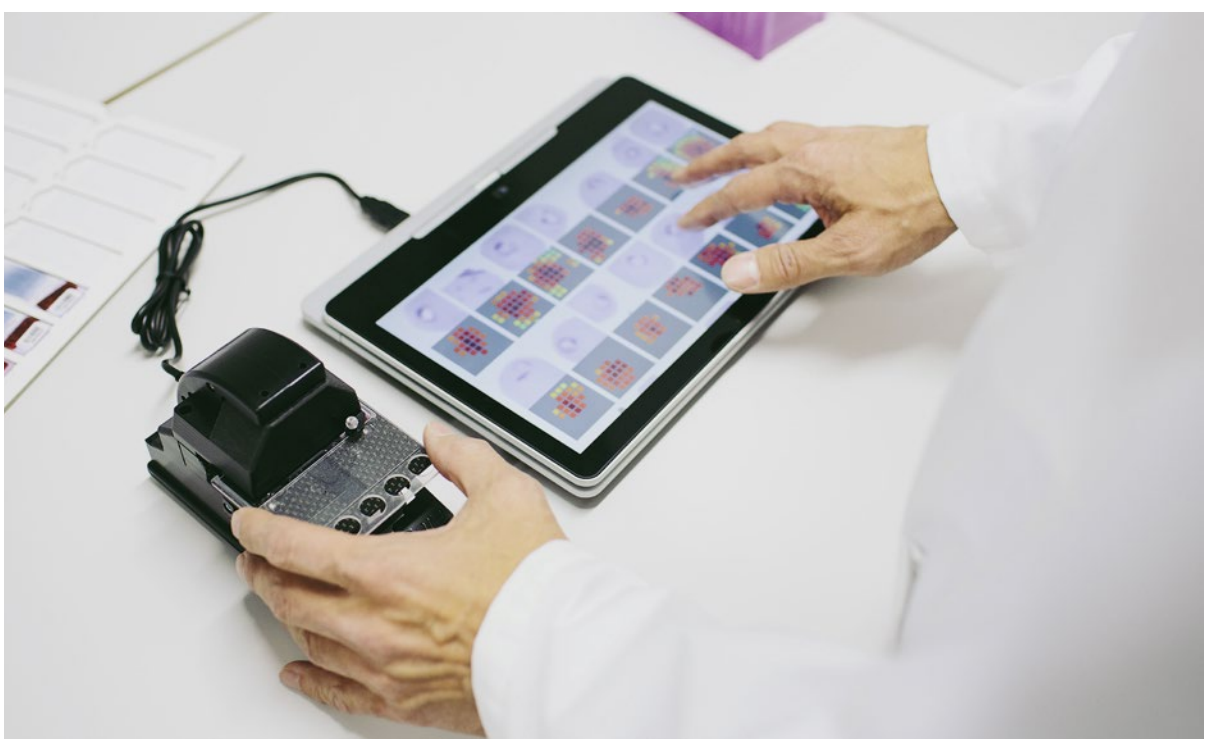
Other tests are under way in Finland for cancer diagnosis during surgery, using the device away from the laboratory for pathologists on the spot to view samples taken, to check tumour margins and to ensure the lymph nodes are clear of cancer.

The next steps, supported by a government innovation grant, are to establish routes to commercialisation with partners identified, to transform the prototypes into a product, with large-scale validation studies planned for next year.

Lundin also sees portable digital pathology microscopy being used in parallel with larger high throughput scanners, supporting single pathologists in smaller units, a move which he believes would open the world of digital pathology to more practitioners.

The professor also believes the mobile microscope would suit research work, including the study of tissue and cell samples to identify the expression of biomarkers in cancer research.

Professor Johan Lundin is Research Director at Finland's Institute for Molecular Medicine (FIMM) hosted by the University of Helsinki and Guest Professor in Medical Technology at the Karolinska Institute, in Stockholm. He is also Associate Professor in Biomedical Informatics at the University of Helsinki. His key research aims are to fully utilise development within information and communication technologies to improve diagnostics and individual care of patients.



Stopping unsafe medical device production

Continued from page 7

medical devices. 'There also will be an additional procedure for high-risk devices such as implants, where not only the notified bodies but also an expert group will assess product conformity.'

Are there figures regarding how many medical devices and IVD launched each year will be affected by these changes?

'There are somewhere between 3,000 and 5,000 IVD products and more than 100,000 medical devices.'

The so-called genetic technology products are also governed by this new regulation. What is the situation in the different EU Member States?

'The European Parliament demands special rules for DNA tests. Obviously we do need strict rules for all diagnostic tests to guarantee the quality of the products as such. DNA tests are a special case as they deal with highly sensitive information. Therefore the European Parliament suggested that such tests only be performed after expert counselling and explicit consent of the patient. In some countries – but not all Member States – this is already standard operating procedure. Since, for IVD manufacturers many things will change, we agreed on a five-year transition period.'

Meaning a transition period to allow all stakeholders to understand and implement the new rules?

'Exactly! There will be a transition period of five years for IVDs after the regulation's entry comes into force.'

Thank you – hopefully the new regulation will increase patient safety with regard to medical devices and IVD for all of us, throughout the EU.

Spanish pathologist highlights image storage issues at ECDP

‘We are staying ahead of the curve’

Compressing and storing digital images in pathology remains technically challenging but there are many options that can help to reduce costs and improve efficiency, as was explained by a Spanish expert in a dedicated talk during the 13th European Congress on Digital Pathology (ECDP 2016) in Berlin.

Report: Mélisande Rouger

High-resolution digital pathology images can weigh up to 1GB. Loaded with information on the patient’s clinical situation, these pictures are a goldmine for investigation and can help tailor treatment for each patient. Digital pathology image analysis already helps quantify biomarkers for cancer treatment and could soon enable detection of tumour areas, just like mammography, according to Marcial García Rojo, director of the pathology department at General Hospital (GH) Jerez de la Frontera in Cadiz, Spain. ‘Microscope images already enable us to identify suspicious areas,’ he said. ‘The big plus is efficiency; image analysis saves us a lot of time,’

These possibilities trigger a growing need for images. But as more and more pictures are generated, they occupy more and more space and current storage systems offered by the industry are unsustainable, Rojo believes. ‘For example, our team generates about 150 digital slides a day. 150GB of images multiplied by 200 working days a year, that’s about 20TB of information volume per year. It’s impossible to sustain this rhythm much longer if we can’t find cheaper storing solutions. Besides manufacturers only reduce the size of images from 1GB to 800MB without losing important information; that’s good but insufficient,’ he emphasised.

Rojo, a pathologist who trained extensively in medical IT, has worked on digital pathology scanners since 2005. He now focuses on transforming pathology images to DICOM to move them onto standardised DICOM servers and repositories, one of the best options to reduce space and costs. ‘Images generated with DICOM can be even smaller than those generated in owner format,’ he explained, before his Congress talk about standardisation in pathology with DICOM and IHE.

Following the radiology example, pathologists can store images in a dedicated picture archiving computer system (PACS). They can also save

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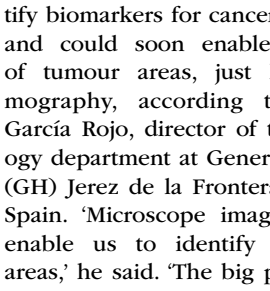


From 2009 to 2013 **Dr Marcial García Rojo** headed the pathology department at Ciudad Real University Hospital and was associate professor of pathology at the Medical School of Castilla-La Mancha University. Today, he directs the pathology department at the Hospital de Jerez de la Frontera in Cádiz, Spain. He also presides over the Ibero-American Association for Telemedicine and Telehealth (IATT) between 2015 -2017 and is vice-president of the Spanish Society of Health Informatics (SEIS), Spanish representative on the International Medical Informatics Association (IMIA) board and past-president of the Internet Association for Biomedical Sciences (INABIS). Rojo collaborates in European research projects on digital pathology such as AIDPATH (Academia and Industry Collaboration for Digital Pathology), and also focuses on medical informatics standards in digital pathology and molecular pathology.

International endoscopic R&D bring distinct rewards

New devices deliver exceptional clarity

This year PENTAX Medical launches three premium products for use in gastroenterology, Ear nose and throat (ENT) and bronchoscopy. These result from highly focused global research and development, for which Mike Drexel, the company's Chief Technology Officer, is responsible. In our European Hospital interview he discusses how the firm's globalised approach to product research and development has taken shape.

Joining Pentax Medical five years ago, Dr Mike Drexel immediately began to globalise the firm's R&D process. 'Originally we didn't have any facilities for R&D beyond Japan, which meant our local market expertise was not as strong as it could be. In the last five years we have established further facilities in the US (Montvale and Boston), and Germany, to work closely with local markets throughout our R&D processes.

'This globalisation project has resulted in four R&D sites across three continents generating local market data and working with regional KOL (Key Opinion Leader) groups, made up of internationally recognised clinicians within the key endoscopic application areas. I believe this global approach to endoscopic R&D is a market first; Pentax Medical is the only manufacturer to work on this global/regional level.'

How are clinical needs established before new product development?

'We have an ethos at Pentax Medical which involves bringing together the elements needed to deeply understand exactly what unmet needs are in the market. The first step is to identify the need by looking at data sets and talking to our global network of clinicians. It's important to consider the market requirement in this process alongside the practical capabilities of the physicians.

'Through our consultation with our KOL network, we have now recognised a suitable unmet need, but what does the solution need? Sometimes consultant clinicians are specific in their requirements and sometimes a consultant can identify the need, but we have to consider the technology best employed to meet that need; it's a two-way process. We are now defining the proposition in-line with all the application requirements.

'Once we've identified an unmet need where we feel we could engineer an effective solution, and then decided on possible solutions, we must consider the product definition – which technologies are best suited to that application. The suitable technologies would be incorporated into prototypes, which then would be bench tested using a number of trials designed to evaluate its performance against a range of parameters. Here, our KOL network plays an important role because further in-the-field testing is conducted through multi-centre studies.

'By analysing all the data from the rigorous testing procedure and looking at the data and consultants' feedback, we can now down-select from our prototypes. Multiple units of the chosen prototype are produced featuring our further defined technology and distributed to our KOL network to see if we now satisfy the unmet need.

'All previous data gathering, consultations, bench and field testing make up the research stage. As we start development, we liaise heavily with all departments within our organisation, clinical specialists, sourcing and quality management.

'We particularly work closely with our quality management and sourcing teams to ensure high standards of quality engineering and of components.'

How do you evaluate and validate a new product?

'With the full specification now complete we can produce a prototype that is so close to a final production model that hopefully consultants can't notice much difference. These final prototypes are then handed to our KOL networks for final evaluation. As part of our continuous development we are further enhancing our KOL programme with the introduction of the Blackbox Innovations project, which looks to build on our existing relationships with KOLs, allowing us to work even more closely and enhance our working relationships.

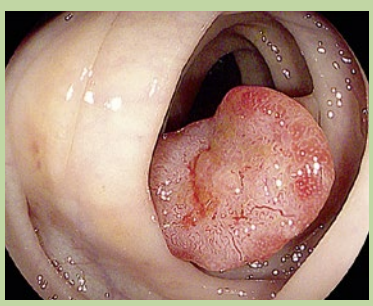
'This year will see the benefit of our global approach with the introduction of a number of key products across three areas of specialism. One key product brings together two technologies, digital and optical enhancement, i-scan and i-scan OE.'

Pentax Medical is now keen to see the market response to the OPTIVISTA EPK-i7010 Video Processor, its unique product launched in May.

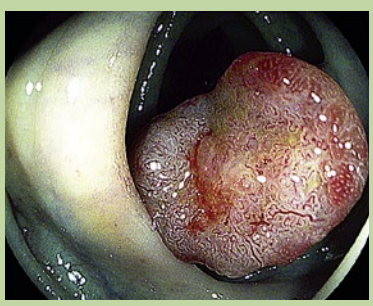
'Our KOLs were clear on the need to identify both vascular and mucosal patterns better, with each technology (digital and optical enhancements) having strengths in the two different applications,' Drexel points out. 'There wasn't a video processor that could offer this, so we understood there was a clear benefit for physicians to be able to employ both technologies through the same device.'

Believing the future of endoscopy lies in ever-closer union between manufacturer and consultant communities, the firm is further evolving its research and development process by introducing a Blackbox Innovations project. In 2016, ten KOLs will visit Pentax R&D World in Augsburg, Germany, to share confidential material on its latest research and discuss the way forward.

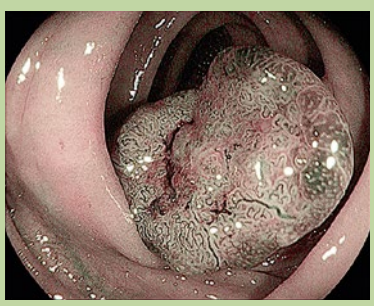
After gaining his PhD in Mechanical Engineering at the Georgia Institute of Technology **Mike Drexel PhD** held senior research engineering positions at GE Global Research, Michelin and the Georgia Institute of Technology, before joining PENTAX Medical in 2012. There, as Chief Technology Officer, he leads the $500 million medical device firm's international technology efforts, coordinating the activities of 60 research scientists and engineers based in Munich and Boston. Dr Drexel is also responsible for initiating partnerships with Universities and industrial concerns.



i-scan 1 – Surface Enhancement



i-scan 2 – Tone Enhancement



i-scan 3 – Optical Enhancement

Application reports

The OPTIVISTA EPK-i7010 Video Processor, which features both digital (i-scan Surface and Tone Enhancements) and Optical Enhancement (i-scan OE), with the new optical filter producing bandwidth-limiting light. This unique enhancement combination delivers detailed information for more accurate endoscopic in vivo diagnosis through improved vessel and mucosal pattern characterisation; for example, the surface structures of blood vessels, glandular ducts and mucosal membrane are displayed in higher contrasts than white light. (Images courtesy of Dr Federico Buffoli, Ospedale di Cremona, Italy)

Internationally-renowned experts have tested OPTIVISTA and switched seamlessly in real time amongst HD+ white light and i-scan 1 (SE), i-scan 2 (TE) and i-scan 3 (OE), to view multiple aspects of tissue structure. Their initial findings have confirmed the clinical value of this unique system, when moving through the clinical pathway for endoscopic evaluation.

Professor Pradeep Bhandari (Queen Alexandra Hospital, Portsmouth) concluded: 'The PENTAX High Definition White Light image is a major advance, but when I switch i-scan 1 (SE) on then the image becomes sharper and crisper without losing any other attribute of the image so I don't see any reason why i-scan 1 (SE) should not be left on at all times. Once I find a subtle abnormality, or any obvious lesion, then I switch on i-scan 2 (TE) and that really highlights the lesion from the surrounding normal mucosa.

'Once the presence of neoplasia is confirmed then I switch to i-scan OE to evaluate finely the surface and vessel patterns of the lesion (to differentiate neoplastic from non-neoplastic lesion) and identify the exact margins of the lesion. The recent addition of i-scan OE to the PENTAX family has been a major step forward in evaluation and characterisation of gastrointestinal neoplasia.'

Dr Michael Häfner, at the Elisabethinen Hospital, Vienna, confirmed: 'i-scan OE combines the versatility and flexibility of i-scan with ever sharper and crisper pictures. While i-scan 1 (SE) is my standard setting during every procedure because it gives you the extra bit of contrast and detail to detect even very subtle changes of the mucosa, i-scan OE offers an extremely sharp view of the surface pattern, for example in Barrett's oesophagus. Combine it with the capabilities of the optical zoom endoscopes and you get the ultimate diagnostic tool in both lower and upper GI tract.'

