Endoscopy jumps the boundaries

‘Health insurers should keep a tighter rein on the quality of endoscopic interventions because, mostly, they represent a gentler alternative to surgery,’ asserts international expert Horst Neuhaus, during an EH interview with Daniela Zimmermann.

In selected cases in the context of studies this latter technique involves insertion of an ultra-thin catheter into the cyst. This allows us to produce endomicroscopic images with a resolution equivalent to what the pathologist sees under the microscope; i.e. current data indicate that we can diagnose safely and can classify our findings as malignant or not. ‘However, it doesn’t always have to be endomicroscopy.’ The new, high-resolution endoscopes are helpful in the early detection of cancer of the digestive tract because we have long-standing training in the recognition of changes to the structure of mucosa and vessels; the key word here being neo-angiogenesis.’

For Neuhaus and team the endoscope offers a gentle method to complement biopsies with interventional imaging diagnostics. ‘When the image has been produced it obviously needs to be assessed. Studies and Working Groups that classify the images, and pathology colleagues who take a look at the images, are helpful here.’

Cooperation with colleagues is very important because, in early stages of cancer in different organs, including the oesophagus, stomach, pancreas and others, there’s always a certain percentage of patients who will have to undergo surgery. ‘The patient benefits from the fact that we can offer everything in one location.’

Diabetes – a new area for endoscopy

The teamwork also continues with diabetologists, with whom Neuhaus, in partnership with the medical technology industry and in the context of international multi-centre trials, is working on a new procedure to treat Type 2 diabetes. ‘Half of all diabetic patients have a raised HbA1c level. We know that patients with a gastric bypass, where the surgeon connects the remaining part of the stomach with the small intestine and therefore disconnects the duodenum, not only lose weight but also that their diabetes improves. One of the reasons for this appears

continued on page 8
Report: Anja Behringer

The precious number of adverse clinical events is difficult to ascertain. Several international studies estimate that medical errors happen in 5-6% of all hospital treatments and that around 30-50% of these could have been avoided. A hospital-acquired infection (HAI) is also considered a medical error. For the past few years, the relevant commissions and medication bodies in Germany reported stable figures: around 25% of 8,000 alleged medical errors investigated were indeed classified as such. However, the number of alleged medical errors has risen significantly every year during the last decade, with a current estimation of more than 60,000 per year. According to the most recent figures, 1,380 patients suffered irreversible health damage, 150 died.

In view of this situation, in 2013 the health objectives working group (Gesundheitsziele) declared patient safety to be the new national health objective. Moreover, safe patient care was included in the Patient Rights Act in 2015. Since 2014 the Federal Joint Committee, (Gemeinsamer Bundesausschuss), the highest decision-making body in German healthcare self-governance, has mandated that hospitals implement more and significant measures regarding patient safety. Modern error management is mostly based on the data is non-compliant, thus significant. All systems are integrated into the certification specs and include a wide range of error analysis: risk management has been integrated into the certificate "Thoracic Centre (DGT)."

Errors are unavoidable but rare in thoracic surgery

Stringent medical risk management

President of the German Society for Thoracic Surgery (since 2009), Christian Kugler is also Medical Director of the Department of Thoracic Surgery at Lungen Clinic, Grosshadern, near Munich, with medical studies and dissertation at Ludwig Maximilian University Munich (LMU) behind him, Kugler became a junior physician at the Department of Cardiac Surgery, Munich, Grosshadern University Hospital, and later at Ulm University Hospital. He trained in thoracic surgery at the Heidelberg Thoracic Clinic. Up to 2009 he was senior consultant at the Department of Thoracic Surgery, Hamburg Thorax Centre, Harburg General Hospital [currently Asklepion].

In German hospitals, medical treatment errors account for 19,000 patient deaths every year, according to the 2014 Health Insurance Scheme Hospital Report. Mistaken patient identity is cited among the errors, which also include interchanged drugs or incorrect drug dosages. A mobile phone and fit easily into any coat pocket. The long-life battery allows several days without recharging. A special advantage is that we supply each unit with a JavaScript license and a selection of pre-installed applications. Code scanners are usable via Bluetooth or WLAN. For safe, quick working, the reader provides feedback about a successful scan. For this the user can choose between an LED, audio sound or a vibration signal. It is also possible to switch off the acoustic signal and to activate it only if the data is non-compliant, thus significantly reducing the background noise in everyday hospital life, the firm reports.

The application can be used during surgical discharge, after X-ray exams or when admitting in-patients.
g the use of nurses

The firm’s report found that, of the 152 FTs (around two-thirds of trusts in England), half ended the year in deficit, with 70% of them acute trusts.

In addition, the waiting list for operations at FTs grew by 8.5% to nearly 1.8 million.

Dr David Bennett, Monitor’s chief executive, observed: ‘The last financial year was exceptionally challenging for the Foundation Trust sector, and it’s clear the current one is following the same pattern. The sector can no longer afford to operate on a business as usual basis, and we all need to redouble our efforts to deliver substantial efficiency gains in order to ensure patients get the services they need.’

Whilst that could lead to changes at some hospitals, Monitor believes this can be carried out ‘without compromising patient care’.

Amongst concerned reaction to the deficit from analysts and organisations across the health sector, Richard Murray, director of policy at The King’s Fund think tank, said the fact that deficits had occurred despite extra money being provided by the government was disappointing. ‘Plugging the growing black hole in NHS finances must now be an urgent priority for the government,’ he added.

NHS Providers’ CEO Chris Hopson said: ‘Despite providers’ best efforts, accident and emergency, referral to treatment, diagnostic wait and a range of other targets have also been missed, representing a rapid and widespread deterioration in NHS performance and finances.’

BMA council chair Dr Mark Porter expressed extreme concern regarding the extent of the deficit financial pressure many hospitals are under. ‘The prices paid to hospitals for work done are being cut year on year to drive ‘efficiency savings’, but the effect is that hospitals are being pushed into deficit. This is no way to run a health service ...’ On behalf of the BMA, he added: ‘We call on government to move away from the current approach to one of investment in health.’

Rob Webster, CEO of the NHS Confederation (representing some 500 organisations that commission and provide NHS services) said the report provided a clear indication of the pressures faced by the NHS but welcomed the Prime Minister’s commitment to find at least €11bn extra investment in the NHS by 2019-20 following the debate around the health service during the general election.

However, he stressed: ‘We now need to change the way care is delivered in many parts of the NHS, with new models of care, backed by strong support from national bodies and politicians. This looks within our grasp if we align behind the Five Year Forward View, secure sufficient funding and back the NHS to deliver.’

Labelling

The challenges of automating a laboratory, whether for the first time or the third, can be formidable. So having a partner with extensive experience can be the key to achieving your goals. Perhaps that’s why more laboratories around the world rely on Siemens for total laboratory automation than any other company.

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Answers for life.
Country profile: Fighting infectious diseases

Interview: Daniela Zimmermann.
Report: Brenda Marsh

Although Romania joined the EU in 2007, only recently has its macroeconomic increases influenced a rise in a middle class and dented the country’s widespread poverty. However, developing countries are still vulnerable to corruption and red tape in its commercial world. Through the post-communist years and EU involvement, various IME, EU and other financial agreements have been made to encourage structural reform and strengthen the financial sector’s stability.

In 2013, Romania’s economic growth rose due to strong industrial exports and an excellent agricultural harvest, and the country’s current account deficit was substantially reduced. At the end of 2014, the economy showed a 2.8% growth – lower than the 3.5% posted in 2013. Industry output came top in revenues with exports (70% to the EU) still behind the 3.5% posted in 2013. Industry reduced.

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although Romania joined

UK will...
cut non-essential medical care

The AMRC hopes the campaign will change the way medicine and medical treatments are prescribed and believe it could potentially have far-reaching implications for the nature of healthcare in the UK, as it has in the USA, Canada and Australia. In Canada, for example, the Choosing Wisely project has already identified treatments whose value should be questioned with patients. They include exercising restraint when ordering X-rays for lower back pain; avoiding the use of antipsychotics as a first choice to treat behavioural and psychological symptoms of dementia; and not prescribing antibiotics for patients with upper-respiratory infections that are likely to be viral in origin.

“This requires a culture change within the NHS but it is a real opportunity to truly put patients first,” Malhotra believes. “I also believe it has the potential to improve health outcomes for our patients in a relatively short space of time. But it is an opportunity for us as medical professionals to really make an impact to improve health and reduce demand on the service.”

AMRC chair, Professor Dame Sue Bailey: “The whole point of Choosing Wisely is to encourage doctors to have conversations with their patients and explain honestly what the value of a treatment is. It’s not, and will never be, about refusing treatment or in any way jeopardising safety. It’s just about taking a grown-up approach to healthcare and being good stewards of the resources we have.”

The AMRC paper published in the British Medical Journal has indicated that a culture of more is better, where the onus is on doctors to ‘do something’ at each consultation, has bred unbalanced decision making. The authors added: “This has resulted in patients sometimes being offered treatments that have only minor benefit and minimal evidence despite the potential for substantial harm and expense.”

Cardiologist Dr Aseem Malhotra, from the AMRC, points out that this culture stems from defensive medicine, patient pressures, biased reporting in medical journals, commercial conflicts of interest, and lack of understanding of health statistics and risk. “Over-diagnosis and over-treatment are the products of a broken system. For the sake of our patients there needs to be a radical overhaul in culture.”

Rather than focusing on a system of payment by results – which encourages doctors and hospitals to do more – the AMRC report suggests that guideline committees should increasingly turn their efforts towards the production of tools that help clinicians to understand and share decisions on the basis of best evidence.

They say it is time for action to translate the evidence into clinical practice and truly wind back the harms of too much medicine.

The world’s largest medical fair

Shanghai hosts the Chinese products gain quality and sophistication

UK will cut non-essential medical care

many foreign companies showed interest in partnerships. Part of the rationale for combining the three events was the interest by pharma distributors, with hospital presidents in tow, in branching out beyond pharma and big-ticket imaging products (CT and MRI). Competitive pricing and controls over abuse of prescriptions and exams are having an impact on sales, and new opportunities are opening for IVD and some other equipment. Many manufacturers used the venue to hold distributor meetings with their partners from China, Southeast Asia and the Middle East.

Raphael Ravet, sales manager for Cefaly Technology, maker of migraine headache relief headgear, found many attendees eager to take a break on the relaxation chairs.

The autumn CMEF – 18-21 October, Wuhan International Expo Centre – will focus solely on medical equipment, accessories and reagents, and include the International Component Manufacturing and Design show.

