England’s harsh slash at cancer drugs list

Around 25 treatments for seriously ill patients with specific cancers listed on England’s National Health Service’s Cancer Drug Fund are to be removed, Mark Nicholls reports. This large change is likely to affect patients with cancers of the breast, bowel, prostate, blood, upper gastrointestinal, brain and central nervous system, as well as gynaecological cases.

The planned removal of many cancer drugs from the Cancer Drug Fund (CDF) list means the NHS in England will no longer routinely fund these treatments. They include Albumin Bound Paclitaxel for advanced pancreatic cancer, Bevacizumab for advanced breast cancer and for second or third line treatment of advanced colorectal cancer; Bosutinib for refractory chronic phase Chronic Myeloid Leukaemia; Getrectumab for third or fourth line treatment of metastatic colorectal cancer; Lenalidomide for second line treatment of multiple myeloma; Radium-223 Dichloride for prostate cancer; and Trastuzumab Emtansine for breast cancer.

UK-based cancer charities have expressed concern at the decision. Andrew Wilson, chief executive of the Rarer Cancers Foundation (RCF), said: ‘We are concerned that these cuts are just the start of even more savage reductions in access to cancer treatment.’

The RCF wants a rethink on the decision by NHS England and believes there is still time for drug companies and the NHS to negotiate on the cost of the drugs.

All patients currently receiving the drugs will continue to do so, but from November no new patients will have access via the fund.

The CDF – made up of a panel of oncologists and other experts – was set up by the UK government in 2011 with a £200m budget to pay for drugs that had already been rejected as too expensive by National Institute of Health and Care Excellence (NICE) – the government’s drugs regulator. While 72,000 patients have benefited, the cost has risen to £540m this year and is set to overspend by £70m in 2015/16, triggering the cuts.

Among the drugs being cut is breast cancer treatment Kadcyla, which can extend life by an average of six months – but costs a £90,000 per year for each patient. Some drugs will remain accessible via the fund, but only for particular cancers.

Avastin, for example, will remain available for ovarian and some other cancers, but not for cervical, breast or bowel cancer.

Baroness Delyth Morgan, chief executive at Breast Cancer Now, said: ‘Kadcyla is a one-of-a-kind drug proven to extend life, but because the government, the NHS and the pharmaceutical industry have failed to agree realistic prices for new drugs, some women will die sooner.’

Samia al Qadhi, the chief executive of Breast Cancer Care, called the dropping of Kadcyla and Avastin, a ‘devastating decision’ while Eric Low, chief executive of Myeloma UK, said the British government had been ‘far too slow’ to address the critical flaws of CDF.

The Association of the British Pharmaceutical Industry said the cuts are ‘extremely disappointing’. Professor Peter Clark, oncologist and chair of the CDF, said it was the organisation’s duty to ensure ‘we get maximum value from every penny available on behalf of patients’ while the NHS stressed that manufacturers still ‘have the opportunity to drop the price they are asking the NHS to pay’, to enable drugs to be retained.

A National Health Service spokesman added: ‘We all recognise that the CDF has been successful by ensuring people with cancer in England have access to the same treatments as people across Europe.’

CONTINUED ON PAGE 2
Where pain relief is a matter of luck

Western Europe can choose from a variety of opioid preparations

The tail end includes Kosovo (four approved none reimbursed), Russia (4/6), Bosnia-Herzegovina (5/6) and the Ukraine where not a single oral opioid is available.

In some European countries the health insurers or public purse reimburses opioid prescriptions automatically, if the medication is approved. In Eastern Europe, the cost of most approved products is reimbursed. However, in most countries the official approval process is distinct from the cost absorption by the health insurers.

In ‘everyday reimbursement practice, access to important pain relievers is restricted although they are officially approved and available from the chemist,’ Kress said. The pain physician at the Medical University of Vienna pointed out an example from Austria, the capsaicin bandage (8%) against neuropathic pain. Initial application must occur in a hospital. However, the health insurer will only assume the costs for the continued treatment if performed by a medical practitioner in the local practice.

However, the physician cannot bill the health insurer for the application procedure that takes some one and a half hours and therefore must offer a few of changes. The practicing physician no longer believes that there is a drug that will allow him to do this. In this way the use of the approved and demonstrably effective medication is indirectly prevented,’ Kress concluded.

‘In Austria, the provision of pain relief medicine has slid into a crisis in recent years,’ according to Dr Wolfgang Jaksh, President of the Austrian Pain Society (ÖSG). Outlining the situation in the alpine republic, he explained: ‘There is no legal mandate that hospitals perform out-patient pain treatment. Since personnel and financial resources are in short supply, just that is just where they are being reduced.’