Dr Rehan Haidry used the i-scan OE combined with optical zoom endoscopy to help diagnose early squamous cell carcinoma, as well as visualise an early neoplastic lesion arising from the Barrett's mucosa. 'Over the past six months I have been using newer optical enhancements that PENTAX have developed above and beyond the conventional i-scan. I have particularly liked i-scan OE, because the filtering technology provides a very distinct and lighter image of the vascularity and mucosal pit patterns that become disordered in early cancer. In my practice, this coupled with i-scan SE have become the two most common enhanced imaging modalities that I use.'

'We're staying ahead of the curve'

Continued from page 9

images on discs and films, a slower but significantly cheaper alternative. 'The point is to use something that is economically relevant to store the huge amount of information and images we need today,' he said.

Pathologists can also use low cost vendor-neutral archive (VNA) systems to store images in a repository cheaper than the one used for radiology images. Several companies, including Agfa HealthCare, Carestream Health, GE Healthcare and Merge Healthcare, now offer VNA products either in-house or through acquisitions.

Another possibility is to erase the images after a given period of time. Pictures do not need to be saved forever; the paraffin block, from which images and slices can be generated anytime, always remains as a back up for future investigation in molecular pathology or genomics.

Twenty-five public hospitals are equipped with digital pathology scanners in Spain, but only five use them in clinical practice: GH Jerez de la Frontera, University Hospital Arnau de Vilanova in Lerida, University Hospital in Ciudad Real, and Barcelona's Del Mar Hospital and University Hospital Clínic. The latter leads the way, with up to 300 preparations a day.

Several digitisation projects for private clinical practice are underway across Spain. Santa Lucia University Hospital in Murcia offers telepathology services to the rest of the country.

'Spanish digital pathology is doing well,' Rojo observes. 'Almost every pathology department now digitises preparations. Sweden, Norway and the Netherlands are still leaders in clinical practice, but the situation across Europe is very irregular. We're doing what we can to stay ahead of the curve.'

Eminent gastroenterologist stresses endoscopy role in therapy

Complex interventions must be learned

Technological advances increasingly enable endoscopists to treat disease and perform surgical procedures. However, professionals must work hard to learn and maintain knowledge of complex interventions, says Dr Ferran González-Huix Lladó, President of the Spanish society of digestive endoscopy (SEED)

Dr Ferran González Huix-Lladó is president of the Spanish society of digestive endoscopy

Report: Mélisande Rouger

Among major developments that emerged over recent years is endoscopy full-thickness resection (EFTR), a technique that enables endoscopists to place a clip before they even begin to pierce a hole inside the intestine wall. Many more systems have been introduced and all are pushing the boundaries of endoscopy further, according to González-Huix Lladó, at Clínica Girona near Barcelona. 'Innovations have opened up the possibility for new indications in endoscopy, especially in therapy. New materials and technology give us the opportunity to foster highly sophisticated techniques, each time bringing us closer to surgery,' he said.

3-D imaging has given birth to 3-D interventional endoscopic ultrasound. And, with endomicroscopy, endoscopists can carry out live biopsies and obtain insights into wall cells as precisely as a pathologist would.

These techniques are being developed at great speed because of their considerable health and economic benefit.

'Our techniques are less and less invasive. Patients can go home after two or three hours,' González-Huix added.

Now, one of the main challenges for endoscopists is to perform anastomosis between two parts of the digestive tube – to link for instance the intestine and the stomach to treat stenosis or narrowing – with lumen-apposing metal stents. This technique can also be used for hepatogastrostomy – linking the stomach with internal liver bile ducts – or to link the stomach and the jejunum (small bowel).

Chromo-endoscopy, echo-endoscopy and therapeutic endoscopy will be highlights of the next SEED meeting, which will be held in November in Valencia. Spanish endoscopists will learn the latest in placing stents, diagnosing and resecting tumors inside the mucosa to access organs outside the digestive tube.

The learning curve for these procedures is long, and maintaining know-how skills is more demanding than other disciplines. Endoscopists need to perform 25 procedures per year on average to be at the top of their game, González-Huix believes. 'If you only do two or three interventions a year, you'd better leave it to another specialist. Our main issue is that learning is not easy. Only the best prepared professionals will be able to properly resect intestine tumors or obtain probes for molecular biology,' he explained.

Sometimes the most appropriate professionals are not endoscopists. Depending on where the lesion is located, surgeons may perform Natural Orifice Transluminal Endoscopic Surgery (NOTES). If the lesion is located outside the tube, it will be easier for surgeons to access it. In fact, surgeons are increasingly carrying out NOTES procedures, according to González-Huix. 'It is becoming a surgery procedure. As soon as we have to access the abdominal cavity we are less habile than surgeons,' he said.

Each case must be discussed in multidisciplinary meetings, but there are many established protocols, which clearly divide the tasks between specialists. For instance, in a patient with colon tumor, obstruction in the intestine and hepatic metastasis, the norm is for the endoscopist to place a sent. Decisions are also based on the level of experience of each practitioner in the given area of intervention.

Education is key and SEED offers various opportunities to gain knowledge in cutting-edge methods, sedation and advanced colonoscopy techniques such as polyp resection and other treatments. The society also initiated a study for endoscopic retrograde cholangiopancreatography (ERCP) and will soon offer training material on echo-endoscopy and guidelines to its 800 members.

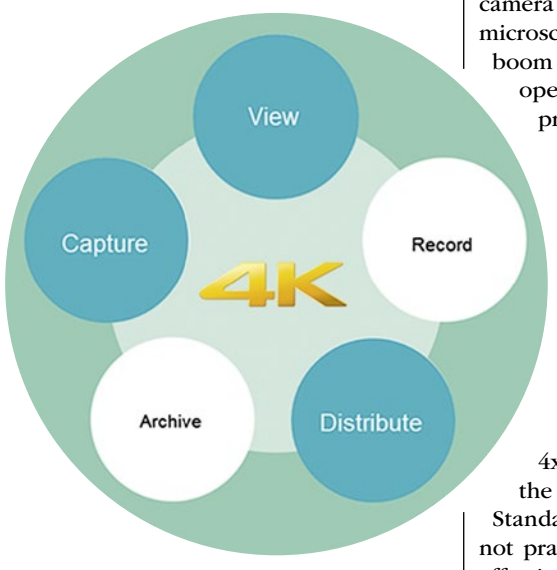
Obtaining the status of subspecialty for interventional endoscopy (IE) in Spain is a long- term goal, as it would facilitate knowledge dissemination. Meanwhile the society is developing a master for certified endoscopists to validate an appropriate set of skills for IE practice.

Bringing a sharper image to surgery

Sony Medical offers an end-to-end video processing chain for medical-grade 4K surgical visualisation, John Brosky reports

The conversion will not happen overnight, but 4K is a natural next step for improving visualisation during surgery, according to John Herman, the European Marketing Manager for Surgical Solutions at Sony Medical.

Standard definition (SD) video gave surgeons a view that was measured in 680 pixels by 480 pixels. Over the past eight years hospitals have progressively converted to high definition (Full-HD) video that gives a sharper view, with 1920 pixels by 1080 pixels. 'If you asked a surgeon whether he would be willing to go back a step and give up HD, he would say absolutely not, he'd argue that SD no longer meets the required standard of care, and that it may even pose a risk for the patient,' said Herman.



The Sony Medical 4K over IP complete workflow solution provides all the necessary end-to-end technology to capture 4K surgical images right through to sharing 4K content for clinical education and training.

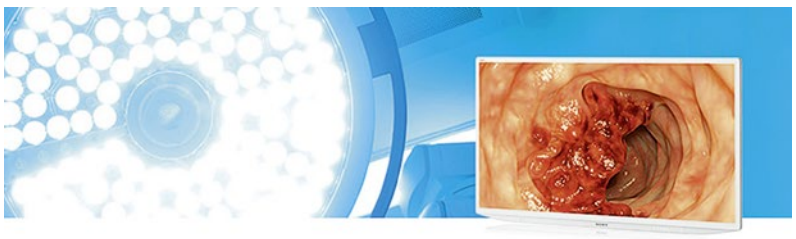
In the same way, he said surgeons will be ready to embrace the ultra-high definition resolution of 4K, which is four times greater than what they are using today with Full-HD.

'It gives a much clearer picture with a greater sense of depth, and for surgeons this means an ability to better distinguish blood vessels or minute structures. It gives them greater diagnostic confidence in what they are seeing, and a greater confidence in making surgical gestures and actions,' he added. '4K also offers an enhanced colour range, providing surgeons with true colour reproduction. This should then lead to better patient outcomes through a visually enhanced procedure.'

Like HD, next-generation 4K imaging is created in a tightly linked video chain from source to final display. In the Operating Theatre, a video signal is created by a camera in an endoscope, surgical microscope, or one mounted on a boom arm suspended above the operating table for open surgery procedures.

'With 4K sources you need 4x the bandwidth to transmit the signal compared to HD. Standard video cables are just not practical to transmit 4K images effectively, as four cables would be needed. So we designed a new platform to convert the video signal to IP format and to transmit secure 4K content via a single cable,' Herman explained. The content can be sent anywhere within a hospital, through the LAN, to be shared or stored. To view the image, the data is converted again to a video format, and while it can be displayed on HD or 4K devices, it is only on a 4K display monitor that the original resolution and sharpness of the image can be appreciated.

This end-to-end chain becomes critical in the operating theatre (OT), where there can be no delay in the processing chain, and here is where Sony Medical brings unique expertise and capabilities from its live broadcasting division.



The Sony 4K surgical monitors are available in two sizes: 55" for big screen surgery, or 31" typically used on an endoscopic cart system.

'The surgeon working with an endoscopic camera cannot tolerate any latency in display of the image, otherwise the movement of the surgeon's hands, while viewing the image, would not be co-ordinated,' Herman pointed out. 'Any visible delay would mean the surgeon would not be able to perform the operation.'

In the surgical imaging industry, Sony Medical is the only company that provides each link in the 4K chain, he said. 'Certainly there is competition in the different segments for surgical monitors, or for surgical recorders, but in the 4K chain from image acquisition through image processing, recording, and to image display, our proposition is unique. We are the only company to have a complete 4K workflow and there is no other company with this breadth of complementary products.'

'We were the first to launch 4K medical-grade monitors, and the first to launch a 4K surgical recording system. We have just introduced a 4K Content Management System and soon we will also introduce our 4K video over IP system,' Herman said. Outside the Operating Theatre, Sony has a huge range of market leading 4K devices for training and education, from 4K LCD Displays, to 4K Laser Projectors and 4K Video Presentation solutions.

Sony is a global leader in image sensors and image processing technology, he explained, adding that the camera modules found inside many of the leading endoscopes are from Sony.

At the same time, he added that a premiere feature of the Sony 4K IP system is that it is an open architecture built on industry-accepted standards (Standardisation process ongoing), with no proprietary requirement, giving hospitals the flexibility to connect any input device or any display device they choose for best purpose.

Sony Medical holds a strong presence in Operating Theatres going back over 30 years, 'to the point where I would guess that the vast majority of hospitals in Europe have some Sony equipment in their operating theatres,' the marketing manager surmised.

Thanks to the infrastructure required in the conversion to Full-HD, many hospitals are ready to share content from a server or CMS system. And the demands for digital capabilities in other areas of healthcare, such as PACS systems and electronic records, mean that most hospitals have a standardised IT infrastructure that can support video over IP.

There are two areas where a conversion to 4K will present challenges that need to be incorporated into planning. Many hospitals have already faced difficulties in archive planning for HD video files and with 4K these problems will only become greater, as 4K files can be over four times larger than HD. However, using Sony's XAVC-S codec format, 4K file sizes can be reduced by a factor of three, depending on image quality settings. This can translate into savings in archive costs and savings in computing hardware needed to edit.

The next area is within the OT. Whereas HD images pass through a video cable, fibre optic cabling is an absolute requirement for 4K, in order to maintain real-time display of the surgery being performed. Incorporating this into an existing OR requires special care and expertise.

Upgrading to 4K within the Operating Theatre opens the possibilities for surgeons to gain access to more information when they need it, with the ability to share images from multiple sources such as CT or MRI scans from PACS systems, patient vital data or even pre-surgical planning data on a single large 4K monitor. Herman expects that the surgeons' drive for 4K visualisation may be the trigger for a decision to make the move.

Beyond enhancing the view for endoscopic surgery, Herman said that Sony is collaborating with companies investigating the potential for 4K in surgical microscopy.

For the fine work required in neuro-surgery or ophthalmic surgery, the surgeon today views the target bent over a microscope, sometimes for hours. 4K camera module technology is compact enough to be integrated inside the microscope to provide a crystal clear 4K image to a 4K surgical monitor, giving a heads-up view, where the surgeon can watch his hands working instead of through the binocular eyepiece.

'There is a potential that, with 4K, we can unlock innovative ways of performing surgeries,' Herman is convinced, 'because the image is that good.'

Natural Orifice Transluminal Endoscopic Surgery

NOTES – An emerging trans-disciplinary treatment

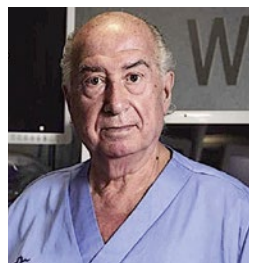
Jose Ramon Armengol-Miro has directed the World Institute for Digestive Endoscopy Research (WIDER) since 2007. There, he leads the investigation of Natural Orifice Transluminal Endoscopic Surgery (NOTES). The technique was introduced to gastrointestinal endoscopy over ten years ago. Speaking with Mélisande Rouger the expert assessed its use and value today

What exactly is natural orifice transluminal endoscopy surgery? 'NOTES represents an emerging trans-disciplinary treatment based on disruptive technology. It is the paradigm between open abdominal surgery, laparoscopic surgery and surgery carried out through natural orifices. In 2000, Dr Sergey Kantsevoy and Anthony Kalloo, from Baltimore, presented their work on transgastric laparoscopy, to avoid abdominal incisions. It's the so-called perfect cosmetic surgery with no scar, less infection risks, quick recovery without pain, quick recovery of the paralytic ileus, less adherence issues and better access in obesity indications.

'Basically it consists of pinching the stomach, dilating an incision with a balloon, introducing the endoscope into the peritoneal cavity and closing the dilated gastric incision. Access is fundamental; it can be trans-gastric, trans-colonic or trans-vaginal. Many indications have emerged in humans since 2000: laparoscopy, appendectomy and trump ligature. In animals we are using NOTES in hysterectomy, cholecystectomy, gastrojejunostomy, splenectomy, gastric reduction, herniography and hepatic resection.

'Advances have focused mainly on basic but essential aspects: suture, endoluminal anastomosis, transluminal drainage and complete tumour resection in gastrointestinal tube and achalasia treatment with peroral endoscopic myotomy (POEM) technique; and other applications of submucous tunnelling, such as pyloric stenosis etc. also the introduction of robotics.'

'NOTES was introduced in June 2007, after attending the first D-NOTES course organised by Dr J Hochberger. In 1986, at Vall d'Hebron Hospital, Barcelona, a team successfully treated two patients with large pancreatic pseudo cysts by performing cystogastronomy and post dilatation of the puncture area with post-cystoscopy, with complete cleansing of the detritus inside the pseudo cysts.



Jose Ramon Armengol Miro heads the gastrointestinal surgery department at Hospital Vall d'Hebron and the gastrointestinal endoscopy department at Quiron Clinic, in Barcelona. He is also associate professor at the medical faculty of Autónoma University, in Barcelona. He is founder and president of the Catalan society of medico-surgical digestive endoscopy. Additionally, Armengol-Miro is vice-president of the World Organisation of Digestive Endoscopy.