In spring, the 2016 CMEF will be in Shanghai again, and the organiser is considering staggering days for pharma and devices to relieve transportation issues to the world’s largest medical product show. Meanwhile, the Shanghai government will continue to extend the infrastructure to ease coming and going, as well as to find lodging and entertainment nearby. For any medical device company considering entry into the Chinese market, this is where it happens.

Moving healthcare forward

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Learn how at Clinical Lab Expo Booth #2409
**Austria’s notable national action plan**

Surveillance, hygiene and infection prevention, antimicrobial stewardship, diagnosis of infectious diseases, use of antimicrobial medicines as well as reporting and information – Michael Krasnitszky reports.

In Europe, Austria statistically ranks in the midfield for antibiotics resistance. In 2013, for example, the country’s Methicillin-resistant Staphylococcus aureus (MRSA) rate was at 9.1%. In comparison, the rate in Sweden was 0% and in Greece around 50%. The issue of antimicrobial resistance is very complex. Therefore we need a concerted strategy to fight this resistance,’ says tropcal medicine and hygiene specialist Professor Petra Apfalter DTMH, who heads the Austrian National Reference Centre for Nosocomial Infections and Antimicrobials Resistance.

In Austria, the Federal Ministry of Health and the National Action Plan for Antibiotics Resistance (NAP-AMR) has been publishing an annual report on antibiotics resistance and antibotics use (AURES) since 2005. In surveillance and reporting Austria fares well. The country’s Federal Ministry of Health has been publishing an annual report on antibiotics resistance and antibiotics usage (AURES) since 2005. In surveillance and reporting Austria axes well. The country’s Federal Ministry of Health has been publishing an annual report on antibiotics resistance and antibiotic usage (AURES) since 2005.

Additionally, for a decade this country has been involved in the European networks for the collection of data on resistance: EARS-Net (European Antimicrobial Resistance Surveillance Network) and ESAC-Net (European Surveillance of Antimicrobial Consumption Network). The NAP-AMR has also uncovered improved potential variation. It contains objectives to capture the most comprehensive data on antibiotics use, to promote feedback systems for surveillance data and to develop information media for the general public. Whilst AURES is well established in specialist readership, the level of general public knowledge is pitiful. According to a Eurobarometer survey around 73% of Australians believe that antibiotics are also effective against viruses.

In respect of hygiene and infection prevention and control the objective, according to the NAP-AMR, is to further develop the existing strategy to consolidate hospital hygiene structures (PROHYG 2.0). This describes the organisation framework for important measures of infection prevention and control in hospitals, such as hand hygiene and hand disinfection. Based on this, a draft quality standard was compiled last year and will be published towards the end of 2015.

A further important component of the NAP-AMR is the National Action Plan for Antibiotics Resistance (NAP-AMR), which concerns the optimised use of antibiotics in veterinary medicine. In Austria there are 40 laboratories that make their bacteriological findings available – not everywhere with high quality because currently no binding standards are in place. The NAP-AMR therefore campaigns for a centralisation of microbiological diagnostics. Sweden, where just a few facilities are responsible for the enrolment of areas of the population, is considered as a role model.

The country has been involved in the National Action Plan for Antibiotics Resistance (NAP-AMR) for a decade this country has been involved in the European networks for the collection of data on resistance: EARS-Net (European Antimicrobial Resistance Surveillance Network) and ESAC-Net (European Surveillance of Antimicrobial Consumption Network). The NAP-AMR has also uncovered improved potential variation. It contains objectives to capture the most comprehensive data on antibiotics use, to promote feedback systems for surveillance data and to develop information media for the general public. Whilst AURES is well established in specialist readership, the level of general public knowledge is pitiful. According to a Eurobarometer survey around 73% of Austrians believe that antibiotics are also effective against viruses. According to the National Action Plan for Antibiotics Resistance (NAP-AMR) is the antimicrobial resistance: global report on surveillance 2014.

**Antibiotic resistance: the biggest single threat to global health**

Within 15 years effective antibiotics will run out and, far from being an apocalyptic fantasy, a world in which common infections and minor injuries can kill is a very real possibility for the 21st Century. One of the world’s foremost wound experts has warned that antibiotic resistance is posing the biggest single threat to global health, Mark Nicholls reports.

Professor Geoff Sussman is concerned at over-prescribing and misuse of antibiotics in clinical practice as well as how they seep into the food chain through inappropriate use – to protect against disease and stimulate growth in animal husbandry and breeding.

Unnecessary and incorrect restrictions are implemented in antibiotics use; he fears the consequences will be disastrous, with drugs that will no longer be effective against infections.

Outlining his concerns to the annual meeting of the International Wound Infection Institute in London, Professor Sussman said: ‘Within the next 15 years we will run out of effective antibiotics against the majority of any antibiotic to which the organism is resistant.’

He said: 'This is a problem,' he added. Professor Sussman, who is also a senior clinician in wound clinic at Melbourne’s Austin Hospital. ‘There is no cure for antibiotic-resistant disease. We have no antibiotic that can cure all infections. We must work together to find new antibiotics and develop new treatments.’

Also, in surgery, it is not uncommon to use prophylaxis before an operation. 'That’s acceptable but some doctors continue using the antibiotic for another five days. That’s no longer prophylactic, that is therapeutic and the overuse of the antibiotic.'

**Bring in stricter controls**

Overuse is common in General Practice with patients demanding antibiotics for colds and sore throats that are virus based and in this area of medicine he believes governments must implement stricter controls on where and who can prescribe some of these more potent antibiotics. 'A bigger problem,’ he pointed out, ‘is in parts of the world such as Asia where you do not need to see a doctor or get a prescription for antibiotics. You just walk into a store and buy them with no restrictions at all.'

To help counter antibiotic resistance, Professor Sussman believes hospitals must work harder to control hospital-acquired infections, curb nosocomial infections with improved cleaning regimes and restrict antibiotics for use on only very serious infections.

Few new antibiotics have been seen in 40 years because it is not economically viable for industry to develop drugs that patients will only use for a matter of days and he believes it should fall to governments to look at ways of funding research and developing new antibiotics.

Sussman also favours a plan unveiled in a report from a UK government-appointed review team in May calling on the global pharmaceutical industry to pay a 2.5 billion innovation fund to revitalise research into antibiotics. In return, guarantees could be given to companies that produce vitally needed new antibiotics.

The move was linked in response to so few new antibiotics in development amid a global spread of resistant bacteria.

The professor also wants to see science develop innovative ways of attacking the bacteria other than antibiotics. ‘There are mechanisms that can attack bacterial cells and do not involve antibiotics. Those methods are then less likely to run into the problems of resistance.’


It states: ‘Antimicrobial resistance (AMR) threatens the effective prevention and treatment of an ever-increasing range of infections caused by bacteria, parasites, viruses and fungi. An increasing number of governments around the world are devoting efforts to a problem so serious that it threatens the achievements of modern medicine. ‘A post-antibiotic era – in which common infections and minor injuries can kill – far from being an apocalyptic fantasy, is instead a very real possibility for the 21st Century.’

Areas taking a pro-active stance are Scandinavia and Australia, which has had therapeutic guidelines of antibiotic use for some years though many countries do not have them in place. ‘But we have seen a concerted effort from the very beginning.’

The World Health Organisation is already Joint Bermuda, the United States, Japan and other countries that will be discussed in the future. The World Health Organisation is already Joint Bermuda, the United States, Japan and other countries that will be discussed in the future.

“People and governments can travel to the other side of the world within a day and we need to develop regulations that apply worldwide.” However, this is a difficult task – considering that, even within the European Union, there are countries that do not even comply with the basic rules outlined in the NAP-AMR.

‘In Austria, and many other EU countries, antibiotics can only be prescribed by the doctor. It can be obtained through prescriptions. In Spain, however, everyone can buy antibiotics in the supermarket.’

Tober also pointed out the need to develop regulations that are binding worldwide. ‘This is why the World Health Organisation take over the reins to control antibiotics resistance.’
About 6-8% of Spanish patients will develop an infection during or after a hospital stay. Can these infections be avoided? How is Spain facing up to the challenge? Dr Juan Pablo Horcajada, Head of the Department of Infectious Diseases at Hospital del Mar, Barcelona, and spokesperson of the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC), assessed the situation and insisted on the creation of a dedicated specialty in an exclusive interview for EH by Mélisande Rouger.

As the trend for ambulatory care grows, patients may acquire an infection during their hospital stay but will actually develop a nosocomial infection when back home. For instance, chemotherapy patients, who tend not to be hospitalised any more, may develop an infection a few days after receiving treatment.

‘The number of ambulatory patients in healthcare is increasing. Therefore we prefer to use the term healthcare-associated rather than nosocomial infections, as the latter only refers to hospitalised patients,’ said Dr Juan Pablo Horcajada, Head of the Department of Infectious Diseases at Hospital del Mar, Barcelona. Two of the most frequent healthcare-associated infections (HAIs) are urinary infections and pneumonia. Surgery patients, who are increasingly sent home a few hours after the procedure, may also develop post-surgery infections. Another area doctors are particularly wary of is bacteremia, i.e. the presence of bacteria in the blood, which can develop after placing catheters in the circulatory system as part of treatment.

Dedicated commissions regrouping doctors from every specialty are put in place at every hospital across Spain to monitor infection development and review antibiotics use. Since 2009, as part of diagnostic and antimicrobial stewardship strategies, Hampshire Hospitals National Health Service (NHS) Trust has used serum procalcitonin (PCT) – an innovative and highly specific marker to diagnose clinically relevant bacterial infections and sepsis.

Consultant Clinical Microbiologist and the Director of Infection Prevention and Control, Dr Kordo Saeed, explained: ‘In our experience, the integration of the PCT assay to our clinical practice, has not only led to safe reduction in unnecessary antibiotic usage and costs in our Trust, but has also potentially resulted in reduction of selective pressure on antibiotics and on hospital beds.’

In early June, Dr Saeed outlined his hospital’s success in ‘rapid proc- alcitonin assay in diagnosis and monitoring of sepsis’ during the national meeting of the Association for Clinical Chemistry and Laboratory Medicine in Cardiff, Wales. There he examined the ‘potential impact and the usefulness of a rapid “quantitative” point-of-care (PCTc) testing in the context of reconfigurations and mergers of diagnostic laboratories.’

Procalcitonin has become increasingly popular since mid-1980s and is interests clinicians because it appears to be more specific for bacterial infection, particularly when there are systemic features or sepsis.