Jaksh named two other countries, which, in his view, act as models of supplying patients on the pain medication. In 2010, Italy adopted a law (Legge 38) in which the foundation for reimbursement in pain medical care was laid. It grants citizens the right to palliative and pain medicine care and enables the Italian regions to provide a comprehensive selection of pain and palliative medicines. ‘It is not only about choosing other things, a post-doctoral masters degree in pain therapy has also been introduced. In the course of a reform in Belgium, two and a half years ago, 54 specialised facilities, situated in hospitals, spread across the whole country, have been approved as ‘multi-disciplinary pain centres’ through an accreditation process. Their job is to treat chronic – and in certain cases malignant – pain, medica care and nutrition, and the Italian regions to provide a comprehensive selection of pain and palliative medicines. ‘It is not only about choosing other things, a post-doctoral masters degree in pain therapy has also been introduced. In the course of a reform in Belgium, two and a half years ago, 54 specialised facilities, situated in hospitals, spread across the whole country, have been approved as ‘multi-disciplinary pain centres’ through an accreditation process. Their job is to treat chronic – and in certain cases malignant – pain, medica care and nutrition, and the Italian regions to provide a comprehensive selection of pain and palliative medicines.

A question of cross-border healthcare

Hungary should re-join the competition for patients willing and able to pay for services, Dr Attila Bodnár believes.

Medical tourism within Europe is not a new phenomenon, 2006 onward saw a surge in European medical tourism, largely involving patients for dentistry. For example, patients from the United Kingdom who struggle with availability in their home country can easily access dental services in the ‘Central-eastern European countries, and save up to 70% on treatment costs. The Directive 2011/24/EU on patients’ rights in cross-border healthcare has been regarded by many as a major achievement of the ‘patient empowerment’ policy promoted by the European Institutions. In granting European citizens the right to access healthcare services in a different member state. Designed to address the obstacles deriving from the diversity of healthcare systems, such as the reimbursement rules and delivery of healthcare services, the ‘Cross-Border Healthcare Directive’ has established a general legal framework aimed at maintaining the sustainability of health systems while protecting patients’ right to seek treatment outside their home country.

Currently, cross-border healthcare accounts for approximately 1% of the overall EU public health spending – around €16 billion. In Hungary this number reaches 1.2% related to the total expenditure of public financed healthcare. Patients want to access cross-border healthcare services when the treatment is not available in their home country, when it is better managed elsewhere, or, as is the case in many border areas, when the nearest available care is in another Member State. According to the World Health Organisation (WHO), the volume of patient mobility with in the EU remains relatively low because people are often unwilling to travel to other countries for care. The Eurobarometer pointed out that ‘only 5% of people living in the EU had received medical treatment in another EU country, and only 2% of patients had treatment abroad because they had actually planned to do so.’ On the other hand, where patient mobility exists, this has raised issues related to its impact for patients, health professionals and health systems. These aspects have provoked calls for better coordination of health systems and policies across the EU, resulting in the implementation of the ‘Cross-Border Healthcare Directive’. However, the Directive appears to leave uncertainties for cross-border patients, such as effective cooperation between national healthcare systems, some of which struggle to provide the same timeframe and of the same quality as is available in other EU countries – including cost reasons. Other uncertainties include the reimbursement rules of the Directive for patients seeking care abroad as well as the inability for some patients to look for care that is not covered under their domestic benefit package. Therefore, the impact of the Directive made established functions in each Member State to handle these kinds of problems.

On the healthcare market there is worldwide competition for patients, while in Central Eastern Europe a market participation process is happening. The Hungarian central government faces the same challenge as other governments: total public annual spending is limited, the healthcare system is very low in terms of GDP. However, thanks to serious efforts are being put into improving access and equipment in most state-owned medical institutions and even private sector providers is revived. Actually, Hungary’s power to struggle for a bigger market share of the health market is also strengthened by the of public sector institutions, because better conditions enable them to provide such

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**Treatments due to be removed from the CDF list, and thus no longer routinely funded by England’s NHS**

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<thead>
<tr>
<th>Treatment</th>
<th>Indication</th>
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<tr>
<td>Albumin Bound Paclitaxel</td>
<td>Advanced pancreatic cancer</td>
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<td>Bendamustine</td>
<td>Chronic lymphatic leukemia</td>
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<td>Bevacizumab</td>
<td>Renal-cell cancer</td>
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<td>Bevacizumab</td>
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<td>Advanced non-small cell lung cancer</td>
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**Continued on page 6**

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**A question of cross-border healthcare**

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A challenging shift from cure to care

John Brosky meets Yann Bourgueil

Healthcare systems need to move beyond cure and transform services for chronically ill patients to be delivered beyond hospitals.