These cases were the foundation of NOTES in our country. Originally we had a few experimental centres that

Continued on page 14

Crystal clear coloured visualisation of body cavities

3-D viewing benefits gastroenterology

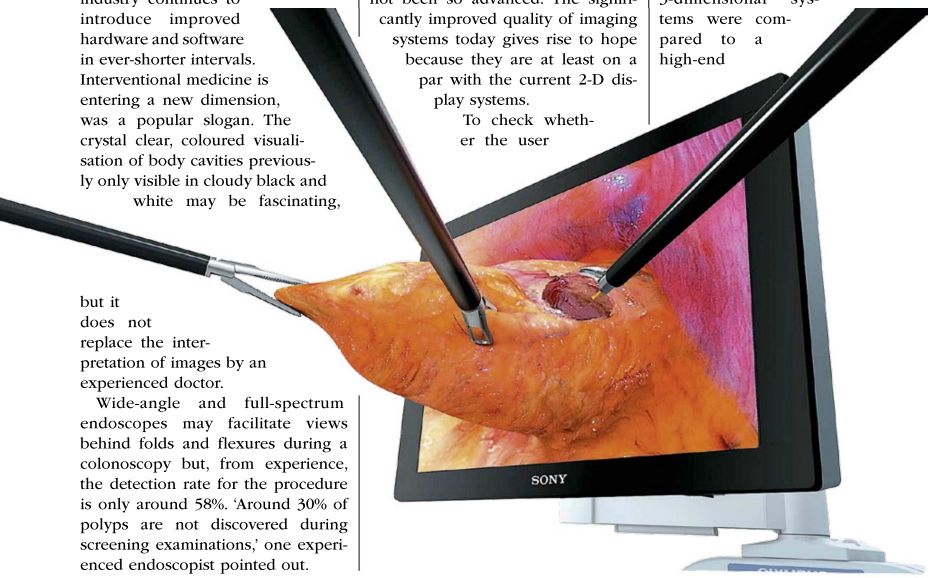
Report: Anja Behringer

During many and various 2015 medical congresses 3-D visualisation has been a key topic as the industry continues to introduce improved hardware and software in ever-shorter intervals. Interventional medicine is entering a new dimension, was a popular slogan. The crystal clear, coloured visualisation of body cavities previously only visible in cloudy black and white may be fascinating, but it does not replace the interpretation of images by an experienced doctor.

Wide-angle and full-spectrum endoscopes may facilitate views behind folds and flexures during a colonoscopy but, from experience, the detection rate for the procedure is only around 58%. 'Around 30% of polyps are not discovered during screening examinations,' one experienced endoscopist pointed out.

Stereoscopic imaging was controversial as far back as the 1990s, but this subsided over time due to improvements in visualisation technology, which, in the early days, had not been so advanced. The significantly improved quality of imaging systems today gives rise to hope because they are at least on a par with the current 2-D display systems.

To check whether the user actually benefits from a measurable added value with 3-D images, under Feussner the MITI Research Group in Munich carried out a prospective clinical study. The latest 3-dimensional systems were compared to a high-end 2-D monitor system for laparoscopy.



European Hospital asked Feussner why promising approaches of 20 years ago were not pursued any further?

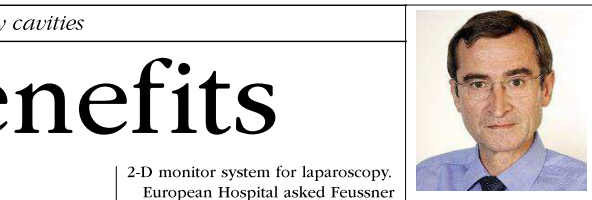
Feussner: 'The technical quality of stereoscopy back then was nowhere near as good as it is today. The cloudy view lead to tiredness and headaches for the users and the monitor glasses caused nausea.'

We cannot all see stereoscopically

The study specifically focused on the difference between doctors with little surgical experience and experts with longstanding surgical experience. 'However, Feussner immediately clarifies, 'Five percent of people cannot see stereoscopically.' Even these days three-dimensional viewing is exhausting and takes getting used to. Despite this, none of the participants of the study complained about visual impairments or paraesthesia, not even with the glasses-based 3-D system compared to a 2-D display.

European Hospital wanted to know about other particular results the study delivered. 'The most surprising finding is that even experienced experts benefited from the visualisation, even though they did not perceive it subjectively. But, we were able to prove this increase in efficiency objectively.' When these findings catch on in the future, 3-D will become standard, at least for laparoscopy, the surgeon foresees.

Asked about further areas of application for this technology he referred to the first approaches in interventional, endoscopic manipulation in gastroenterology. 'Theoretically our findings can be transferred here as well. However,' Feussner stresses, 'one limitation is that the technical requirements for such 3-D systems in endoluminal endoscopy are respectively even higher than in laparoscopic surgery, due to their significantly lower spatial depth.' Nonetheless, he still believes that experimental and clinical studies on the subject will be beneficial for gastroenterology.

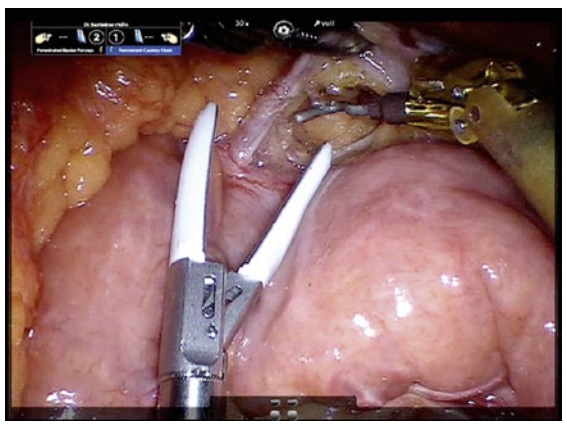


Hubertus Feussner MD studied medicine at the Philipps University Marburg, and, following military service, took further medical training in Kassel, Bad Kissingen and at the Technical University of Munich. Specialising in internal medicine he pioneered minimally invasive surgery and was a founder and leader of the interdisciplinary research group 'Minimally Invasive Interdisciplinary Therapeutic Intervention' (MIT Institute)/ Other roles include Chairman of the Section for Computer- and Telematics-Assisted Surgery at the German Society of Surgery (CTAC) and board member of the German Society for Computer- and Robot-assisted Surgery (CURAC).

Robots for neurosurgery? The brain is a delicate place

Their parts are simply too big

'An autonomously working robot in the operating theatre will continue to be a vision of the future for a long time to come,' according to Professor Uwe Spetzger, Clinical Director and Neurosurgery Specialist at Karlsruhe City Hospital. At the same time, he is calling for political support for the development and promotion of these innovative technologies and asking funding bodies to rethink their strategies. 'The topic obviously easily lends itself to ethical discussions,' he adds, 'but, in some cases, an assistance system can actually be more reliable than a human colleague.'



An assistance system for minimally invasive spinal surgery: Robot-assisted positioning of screws on a model of the lumbar vertebrae at the Research Project Centre for Sensor Systems (ZESS), University of Siegen and Neurosurgery Karlsruhe

A setback for science

The big boom in robotic medical technology in Germany occurred around 15 years ago. At the end of the 1990s to the early 2000s robots conquered operating theatres, carrying out hip replacements more or less autonomously – often with little success. Why? Because those robot-assisted operations failed due to mistakes. 'The errors were human and actually quite banal, because the robots were often not programmed correctly; calculations were carried out wrongly and user errors occurred,' Spetzger explains. 'In principle the robots were very precise and performed good work on components. However, they had not been specifically manufactured for the medical market but mostly rather adapted from the automotive industry.'

'What followed was a general loss of trust and a setback for robot assisted surgery. 'This not only resulted in harm for some of the patients treated but also in enormous damage for science per se because, consequently, not one single EU or German Research Foundation (DFG) application was approved that included the word robotics.'

Da Vinci: outstanding for MIS

Interest in robot-assisted surgery is now slowly re-awakening. At Karlsruhe City Hospital the Da Vinci Surgical System, developed in the USA and largely based on remotely-controlled assistance systems that aimed at guiding small camera systems and small instruments directly to where needed is mainly used by urologists, specialists in abdominal surgery and gynaecologists. 'The system is outstandingly suitable for minimally invasive surgery (MIS) in the abdominal cavity,' explains Spetzger, whilst also limiting the advantages. 'However, for neurosurgeons the system is of no use. The basic problem is the access needed to the surgical site. You would have to drill four or five holes into a patient's head to place a camera, a mounting system and the actuator arm into position and into the brain. That would be a catastrophe.'

Nonetheless, neurosurgery could actually benefit from further developments of this technology as it predominantly uses mounting fixtures for endoscopes or instruments. 'For this application, a robot is almost more reliable than a human colleague because it always works based on exact calculations and with high precision, and it doesn't shake, which is a big advantage particularly for the brain,' Spetzger emphasises. Neurosurgery is based on image-guided operations; each intervention is carried out under navigation, so computer assistance is already standard nowadays. 'Therefore, it's not actually that far to go towards partial automation,' Spetzger points out.

Most assistance systems are still currently far too big and not easy enough to handle. 'And, above all, they are too expensive,' the neurosurgeon emphasises. 'The Da Vinci System, for instance, works with disposable instruments, which must be discarded after each operation. This creates additional costs in the region of €2,500 – essentially an amount usually spent on care, medication and hosting the patient after the operation. This clearly needs rectifying.'

The need for future improvement

Spetzger believes that politicians and funding bodies need to up their game and hopes for restructuring. 'There are many companies which have been developing innovations in the field of robotics. This should be promoted, he suggests.

He cannot conceive of a further setback such as that experienced 15 years ago with robot assisted hip surgery. 'Modern assistance systems do not work autonomously,' he explains. 'Even then it wasn't actually the devices that went wrong – there were simply calculation and user errors. Working with robots in medicine requires solid training and continuing education.'

The specialist, who also lectures at the Department of Robotics at the Karlsruhe Institute for Technology (KIT), does not believe there will be a quick development towards completely autonomous assistance

Maintaining hygiene in Xi and Si robotic instruments

Have an ultrasonic bath

The Trison 4000 ultrasonic bath from Berlin manufacturer Bandelin electronic is reported to make reprocessing of highly sensitive robotic instruments even easier and exceeds any manual cleaning effectiveness. For best results, during pre-cleaning, the device combines ultrasound, moving of all instrument axes and individual channel rinsing.

Ultrasonic cavitation reaches difficult to access areas, joints and Bowden cables, and mechanical damages, such as scratches, are avoided due to electronic brushing.

The new TRISON Twist is reported to be the first to move all instrument axes of up to four robotic instruments separately – for an improved ultrasonic effect. This is available as a Si or Xi version, in respect of instrument types, the manufacturer reports, adding: 'A new ergonomic innovation is the new pivot mounted arm Trison Lift. It allows a simple connection of the instruments and a comfortable lowering of the Trison Twist into the ultrasonic tank.'

An alternating suction and pressure rinsing of every instrument lumen, combined with an individual examination, completes the cleaning process.

Notes – An emerging trans-disciplinary treatment

Continued from page 12

tested NOTES in animals to help develop the technique and train our teams in carrying out procedures.

'Now the most active institutions are the Centre of Minimal Invasion Surgery Jesús Uson in Cáceres (CCMIJU), the Centre of Training in Endoscopic Surgery in Santander (CENDOS) and WIDER, where we are working on procedures for clinical practice. We also launched an international course, celebrating its 10th anniversary this year. 'There are many more centres, but only for investigation. Many other centres perform hybrid NOTES, i.e. endoscopic surgery assisted by laparoscopy, for digestive, urology and obesity surgery.'

'NOTES requires tight cooperation between endoscopic and laparoscopic surgeons in physiological research, new instruments development, personnel training. Cooperation trials are absolutely mandatory for the development of the technique.'

'Benefits potentially include significant post-surgery comfort, less pain during surgery, less inflammatory response, less intraperitoneal adherence, less parietal complications, reductions in hospital stays and incapacity for work.

Disadvantages are risks related to surgery, intraperitoneal infection, visceral parietal haemorrhage in the portal entry, visceral parietal suture dehiscence, adjacent visceral lesions in the entry and dissection, and difficulty in complications control. '

Why is NOTES not used as extensively as previously thought?

'It's true; the technique has not delivered everything we hoped for. The crisis clearly had an impact on investment from cutting edge industry.

'NOTES is now being used to develop treatment of digestive tube tumours, sub mucosa dissection, subserosal dissection and thickness resection with complete endoscopic suture. In echo endoscopy combined with ERCP, it is also used in biliopancreatic pathology and in anastomosis between viscera, stomach liver, bile ducts and intestine.

'We still face many challenges in pneumoperitoneal gastric overture, orientation and navigation, characteristics of the endoscope, sterility, tissue manipulation, triangulation, haemostasis, gastric closure, quality visceral sutures and ergonomic work platforms.'

How might NOTES develop and what may change?

'We must continue to evaluate NOTES development and viability in animal experiments. New technologies will be needed to meet objectives we set ourselves. NOTES has already led to great advances in conventional endoscopic surgery and fibre, tube endoluminal endoscopy.

'This new paradigm will change our conception of conventional endoscopy teaching, in diagnosis and therapy. Specialist training will be multidisciplinary and require in-depth knowledge of gastroenterology and laparoscopic surgery, NOTES will change medico-surgical specialist training in digestive endoscopy.

'Its evolution will require true innovation and cooperation between endoscopic and laparoscopic surgeons through experimental work and physiological research, and the development of new instruments, accessories, procedures and cooperation trials.

Robotic surgery, well established in urology, is conquering colorectal surgery

Promising tool for abdominal surgery

600,000 robot-assisted surgical interventions were performed in 2015 worldwide, most of them urological procedures, particularly radical prostatectomies. In the USA, today 85 percent of these interventions are performed using a robot-assisted system that provides a magnified 3-D image of the internal body. The surgeon controls the robot arm via a console.

Uwe Spetzger gained his medical degree at Heidelberg University and the University of Zurich. Following work in Aachen, Brussels and the USA, in 2002 he became Director of the Neurosurgery Clinic at Karlsruhe City Hospital. From 2005 he has been a member of the Faculty of Informatics at Karlsruhe Institute of Technology and the Institute for Anthropomatics and, from 2013, has been a cooperation partner of the RadioChirurgicum – Cyberknife Centre Southwest (robot assisted stereotactic precision radiation). A member of many national and international specialist societies he was a founder member of the German Society for Computer and Robot Assisted Surgery (CURAC), past-president of the International Society of Medical Innovation and Technology (SMIT) and past-president of the 66th Annual Conference of the German Society of Neurosurgery (DGNC) held in Karlsruhe in 2015.

Now, robotic surgery is proving its value in a second discipline: abdominal surgery.

'The surgical robot is a promising tool, which today covers the entire range of abdominal surgery,' Professor Thomas Bachleitner-Hofmann pointed out in his presentation at the second Symposium held at the Centre of Perioperative Medicine in the General Hospital and Medical University in Vienna, Austria.

Whilst globally the number of robotic surgery procedures is growing in a linear manner, the number of robot-assisted abdominal surgeries is growing exponentially, Bachleitner-Hofmann reports. Robotic surgery, he points out, presents several crucial advantages, listing:

- The 3-D view of the operative site
- up to tenfold magnification
- stable camera control
- automatic correction of unintentional movements, such as trembling hands
- instruments can be moved in seven degrees of freedom
- even minute movements can be performed thanks to a fivefold reduction
- surgical procedures can be performed very well even in smallest spaces.