This has proved advantageous because it enables clinicians and hospitals to make more informed decisions on treatment, particularly when clinical presentations of some viral infections, inflammatory conditions and bacterial infections can be similar, making a clinical diagnosis and appropriate treatment of infection challenging.

‘Additionally,’ Dr Saeed said, ‘clinical signs and laboratory findings may be subtle in the early stages of infection. There is a tendency among many clinicians to treat for potential infection if they have doubts, just in case the cause is infectious. This in turn leads to inappropriate antibiotic use and higher costs. PCT also has other advantage because, apart from being more specific for bacterial infections than other biomarkers, it is quick and relatively easy to measure.

‘Anything that can complement our clinical findings in a timely manner and support differentiating bacterial infection from non-infection can help to improve not only patient management, but also the appropriateness of use of antibiotics. In this context and in our experience PCT appears to be an effective marker,’ he said. Research published by Dr Saeed and colleagues has suggested that in about 50% of those ‘just in case’ cases, PCT has resulted in either withholding and/or stopping antibiotics without adverse effect in those patients, whilst continuing antibiotics in cases of patients who need antibiotics. ‘Overall by introducing PCT, there were around 15% reductions in antibiotic use and, based on British National Formulary prices, this has resulted in direct savings in antibiotic usage of around £14,450 ($20,000) for every six months,’ he added. There are additional savings from hidden costs associated with giving antibiotics, such as IV sets, pharmacy time, nursing time and storage. PCT has helped the clinicians to make clearer decisions on giving antibiotics to patients who need them, but also preventing patients unnecessarily receiving antibiotics or suffering adverse effects of antibiotics.

In the case of sepsis, PCT has been a major benefit. Dr Saeed concluded: ‘Diagnosis of Sepsis can be challenging and we need biomarkers that can assist doctors to diagnose sepsis in a timely manner in order to achieve the best outcome for patients. Real life evaluations of the newer and more rapid PCT test in Emergency Departments, General Practice and/or inside ambulances may provide us with additional armaments to achieve this.’

However, he stressed procalcitonin is NOT a magic bullet, and like other clinical tests, PCT results must not be acted upon as an individual marker or without considering full history, physical exam and other investigational findings. ‘It is,’ he said, ‘part of a jigsaw and can be used to complement clinical judgments and physical examinations.’

Carrying home a nosocomial infection

In Spain, the number of legal actions taken against doctors for HAI cases is rising, a phenomenon spreading from the USA. Instead, patients should acknowledge that every procedure carries a risk, which doctors can only try to minimise, Horcajada believes. ‘Maybe our problem is lack of communication. If patients were well informed about the risks and took greater part in their treatment, they would not think of suing their doctors. Somehow, the doctor-patient relationship was lost and we need to get it back. The moment it’s back, I don’t think we’ll have a problem anymore.’

Horcajada deplores the short time doctors can spend with patients under the current scheme, and warned against the impact of money-saving policies on healthcare quality. ‘His wish is for the establishment of a proper infectious diseases specialty in Spain. ‘Currently infectious diseases are a subspecialisation of internal medicine, whilst they are a proper specialty in many other countries. If this were the same in Spain, HAI’s management would certainly improve.’

Antibiotics tend to be given too often and used for too long

## NEWS & MANAGEMENT

### Antimicrobial stewardship strategies

**Summary**

- **A diagnostic marker requires antibiotics use**
- **Carrying home a nosocomial infection**

**Key points**

- **Antimicrobial stewardship strategies**
  - **Procalcitonin (PCT)** is a useful marker for bacterial infection and sepsis.
  - **Hampshire Hospitals National Health Service** has seen reduction in antibiotic usage and costs.
  - **Sepsis** can be challenging, and biomarkers like PCT are helpful.

**Further reading**

- Saeed, K.: Innovative and highly specific marker – procalcitonin assay in diagnosis and monitoring of sepsis.
- Horcajada, J.P.: Diagnosis of Sepsis can be challenging and we need biomarkers that can assist doctors.

**Image credit**

- Kordo Saeed is Consultant Clinical Microbiologist and the Director of Infection Prevention and Control at Hampshire Hospitals NHS Foundation Trust and also an Honorary Senior Lecturer Southampton University Medical School.

**Report: Mark Nicholls**

**About**

- **Medicine** in Cardiff, Wales. There he examined the ‘potential impact and the usefulness of a rapid “quantitative” point-of-care (PCTc) testing in the context of reconfigurations and mergers of diagnostic laboratories.’
- Procalcitonin has become increasingly popular since mid-1980s and is interests clinicians because it appears to be more specific for bacterial infection, particularly when there are systemic features or sepsis.
- This has proved advantageous because it enables clinicians and hospitals to make more informed decisions on treatment, particularly when clinical presentations of some viral infections, inflammatory conditions and bacterial infections can be similar, making a clinical diagnosis and appropriate treatment of infection challenging.
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- ‘Anything that can complement our clinical findings in a timely manner and support differentiating bacterial infection from non-infection can help to improve not only patient management, but also the appropriateness of use of antibiotics. In this context and in our experience PCT appears to be an effective marker,’ he said. Research published by Dr Saeed and colleagues has suggested that in about 50% of those ‘just in case’ cases, PCT has resulted in either withholding and/or stopping antibiotics without adverse effect in those patients, whilst continuing antibiotics in cases of patients who need antibiotics. ‘Overall by introducing PCT, there were around 15% reductions in antibiotic use and, based on British National Formulary prices, this has resulted in direct savings in antibiotic usage of around £14,450 ($20,000) for every six months,’ he added. There are additional savings from hidden costs associated with giving antibiotics, such as IV sets, pharmacy time, nursing time and storage. PCT has helped the clinicians to make clearer decisions on giving antibiotics to patients who need them, but also preventing patients unnecessarily receiving antibiotics or suffering adverse effects of antibiotics.
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- However, he stressed procalcitonin is NOT a magic bullet, and like other clinical tests, PCT results must not be acted upon as an individual marker or without considering full history, physical exam and other investigational findings. ‘It is,’ he said, ‘part of a jigsaw and can be used to complement clinical judgments and physical examinations.’

**Carrying home a nosocomial infection**

- About 6-8% of Spanish patients will develop an infection during or after a hospital stay. Can these infections be avoided? How is Spain facing up to the challenge? Dr Juan Pablo Horcajada, Head of the Department of Infectious Diseases at Hospital del Mar, Barcelona, and spokesperson of the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC), assessed the situation and insisted on the creation of a dedicated specialty.
- As the trend for ambulatory care grows, patients may acquire an infection during their hospital stay but will actually develop a nosocomial infection when back home. For instance, chemotherapy patients, who tend not to be hospitalised any more, may develop an infection a few days after receiving treatment.
- ‘The number of ambulatory patients in healthcare is increasing. Therefore we prefer to use the term healthcare-associated rather than nosocomial infections, as the latter only refers to hospitalised patients,’ said Dr Juan Pablo Horcajada, Head of the Department of Infectious Diseases at Hospital del Mar, Barcelona.
- Two of the most frequent healthcare-associated infections (HAIs) are urinary infections and pneumonia. Surgery patients, who are increasingly sent home a few hours after the procedure, may also develop post-surgery infections. Another area doctors are particularly wary of is bacteremia, i.e. the presence of bacteria in the blood, which can develop after placing catheters in the circulatory system as part of treatment.
- Dedicated commissions regrouping doctors from every specialty are put in place at every hospital across Spain to monitor infection development and review antibiotics use.
Genetic alteration

Professor Christine Mannhalter highlights the impact changes have on the occurrence and severity of diseases and their influence on therapy response.

Many different genetic alterations (mutations) influence the clinical phenotypes of monogenic and polygenetic inherited but also somatic diseases. Germ line mutations that confer a severe impact on the phenotype are usually found in rare diseases (orphan diseases). In contrast, common germ line mutations (polymorphisms) with little negative selection pressure occur frequently in the gene pools of populations (e.g. the factor V Leiden mutation, associated with venous thrombosis, has a frequency of about 5% in Caucasians). It is important to be aware that mutation carriers do not always develop the disease. Furthermore, mutations do not necessarily lead to the same phenotype in every mutation carrier, which is due to endogenous and exogenous modulators.

Up to now, the influences of modulators are not well known, and it is often difficult to predict the consequences of a mutation for individual patients. Despite these limitations, genetic tests are very valuable because they allow the early detection of mutations and are important for diagnosis, prognosis, prediction of relapses, selection of therapies, monitoring of therapy responses and family studies (identification of carrier relatives).

This article discusses examples of applications of genetic analyses in coagulation disorders and haematological and oncological diseases.

**Molecular genetic analyses in coagulation disorders**

Most proteins involved in blood coagulation are well characterised, and their genes have been cloned and sequenced. Nevertheless, genetic tests during imatinib-therapy may occur, which is usually due to mutations in the BCR-ABL1 fusion gene. Monitoring of minimal residual disease with molecular genetic tests during multi-therapy is of high importance. If BCR-ABL1 is detectable, sequence analysis has to be performed to identify the type of the mutation. This is relevant for treatment switch to other tyrosine kinase inhibitors.

In chronic myeloproliferative disorders, point mutations can be disease relevant in hematologic leukemias. Until about a decade ago, no molecular abnormalities were known for polycythemia vera (PV), essential thrombocythemia (ET) or myelofibrosis (MF). The discovery of a point mutation in codon 617 (valine to phenylalanine) of the JAK2 gene in a large percentage of these myeloproliferative neoplasms increased our understanding of these diseases and improved their diagnosis. The Molecular genetic analyses in haematology-oncology

The finding that every gene has a specific position in the genome is of central importance. The loss of the appropriate position by e.g. translocations or inversions usually leads to significant changes in the gene expression and subsequently to severe diseases. Chronic myeloid leukemia (CML) is a stem cell neoplasm caused by the reciprocal translocation t(9;22). The translocation generates the fusion gene BCR-ABL1, which is found in leukaemic cells of more than 95% of human CML patients and about 30% of adult patients suffering from ALL. BCR-ABL1 is a constitutively active tyrosine kinase activating several signalling pathways. The constitutively active tyrosine kinase is responsible for impaired apoptosis and uncontrollably proliferation of cells, and the initiation and manifestation of the disease.

The identification and understanding of the molecular lesion led to the first targeted therapy. The first BCR-ABL1 kinase inhibitor was imatinib, a small molecule, which inhibits the catalytic domain and stabilizes cytogenetic responses in a majority of patients in chronic phase of CML.