After 20 years of reform and reorganisation efforts, many countries in Europe continue to deliver antiquated and inadequate care for chronically ill patients, according to Yann Bourgueil, the Director of the Institute for Research and Information in Health Economics (IRDES) in Paris, France.

Many of these initiatives have been implemented slowly or have met with outright resistance. In some cases they have been simply abandoned and, considering the expectations for change, success has been limited.

Bourgueil suggests the difficulty comes from hospitals and large organisations trying to extend their model for curative activities rather than looking at alternative approaches that allow more innovative models for patient care.

At the 18th European Health Forum Gastein (30th September - 2nd October 2015), Bourgueil offered insights into the French experience during a workshop on ‘Improving the Skill-Mix for Chronic Care.’

When it comes to caring for the chronically ill patient, he said, healthcare institutions tend to concentrate on tools and technologies to externalise services. For example, great expectations are placed on electronic medical records (EMRs) and information technologies (IT).

‘You are not going to suddenly create coordinated care for patients by introducing IT like some magic wand that will solve all the problems,’ he said. ‘IT can only come in support of a coordinated care that has already been established through changes to the culture among care givers.’

Today we have sophisticated telephones, yet care professionals do not even use these to cooperate where they have not learned how to cooperate, he said. ‘The challenge we all face is to change the culture so there is a willingness to work together, where there are common objectives, where we have provided the right training, and have made sure the incentives support this organisation of care and team work. Healthcare is a human activity, and if we want to change a process of care, then we need to change how people work to deliver that care.’

The fundamental challenge is that care today is still centred on the hospital, and with chronic care, the centre of gravity shifts away from the hospital to the community. Yet financial incentives continue to be built around the separation of specialties in a hospital.

In France, Bourgueil pointed out, patient ambulatory care continues to be guided by principles that were defined back in 1927. Doctors, nurses, physical therapists, pharmacists and even social care workers are all paid a fee for a specific activity or medical act, and these actors required for coordinated care do not have an incentive to spend time with a patient beyond that activity, for example for education or counselling, to explain to the patient how to deal with their condition or the prescribed treatment.

Unfortunately, the coordination of these different services most often depends upon the patient, or the patient’s family when there is such support. As a result, chronically ill patients tend to be heavy users of the emergency medical network, which often puts them back in the hospital.

‘We have a great opportunity to effect change in France at this moment because there is a change underway in the workforce with young doctors and allied health workers who have different expectations than the older generation,’ Bourgueil said. ‘This new generation is more open to the idea of working in teams, to sharing the workload with other professionals, and they are open to new methods of payment.’

There are also new opportunities to facilitate change with the tools and techniques available through IT when applied to an appropriately transformed approach, he added. Additionally there is a great opportunity to accelerate change through the emergence of patient groups that bring a new kind of organisation into the mix, one that is specific to the needs of their members and which is an active player in this landscape, he observed.

‘These are good levers for bringing about change, and though it is a slow process, it will take some years, but we will see a lot of change.’

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New drugs – especially for cancer care – are increasingly expensive. How, in times of austerity, can patients’ access to new medicines be ensured? EH reporter Michael Keaschnitzer sought answers from Dr Stanimir Hasurdjiev, Board Member of the European Patients’ Forum

‘Today, we see innovative new treat-ments for diseases that have once been untreatable; there is also per-spective on the healthcare budget is definitely a big obstacle – especially when considering the positive decisions for the patients and citizens can benefit from the innovation.’

Dr Stanimir Hasurdjiev (also Hassadzhev) is a board member of the European Patients’ Forum as well as a member of local and regional and international organisations and networks. He is among the initiators and founding members of the joint initiative of the European Patients’ Forum and the Bulgarian National Patients’ Organisation – the Patient Access Partnership – a multi-stakeholder platform for finding innovative solutions to reduce inequities in access to healthcare in Europe.

The company keeps similar prices for the whole European market. What should be done concretely?

‘Probably we should think of ways to restrict parallel trade – at least within a cluster of countries with similar economic development. The most important objective is to ensure that every European patient has similar access to innovation in his own country. Poor access to new drugs in a Member State creates not only problems for this state, but also for other states. The lack of adequate healthcare in your country, that can save your life, or the life of your child, is a very good reason to migrate and to find a country where you have better chances for survival.