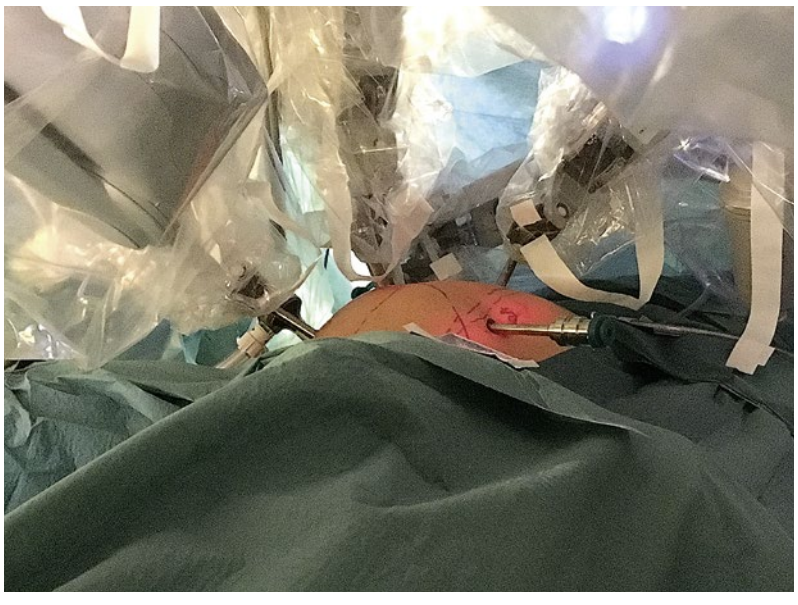
The major benefit of robotic surgery, he adds, is achieved in colorectal surgery, where this system is particularly useful for the resection of deep rectal carcinomas due to the small operative site. Interdisciplinary, the robot-assisted treatment of endometriosis involving the rectum shows positive outcomes.

However, robotic surgery is expensive: a system can come with a price tag of up to €2 million, not including service and training costs.

Bachleitner-Hofmann has compiled evidence regarding colorectal surgery. 'There are reliable data indicating that, in colorectal surgery, the preservation of the autonomous nerves in the pelvis is much more successful than in conventional laparoscopic interventions. That means the outcomes regarding voiding disorders or erectile dysfunction are much better,' he underlines.

According to a meta-analysis robotic colorectal surgery takes longer, but blood loss is reduced and fewer conversions occur, that is pre-operative unplanned additional incisions. The meta-analysis did not show any statistically relevant differences in complication rates, length of hospital stay or status of the resection margins. The Robotic Versus Laparoscopic Resection for Rectal Cancer (ROLLAR) trial, with partial results published so far, sees identical outcomes of robotic and laparoscopic surgery. 'However, this study does have a weakness,' Bachleitner-Hofmann concedes. 'The laparoscopy group consists only of highly experienced surgeons whilst surgeons in the robotic group were obviously far less experienced. Who knows what the results of the study would look like if highly experienced laparoscopy surgeons had been compared to highly experienced robotic surgeons.'

Robotic Surgery has several advantages but is quite expensive



While the major issue is the benefit for the patient, Bachleitner-Hofmann nevertheless points out, 'We also have to take into consideration the surgeon's benefit.

'Sitting at a console is much less strenuous than standing next to the OR table.' The well being of the surgeon translates into improved quality and cost savings: 'A well-rested surgeon can operate better and longer.'

© Fotostudio Wilke, Wien

Viennese surgeon **Professor Thomas Bachleitner-Hofmann MD**, Resident Physician and head of the 'Treatment of peritoneal neoplasms' programme at the Surgical Clinic in Vienna's Medical University, is also a certified specialist in abdominal surgery. His memberships of international professional associations include the European Society of Surgical Oncology (ESSO), European Society of Coloproctology (ESCP) and the American Society of Clinical Oncology (ASCO). Beyond recognition as a top surgeon, Bachleitner-Hofmann is an accomplished pianist; he took third place in an international piano competition in the USA.

Live-streaming robotic cancer surgery

Doctors and students participate worldwide

Report: Mark Nicholls

UK-based surgeons have taken a significant step that they believe could have major implications for the development of robotic tele-surgery.

Rectal cancer surgery - using a Da Vinci robot and conducted by Tas Qureshi, Consultant Surgeon and robotic lead at Poole Hospital NHS Foundation Trust - was beamed live from his operating theatre by satellite to an international conference of specialist doctors, student doctors and to a worldwide audience via multimedia platforms with live audio and twitter feedback.

The stream – part of an educational programme by Poole Hospital NHS Trust at its International Symposium of Minimal Invasive Surgery for Rectal Cancer – offered a 360-degree perspective of the operating theatre, as well as a 'robots-eye-view' of the inside of the 60-year-old patient.

'The live stream, the first ever for a robotic case, enabled surgeons to have the opportunity to listen to lectures from the international symposium from recognised authorities in the field,' Qureshi said. 'They also witnessed live surgery performed on a patient with rectal cancer, with the opportunity to interact with us in real time.

'In addition, through an affiliation with the University of Portsmouth, the case was recorded using Virtual Reality technology, allowing anyone with a smart phone to have an "immersive experience" of the theatre environment, a world first for a robotic case, we believe.

'Therefore, this event provided a huge learning opportunity for people with no access to the robot both in terms of the latest evidence from lectures and live surgery from experts.'

Surgeons believe the mode of transmission of the live stream using satellite rather than physical ISDN lines has implications, not just for real-time teaching, but also for the potential of robotic tele-surgery in the future.

Potentially, they say, a specialist can operate remotely from an identical console on a patient from anywhere in the world or even assist a colleague on a similar console in the operating theatre remotely.

The surgeons suggest the current constraint for robotic tele-surgery is a physical reliance on the Internet with its potential to slow down transmission, especially during times where an unforeseen peak in social media may suddenly devour redundant bandwidth. Point-to-point satellite overcomes this potential hurdle.

'It will be exciting to see this technology develop further in the coming years, providing a fantastic teaching and training platform, and perhaps allowing patients to be operated on remotely, all over the world, by the best surgeons,' Qureshi enthused.

He was assisted in the operation by Professor Amjad Parvaiz, a specialist colorectal surgeon Professor of Surgery at Poole, Head of Minimal Access and Robotic Colorectal Surgery at the Champalimaud Foundation in Lisbon, Portugal and a founding director of the European Academy of Robotic Colorectal Surgery (EARCS), for the procedure.

'Historically, the robot has been used almost exclusively for prostate cancer surgery by urologists. Currently, there are very few general surgeons like us who perform robotic resections on rectal cancer,' Qureshi continued. 'In fact, however, general surgeons have been sceptical about the prediction from experts in the field that the number of general surgeons wishing to have access to a robot will increase significantly as they develop an understanding of what is possible and as new evidence starts to appear in medical literature.'

The symposium drew many of the world's leading authorities in this field to Poole Hospital, which has recently named as the European epicentre for robotic colorectal surgery.

Qureshi: 'This means Da Vinci recognise the quality in Poole and have appointed us as their preferred "epicentre" or Centre of Excellence in Europe for robotic colorectal surgery, meaning any surgeon in the UK and Europe approaching Da Vinci wanting exposure to robotic surgery will be directed to our unit for "observerships".

'Those surgeons who already have access to a robotic system, but are finding it difficult to start operating, or are unable to progress, will also be directed to Poole to attend Master classes that we run.'

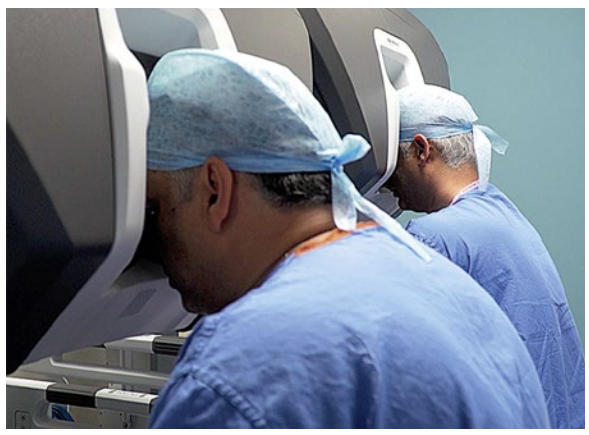
The Da Vinci robot used for the surgery provides high definition 3-D images with sophisticated instruments, allowing for greater precision, which in turn deliver significant benefits for patients in the short and long term, such as reduced trauma to the body, reduced post-operative pain, shorter hospital stay and faster recovery.

The Da Vinci System has been designed to improve upon conventional laparoscopy, in which the surgeon operates while standing, using hand-held, long-shafted instruments, which have no mechanical wrists.

In contrast, the Da Vinci System's design allows the surgeon to operate from a seated position at the console, with eyes and hands positioned in line with the instruments and using controls at the console to move the instruments and camera. Surgeons can also sit at dual consoles and remotely work collaboratively to assist one another.

Commenting on the enhanced performance of the robot, Qureshi said: 'Traditional laparoscopic surgery has instruments with very primitive movements. The robot provides me with 3-D high definition views and wristed instruments able to perform seven degrees of movement - the human hand has only six.

'This means I can very precisely access difficult areas in the body and take cancers out with better precision and with much more confidence that the whole cancer can be taken out,' Tas Qureshi confirmed, adding: 'This hopefully will mean patients require less radiotherapy and chemotherapy.'



Working together: Surgeon's sit at dual controls to remotely work collaboratively to assist one-another. The robot provides 3-D high-def views and instruments wristed and able to perform seven degrees of movement – the hand has six

Tas Qureshi is a Consultant Surgeon at Poole Hospital NHS Trust with a recognised expertise for embracing the latest techniques in laparoscopic surgery. He specialises in minimally invasive surgery (MIS) for bowel cancer, inflammatory bowel disease, hernias and gallstones, amongst other conditions. He is the first General Surgeon in Dorset and one of the first in the South of England trained in Robotic Surgery for these procedures.

Helping scie

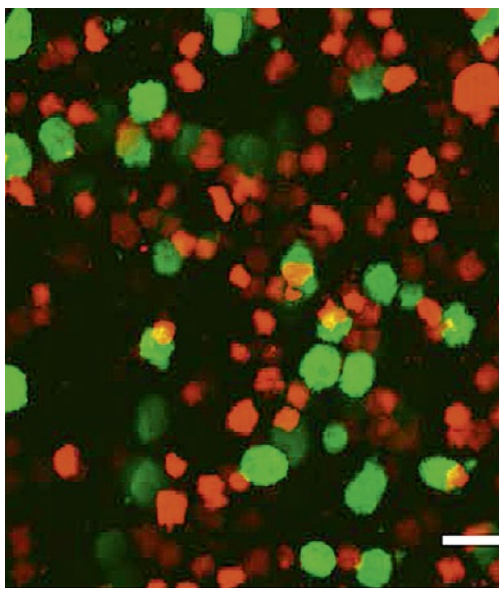
The 3-
brain t

Report: Mark Nicholls

3-D printed tumour-like constructs will be used by a research team at Scotland's Heriot-Watt University in Edinburgh, to raise research to a new level and successfully lead to new treatment options.

The project brings together tumour biologist Dr Nick Leslie, at Heriot-Watt University's Institute of Biological Chemistry, Biophysics and Bioengineering, with 3-D printing expert Dr Will Shu as well as neuropathologists and neurosurgeons, engineers and clinicians.

The collaborators have developed



Embracing a new visual tool for cardiology

Spain takes medical 3-D print to heart

3-D print technology is expanding to cardiology surgery and interventional procedures. Research is scarce in Europe but a group of Spain-based cardiologists are currently developing 3-D print models to assess their value in the heart, Mélisande Rouger reports

Traumatology and maxillofacial surgeons have been using 3-D models to improve their performance for about a decade. Practicing on organ-sized models enables surgeons to prepare for the intervention better than any image, and considerably reduces complications during and after the act.

Cardiologists and interventional cardiologists are catching up and a group of specialists in Spain are working to introduce 3-D print in the treatment of congenital heart disease, Dr Edwin Tadeo Gómez Gómez, one of the leading researchers, explained during our interview.

'Using 3-D models facilitates interventional procedure planning and reduces time of the procedure. Experience shows that it also diminishes complications and errors when calculating the size of devices used in transcatheter aortic valve implantation (TAVI) or when placing MitraClip or Watchman devices in closure of left atrial appendage,' he said.

Gómez's company Healtix is working with two organisations, TECHFIT, a Colombia-based specialist in medical 3-D design, and MIZAR, a Spanish company that produces 3-D material – using mainly titanium and thermoplastic – on the project. The group plans to work with different cardiology departments in Madrid to study the educational and clinical applicabilities of 3-D printing.

There is also reason to believe that using 3-D print models beforehand may reduce complications in heart surgery, based on results obtained in traumatology and odontology.

In both fields, using 3-D models enables reduction of risk complications by 30 to 40% during surgery, shortens surgery time by half and diminishes hospital stay. But large-scale randomised studies must still be carried out to confirm this potential.

'Everything is new in cardiology, so we need more studies. In addition, congenital heart disease is rare, affecting only 1% of the population, of whom 30% can benefit from surgical treatment,' Gómez said.

Simulation would be another area of development in cardiology. 3-D print could significantly shorten the duration of the learning curve, for instance in TAVI interventions.

Interventional cardiologists need to perform about 100 procedures to master the technique; however, by being able to practise on 3-D print models, they could need only 70 interventions to prepare. Complications during the learning curve would also be reduced by 50%, according to Gómez.

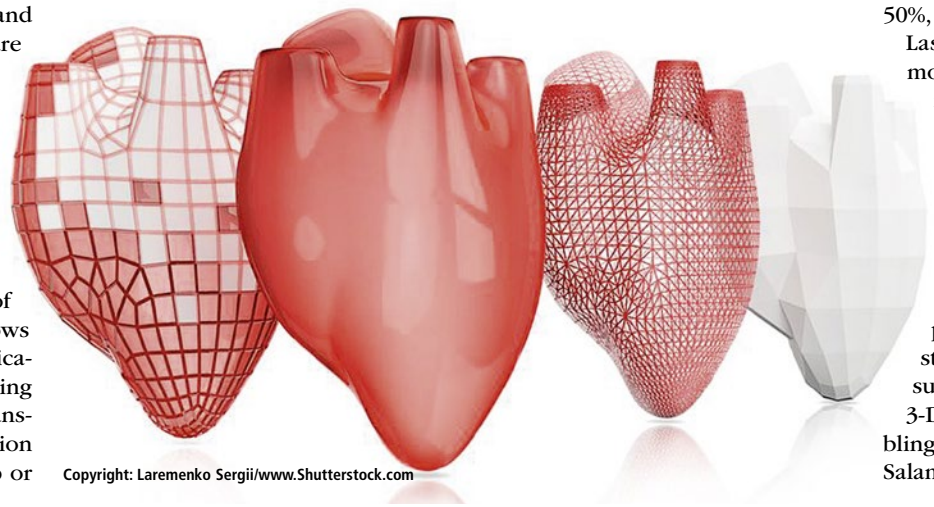
Last but not least, 3-D print models could serve to design mechanical valves and other devices for each patient, to avoid current issues with size and post surgical complications. 'In traumatology, evidence shows that artificial hips developed from 3-D print models last longer. Using personalised valves instead of standard devices would boost surgery outcome,' he said.

3-D medical technology is babbling in Spain. For the moment only Salamanca and Gregorio Marañon hospitals have performed a few closures of left atrial appendage based on 3-D print.

Expanding the use of 3-D print technology to cardiology would be a relevant move for the country, where imaging and image analysis are covered by the national public health service.

"The most expensive aspect of 3-D technology is imaging and image post processing, which represents about 80% of the total cost. In Spain, MR and CT examinations are entirely covered by the national health service, and image post-processing is done by a radiologist and not a cardiologist, so this saves a lot of money,' Gómez said. 'Once the model is ready to become print the intervention could cost between €400 and €1,500, depending on the material used.'

Edwin Tadeo Gómez is a cardiologist at Gregorio Marañon University Hospital in Madrid. He has extensive experience with cardiac CT, 3-D trans-oesophageal echocardiography, 3-D post processing in cardiology, especially in congenital and structural heart disease, and interventional cardiac imaging. Born in Medellin, Colombia, in 1981, he worked as an emergency doctor at several hospitals in Colombia before moving to Spain.



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entists to fathom malignant tumour biology

D printed umour

several types of 'brain tumour in a lab' to study such tumours and test drugs to treat them. This has included taking brain tumour stem cells from patients, but they point out that if these cells are simply lab grown they behave very differently from how they do in a real tumour – because cell behaviour depends on its environment and the same tumour-like environments cannot be created in a lab, yet.