Although a large percentage of patients show complete cytogenetic responses, disease recurrence or resistance may occur, which is usually due to mutations in the BCR-ABL1 fusion gene. Monitoring of minimal residual disease with molecular genetic tests during multi-therapy is of high importance. If BCR-ABL1 is detectable, sequence analysis has to be performed to identify the type of the mutation. The type of the mutation is relevant for treatment switch to other tyrosine kinase inhibitors.

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This is where the endoscope comes into play - by helping the doctor to insert a special balloon in to the duodenum, heating it and ablating the mucosa. The duodenal mucosa regenerates, but then appears to have different characteristics from the original one, he said, summarising the result of a pilot study in a Chican hospital.

In Europe this new procedure is currently being tested in several clinical centres including, in Germany, the Evangelical Hospital in Dusseldorf. Two other German hospitals will also participate.

The basis for this advance in intervention is the continuous technology development. ‘It’s not only about the camera but also about the control and mobility of the endoscope, which has to be thin enough to enter the small channels in the gastric wall in addition, without a very good flushing function we cannot carry out any surgical intervention’, Neuhaus said, mindful of the interest in cooperation with the industry. ‘The devices need to be developed further, and engineers regularly visit to watch us at work. With them we discuss various possibilities based on clinical need.’

To promote the international exchange on procedures and technologies, many years ago Neuhaus founded the International Endoscopy Symposium, held annually in Dusseldorf.

‘What’s on the 2016 agenda? ‘Our work increasingly revolves around treatment and intervention, but also good diagnostics must not be neglected. The new possibilities offered by interventions under endoscopic ultrasound guidance are particularly exciting. In one endoscopy intervention, they are examining several organs and positioning stents to create anastomoses, for example after stomach surgery,’ Neuhaus said. ‘In addition, small intestinal surgery, for example after gastric bypass, small intestine. Moreover, new opportunities to carry out endoscopy of the entire colon without using a colonoscope are possible in a targeted fashion in certain organs or tumours certainly will be on the 2016 agenda.’
Evolutionary POCT

Report: Mark Nicholls

A growing number of clinical tests are being delivered in community hospitals with more patients receiving quicker, accurate diagnoses closer to home, without stays in acute hospital beds. Professor Daniel Lasserson, an Associate Professor in the Nuffield Department of Primary Care Health Sciences at Oxford University, shares the opinion that using point-of-care-testing (POCT) to facilitate high quality ambulatory care is a critical step towards defining hospital care in the future. As a senior interface general practitioner (GP) within the Oxford University Hospitals NHS Trust, he is part of the medical team working on the Emergency Multidisciplinary Unit (EMU) at Abingdon Community Hospital and sees patients referred from GPs, community nurses or paramedics. Supported by nursing, physiotherapy, occupational therapy and social work teams, and with access to X-ray, the availability of POCT enables a comprehensive geriatric assessment for frail older patients with acute illness, picking up acute kidney injury or infections more quickly, as well as delivering and monitoring intravenous treatments on an ambulatory basis. ‘Patients do not need to have an acute hospital bed, because of point of care testing,’ he said. ‘I see POCT as a new safety envelope for out-of-hospital care.’

Making informed decisions through POCT in a community setting – and delivering acute therapies – can avoid admission to acute hospitals. ‘You can assess risk and treat the patient in a more precise way and much earlier than you would if you had to wait until they were transferred to hospital and had laboratory testing in the standard way.’

Dr Lasserson outlined the value of POCT as an enabler of new care models, during the national meeting of the Association for Clinical Chemistry and Laboratory Medicine in Cardiff, Wales this June: He pointed out that it is still hospital practitioners conducting the assessment, but added ‘They are practising in a different way; they have an acute ambulatory function, and POCT is enabling us to safely assess, treat and monitor response to treatment for patients with acute illness but without them going anywhere near a traditional acute hospital.

“They are patients with acute medical needs, so we need to provide a credible alternative to the acute hospital pathway, but they can be managed out of hospital provided you have the backup of the diagnostics and multidisciplinary team. Our experience is that you can deliver that out of hospital, although the only way to do that with any accuracy and safety is by using POCT.’

Nonetheless, patients with acute coronary syndrome, stroke and other serious conditions will still be admitted to the acute hospital for the onward treatment. Carried out by healthcare assistants, with results available within minutes and assessed by senior clinicians, such tests include clinical chemistry, sodium potassium, urea, creatinine, glucose, ketones, INR and troponin, blood gases and lactate, and absolutely everything.

The Abingdon service, established in 2010, has evolved and been refined, moving from a five- to seven-day service, with the scope of POCT also increasing – because you can start delivering treatment in the acute care pathway without transferring patients to hospitals; Lasserson underlined.

The evolution of this style of treatment sits with the Royal College of Physicians’ Future Hospital Commission vision of future hospital care within the NHS.

POCT benefits

Lasserson: ‘For hospitals POCT means they can manage more of their acute medical patients without using hospital beds and have patients treated at centres closer to their homes. For clinicians, it’s fantastic to see a patient and have all that information rapidly at your fingertips, to make a much earlier decision, start treatment earlier, and see an improvement before you send someone home. It means patients are not in hospital waiting for results.’ Patients get a ‘holistic assessment’, are seen in one visit and can clearly see how technology is working for them. ‘That reduces anxiety and, by seeing such great diagnostic back-up, they have more confidence in the service,’ he believes that units such as this, ‘as they evolve around the country, will make a contribution to defining what a future hospital will be’.

Most would agree that urinalysis testing is labor intensive and time consuming. When labs are overworked, testing accuracy may be compromised. The CLINITEK Novus® analyzer is changing that by addressing the relationship between the two.

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With the CLINITEK Novus analyzer, Siemens answers the need for faster, more reliable urinalysis testing.
Haemolysis must be avoided

Blood sampling via intravenous catheters frequently occurs because patients in intensive care already have intravenous catheters in place, and patients admitted to accidents and emergency units are immediately set up with intravenous catheters – providing easy access to blood.

However, studies have identified this route as a cause of haemolysis (rupture of erythrocytes causing haemoglobin release into the plasma or serum), as well as meaningful biases in blood/gas analyses.

Poor blood sampling will not only delay treatment, waste lab time, result in incremental material costs for re-testing and, potentially, cause discord between doctors and nurses – usually responsible for blood collection. Therefore, understanding why samples can become useless is vital for better healthcare.

They found the risk is even greater in blood collection when intravenous catheters are used combined with primary evacuated blood collection tubes, and less with blood collection tubes with manual aspiration.

An essential part of the clinical decision-making is laboratory diagnostic support that the testing process goes along with a high degree of quality. Several lines of evidence attest that the manually intensive activities of the pre-analytical phase are more prone to uncertainties and errors than those belonging to the analytical and post-analytical phases. This inherent vulnerability is monitored by testing to ascertain the correctness of the processes and, if incorrect or mishandled procedures were used for obtaining blood specimens (Diplock et al ClinBiochem 46 (2013) 561-564).

The researchers pointed out that artefactual and pre-analytical non-conformances that can be encountered in routine laboratory practices, sample haemolysis represents the primary source of problems, in terms of prevalence and likelihood of sample rejection. The in vitro haemolysis is occurring during, or after sample collection, once potential sources of haemolytic anaemia have been ruled out.

Although artefactual (in vitro) haemolysis recognises that sampling, sampling process goes along with a high degree of quality. Several lines of evidence attest that the manually intensive activities of the pre-analytical phase are more prone to uncertainties and errors than those belonging to the analytical and post-analytical phases. This inherent vulnerability is monitored by testing to ascertain the correctness of the processes and, if incorrect or mishandled procedures were used for obtaining blood specimens (Diplock et al ClinBiochem 46 (2013) 561-564), cited literature 4).

The reasons for poor sampling include difficult venipuncture(s), use of unsuitable blood collection devices, poor handling (i.e. vigorous mixing) and transportation (freezing or thawing) of blood tubes.

Regardless of specific causes, the receipt of haemolysed specimens is always a problem, wherein test results of some analytes, such as potassium, lactate dehydrogenase (LD), aspartate aminotransferase (AST) or cardiac-specific troponins, among others, should be suppressed, reported with comments, corrected or recalculated or even provided with semi-quantitative comments indicating likely range of results.

The authors, Halm and Geaves reported that haemolysis occurs in 3.3 to 7.7% of blood samples obtained through intravenous catheters, whereas the frequency is nearly 20 times lower when blood specimens are drawn by direct venipuncture. When combining intravenous catheters and vacu-um tubes, artefactual haemolysis can be as high as 77%, while the use of swab draw is effective to decrease the rate of haemolysed specimens by nearly half. Regardless of the specific cause, the generation of catheter-related haemolysis generates a variety of clinical, organisational and economical issues, which are mainly attributable to specimen rejection and / or recollection, suppression of those tests most sensitive to artefactual haemolysis, delayed diagnosis and overcrowding due to increasing length of stay of patients in A&E, as well as frequent inquiring between the A&E and laboratory personnel.

The greatest number of haemo-lysed specimens is taken in A&E where the relative prevalence can be as high as 10-30% (Lippi et al ClinBiochem 46 (2013) 561-564), cited literature 4).

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The results of the meta-analysis – which is limited to published data and the A&E setting – attest that sample collection through intravenous catheters is associated with significantly higher risk of haemolysis as compared to standard blood drawn by straight needles, and that this risk is further amplified when intravenous catheters are associated with primary evacuated blood collection tubes, as compared with blood collection tubes S-Monovette (Sarstedt AG & Co., Numbrecht, Germany) used in the aspirating mode.

Blood collection is the most vulnerable step throughout the testing process. Although sample collection via venipuncture rather than through intravenous catheters should be the method of choice of care throughout healthcare [17], the latter procedure is virtually unavoidable in procedural or short-stay units such as A&E or cardiac intensive care units.

A potential option to reduce the chance of collecting unsuitable samples entails work in the aspiration mode rather than using vacuum force for drawing blood from intravenous catheters, since the former practice involves a larger shearing stress due to the negative pressure when blood is collected by the vacuum technique, as well as turbulence due to difference of pressures between veins, catheter needles, valves and evacuated collection tubes.

Results show that the S-Monovette collecting blood by the aspiration technique may be effective to dramatically reduce the likelihood of erythrocyte injury when drawing blood from intravenous catheters. The frequency of samples with a haemolysis degree equal or greater than 0.5 g/l has been reduced by more than 10-fold using S-Monovette in aspiration mode.

In conclusion, the use of S-Monovette presents several advantages, especially for drawing blood from intravenous catheters or canu-lane. The device can be used with either vacuum or aspiration principle of collection, thus virtually mimicking the functioning of a syringe.

This latter approach allows blood aspiration from catheters, whereas the closed connection for line draws is effective to abolish the hazardous blood transfer from syringe to blood collection tube.

The S-Monovette blood collection system combines two blood collection techniques – aspiration and vacuum – and presents advantages in collection from intravenous catheters or cannulae.

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Imagine improved patient care. Imagine improved workflow. We listened to our customers who asked for more accurate results routinely. Follow along when we push the boundaries beyond what is available today. Stay tuned as we pursue a fresh vision for clinical testing with fully automated LC-MS/MS technology.

The importance of flexible connectivity

When analysing the market situation we found that our customers are in very different stages with their connectivity requirements; ranging from a single computer in a doctor’s office to full, direct integration into lab information systems (LIS) in hospitals, or web-based solutions for disease screening programmes.

There are numerous vendors for software solutions in healthcare and each have their specific interfaces. The new generation of Hemo Control devices use a public standard communication protocol (LIS2-A2) and a bi-directional interface. This enables direct integration of the device with third party software.

The new Data Management “add pack” is used to upgrade a basic Hemo Control device with data management functions at a later stage. This is ideal for customers who are planning future connection of POC devices to electronic patient records or LIS, but have not yet decided, or who would like to split the costs of investment. It helps them to keep their options open for upcoming connectivity requirements. In some countries electronic patient data management will become a general requirement in 2017.

Data management functionality

Hemo Control devices with data management functionality can be configured to capture all information around the analytical result by using simple barcode scans. In the most basic case, this would be a direct link of the test result with the patient ID, which is a mandatory requirement at many sites now. Other available functions include operator identification to ensure that only trained personnel are using the device and tracking of the materials used to perform a test. A fixed QC scheme can be programmed into the device to request and validate a control measurement at certain points of time. Modern data management of POC devices, such as Hemo Control, increases patient safety and simplifies the documentation process.

Further details: www.ekfdiagnostics.com

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Katja Lemburg, Global Product Manager for Haematology, EKF Diagnostics

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Identifying a single isolate in minutes

When trialled in Swansea, Wales, Matrix Assisted Laser Desorption Ionisation – Time of Flight (MALDI-TOF) demonstrated sufficient advantages over conventional methods to be introduced into routine practice.

Report: Mark Nicholas
Dr Angharad Davies is Clinical Associate Professor and Honorary Consultant Microbiologist at Swansea University Medical School, where she leads the Infection and Immunology Group, teaching for graduate entry students. Her key research interests include Cryptosporidium and mycobacterial infections.

How a UK NHS trust became one in the top 100 'Best Places to Work'

Fostering a collaborative way of working won the UK's Dartford and Gravesham NHS Trust recognition as an elite public sector health-care employer, recently judged one of the top 100 'Best Places to Work'. The trust, led by chief executive Susan Acott, has created an energy-driving, patient-focused culture within the hospital, reflected by staff at all levels. This has been the driving force behind the creation of its new pathology service, led by pathology service general manager Chris Gunn and team.

The hospital's long-term vision has been to deliver an improved, cost effective and expanded diagnostic service to the UK's South East for at least the next 10 years.

System introduction

The hospital required a long-term, cost effective and automated solution, which had to be fully operational from the start. The team chose Beckman Coulter UK as its managed service partner.

The main blood sciences section has been refurbished, and equipped with some of the latest instruments from Beckman Coulter as well as third party suppliers.

Together we are determined to create a substantially enhanced service in the region,’ said Chris Gunn. Our 10-year plan is to drive ahead with increased turnaround time (TAT) efficiencies for existing customers, such as A&E and our local GPs, as well as competing for more external work.’

Automation drives expansion

Currently, the lab processes 1.2 million biochemistry and 446,000 haematology tests a year, of which over 50,000 alone are from the Emergency Department (Biochemistry and haematology in total).

Handling 2,000 tubes daily, the lab expects this to reach 7,000 by the end of the decade. Gunn also predicts GP test demands will account for 50% of the lab's total workloads.

The lab currently handles 152,000 GP biochemistry requests annually. Even so, more than 92% of full blood count requests are completed in less than two hours. ‘And, be added, 'we’ll be partnering with outside organisations to win further business.'

Within a newly built laboratory interior and an overall workflow design reflecting Lean working practices, Beckman Coulter installed its Power Processor, dynamic inlet and automated sample handling track.

'Ve are improving the patient experience,' he said. ‘And we have improved the efficiency, which means that the ability of the equipment means it is not present on every site – isolates now have to be transported in a timely fashion to a lab with MALDI-TOF, meaning that reliable and efficient transport arrangements need to be in place to deliver a reliable reporting system for results.

Rheumatology Workcell - UniCel DxI 2401

Automation is critical to the efficient running of the laboratory. Automation of key processes, such as sample transport and data management, reduces the risk of errors and helps to improve turnaround times.

The UniCel DxI 2401 Workcell is a fully automated, high throughput analyzer for 240 samples per hour. It is equipped with advanced technologies such as Automated Intelligent Morphology (AIM), which provides accurate and consistent results for all types of cell morphology.

The AIM technology enhances the accuracy and consistency of cell morphology analysis, reducing the risk of misinterpretation and ensuring accurate and consistent results for all types of cell morphology.

In terms of cost and efficiency for hospitals it allows better empirical antibiotic choices and, in the lab, reduces cost and time from sample to result. It is also able to identify isolates at an earlier stage, considerably increasing the turnaround time for results.

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Full integration is key to the future of LC-MS/MS

Connected components are not enough

Bringing liquid chromatography and tandem mass spectrometry (LC-MS/MS) testing into clinical laboratories has been a slow process but continues to show promise to help improve patient care. The medical device industry is on the edge of fundamental breakthroughs that can help drive the adoption into more mainstream clinical laboratories. We recently sat down with Dr Bori Shushan, Mass Spectrometry expert, to ask about LC-MS/MS adoption by clinical labs and what could leverage the technology to benefit more patients.

Explaining the importance of liquid chromatography/tandem mass spectrometry (LC-MS/MS) in the clinical lab, Dr Bori Shushan, of Clinical Mass Spec Consultants, pointed out that spectrometry’s ability to be very specific to the target analyte can enable clinicians to make more informed decisions. ‘Select immunoassay based methods have known interferences due to cross reactivity that can produce a less accurate result, especially in the areas of endocrinology, therapeutic drug monitoring and drugs of abuse testing.’

Why, then, aren’t labs rapidly adopting LC-MS/MS technology?

‘First, the customer is faced with many choices in the market to piece together a comprehensive solution. It can be overwhelming to decide which LC or MS to use plus a wide range of calibrators, controls, and calibrator kits. LC-MS/MS reagents need to be expertly by which to develop and validate their own methods, and set up and run their experiments on a daily basis. Third is cost, especially when considering automation components to help reduce high labour requirements for sample preparation, finance options are typically limited.’

What is changing to take LC-MS/MS into a greater number of clinical laboratories?

‘I think the basic needs of the routine clinical lab are quite clear. This includes systems that are easy to use, reliable, connected to the laboratory information system, and complete solutions including diagnostic kits that are regulatory compliant. ‘In Europe, many suppliers have pursued the creation of internal quality systems and product controls to enable them to affix the CE-IVD mark. There also have been recent efforts to package compatible technologies to help labs be more productive. We see this in the provision of compatible but previously stand-alone elements, such as automated sample handlers, LC-MS/MS reagent kits, and software provided together to better manage workflow. I like to think of this emerging category of LC-MS/MS systems as “connected components.” It does simplify the number of decisions to be made by the lab, because these components are provided together. It's a step in the right direction, but there's still more that can be done.’

The clinical lab is accustomed to using automated easy-to-use clinical chemistry analysers along with what is changing to take LC-MS/MS into a greater number of clinical laboratories?

Thermo Scientific Orbitrap Fusion TriBrid LC-MS (i) with Thermo Scientific Dionex UHPLC 3000 Series UPLC

Thermo Scientific Orbitrap Fusion TriBrid LC-MS (i) with Thermo Scientific Dionex UHPLC 3000 Series UPLC

The new Forensic and Postmortem Microbiology Study

Seeking to identify what causes death

A new study group that aims to establish guidelines on forensic microbiology sampling and encourage increased communications between European and global organisations, has been launched by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID).

Named the Forensic and Postmortem Microbiology Study Group (ESGFOR), the aim is to create a new network of microbiologists, virologists, anthropologists and archaeologists working in the field of forensic sciences. The European Network of Forensic Science Institutes (ENFSI) and head of ESGFOR, stresses the importance of this group in facilitating cooperation between (forensic) pathologists and (forensic) microbiologists. Microbiology, she explains, is a new area of involvement for forensics and it is important that these two areas can work together to detect and defeat diseases. Speaking on behalf of ESGFOR, she said: ‘We are trying to convince medical examiners and judicial authorities of the importance of performing postmortem microbiology studies to learn from how people have died and prevent future occurrences.’

The ESCMID study group

Identifying the causes behind a person’s death can help trigger a prevention plan. In discovering the bacteria involved, correct treatment strategies can be implemented and, in some cases, vaccines can be administered. Fernandez-Rodriguez spoke at the ESCMID 2015 conference in Copenhagen on the group’s goal to establish European guidance for standardised microbiological sampling in forensic cases.

Another focus for the new group is to instigate increased cooperation between different societies and networks. ESGFOR, for example, is working to establish collaboration with the European Network of Forensic Science Institutes (ENFSI).

Further details: https://www.escmid.org/research_projects/study_groups/forensic_postmortem_microbiology
The need for WHO reforms and secure global research

Health always has a political dimension, as seen at two recent international events - the World Health Summit in Geneva in May and the G7 Summit in the Bavarian Alps near Garmisch at the beginning of June, Anja Behringer reports.

In Geneva, German Chancellor Angela Merkel canvassed for reforms in the World Health Organisation (WHO) and for a global disaster management plan amongst the representatives of the 194 WHO member states, alleging that mistakes were made in the management of the Ebola outbreak in West Africa and that reaction and actions were too hesitant. This insight obviously comes too late, but there is hope that future disasters will be managed in a better way. As the pathogens spread worldwide they should be fought on a global level.