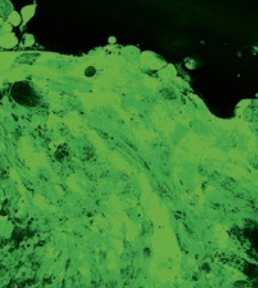
New research methods

With a key focus on malignant tumours, specifically glioblastoma the interdisciplinary team intends to apply the novel 3-D bio-printing technology to produce more realistic models for drug testing and research into glioma biology, whereas previously they used pre-clinical animal models with poor relationship to human brain tumour pathology.

Leslie explains: 'We have two main goals: to reproduce constructs for drug testing and to reach a resolution from the 3-D technique that is good enough so that we can start to do more detailed studies of the tumour micro environment.

Brain tumour cells (green) and immune cells (red) 24 hours after being 3-D printed with mechanical support only (left) or with extracellular matri

Right: Cells at Day Nine



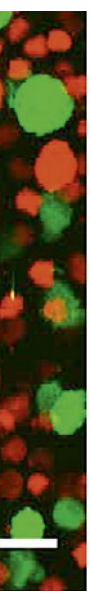
Having first studied for a Genetics degree at Cambridge University, **Nick Leslie** gained his PhD at Glasgow University. Today, he is Associate Professor at the Institute of Biological Chemistry, Biophysics and Bioengineering at Heriot-Watt University in Edinburgh where he heads a laboratory with study focus on how cells regulate their behaviour and how this regulation fails in cancer. His group has particularly investigated the tumour suppressor protein PTEN and why the loss of PTEN function isa common step in the development of many cancers.

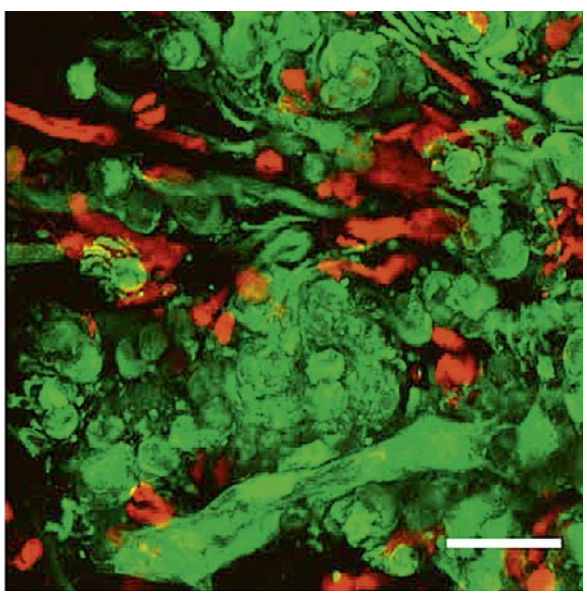
What the Heriot-Watt researchers have done is printed 3-D brain tumour (glioma) stem cells and other cell types isolated from patients' brain tumours, using their own novel technique. This recreates tumour-like constructs with a dense mixture of matrix proteins and diverse neighbouring cells, which will continue to grow rapidly as tumours do in real life.

'We hope to be able to provide brain tumour models for experiments that will give closer results to a real human setting and will, within 5-10 years, see drugs tested using these models in a way that will hopefully help weed out problems before they reach animal or human trials.'

* The Brain Tumour Charity, in the United Kingdom, funds malignant brain tumour research.

More than 10,600 people are diagnosed with a brain tumour annually in this country, the charity reports, and the survival prognosis is low – around 5,000 of them die every year.





We need to assess IR efficacy compared to surgery

'Interventional radiology has become fashionable!'

Fernando López Zárraga is a member of the Executive Board of the Spanish Society of Vascular and Interventional Radiology (SERVEI). In an interview with Mélisande Rouger he explains issues facing interventional radiology in Spain and why this is becoming an increasingly attractive field

Rouger: How did the audience respond to the central interventional radiology (IR) theme at the recent meeting of the Spanish Society of Radiology?
Fernando López Zárraga: 'Pretty well, judging from attendance. The interventional committee held ten sessions and every other committee (thorax, abdomen imaging, etc.) organised at least one session on IR. One of the three pre-courses before the meeting was dedicated to IR, and even radiographers sessions featured a session on embolisation. It seems IR has become fashionable!

'Many sessions focused on drainage; but there are many general radiologists who already perform liver or breast radiofrequency, or are interested in puncturing with fine needles or thick probes. We can see that people are overcoming their fear of needles, at least within their own area, which is very positive.

'In Spain the newest application is probably thermo-ablation with microwave, cryoablation and NanoKnife; it's showing good therapeutic results in liver metastasis and kidney tumours smaller than 2 cm. These techniques should be performed more often, but we need more experiments and prospective methodological studies. Cryoablation is very interesting for patients who are not candidates for surgery.

'Radiofrequency in thyroidal nodule has been around for many years and some surgeons even prefer this option to avoid complications in the neck, a delicate area.

'Next should come embolisation of the haemorrhoidal arteries and percutaneous creation of arteriovenous fistula for haemodialysis.

'Prostate embolisation is an interesting option for patients who usually wear a urinary bag; it's an established procedure in Portugal, even if urologists have recently questioned it.'

Spain has a long research tradition. Are there interesting projects in this field at the moment?
'Various studies are underway; teams at Navarra University and La Fe Hospital, in Valencia, are assessing the impact of Ytrio 90 radio-embolisation in hepatic tumour. Other researchers at Hospital Reina Sofia in Cordoba are leading a study on stem cells in peripheral revascularisation; they have already obtained good results and helped reduce the number of amputations of lower limbs with significant ischemia. In Zaragoza, Dr Gregorio is leading a multicentre registry on vena cava filters.'

Could bariatric arterial embolisation (BAE) gain ground in obesity treatment?
'In the Vitoria area surgeons treat morbid obesity; they are not really asking for our participation.'

'BAE is co-adjuvant to surgery; it helps to prepare a patient by cutting the production of satiety hormone ghrelin and helps avoid complications during surgery.

'Interventional radiologists can place prosthesis inside the digestive track, to secure suture or for the embolisation of potential haemorrhage in post surgery.

'Now we need to convince surgeons of our efficacy!'

Might IR applications also increase in oncology?
'Spain has one of the leading hospitals in liver cancer treatment: the Hospital Clínico in Barcelona. IR applications here are growing, especially in thermo-ablation or thermo therapy. Some specialists also perform Ytrio 90 radio-embolisation and a many work with electroporation NanoKnife and microwaves in pancreatic cancer and kidney tumours.'

How many interventional radiologists are there in Spain?
'SERVEI has 327 members; there are potentially more interventional radiologists in Spain. On average every centre has three to four specialists.'

Are there issues with contrast products or devices?
'Recently an important company had to take off one of its diagnostic catheters because of a series of bad events. The cause of this problem still needs clarification.'

What are the challenges in IR?
'We need good registries to assess our own activity and IR therapeutic efficacy compared to surgery.

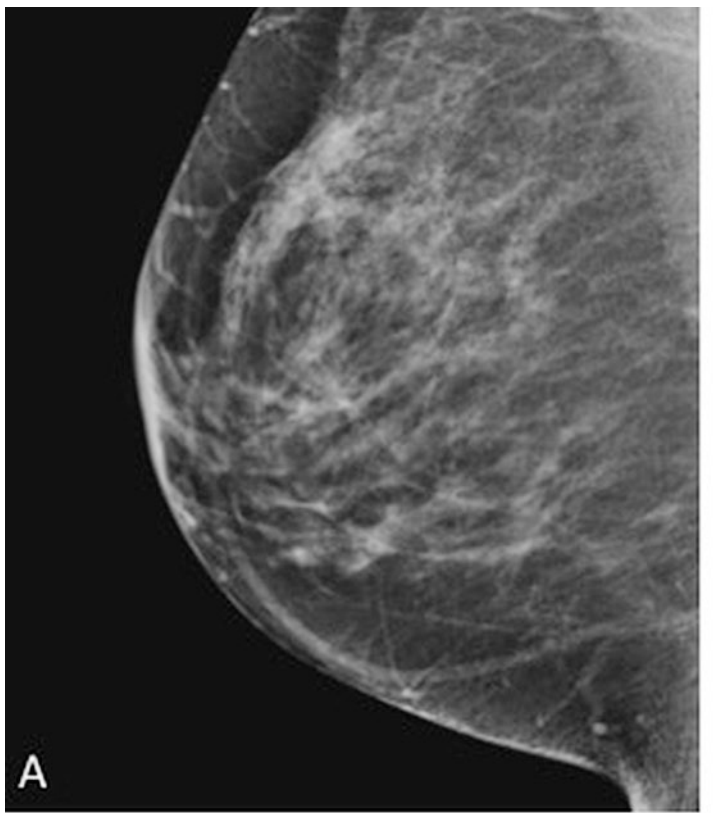
An interventional radiologist since 1997, **Fernando López Zárraga** was instrumental in establishing the vascular and interventional radiology department at Santiago Apostol Hospital, now part of Álava University Hospital. He is also second chair of the Executive Committee of the Spanish Society of Vascular and Interventional Radiology, as well as president of the society's annual congress in 2017 to be held in Vitoria – Gasteis. He was part of the working group for quality in a radio-diagnosis programme for the ISO 9001 (IQN – AENOR) Certificate and helped to establish protocols for on call security in Álava and the Codigo Ictus.

'Obtaining subspecialty certification would be another important step forward. We also need to become more visible to the patient. We are not regarded as interventionists; the referring clinician is. We must succeed in following up patients before and after an intervention. We are like navy seals: they only want us when things are going really badly!'

How can you rouse general radiologists' interest in IR?
'A part of training should be dedicated to learning basic interventional procedures. This is a challenge now with the 'core training' scheme, which fuses radiology and nuclear medicine during the first two years; but, if we succeed in being recognised as a subspecialty, students may have the opportunity to spend some time in our operating room (OR).

'The Fellows programme, being developed at 25 centres, and which can certificate IR in Spain, is a potential hotbed.'

Other specialists perform their own interventional procedures. What is the added value of being radiologists?
'We know imaging of all the body; we work not just on pathology but also everything around it. We have a sort of integrated GPS in our brain; this enables us to improve intervention quality significantly. It's a strength we should use. Also we know how to adapt and work with other medical professionals; collaboration is in our genes.'



Mediolateral oblique views of right breast in 49-year-old woman. A, Mammogram was reported as n image shows an architectural distorsion not visible in the standard mammography. Ultrasound and M underwent vacuum assissted breast biopsy under tomosynthesis guidance and the result of the histo was considered a false positive for tomosynthesis

Add US or to synthesis to

Report: Mark Nicholls

Italian-led research has highlighted the value of utilising additional screening technologies to help diagnose breast cancer in some women.

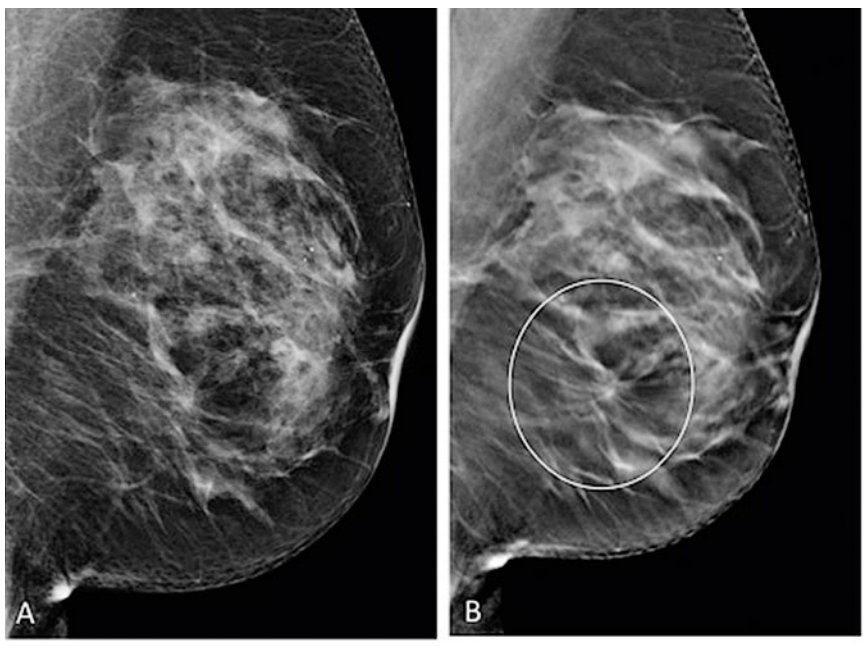
Interim analysis from the Adjunct Screening with Tomosynthesis or Ultrasound in Women with Mammography-Negative Dense Breasts (ASTOUND) study has delivered evidence of the potential benefit of adding either ultrasound or tomosynthesis to standard mammograms for screening women with dense breasts.

Heading the team of researchers, radiologist Dr Alberto Tagliafico, Assistant Professor of Human Anatomy at the University of Genoa, Italy, explained that interim analysis showed that ultrasound had better incremental breast cancer detection than tomosynthesis in mammography-negative dense breasts at a similar FP-recall (false positive) rate.

However, he pointed out that future application of adjunct screening should consider that tomosynthesis detected more than fifty percent of the additional breast cancers in these women and could potentially be the primary screening modality.

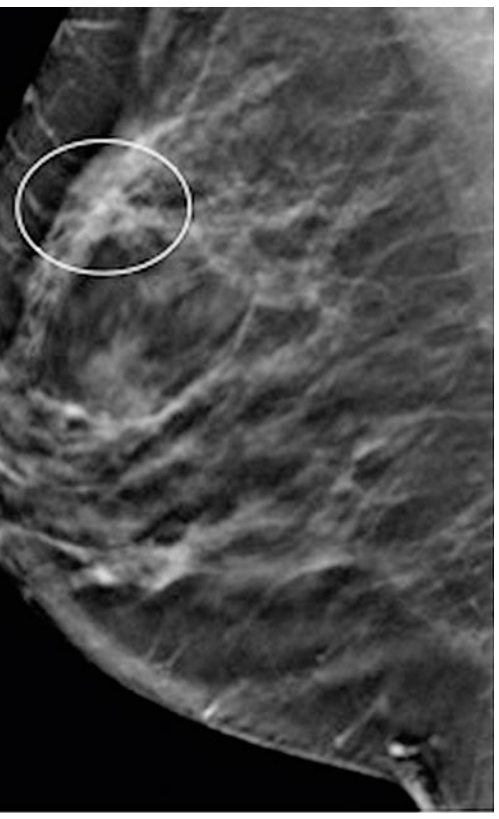
It is the first time the addition of ultrasound or tomosynthesis – which can detect breast cancer in mammography-negative dense breasts – have been directly compared when added to standard mammograms in prospective trials and comes at a time of on-going debate on screening in women with dense breasts.

For the prospective multicentre study, eligible women had tomosynthesis and physician-performed



Mediolateral oblique views of left breast in a 67-year-old woman. A, Mammogram shows normal fin distorsion (white oval). C, Ultrasound image demonstrates a small irregular hypoechoic mass with in An 5-mm invasive ductal carcinoma was diagnosed at histologic examination. Note that on DBT the radiating lines that converge to the lesion site. This case was considered a true-positive for tomosyn

Additional cancer screening for women with dense breasts



ormal. B, Tomosynthesis medio-lateral oblique view MRI examinations showed normal findings. The patient blogical exam was usual ductal hyperplasia. This case

omo-scans

ultrasound with independent interpretation of adjunct imaging. Outcome measures included cancer detection rate (CDR), the number of false-positive recalls, and incremental CDR for each modality.

Tagliafico said that, among 3,231 with dense breasts where standard mammograms had not detected any cancer, 24 additional breast cancers were detected.