Presently, Germany, which holds the current presidency amongst the seven most important developed nations (G7), wants to address the topic at the June summit. The development of new antibiotics, diagnostic tests and alternative methods of treatment are also to be promoted. This is a long-standing postulation as the German Law on Infection Prevention and Control was revised four years ago and the German federal states passed new directives for infection prevention and control in hospitals and tightened existing regulations.

The need for WHO reforms and secure global research

The S4 laboratory

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Reaching security level 4

However, the federal German government now has another ace up its sleeve: the high security laboratory at the Robert-Koch-Institute (RIK) at the Virchow Clinic of Charité University Hospital in Berlin, which opened in February and has security level 4. This is the only federal medical institute with an S4-laboratory. This facility will allow safe research into the most risky pathogens, such as Ebola, Marburg and Lassa viruses, along with the Crimean-Congo haemorrhagic fever virus that occurs in Greece. The lab has its own air, electricity and water supply, and multi-level security systems prevent the escape of pathogens.

The RKI is a regional WHO reference laboratory for polo, measles and mumps and, as a central facility for infection prevention in Germany, carries out numerous diagnostic and experimental procedures. Imported, highly contagious diseases call for a fast diagnosis so that quarantine and treatment options can be decided.

The lab also enables scientists to research highly pathogenic bacteria and combat them. Laboratory capacities are also made available to external scientists and for training. (The installation of mirrors also facilitates effective training."

To ensure no pathogens escape, all outgoing air from the high security laboratory is treated with a multi-level filter system with HEPA filters. The outgoing air flow rate is more than 20,000 m³ per hour.

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From alcohol to cancer detection

Clinical trials are underway at two NHS hospitals in England to assess breathalyser technology to detect lung cancer.

The research, led by Professor Hossam Haick from the Department of Chemical Engineering and Russell Berrie Nanotechnology Institute in Haifa, also suggests that the technology could be used not only to test for the presence of stomach cancer, but also to monitor those at high risk of subsequently developing the disease. Gastric cancer develops in a series of well-defined steps, but there is currently no effective, reliable, and non-invasive screening test for picking up these changes early on.

Nano-array analysis is accurate, highly sensitive and cost-effective and its ability to accurately differentiate between low and high-risk changes would avoid unnecessary endoscopies and enable any progression to cancer or signs of disease recurrence to be monitored.

A large trial, involving thousands of patients, is now underway in Europe to test the technology’s suitability as a screening method.

MRSA (Methicillin-resistant Staphylococcus aureus) is recognized worldwide as the most significant cause of nosocomial infections. Clostridium difficile infection (CDI) is the most common healthcare-associated infection causing antibiotic-associated diarrhea (AAD) potentially leading to pseudomembranous colitis and even death. Both infections increase mortality rates and prolong hospitalization and represent a major burden for healthcare systems across Europe.

It is therefore essential to detect these pathogens as soon as possible and, if necessary, to treat patients separately from other unaffected patients.

To achieve the rapid identification of nosocomial infections in general, Greiner Bio-One has developed the Genspeed® Test System, a unique molecular diagnostics system that combines crude lysis of bacteria with multiplex-PCR before the final automat ed analysis of PCR-products in the new Genspeed® R2 Analyzer.

The Genspeed® MRSA test is a DNA-based CE-IVD certified test for qualitative detection of MRSA within 100 minutes from human nasal and pharyngeal smears, targeting both resistance genes meca and mecC.

The Genspeed® C.Diff OneStep test is CE-IVD certified and identifies toxigenic C. difficile by detecting glutamate dehydrogenase (GDH), toxin A, toxin B and binary toxin genes in one step in less than 100 minutes. The one-step differential diagnosis procedure represents a true alternative to currently used sequential two-step diagnostic procedures, e.g. a GDH antigen assay followed by a toxin assay.

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**Literature:**
3. E. Bours, Consequences of Clostridium difficile infection understanding the healthcare burden. Clin Microbiol Infect. 2010, 16 Suppl 5:S1-5.

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Diabetes mellitus is a chronic disease that affects millions of people worldwide. According to the International Diabetes Federation (IDF) in 2021, it is estimated that 463 million people worldwide have diabetes, and this number is expected to rise to 700 million by 2045. Diabetes is caused by a lack of insulin or by the body’s cells becoming resistant to insulin, which leads to high blood sugar levels.

Diabetes can be broadly classified into two types: Type 1 and Type 2. Type 1 diabetes is an autoimmune disorder where the immune system attacks and destroys the insulin-producing beta cells in the pancreas. This type of diabetes is typically diagnosed in children or young adults, and it requires insulin injections or an insulin pump to manage blood sugar levels.

Type 2 diabetes is a chronic condition that affects people of all ages, but it is more common in adults. In Type 2 diabetes, the body becomes resistant to insulin, and the pancreas produces less insulin to compensate. This type of diabetes can be managed with medication, lifestyle changes, and in some cases, insulin therapy.

The symptoms of diabetes include frequent urination, increased thirst, fatigue, unexplainable weight loss, blurred vision, and slow healing of wounds. Early detection and management are crucial to prevent complications such as heart disease, kidney disease, and neurological problems.

Prevention strategies include maintaining a healthy weight, regular physical activity, a healthy diet, and ruling out certain risk factors such as family history and ethnicity. Treatment aims to control blood sugar levels, manage complications, and improve quality of life.

In conclusion, diabetes is a serious health condition that requires proper management. Regular monitoring, lifestyle changes, and timely medical intervention are crucial to prevent complications and improve the quality of life for people with diabetes.
**DIABETES**

**Epidemic of the 21st century**

Diabetes mellitus affects millions of people worldwide, the epidemic of the 21st century. The situation is exacerbated by the fact that, within the past one or two decades, the number of child and adolescent diabetes has risen sharply. IDF estimates that, in Germany in 2007, 15,000 to 20,000 children under 15 had type II diabetes. Since then, 2,500 new cases were reported every year, with an annual rate of increase of 4%. IDF assumes a global prevalence among children 0.02 percent, which translates into 450,000 children globally, with an annual increase of about 3%.

Some European figures illustrate the problem: the highest incidence of type I diabetes in children under 15 years of age is found in Finland, with close to 58 cases per 100,000 inhabitants. The lowest figures were reported in Romania with 5.5 cases. Further countries reporting high incidence rates are Sweden (approx. 45 cases), Norway (52 cases), UK (29 cases), Germany (22 cases) and Spain (20.5 cases). Switzerland, France and Italy reported between 12 and 13 cases per 100,000 inhabitants. While DM diagnostics is ever more efficient and precise, and applied at an earlier stage, it can and has to be the basis for intensive research of all relevant causes and issues that surround the disease, accompanied by better, more effective and earlier prevention covering a broad range of leverage points from physical education in schools to nutrition.

An initiative by a group of scientists who want to explore basic health research questions in a national cohort is a step in the right direction. They will, for example, question the effect of lifestyle on diabetes risk. The team plan to examine 200,000 people between 20 and 69 years in 18 centres all over the country, and collect data on their lifestyle. The aim is to improve prevention, early detection and treatment of chronic diseases such as diabetes, cancer, polynoary and cardio-vascular diseases.

Every fifth participant will be administered an oral glucose tolerance test (OGTT) for early detection of diabetes. Experts assume that, despite all the well-known data, by far not all people suffering diabetes mellitus are diagnosed. A significant number of unreported and/or undetected cases is expected.

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**Constantine the African, a doctor in the Berber Zirid era in the 11th century, examines patients’ urine.**

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Left: Andrey Zeyfang, Dir
Report: Karoline Laarmann

Pathology is the gold standard of prostate diagnostics. Whilst the radiologist makes interpretations based on shadows and grey scale values visible on an image, the pathologist has the ‘fait accompli’ under the microscope. Professor Glen Kristiansen, Director at the Institute for Pathology at the University Hospital Bonn, explains why image-guided biopsies also make sense from the pathologist’s point of view and why the prognosis for prostate cancer is a special case.

No pathologist in Germany has published as many scientific works on the topic of prostate cancer as Glen Kristiansen. He believes that a qualified specialisation in specific organs, as is common in the USA, makes sense, but that it cannot be realised in Germany: ‘There is an increasing lack of qualified staff in pathology. When we look at how many pathologists per resident Germany has, we’re in third place from the bottom, ahead only of Turkey and Poland. The situation is bound to get worse over the next few years as our field suffers from ageing, recruitment problems and, to make matters worse, from requirements planning.’

Kristiansen specifically welcomes advances in imaging because these developments also lead to reduced workloads in pathology. He approves of the demand for image-guided prostate biopsies: ‘In every other case seen by pathologists the tissue sample is negative. However, we obviously never know whether the patient really is free of cancer or whether the biopsy was taken ‘blind’ from the wrong area. This is like playing Battleship.’

The International Society of Urological Pathology introduced one important advance from the pathologist’s viewpoint, in November 2014. The Gleason-Score, i.e. information about the growth pattern, and therefore aggressiveness of a prostate cancer, was divided into five prognostic groups. Kristiansen explains why this is so important: ‘Most patients with prostate cancer are already of an advanced age. At the same time this cancer grows very slowly. So, the question is: Will the patient actually be alive for long enough to benefit from treatment or not?’ This group division helps to advise patients in a forward-looking manner.

Over the last decades there have already been several shifts in paradigm regarding the prostate cancer treatment, the pathologist notes. ‘In the 1980s prostate cancer was still treated as some form of ‘senile wart’ occurring in men. The motto was: You die with prostate cancer but not because of prostate cancer. Therefore, it mostly wasn’t even treated. However, the available data has shown that there definitely are patients who die from this cancer. The pendulum swung then changed direction and the strategy was to find and treat as many cases of prostate cancer as possible.’

Although surgery and radiotherapy are treatment options, they are not without risks and side effects. A prostatectomy for instance can lead to incontinence and problems with potency and can therefore limit a patient’s quality of life significantly.

The high prognostic significance of the Gleason-Score has turned it into an important parameter for treatment planning, but the problem of tumour heterogeneity remains – despite multiple, blind biopsies, as the aggressiveness of a cancer can be very different in different parts of a tumour. In this context the pathologist emphasises once more: ‘If we had image-guided prostate biopsies we could hold better, pre-therapeutic case conferences, where radiologists can present the

Well-differentiated prostate cancer with a Gleason-Score of 3+3=6

Poorly differentiated prostate cancer with a Gleason-Score of 5+5=10. The poorly differentiated prostate carcinoma in the centre of this overview image, as well as on another image with higher magnification, shows a perireal invasion frequently occurring with all prostate cancers.
‘We need more feedback’

**Report: Karoline Laarmann**

**What you see is what you get – unfortunately, this doesn’t always apply in cancer imaging. Why is it that something which looks conspicuous on an image later turns out not to be a tumour? Why, on the other hand, are things overlooked that later turn out to be cancer? Pathological findings are extremely important to help improve diagnostic precision in radiology. Both disciplines therefore engage in an intensive dialogue at German Congress of Radiology in May.