Results published

The findings were presented at the 10th European Breast Cancer Conference (EBCC-10) in Amsterdam and published in the Journal of Clinical Oncology.

'Dense breast tissue, where there is a high amount of fibrous and glandular tissue in the breast, is not abnormal but makes it harder for standard mammography to detect any signs or other abnormalities that could be cancer,' Tagliafico said, adding: 'It also associated with a higher risk of developing breast cancer, for reasons that are not yet fully understood.'

Tagliafico said that although there were an additional 107 false positive recalls for further investigation they were shown to be false alarms on subsequent investigation and there was no difference in the additional false recall rate between tomosynthesis and ultrasound.

Nehmat Houssami, Professor of Public Health at the University of Sydney, who was also involved in the research with Genoa University's Tagliafico, commented that the findings would have 'immediate implications for both screening practice and for guiding new research in dense breasts.

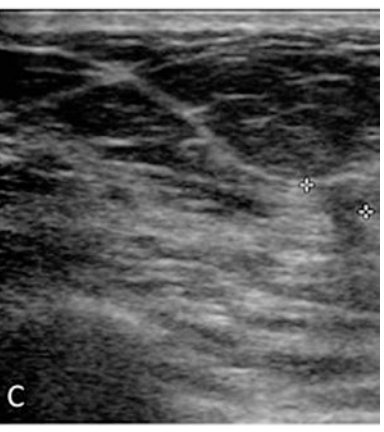
'We have found that ultrasound does better than tomosynthesis,' the professor added, 'but ultrasound is a separate test, it is time-consuming and, in less experienced hands, it can lead to a lot of false alarms.

'However, tomosynthesis, which is a form of refined mammography, can be carried out as part of the standard two dimensional mammogram screening, or even instead of that method.'

'Given that tomosynthesis detected more than fifty percent of the additional breast cancers in these women, the implications are that tomosynthesis has the potential to become the primary mammography screening method – without the need for an extra screening procedure.'

The researchers acknowledged that further research and cost analysis studies must be conducted before specific recommendations and guidelines could be issued or changes made to current screening practices.

Assistant Professor of Human Anatomy at the University of Genoa, **Alberto Tagliafico** is also a member of the European Society of Radiology, the European Society of Breast Imaging, and the European Society of Musculoskeletal Radiology. His research interests lie primarily in musculoskeletal and breast radiology.



dings. B, Tomosynthesis image shows an architectural distinct margins and posterior acoustic shadowing. image allows the radiologist to better visualize the thesis.

From qualitative to quantitative imaging

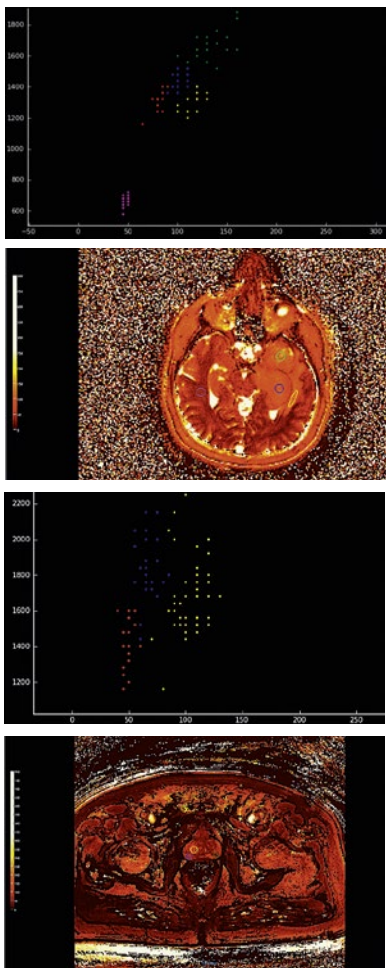
Magnetic Resonance Fingerprinting

From the beginning of MRI scientists dreamed of not only translating data sets into images, but also classifying tissue directly. Five years ago this would still have been inconceivable. However, MR fingerprinting might now make it possible to diagnose a disease from a distinctive combination of information about the tissue. This original technology is being largely driven by Case Western Reserve University and Cleveland University Hospitals, Ohio, with research support from Siemens Healthineers. Reto Merges, Head of Scientific Marketing for the Magnetic Resonance Business Line, discussed the technique and how it could change MRI diagnostics in the future.

Report: Karoline Laarmann

Just as each person has a unique fingerprint, each body tissue, whether diseased or healthy, also has an individual, physical pattern. This pattern is encrypted in signals sent by the tissue during an MRI scan. To date, it has only been possible to measure different signal intensities, which are then represented as light/dark contrasts on the MRI image. However, this qualitative and relative measurement alone does not allow for straight forward conclusions as to whether the tissue is healthy or diseased.

However, MR Fingerprinting (MRF) could open up entirely new opportunities for quantitative measurements, explains Reto Merges: 'This procedure now could make it possible to obtain quantified information about a tissue section without having to consult reference values. With this method we do not record the signal intensities of individual image sequences or weightings that can vary according to the device and data acquisition. Instead, we record the signal evolution from one single pseudo-randomized sequence that contains a multitude of parameters that can be characteristic for a certain type of tissue. These signal evolutions are correlated with simulations in a digital MRF dictionary, similar to a fingerprint, which is fed into a database to find out to which person it belongs.'



1.5T MR Fingerprinting T1 and T2 map of high grade glioma. MRF promises the possibility to differentiate solid part of tumour, central necrosis, lower grade part of tumour, surrounding oedema and tumour infiltration from normal appearing white matter. (Courtesy of Medical University of Vienna. MR Fingerprinting of the brain)

3-T MR Fingerprinting T1 and T2 map of a biopsy confirmed low grade prostate cancer. (Courtesy of University Hospital Essen, Germany. MR Fingerprinting of the prostate)

Currently this database, developed by researchers at Case Western Reserve University and the University Hospitals, contains simulations for all T-1 and T-2 weightings. The aim is to successively add simulations for other tissue features, such as relative spin density, B0 or diffision. The procedure is already delivering the first promising results, which radiologist Vikas Gulani and physicist Mark Griswold along with their US research team already presented in Nature magazine in 2013, attracting worldwide attention. At the moment the particular focus of clinical trials is on oncological applications for the head, prostate, breast and liver, but also for cardiac examinations and multiple sclerosis.

MRF advantages

Compared to conventional procedures for quantification MRF has the potential to offer some decisive advantages, Merges confirms. 'Firstly, the procedure is very fast. The various parameters are not consecutively recorded in different sequences but captured simultaneously. This not only shortens the examination period to just five minutes, but it also makes the procedure more robust. If a patient moves during a conventional MRI examination the entire aquisition sequence that has just been run can lose its diagnostic relevance. With the fingerprinting procedure the signal evolution measured up to that point remains useable.'

The procedure also copes very well with field inhomogeneities; whether or not a signal is a little stronger or weaker is not that important for the general pattern of the signal evolution. A further strength of MRF, along with its speed, is its great consistency. 'We are currently experimenting with transferring the procedure to different MRI scanners and field strengths,' Merges explains. 'The technology is now at a point where we have also been able to trial it in other international centres, such as Essen University Hospital and the Medical University of Vienna from the beginning of this year.

'Phantom measurements carried out with all of our clinical cooperation partners, have already shown that fingerprinting delivers consistent, comparable results measured on different devices and in different locations. This is an important step towards introducing MRF into clinical imaging. However, we currently cannot say exactly when this will be.'

After gaining an electrical engineering and IT degree at Karlsruhe Institute of Technology, Germany, **Reto Merges Dipl.-Ing** began his career at Siemens, developing segmentation algorithms for coronary artery segmentation on CT data. Based in China for four years, he built up an organisation for research collaboration for the CT division in greater China and South Korea. Within the Magnetic Resonance Business Line, Merges has held various positions in global marketing, which included heading the clinical marketing team, before he was appointed director of scientific marketing in early 2015. In this role he focuses on innovations, education and the future of value-based imaging.

SERAM President bets on education and professionalism

e-learning could help and certify radiologists

Dr Angel Gayete Cara took over the reins of the Spanish Society of Radiology (SERAM) in May, immediately after the society's meeting in Bilbao. In an exclusive interview with Mélisande Rouger he revealed his vision for the next two years and how he means to help radiologists in their increasingly clinical role

'Education is a top priority,' said Dr Angel Gayete Cara, newly appointed President of the Spanish Society of Radiology when asked about his agenda for SERAM. 'We are betting on e-learning to help and certify radiologists, both specialists and residents. We also offer transversal courses, for instance in publication and management, and are working on a university Master [degree] in quality in radiology management.

'Radiographers want homologation at the European level and we absolutely support this claim. Recently we published a manual for their attention. We try to integrate them as much as possible in our activities.

'EU member states must transpose Council Directive 2013/59/Euratom into national law by 6 February 2018; this directive will change substantially the way we register dose and dose value levels. We are working together with the industry and health ministries and other scientific societies to help integrate these aspects in daily practice.

'We are also very concerned about technical obsolescence, as Spain has some of the oldest imaging equipment in Europe.

'Additionally, we work to improve professionalism by publishing good practice guidelines and tackling issues related to management, quality, risk planning or informed consent. We are developing models for imaging equipment contests together with the industry and radio physicians to help radiologists in this complex task.

From left to right: Dr. Ángel Gayete (SERAM president), Dr. Cosme Naveda (Bizkaya, Board of Doctors President), Mikel Alvarez (Bilbao City councilor), Iñaki Berraondo (Basque Country Health Planning and Evaluation director), Dr. José Luis del Cura (SERAM immediate past president), Dr. Arsenio Martínez Pérez (SERAM meeting Local Organizing Committee chairman), and Dr. José Carmelo Albillos (SERAM meeting Scientific Committee president)

'Furthermore, we plan to organise meetings with professionals from partner disciplines to determine ways to assess treatment response and potentially publish guidelines together. We are also considering the possibility of acting as mediators between research groups and the industry, by helping them get in touch and following up on their projects. We see ourselves as a possible intermediary between both parties.'

Rouger: General elections will soon be repeated in Spain but the 'core training', in which radiology and nuclear medicine are fused for the first two years of a four-year plan, is going ahead. What is SERAM's position on this matter?

'We can't legislate but we can opine. We have representatives who work on the issue with the authorities. It's an important challenge; depending on how the situation evolves, radiologists' training may change a lot in the near future. The number of places available for radiologists may be reduced and tutors would need to be trained adequately.

'But we don't want to assume that it will be two years of core training and two years of specialisation in radiology. The ministry itself said that skills first need to be evaluated, so this is what we'll do, bearing in mind that the European recommendation is a five-year training plan.'

How did the society's meeting go and what can you tell us about the next?

'We had 1,933 participants this time, 122 more than last year, and 35 industry exhibitors. We hope to have more delegates during our next gathering, to be held in Pamplona in two years. We are just beginning to decide on the programme. Certainly there will be contents on the increasing role of imaging in treatment response evaluation in oncology and other fields of personalised medicine.'

Are Spanish radiologists coping better with austerity and shortages?

'We are coping with difficulty, patience and compromise! Staff shortage and terrible contracts mean there is work overload for acting radiologists to manage waiting lists. Coupled with technical obsolescence, this can be a challenge for patient safety and it generates inequity in assistance. The situation is more precarious in some regions than others, and each has its own problems; for some it is radiotherapy, others PET/CT, etc. The situation is heterogeneous and definitely improvable.'

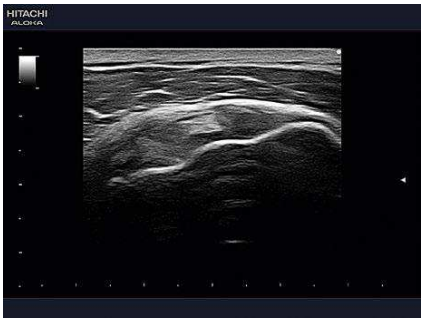
What are today's biggest radiology challenges?

'With the growing number of clinical applications, tools and minimally invasive procedures in both diagnosis and treatment our role is increasingly clinical. Long gone are the days when radiologists sat alone in a basement! We are now

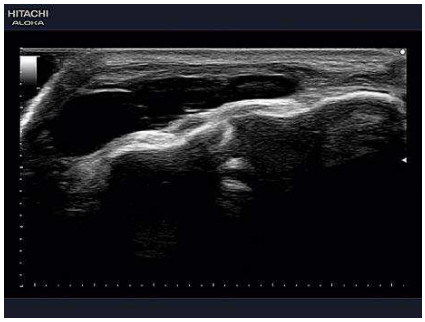
Compact and powerful: ARIETTA Prologue muscles up capabilities for MSK exams and interventions

Hitachi puts punch in portablility

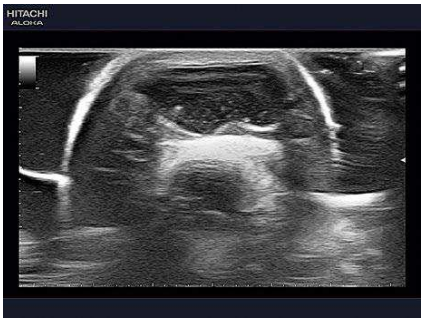
When Ferdinando Draghi, M.D. speaks, the world of ultrasound listens carefully. The Editor-in-Chief of the Journal of Ultrasound, the author of 90 publications that have been cited in other peer-reviewed publications hundreds of times, Dr. Draghi is widely known for his authoritative knowledge in diseases affecting the musculoskeletal (MSK) system.



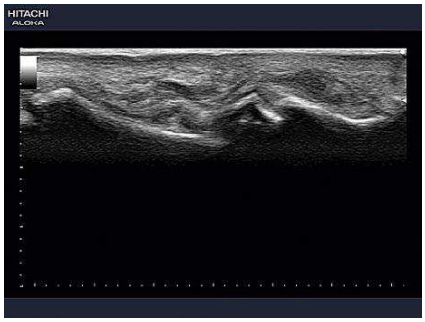
Shoulder with inflammation



Mucoic cyst (ganglion) 4th finger attached to the metacarpal articulation below



Inflammatory lesion 1st finger – axial view



Rheumathoid arthritis 2nd finger

Thanks to the ongoing technological development of hardware and software, he recently wrote, ultrasound has acquired a leading position for the diagnosis of MSK conditions as it is inexpensive, non-invasive, easily available and dynamic. Sonography is also proving to be an excellent technique for guiding therapeutic procedures with an ability to monitor in real time interventional tools, such as needles and catheters.

He literally wrote the book that serves as a reference for Ultrasonography of the Upper Extremity. And over the past three years has published papers that share his experiences with ultrasound evaluations of lower extremities such as the knee and the ankle.

Seeing and treating MSK disease is his main focus at the Fondazione IRCCS Policlinico San Matteo in Pavia, Italy, a university hospital of 1,000 beds where he is Director of the unit of ultrasound and diseases of digestive system of the Institute of Radiology.

Ultrasound plays a highly important role in the study of tendons of the hands and wrists, he notes, as well as providing essential information of other structures including bones, cartilage and synovial membranes.

Increasingly the enhanced power of high-end systems, such as platforms from Hitachi, are enabling studies of the nerves, vital for an evaluation of conditions such as Carpal Tunnel syndrome.

The ARIETTA Prologue system has become a workhorse at the IRCCS Policlinico, used in everyday practice thanks to what Dr. Draghi called it "great manageability, particularly thanks to the advantage of working with the detachable monitor."

"The ARIETTA Prologue can be handled like a tablet or a smartphone, something especially attractive for younger sonographers without posing any particular problems to us, older practitioners," he said.

Functionalities can be managed using the detachable screen with a user interface on a touch screen that Dr. Draghi said he finds is easy and intuitive with an image quality equal to the cart-based ARIETTA systems used by the Institute of Radiology.