One focus of this interdisciplinary exchange was the diagnosis of prostate cancer. In this field, Dr Matthias C Röthke, Senior Consultant at the Department of Radiology at the German Cancer Research Centre, in Heidelberg, is among the leading imaging experts.

Currently, the procedure of choice for prostate imaging is multiparametric MRI, which supplements morphological image data with functional parameters. ‘The term functional basically refers to the diffusion behaviour in the tissue,’ Röthke explains. ‘Tumours are characterised by a high cell division rate. When you look at them under the microscope you see that the tissue consists of many large cell nuclei and little cytoplasm.

Accordingly, measurements carried out with diffusion weighted MRI show that the water molecules move around less freely in this type of tissue.’ A further, functional criterion, which is examined with the help of contrast media dynamics, is perfusion behaviour, because the perfusion patterns of tumours differ from those in healthy tissue.

If all available radiological measuring procedures are combined, this results in a sensitivity of 90%. ‘The diagnostic precision obviously also depends on the examiner,’ the radiologist admits. ‘If a procedure is carried out by an expert, the rate is higher than that achieved by a less experienced examiner. Unfortunately, there are as yet no certified radiologists who are specifically trained in prostate imaging, unlike those specialising in mammography. The referring urologists are making increasingly frequent demands for this further training because they are looking for reliable quality standards for prostate MRI procedures carried out by radiologists.’

Dr Röthke believes that organisational structures similar to those in place for the diagnosis of breast cancer are absolutely essential. This starts with the biopsy. The prostate is the only organ from which tissue samples are taken at random – with the help of transrectal ultrasound to assist with orientation – as part of the primary diagnosis. With all other organs, suspected lesions are precisely targeted under imaging guidance these days. ‘A prostate MRI should at least be carried out in patients whose primary, ultrasound-guided ten or twelve stent biopsy was negative, but whose PSA level continues to rise so that a possible lesion can be precisely targeted with a repeat biopsy,’ Röthke says.

His demands go beyond that. ‘What we need for prostate cancer are interdisciplinary case conferences as we know them from the field of breast cancer diagnostics. This would give us a quality forum where radiologists, urologists, radiotherapists and pathologists could exchange and update their knowledge. Such feedback discussions are currently usually carried out on an occasional and informal basis, whenever it fits into clinical routine. However, we need an official framework to achieve comprehensive and competent care for the imaging of prostate cancer.’
Molecular imaging will help to keep therapies will not work without sufficient imaging. When we realise that many new therapies will not work without sufficient imaging, the development of new diagnostics in Europe continues to be rather sluggish by comparison. 'But this will change,' Professor Fabian Kiessling is sure, 'at the very point when we realise that many new therapies will not work without sufficient imaging, molecular imaging will help to keep down costs and resources.'

PET - gentler, faster and used intraoperatively

Molecular Imaging is no longer the playing field of individual researchers. To the contrary: We are now pretty certain what actually works, and there are intensive efforts to bring these applications into clinical routine. One good example of this is PET, and in particular hybrid imaging with MRI. 'For a long time it was thought that PET has reached the zenith of its capabilities but, thanks to the new detector technology with fully digitised sensor arrays, the tracers can be detected with even more sensitivity and their spatial attribution has improved. The procedure is further advanced through new geometries, such as whole-body scanners and the development of new calculation procedures. This will further enhance the sensitivity of the procedure,' Kiessling foresees. In future we will not only require significantly smaller amounts of radioactive substances but scanning will also become much faster and therefore considerably cheaper. He believes that, in the long term, MRI/PET will become fully established at least at university hospitals because of its clearly improved soft tissue contrast.

Next to PET, Kiessling also sees a big potential in Cherenkov imaging. The idea behind this is initially to localise a tumourous lesion, or the lymph nodes, with PET imaging. During the operation a camera then enables detection of the area in vivo through light emission during the radioactive decay of the tracers. The procedure has now been developed to such an extent that the first patient examinations are being planned in New York.

Magnetic particle imaging (MPI)

The professor is particularly proud of the first ever presentation of an image from a hybrid MRI-MPI scanner. Since Bernhard Gleich first published the magnetic particle imaging procedure about 10 years ago there has been intensive research in this field. The principle behind it is that, in a magnetic gradient field, small iron oxides display harmonic distortions through periodic stimulation, which can be measured and which can then be utilised to carry out fast, highly sensitive imaging. The Hybrid MRI-MPI scanner also allows switching between MRI and MPI. This enables visualisation of small iron oxide particles in the body with high sensitivity, which can then be hybridised into morphological MRI images. The areas of application for the hybrid scanner are still subjects of research. The first clinical MPI is located in Hamburg and will be used for cardiovascular imaging, and in particular for the fast acquisition of lung- and myocardial perfusion.

The determination of the oxygen content in tissue, dynamically and without any additional contrast media, is a particularly interesting application of photonic acoustic imaging. Kiessling: 'It allows the detection and characterisation of tissue that is poorly supplied with oxygen, and the observation of the effects of treatment. The procedure is used in oncology, for cardiovascular disease, multiple injuries and inflammatory diseases.'

The user can also inject a fluorescent dye to make the tissue visible to PET and MRI imaging, and PET/MRI can be used intraoperatively to detect sentinel lymph nodes. It is specifically these simple applications that should be tested a lot more because they can be quickly, clinically implemented with existing technology.

Molecular ultrasound

Kiessling is working on the discovery of new indications for the first molecular contrast medium with target-specific microbubbles. He has also achieved early measurements of perfusion and relative blood volume following the administration of only one dose of contrast medium, later obtaining molecular information on metabolism.

High-res endo-megapixel

Medical imaging technology has shown tremendous innovation in recent years, with devices such as CT and MRI scanners yielding ever-higher resolution to gain great image detail and therefore better diagnoses. Modern sensors must meet even higher standards. Recently produced and soon established as standard in many medical imaging areas, monitor devices can deliver eight-megapixel resolution. For example, NEC Display Solutions, which produces 10-bit grey scale diagnostic and review monitors, reports: 'From our medical imaging display range the current top of the line monitor is the MD522C, a 51.5-inch screen offers a generously wide-format workspace with remarkable eight megapixel resolution. The MD522C display works seamlessly with NEC's hospital-wide Quality Assurance Solution GammaCompMD QA. This specialised medical quality assurance software meets all challenges and demands head on by providing either an entry-level QA solution for small practices or clinics or a comprehensive solution for a larger hospital environment.'

The GammaCompMD QA ensures that all the hospital monitors conform to the DICOM standard and the display also follows all other quality control routines, including AAPM TG-18, IEC62563-1 and the latest German DIN 6868-157 for Fluoroscopy and Computer Tomography.

The high quality eight megapixel image is further enhanced with the Digital Uniformity Control (DUC) function, which optimises colour and luminance uniformity throughout the entire display.
Multiparametric imaging

The vast amounts of data accumulating in breast diagnostics require new methods to extract clinical information in a practical way. When dealing with large amounts of data that is too big or too complex to be analysed with traditional data processing applications, the talk today is of ‘Big Data’. The data volume accumulating in breast diagnostics has become increasingly complex over recent years: multiparametric MRI including diffusion imaging and MRI spectroscopy, positron emission tomography (PET) and tomosynthetic (3-D mammography) along with the various ultrasound procedures, generate such vast amounts of data that its evaluation is turning into a Herculean task. It’s becoming ever more difficult to view and sort all the data and finally to make a diagnosis for the individual radiologist, according to Associate Professor Dr Pascal Baltzer, at the Clinic for Radiology and Nuclear Medicine, Medical University of Vienna, who lectured on Big Data in Breast Diagnostics at the 96th German Radiology Congress.

Multiparametric MRI for instance – Baltzer’s specialist area of research – delivers a multitude of results. Based on blood pressure measurements alone, through signal changes caused by contrast media injected, different distribution volumes and perfusion parameters can be calculated with pharmacokinetic models (such as perfusion rate of tissue, extracellular distribution volume). If you then add the other technologies, all of which show different functional aspects of a tumour – be it biochemistry, microanatomy or perfusion – you obtain a very comprehensive but also very complex image of the tumour. Baltzer explains. However, this also raises a number of questions: What does the parameter measured mean in an individual case? How should individual parameters be combined? Could a parameter that proved meaningful in a study also extract usable information under clinical conditions and with other devices? There is significant demand for empirical data acquisition that not only validates the above mentioned technologies multielectronically, but also examines them as to which data parameters can be calculated with pharmacokinetic models, and with other devices? Baltzer believes. Therefore he believes that the order of the day is data mining. This means disposing of the data ‘waste’ within the ‘mine’ of data whilst extracting the diamonds. By using methods of machine learning and multivariate statistical models, the flood of data is reduced and patterns are recognised. This obviously requires a correspondingly large database – containing many hundreds or even thousands of multiparametric sets of data. This is only available in very few facilities, Baltzer regrets. The Medical University of Vienna, where he carries out his research, is one of those facilities. The point of this undertaking is solid. Whilst the approach with other organs, such as the prostate, can be described as ‘active surveillance’ in breast cancer diagnostics there is a heated debate involving the terms ‘over diagnosis’ followed by ‘under treatment’ by over treatment. Baltzer emphasises. ‘We know from studies that a not insignificantly high number of tumours, and particularly precancerous conditions grow so slowly – or do not develop at all – so it would be better to leave them be or to just actively monitor them.’ Multiparametric imaging makes it potentially possible to differentiate between aggressive and less aggressive tumours without a needle biopsy. The detailed information about the type of tumour is, of course, not only of great importance for diagnostic but also for treatment planning and monitoring. As with all these procedures, a lot of ground work is needed, warns Baltzer. ‘You have to identify these procedures, test them, check their reliability and then validate them.’

The Medical University of Vienna and the Medical University of Innsbruck cooperate in the implementation of multiparametric imaging at the Breast Imaging Division of the Institute of Medical Physics and Medical Imaging at the Medical University of Vienna, Austria.
Radial artery catheter failure

High-res ultrasound study reveals cause

2.5 million radial arterial catheters (RAC) are used annually in Europe (USA: 8 million), commonly to monitor arterial blood pressure and take blood samples in surgical, A&E and ICU units. They can fail.