Designed to bring high-end capabilities to the frontline of healthcare, Hitachi refined the technology behind its ARIETTA line of ultrasound platforms to give the ARIETTA Prologue a compact design that makes it highly mobile with a wireless connection between the base unit and the detachable monitor without any deterioration of image quality and delay.

"Certainly the small size and easy handling make this equipment particularly suitable for bedside examinations that become easier and faster," he said.

Dr. Draghi said that with the high image quality, along with the compact and portable design, he now brings the ARIETTA Prologue with him into the operating suite for ultrasound-guided interventional procedures.

"We use it in everyday practice but especially for ultrasound-guided therapy of the musculoskeletal system," he explained. "We normally use the 18Mhz probe that helps us to get a very good image quality and the Needle Emphasis (NE) function to enhance visualization of the needle, increasing the safety for the patient and the accuracy of the procedure."

Ferdinando Draghi, M.D., is a leading member of the Società Italiana di Ultrasonologia in Medicina e Biologia (SIUMB) and leads the society's study group on Musculoskeletal Sonography. A featured speaker at international congresses, he is a prolific author of scientific papers and serves as the editor of the SIUMB's Journal of Ultrasound since 2010. He is also an adjunct professor at the School of Radiology Technologists and of Orthopedic Technologists of the University of Pavia and director of the simple unit of ultrasound and diseases of digestive system of the Institute of Radiology, IRCCS Policlinico S. Matteo, Pavia.

Ángel Gayete Cara is clinical head at Parc Salut MAR (PSMAR), Hospital del Mar, in Barcelona. He is also vice president of the Docent Commission at Parc Salut MAR and Chair of Radiology at the Medical Faculty of Universitat Autònoma de Barcelona and Universitat Pompeu Fabra in PSMAR. Previously, he served as Head of Education of SERAM and Chair of the Education Committee of the Catalan Association of Medical Radiology and the Catalan Society of Imaging Diagnosis and Radiology. He is immediate past president of the Spanish Society of Chest Imaging (SEICAT) and sits on the Board of Directors of the Under- and Postgraduate Education Section.

part of team meetings and care units as much as other medical specialists. If these changes are not well addressed, then we have complicated situations, such as the lack of regulation surrounding teleradiology, which we addressed in our 2015 good practice catalogue, or there are turf battles with other healthcare professionals, for instance in echography, and vascular and cardiac imaging. Being experts in imaging, we should lead its applications and user education. This is a permanent and constant challenge.

A universal platform at the heart of communication

Cardiac IT made simple

When Michael Ziller, Head of IT at the Bethanien Hospital in Moers, Germany, was looking for a provider of cardiac IT applications that not only offered standard applications for ECGs as well as long-term ECGs and long-term blood pressure measurements, he realised there was not much on the market. 'We had an additional challenge for this project in that we wanted all data to run via just one server,' he explains. The hospital opted for a product called SEMA supplied by SCHILLER AG, which allowed us to customise and further evolve it

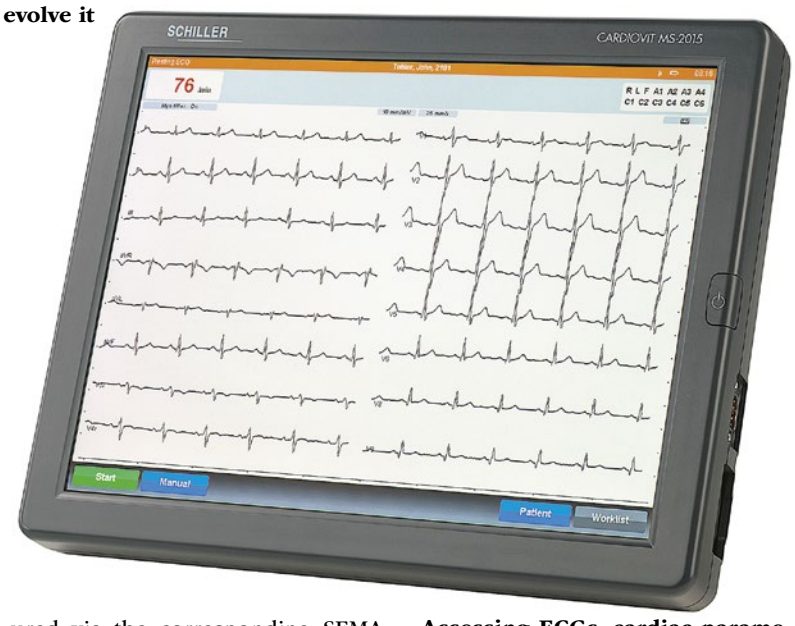
The particular feature of an IT project at Bethanien Hospital was that there was no comparable solution available based on using just one communication server, until Schiller's introduction of SEMA 3, Michael Ziller, the hospital's IT head, explained: 'The implementation at Bethanien Hospital was basically a joint effort as both parties could mutually benefit from their respective experience.'

The platform covers everything

SEMA 3 is a platform that covers all needs, from measuring to evaluating ECGs, including resting and stress ECGs. Additionally, the data collected can also be evaluated with the standard IT sub-systems used in cardiology.

The big advantage is that SEMA 3 is a collection point for all ECGs recorded in the hospital. 'This applies to PC-based ECGs as well as those measured on mobile devices,' Ziller explains. 'Mobility and mobile devices are increasingly important for us. We have an additional six mobile devices next to our five PC-ECGs. These are tablets we can use to access the ECGs from any location in the building.'

The ECGs can be directly measured via the corresponding SEMA-Client without needing to communicate with the server. Younger generation doctors particularly take advantage of this benefit. 'We've found that old-school cardiologists prefer to work with known templates. The generational change is clearly visible and we have to adapt technologically,' Ziller believes. It is a clear advantage that both options can be implemented with Schiller's technology.



Assessing ECGs, cardiac parameters or cardiac catheters together on one viewer

Organised chaos

The 510-bed Bethanien Hospital needs to organise patient flow and data volumes well. 'In our case this means duplicate data management,' Ziller points out. 'Doctors receive patient data via an interface on the HIS and it is processed via HL7. This means the doctor makes a request, which also appears on the SEMA Client, i.e. on the individual ECG devices. To ensure there are no mix-ups each ECG device has its own name.'

Then the respective patient only appears on the allocated ECG device because only one device is individually accessed. This avoids chaos in the database. 'No other procedure is conceivable given the large patient flow in our hospital and the enormous volume of ECG data,' Ziller explains.

A big advantage: one viewer

After the completion of an ECG measurement the data is sent directly into the PACS as DICOM data. 'All Non-DICOM data is visualised with JiveX. The advantage is that this PACS-viewer allows the visualisation of data from several systems at the same time and next to one another. We can assess ECGs, cardiac parameters or cardiac catheters together, without needing different versions or viewers,' Ziller reports.

'Ultimately, this was why we chose SEMA 3. It was also important for me that all modalities that can transmit images, from C-arms to ECGs to endoscopies, are organised via one viewer and that doctors don't have to view different monitors and specialist software.

'We obviously also save on software licensing fees in this way.'

A further advantage is that all recorded ECGs can be re-measured via JiveX. Ziller: 'Maybe this is not as cleverly done as it is with SEMA but, for our purposes, it's perfectly adequate.'

Michael Ziller has worked in the information technology department at the Bethanien Hospital in Moers, Germany, for 14 years. Over the last decade, as head of the department, he has been responsible for all IT processes in the hospital.

Updates and upgrades

Updates carried out over the last few years have also all been successful. After all, it is not customary that updates are carried out on individual devices little by little. 'Normally all Clients need to be directly updated once the server has already received a new version,' he explains. 'This would be difficult to do in day-to-day hospital operation. With SEMA 3 we can upgrade the devices individually to the new versions, depending on which Client is available at the time. Even if the server has already been upgraded the Clients can still work with the old version.'

For Ziller, this leaves nothing to be desired for the future. 'The system is running continuously and we are more than satisfied with it. If the Diagnosis Client was also run via the web this would enhance mobility in the hospital even further.'

To maximise IT benefits team insecurities must be overcome

Fear defeats progress

The development of a healthcare IT infrastructure in European hospitals faces two major hurdles, Ben Giese reports: 'contradictory return on investment (ROI) reports and the unquantifiable risk of security breaches'

Known and quantifiable – Industry will pitch to clinicians and administrators the ever-increasing benefits of IT implementation within multi-functional institutions or individual private practices. Indeed, the accurate, easily accessible flow of all healthcare delivery data can provide benefits. For example, lead poisoning of the public water source in Flint stands out. Paediatrician Dr Mona Hanna-Attisha utilised the searchable electronic records database of Epic Systems to discover parameters indicating population poisoning – impossible to demonstrate otherwise. However, such solutions carry impressive price tags. The wide-ranging deal between the Mayo Clinic and Epic broke the billion-dollar threshold.

Even smaller medical systems face impressive bills from electronic medical record (EMR) vendors, plus poor results and internal strife. England's Cambridge University Hospital engaged with two prominent vendors to overhaul its IT systems – cost £200 million. The implementation is not going well. The BBC reported that multiple high-level departures began within a year into the 10-year deal.

The institution received poor quality control (QC) ratings, e.g. EMR operability is insufficient, partially due to the new system's rollout. In New England, the South-Coast Health Group cited its new EMR implementation costs forced the lay off nearly 100 staff members in March.

These, say industry providers, are isolated examples appearing as 'front and centre' exceptions to a generally successful but rarely headline-grabbing service. However, many of Europe's segmented, smaller, conservative hospital systems use that negativity as evidence that full scale digitisation is not worth the cost, especially if economies of scale cannot be realised at individual institutions. Both are somewhat correct. If an institution is tied to short term ROI and that success is measured in immediate procedural efficiencies alone, the investment will not be worthwhile. If success is measured more holistically and contains much harder to quantify parameters, including overall population health, reduction of errors, and a database of medical records accessible by a range of users for research and predictive analytics, the investment is entirely justified.

The unknown and unknowable

Hospitals are increasingly influenced by and driven towards IT reliance – whether internally sanctioned or mandated by regulatory bodies. Hospitals have had plug-and-play operating systems for years and use of networked devices is exponential. Hospital employees access multiple interfaces concurrently, creating massive challenges in authentication and open portals to large swaths of data.

Highlighting this danger, an NHS report found that 72% of logins had no time limit, 87% of staff could log into multiple units and 44% had no unique login whatsoever. In patient data security alone there is an open invitation to nefarious intentions.

In reality, individuals and organisations view healthcare systems as a prime target for cyber-attacks, for they fulfil a checklist of characteristics that make them vulnerable and attractive. Security is not part of a mentality born of open scientific research. To be effective, communication systems and patient records need real-time access and manipulation by many staff members.

Legacy devices, from multiple vendors, employ myriad operating platforms and, paradoxically, the maker is responsible for their security. Yet, these systems control life and death and hospitals are targets considered worth the time of hackers.

Progress

Directors need to help produce a comprehensive risk assessment and mitigation plan – alongside hospital IT specialists and all higher administrator levels, enabling everyone to discover and admit on-going deficiencies, engage with outside consultants, and most importantly, become aware of and report on possible vulnerabilities in their existing responsibilities. This goes well beyond the medical staff – the costliest data breach in history, credit card data theft at US 'Target Stores', originated with a hack in a networked HVAC unit.

Initially survey hardware, software and data

IT departments should be able to identify data sources from networked devices and data entry, the types of data transferred and stored, and the channels and locations through which the information is transferred and stored. This is the foundation of protection. Any mitigation is based on an accurate catalogue of assets – both physical and digital.

Intermediate term – risk evaluation

Many European hospitals have no dedicated IT security employee, but the evaluation should be developed in conjunction with knowing risks to the individual systems. Thus an outside expert should evaluate the initial IT infrastructure survey and provide an accurate risk assessment. This will involve an outcomes assessment following a malicious attack and the likelihood of a breach. For example, at one extreme, if a networked ventilator is easily hacked, it is top priority. Or, what can wait is a staff member perhaps accessing the EMR of a past romance, although against protocol this happens more than any administrator wants to admit.

Action

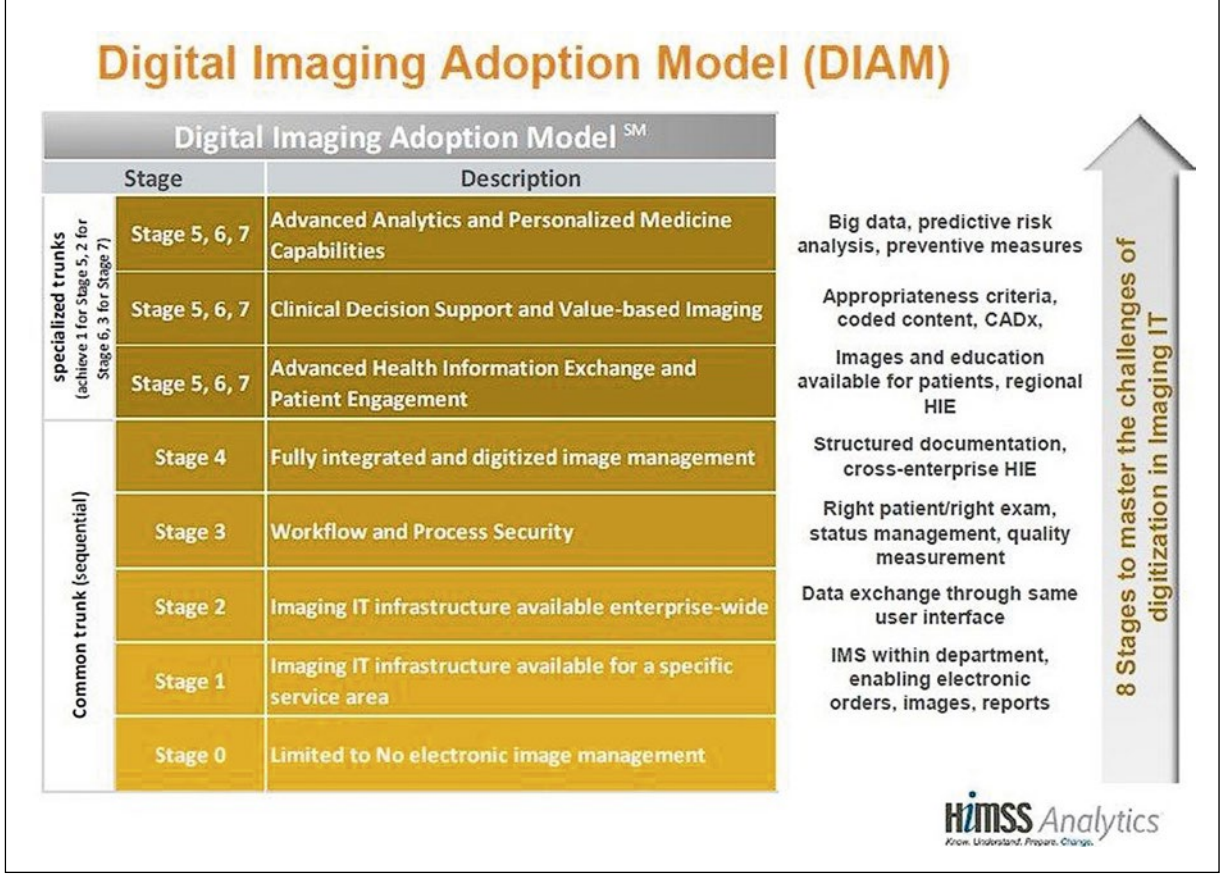
An evaluation and recommendation report must be generated and shared with stakeholders, to ensure awareness of potential threats and agree to an action plan. This crucial step ensures clear understanding of a threat, actions taken, everyone's responsibilities and any risk remaining. The proactive stance this process achieves allows institutions to maximise existing systems efficiency, now free of the paranoia of not knowing an actual risk level. As an added benefit, purchasing decisions are simplified with vendors by concisely communicating the security expectations in new device and software acquisition, implementation and use.

The on-going discussion of data management efficacy within institutions remains dynamic. An evaluation of existing and future systems, plus costs and benefits, cannot be accurately achieved unless the parallel issue of security is managed in a holistic and honest discourse, with agreed action plans. Over a longer period this will add overall cost though a patchwork of reactive security measures. Innovation will also suffer as hospitals develop a bunker mentality towards a threat, which, although real and permanent, is manageable.

Hospital managers face a plethora of questions in IT choices

DIAM guides vital IT decisions

Which is the best way to implement imaging IT in a hospital? How can new technologies be integrated into existing IT infrastructures? What risks are associated with our systems? The Digital Imaging Adoption Model (DIAM) is a new benchmark 'designed to support healthcare facilities with the analysis, planning and implementation of a digital strategy in their imaging departments,' explains Dr Peter Mildenberger, Professor of Radiology at Mainz University Hospital, in Germany, who is also the initiator of the annual DICOM meeting held in Mainz.



Partners HIMSS Analytics in Europe and the European Society of Radiology (ESR) presented the model to the healthcare community at ECR 2016. 'While using a similar approach as EMRAM, DIAM goes far beyond the EMRAM parameters,' Mildenberger points out.

A scoring system defines parameters in 10 areas

DIAM encompasses eight stages of a digital imaging adoption strategy with 0 denoting 'low maturity' and seven 'advanced maturity'. A scoring system of more than 100 indicators defines parameters in ten areas, such as software infrastructure, health information exchange, workflow and process security, quality and safety management or patient engagement.

'In a way,' Mildenberger explains, 'it's a self-assessment of the participants. They complete a survey covering general data, such as department size, number of employees and exams, etc. However, it also includes questions regarding a RIS, or the link between department and RIS, the use of language recognition, and it asks how many reports are processed and when.'

However, benchmarking specific equipment or employees is not within the scope of the analysis.

The participating facility receives the results of the analysis – a detailed report on the strengths and weaknesses of the IT structure surveyed, including potential areas of investment or specific compliance objectives for each stage.

Professor Peter Mildenberger, Senior Resident at the radiology clinic in Mainz University Hospital, heads Image Data Management in which he is responsible for all operations. His particular interests lie in radiological software applications – image processing, archiving and communication systems (PACS), telemedicine, eHealth, and eLearning.

What's in it for a hospital? With the project still in the pilot phase in Mainz University Hospital, and several European facilities, a definite assessment is not yet available.

Assessing any problems in the infrastructure

Professor Mildenberger is, however, sure that DIAM can support users and buyers of imaging technologies with their operative and strategic decisions. 'It's important for decision makers to see whether their institution has a well-crafted infrastructure, or whether there are problems lurking that nobody has noticed yet, or where the improvement potential is.

'Last, but not the least, DIAM can help hospital management to pursue the right digital strategy when planning or investing in IT projects.' Experts from HIMSS Europe or ESR are available to support these endeavours.

Discussed with SAP at conhIT 2016

Offbeat ideas for bespoke therapies

Report: Sascha Keutel

'Big Data analysis,' explains Dominik Bertram, SAP Development Manager and Head of the Personalised Medicine section at the SAP Innovation Centre in Potsdam, 'allows us to tailor therapies better, based on the individual patient's status – that is to implement personalised healthcare.'

Patients are developing from payers to players, and are informed, moving in digital networks and playing an active role in their own medical care, Bertram points out. 'As healthcare providers we must rethink our preconceptions and see the patient as consumer. But if we want to place the patients at the centre of our endeavours, we have to know their needs.

'In our SAP Innovation Centre we try to facilitate this transition. Here, our staff can test unconventional ideas in a protected space, develop them and turn them into marketable applications. It is our aim to open new markets and create new business models and disruptive technologies for SAP.'

However, he added, very early on identified consolidating data from different sources as a problem. 'Medical facilities use dozens of different IT systems, populated with relevant patient data: radiology and pathology images, genome data or clinical studies to name a few. The data are scattered all over the place, nobody can access all of them and we have problems interpreting them.

'With the SAP Foundation for Health we created a platform that offers healthcare organisations, life sciences companies and research institutes, a tool to cull valuable medical information from Big Data analyses.'

Applications

Based on the SAP HANA platform, the solution is a flexible and scalable data warehouse model for clinical information and industry-oriented data integration management, he explained. 'It integrates data from different clinical source systems, be it patient data, biomedical data or clinical studies. It is configurable and can analyse each data pool individually.'

This solution is the foundation for the Medical Research Insights application, which enables patient data access in real-time, and profile comparisons from different sources.

Projects

Bertram: 'Particularly in oncology, physicians want to exchange data and they confirm that the more we know about individual tumours and cancer types the more they are recognised as individual rare diseases.

'Moreover, it is well known that many cancer patients do not respond to chemotherapy. We have to personalise cancer therapy more strongly; therefore, we are, inter alia, working on a joint project with the German Cancer Research Centre in Heidelberg. Their specialists at the National Centre for Tumour Diseases offer their patients a genome analysis of their cancer cells, and individual therapy recommendations are based on the results of this analysis.

'The possibility to compare profiles from different sources helps the Heidelberg team to decide quickly and easily which patients fulfil defined inclusion or exclusion criteria for a certain study. Previously, databases had to be searched manually; patient lists compiled and patient records reviewed. The new solution dramatically shortens study times.'

Anonymity – a major challenge

'If we anonymise data parameters we protect the patient, but compromise the data set's useable value. It will be impossible to achieve 100 percent anonymisation while maintaining the full use value of the data. Here, we have to find a balance.

'In Germany, or Europe for that matter, we create many obstacles for progress. We have to be able, obviously with the patient's consent, to use the patient data for research purposes and to exchange the data with other institutions. If we can't do that for many pathologies, we will not have sufficient case numbers to map them.'

Patients publish their data from wearables and apps on the internet, but legal requirements exist to protect that. How does SAP tackle this contradiction?

'Our approach is "cooperation" – we talk to physicians and patients. Whilst some patients are concerned about privacy, at the same time they don't want their data to be buried so deeply that they are no longer useful. It's in the patient's interest to provide data access for the physician, to receive the best possible treatment.

'We must be transparent about the conditions for data exchange. Without clear standards we run the risk of data being channelled to businesses where they are abused for commercial purposes or – even worse – that the data are moved and processed outside the EU and any control over the data is lost.'

Resolving the problem – standards

'We see a great need for networks. Big Data, genome analyses, you name it – healthcare is, above all, one thing: it is complex! There are not only innumerable diseases of any level of complexity, there are also many different players who must cooperate: in- and out-patient care, medical technology, pharmacies, and so on.

'What is really stunning is that, even today, communication between these players is barely digitised. This is what we are aiming at: we must establish a digital health network in which all parties involved can exchange patient data – certainly with full legal. In this scenario, healthcare services play an important role; my physician, for example, could send me a medication plan on my smartphone or, if I had a chronic disease, I could share my digital journal with my physician. I see many benefits for patients and physicians alike.'

After completing computer science studies at the Karlsruhe Institute of Technology (KIT), in 2006 **Dominik Bertram** joined the software development team for Lifecycle Management at the SAP HQ in Walldorf, Germany. In 2014 he moved to the firm's newly founded Innovation Centre Network in Potsdam, to head the 'Personalised Medicine' section.

NHS England adopts Translational Medical Information Server (TMIS)

Integrating imaging and metadata on any device

England's NHS has received an advanced medical imaging and genomic data integration platform from a global healthcare information systems specialist, Mark Nicholls reports

A Translational Medical Information Server (TMIS) that aims to prevent adverse medication events, assist in pre-operative genomic screening and establish telemedicine networks is being adopted by NHS England's Open Source and Code 4 Health Programmes.

Developed by Kanteron Systems (founded 2005), the TMIS platform integrates genomics, pharmacogenomics, digital pathology, radiology, biosensors, and analytics into a single unified workflow at the point of care.

The system can, for example, allow oncologists to access radiologists' images and studies, pathologists' biopsies and reports, lab genomics sequences, pharmacogenomics databases, and biosensors' readings and combines all that information to enable analytics via single-sign on, single interface, and single point of access.

Shawn Larson, Senior Project Manager at the Health and Social Care Information Centre and creator of the OpenPACS project, explained the agreement with Kanteron brings the NHS a set of 'quality, cutting edge and medical device certified diagnostics' combining, he added, imaging genomics and pathology into a single system.

Accessed via NHS England's Open Source/Code 4 Health repository and managed on an on-going basis by a clinically led NHS custodian group, this will take NHS informatics capability to a new level, with Open Source now a 'genuinely viable and affordable alternative to proprietary solutions.'

The company reports that the National Health Service will make financial savings by improving patient outcomes via improvements in the diagnosis of conditions including cardiovascular disease, cancer, obesity and diabetes; support personalised therapies; and deliver more focused medication.

Founder and CEO of Kanteron Systems, Jorge Cortell, said that, as a complete personalised medicine solution, TMIS integrates 'silos' currently existing in many hospitals such as genomics, pharmacogenomics, digital pathology, radiology, biosensors, and analytics into a single unified workflow to produce a complete visualisation with deep integration, enabling researchers and clinicians to reach precise diagnostics with ease and speed. 'While any of those components provide all the functionality needed by each area, when we connect them, tremendous synergies and efficiencies are enabled, such as Virtual Multidisciplinary Collaboration, Adverse Medication Event Detection, Radiomics Analysis,' he added.

NHS institutions gain unlimited access to Kanteron's TMIS platform source code and free use. For Kanteron this entails close NHS collaboration to co-develop specific tools and functions needed by the clinicians.

The system works via a web browser and runs either on-prem or in the cloud to provide data (including imaging and metadata) storage, management, integration, collaboration, normalisation, as well as visualisation.

Shawn Larson is a Senior Project Manager at the Health and Social Care Information Centre and creator of the OpenPACS project. Following 18 years in frontline diagnostic imaging, he spent time in industry and private healthcare before joining government healthcare IT where he has been involved in a variety of national projects.

Currently with customers in 15 countries, Kanteron reports that the key benefits for the NHS in terms of workflow, cost and clinical outcome will be increased interoperability, enhanced collaboration, faster diagnoses, improved diagnostic tools, flexibility, better control of the data, avoidance of vendor lock-in, and considerable savings.

Cortell: 'Our experience in other countries is that patients benefit from faster diagnosis, access to their own data (if hospital administrators allow it), reduced errors from identification to double data entry or adverse medication event, and overall improved outcomes.'

Other areas it will be particularly beneficial are those involving complex cases and a multitude of tests, exams, images and reports in oncology, cardiology, neurology and so on, will particularly benefit most from the integrated platform.

Work with NHS pilots currently using the in-built development platforms to enhance and innovate the system is continuing, as well as progression in existing relationships with higher education institutions, schools of radiology and universities to create a unified diagnostics solution, and to continue to promote the growth and adoption of open source in the NHS.

Founder and CEO of Kanteron Systems, **Jorge Cortell** lived in New York, but moved to London with his family to personally support and manage the collaboration with the NHS. Kanteron Systems has offices in New York, London, Lima, as well as a European HQ in Valencia.

OT efficiency impacts on quality care

Given mounting financial pressure, a hospital needs greater efficiency in medical service structures. Staff and materials for operating theatres (OTs) account for about a third of the overall expenditure. Working closely with all other hospital departments, OT efficiency can affect a hospital's overall efficiency and costs, reports Cornelia Wels-Maug

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45133 Essen, Germany
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Subscriptions
Janka Hoppe, European Hospital,
Theodor-Althoff-Str. 45, 45133 Essen, Germany
Subscription rate
6 issues: 42 Euro, Single copy: 7 Euro.
Send order and cheque to:
European Hospital Subscription Dept
Printed by: WVD, Mörfelden-Walldorf, Germany
Publication frequency: bi-monthly
European Hospital ISSN 0942-9085

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Operating theatre management was established to ensure better deployment of theatre resources by

- Ensuring patient safety during surgery
- Ensuring that all clinical departments have access to the OR-facilities
- Maximising the use of theatre resources
- Minimising waiting times for surgical procedures
- Enhancing satisfaction among patients and staff.

However, to measure the efficiency of a given OT, as well as the quality of its performance clearly defined, measurable indicators are needed to establish a reliable set of benchmarks as opposed to relying on qualitative impressions as to how well or badly the perioperative process has been executed.

Professor Martin Schuster MD, Head of the Department of Anaesthesiology, Intensive Medicine, Emergency Medicine and Pain Management, at the Fürst-Stirum-Klinik, Bruchsal, Germany, was among a group of physicians and OT managers who set up a benchmarking programme for perioperative process data: 'It's really hard to know how many resources are used per patient per surgery,' he explained. 'For this, you need to know all the different processes involved in a procedure, from entering the pre-operative unit all the way to leaving the operating theatre. To obtain reliable, reproducible data, a group of hospitals has united to define the different underlying processes and agree on indicators to build up a repository for benchmarking data.'

Beginning in 2009, with 20 hospitals and about 192,000 data sets, there are now (in 2016) 220 participating hospitals, which produce more than 1.5 million data sets per year.

Although the definition of the key indicators for the benchmarking platform are handled by a clinical consortium consisting of the Working Group on Key Figures of the Association of OT Management (VOPM), the German Association of Anaesthesiology and Intensive Medicine (DGAI), the Professional Association of German Anaesthetists (BDA) and the Professional Association of German Surgeons (BDC), all aspects associated with the collection of data are taken care of by Hamburg-based digmed.

This company is responsible for ensuring that the used infrastructure is compliant with current safety and privacy legislation. 'At the very beginning, we handled the data ourselves at Göttingen university hospital,' Schuster added, 'but when this became too contentious, we decided to transfer the job to a neutral intermediary – digmed.'

Hospitals transmit the data electronically to digmed. Those measurements have already been generated as part of a hospital's routine documentation of each OT case and reside in its hospital information system. However, the data transfer is not in real-time, but typically occurs once a month. In turn, the Hamburg firm performs a centralised plausibility test of the data, e.g. 'anaesthesia administered prior to incision time' points to a problem in the data set and the reporting hospital is asked to check its data.

Designated users of all registered hospitals can access the database via an internet portal to look at their institutions' data and compare them to the overall benchmark. 'The data is used to generate reports as well as benchmarks. We also offer the option to compare an institution with its peers. For example, a university hospital can measure its performance with that of other university hospitals', Schuster points out.

However, the data is not accessible for non-participating institutions. 'Modifications and the achievement of objectives can be monitored continuously and made generally available by means of an adequate communication structure', he stresses.

To ensure a high rate of acceptance among hospitals, the benchmarking process is governed by the underlying principles of 'origin and quality of data', 'usefulness and benefit' and 'safety and acceptance'. The actual set of key indicators for process efficiency presently comprises 38 measurements, among them 'Start-time tardiness', Suture-to-incision time', 'Changing time', 'Incision-to-suture time', 'Degree of OT capacity utilisation', 'Number of surgical interventions', 'Total incision-to-suture minutes per case' and 'Staff costs per surgical intervention/incision-to-suture minute'. Schuster calls attention to the fact that distribution curves are often more meaningful than absolute values and shares some snippets of the insights from the benchmarking exercise.

'Delays in transporting the patient to the operating theatre are the number one cause for tardiness of surgeries.

'Additionally, there is often no positive linear relationship between the frequency with which an operation is performed and the time the procedure takes.'

By using the data provided by digmed, participating hospitals have the tools to render their OT processes more efficient, hence, creating additional value for their institutions. However, as useful these key indicators may be, Schuster also warns: 'They are important tools, but there are pitfalls associated with them because one needs to know exactly how to interpret them, especially around utilisation rates and turnover times.'

As the quality of the benchmark is positively linked to the number of participating hospitals, it will be important, for the future, to win additional institutions and, with it, additional data sets. This will also open the door for applying analytics to the data to uncover hitherto undetected relationships between the process times and the quality of medical care.

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