For a study of mechanisms that might lie behind premature RAC failure and complications related to RAC in clinical use*, at team at the Radiology/Ultrasound and Anaesthesiology Department, Sidney Kimmel Medical College of Thomas Jefferson University, Philadelphia, USA, used SonoScape’s S9 hand carry ultrasound system.

The clinical trial aimed to determine the causes of RAC failure and confirm whether a low artery diameter to catheter diameter ratio leads to decreased local blood flow and thrombosis.

Using the S9 ultrasound system with a 12 MHz linear array probe to evaluate and monitor the RAC insertion as well as blood flow dynamics in the radial and ulnar arteries, the 25 enrolled patients were scanned before RAC insertion, immediately after, and intermittently every two to four hours during the day and every four to six hours during the night (for 24 to 36 hours). By using the S9 ultrasound, the researchers could literally see what was happening in the ulnar and radial arteries of the patients, SonoScape reports.

‘Using the S9’s greyscale and Doppler technology, measurements were taken of blood flow and the diameters of both the ulnar and radial arteries. Assessments of RAC insertion factors also allowed for measurements for the composite vessel trauma score for respective arteries after insertion. To analyse the data, a paired Student test and a Wilcoxon Rank-Sum test were used to compare results.’

For the study, RAC initial failure and final failure were classified as difficulty/inability to aspirate blood through the RAC or a dampening/loss of the blood pressure waveform.

211 ultrasound scans were obtained from 25 patients. 21 had experienced a RAC initial failure; four experienced RAC final failure.

‘With the S9’s high image clarity, the reasons for RAC failure were easily revealed,’ SonoScape reports. ‘Each failed for a different reason: ranging from the catheter being outside the vessel and in the subcutaneous tissue, the RA catheter tip against the arterial wall, thrombus on the catheter tip partially/completely obstructed the RA catheter lumen, and thrombus within the RA lumen partially/completely obstructed RA blood flow.

Soon after RA catheter insertion, the RA and UA inner diameters increased from 2.21±0.4 mm to 2.45±0.45 mm and from 2.91±0.4 mm to 2.35±0.48 mm respectively (no significant differences in RA and UA diameters), the study showed.

For the 24 RACs that did not have a final failure, the median number of cannulation attempts was nine and the median CVTS was 8.5. Comparatively, the CVTS for the four RACs that developed a final failure was 8.3 and the mean number of blood draws was 53.3. Median time to initial dampening of the RA waveform was 5.9 hours in 22 cases.

Using the S9’s colour Doppler the team could measure the velocities in the RA and UA arteries after RAC insertion. In the RA artery, the peak velocity decreased from 56.2±18.7 to 56.6 cm/s after the RAC was inserted. Peak velocity in the UA, however, increased from 53.7±19.3 to 65.4±20.5 cm/s after insertion of the RAC. Ultrasound scans also did not indicate a difference in vessel diameter or blood flow velocity when comparing successful RACs to that of the four that developed a final failure; however, this may be attributed to the limited number of final failures that were observed. There was also no difference in velocity patterns or in diameter in the RACs that failed compared to those that did not fail.

A threefold conclusion

Both the RA and UA experienced significant dilation after RAC insertion. The data suggested that vasodilation and increased blood flow around the catheter might help to prevent thrombosis and protect the function of the arterial catheter. In some patients the peak blood flow velocity significantly decreased after insertion of a 20g catheter, especially in the RA with a small inner diameter.

With the S9’s high-resolution ultrasound imaging abilities, in vivo observations were possible to reveal what caused RAC failure during the patient’s clinical course. Failures consisted primarily of tortuous vascular anatomy and RAC tip obstruction, thrombus formation on the RAC tip, and partial/complete thrombosis of the RA lumen.

Light up your exams and minor ops

LED Soled15 lighting supplements the Starel lamps manufatured by Acem Medical Company from Bologna, Italy. The firm reports that this model has excellent light intensity, IR-free light beam, colour temperature (CCT) of 4 500 K, a colour rendering index (CRI) of 95, long life and low power consumption. *

The high technological level combined with the use of high-powered LEDs allow Soled15 to have a very linear yield and a negligible performance decay for its entire life duration,’ Acem adds. ‘Thanks to the high efficiency achieved, Soled15 has a light intensity of 65-000 Lux (80-000 Lux with “Boost” function) and a low power consumption (16W).’

The ‘LEDs layout gives visual comfort and produces a uniform, homogeneous and shadowless light.’ Soled15’s roundness contributes to its easy movement and suitability for diagnostics and test labs and the easy-to-grip, removable, autoclavable handle makes it suitable even for critical sanitary applications, the firm points out. All the lamp’s functions – light intensity adjustment, parts selection (SEL), brightness increase (Boost), are controlled via the I-Sense touch panel. That ‘SEL’ function is new. Using it, you can select single parts of the light beam and activate the desired LEDs in a sequential way according to your needs. ‘Boost’ is used to reach a maximum limit intensity when the light field is wide. This approximate 20% increase deactivates automatically after five minutes. Soled15 can be ceiling, wall, trolley mounted (battery on demand) – just make your choice.

* Study presented at the World Federation for Ultrasound in Medicine and Biology (WFUMB) Annual Convention and Preconvention Programme in October. Source: SonoScape Medical Corporation.
Six international studies endorse thrombectomy

Results from six international randomised controlled studies conclusively and uniformly confirm, for the very first time, the effectiveness of thrombectomy in patients with acute, severe ischaemic strokes caused by a blood clot in one of the proximal cerebral arteries. The endovascular procedure is an add-on to conventional thrombolysis. Bettina Dübener reports from a German Stroke Society (DGS) press presentation held this May in Berlin.

The interventional procedure of endovascular recanalisation, in short thrombectomy, for acute severe ischaemic strokes, is not new. With this procedure, which has been carried out worldwide for several years, the occluding blood clot is mechanically removed with the help of a so-called stent retriever – a micro-catheter developed just quite recently – which is guided to the cerebral artery from the femoral artery.

The procedure is carried out in addition to the administration of thrombolytic medication within the first six hours of the start of symptoms and facilitates recanalisation, which cannot always be achieved with thrombolysis alone (general recanalisation rate in severe strokes around 55%) – particularly for clots >1cm (recanalisation rate for thrombectomy around 80%).

Until now no studies could prove the benefit of the endovascular recanalisation for patients with regards to lasting disabilities and mortality compared to the conventional procedure of intravenous thrombolysis. However, this has now changed.

‘We now have the certainty, for the first time, that if this procedure is used in a specific and systematic way, our patients experience fewer lasting disabilities and lower mortality, in particular,’ said Professor Matthias Endres, Director of the Clinic for Neurology at the Charité Universitätsmedizin in Berlin, Germany and Deputy Chairman of the German Stroke Society, during its related press presentation.

The first of this round of six studies, that recently scientifically confirmed the benefit of thrombectomy was the Dutch MR CLEAN study published in October 2014. This showed that the functional independence rate which scores how patients can independently cope with their daily lives 90 days after the procedure (modified Rankin score 0–1) was 15.4 percentage points higher in patients who had received an additional thrombectomy compared to the control group where patients only received thrombolysis (52.6% vs. 37.1%).

The following five studies were all terminated early because their preliminary results were, in some cases, significantly higher still than the results of the MR CLEAN study. The continuation of the studies would not have been justifiable for ethical reasons. The first three of these studies – presented at the International Stroke Conference in Nashville, USA in February this year (EXTEND-IA, ESCAPE, 2, SWIFT-PRIME) – confirmed that the chances of patients achieving a favourable treatment outcome through thrombectomy were 20–30% higher overall than those of patients in the control group, Endres said.

Patients’ independence was maintained more frequently, as confirmed in the EXTEND-IA study: 90 days after the stroke occurrence almost twice as many patients could lead their lives without any functional impairments (71 vs. 40%) compared to the control group. Mortality was also considerably reduced from 19% to 10.4% in one study (ESCAPE). These results were also confirmed by the results achieved with the latest and best procedures so far, which were presented at the European Stroke Organisation Conference in Glasgow in April this year, with some minor deviations attributed to the design of the studies.

Professor Bernd Eckert, Head of the Department for Neuroradiology at the Asklepios Clinic in Altona, essentially attributes the positive results of the new studies to the utilisation of modern diagnostic imaging procedures as the basis for precise patient selection, and, in particular, to CT angiography (vs. unenhanced CT as in the 2013 studies), and overall also to considerably shorter procedure times and the predominant use of modern stent retrievers (see image 2).

The rate of complications for a thrombectomy compared to the rate of complications for alternative procedures is relatively small and in view of its large benefits negligible, Endres and Eckert said. One possible complication is that a blood clot floats upwards. New procedures that produce a vacuum in the carotid artery when the catheter is removed could lower the risk to below 5% of cases, Eckert said.

A further risk lies in the fact that blood vessels may be damaged or burst while the catheter is being guided, resulting in bleeding. However, said the neurologist, ‘studies show that this risk, at 5%, is comparatively low in experienced hands.’

Thrombectomy as acute therapy is suitable for only 5–10% of all patients who have suffered an ischaemic stroke, said Endres. ‘In Germany this corresponds to at least 11,000 patients a year. Ischaemic stroke caused by a blood clot must be confirmed in the proximal cerebral arteries and the patient must be treated no later than six hours after symptoms first appear. The extent of irreversible damage suffered must be low and there must be malleable ischaemic tissue for thrombectomy to be effective.’

Germany is not alone in preparing to continue to offer high quality thrombectomy to all patients who would benefit from it is, based on the scientific evidence of the effectiveness of the procedure. The European Stroke Organisation, European Society of Minimally Invasive Neurological Therapy and European Society of Neuroradiology are already working on respective updates of their guidelines. Up till now, the Consensus statement on mechanical thrombectomy in acute ischaemic stroke, jointly published in February this year, will continue to be the binding recommendation for the use of this procedure.

A new super-smart medical mobile

A new portable mobile-device style, supports even earlier therapy adjustments in cardiac patients with pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronisation therapy device (CRT) and biomonitors.

CardioMessenger Smart provides fully automatic transmission of vital information from a patient’s cardiac implantable device via Biotronik Home Monitoring

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Gerd Just is Deputy Chairman of the German Stroke Society, Director of the Berlin Hospital for Neurology, and head of the Department of Neurology at the Humboldt University. He is also President of the German Stroke Society (DGS) and a member of the German Academy of Sciences Leopoldina.

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