New studies reveal the heightened risk of death that patients face if admitted to hospital over a weekend, Mark Nicholls reports

Researchers have studied what effect the day of hospital admission has on death rates across England in 2013-2014, as well as on hospitals in other countries, such as Australia, the USA and The Netherlands.

Professor Paul Aylin and team at Imperial College London found that the heightened risk of death after weekend hospital admission – the so-called ‘weekend effect’ – is a feature of several developed countries’ healthcare systems, i.e. not just a problem in England.

Drawing on international data from the Global Comparators project – a longitudinal study involving more than 50 hospitals in the UK, USA, Australia, The Netherlands, Italy, Spain, Belgium, Finland, Norway and Denmark contribute – the researchers looked at data on almost three million admissions between 2009 and 2012 from 28 metropolitan teaching hospitals. They focused on deaths occurring in hospital within 30 days of an emergency admission or elective surgery and found that, after taking account of influential factors, the risk of dying within 30 days for emergency admissions at weekends was 8% higher in 11 hospitals in England, 13% higher in five of the US hospitals, and 20% higher in six Dutch hospitals, though there was no significant daily variation within one weekend.

Although these results are limited to the small number of participating hospitals, the international nature of our database suggest that this is a systematic phenomenon affecting healthcare providers across borders,’ the researchers conclude. Further investigation is needed to understand the factors that give rise to the weekend effect.

Focusing on the UK – examining data for 2013-2014 – the team said their findings suggest a generalised ‘weekend effect’ which can be partly explained by the reduced support services from late Friday through the weekend, leading to disruption on Monday morning.

The analysis, carried out by University Hospital Birmingham NHS Foundation Trust and University College London, stressed the need to ‘determine exactly which services need to be improved at the weekend to tackle the increased risk of mortality.’

In the UK an average of 2.7 million patients were admitted to hospital on each weekday, while an average of 1.2 million were admitted on Saturday and one million on a Sunday. Saturday and Sunday admissions were more likely to be emergencies, 50% and 65% respectively, than on weekdays (29%) and length of stay was also higher for patients admitted at the weekend.

Patients admitted to hospital at the weekend were more likely to be sicker and have a higher risk of death, compared to those admitted during the week.

Researchers discovered that around 11,000 more people die each year within 30 days of admission to UK hospitals on Friday, Saturday, Sunday, or Monday, compared with other days of the week.

The findings from both studies – published in The British Medical Journal – come amid proposals for seven-day working week within the NHS and follow health secretary Jeremy Hunt’s recent proposal to hire extra hospi-tal doctors to work at weekends to improve quality of care and reduce deaths.

Professor Aylin suggests more research is needed to determine the complex relationship between staff-
faces unprecedented threats

For political giants in Europe

- a WHO Collaborating Centre that comprises the largest team of researchers working on health and health policy in central and Eastern Europe and the former Soviet Union – also remains concerned that the impact of bailout mechanisms on Greece and other member states were limiting the freedom of democratically-elected governments to act in the interests of their citizens.

His specific theme of ‘Securing Solidarity in Europe – From Mare Nostrum to Mare Europaeum’ is based on the belief that there is a common European identity, and as someone who sees himself as a European first he believes Europe must work together for a better future for all. ‘It’s only by creating a genuinely inclusive society that we can secure the economic growth, better health, and overall well-being that we all desire,’ he added.

Over the past decade the European Health Forum Gastein has made a significant contribution to the scope of European health policy in the development of guidelines and cross-border exchange of experience, information and cooperation.

The 2015 event (30 September to 2 October) welcomed the participation of 600 representatives from the areas of health policy, administration, science, business and patient organisations.

Whilst the past few decades have seen progress in improving health in Europe – with increases in life expectancy and falls in death rates from conditions such as heart attacks – Professor McKee fears the security and resilience of European health systems and the strong value of solidarity are being tested, particularly in countries such as Greece that are most severely affected by austerity.

He outlined how health improvements have been achieved by a combination of measures against tobacco and greater access to effective healthcare but feared powerful vested interests are putting profit before health with real concern about the impact of trade liberalisation – which has driven tobacco-related illness, diabetes, and other conditions in low and middle income countries.

Mark Porter MD is the elected BMA council chair and a consultant anaesthetist at the University Hospitals Coventry and Warwickshire (UHCW) NHS Trust. His special interest is in obstetric anaesthesia and the continual development of maternity services to improve mothers’ experience. Previous roles in the BMA have included chairmanship of the consultants committee (2009-2012) and its deputy chair responsible for pay and conditions of service (2006-2009).
Update: Hepatitis C management in Spain

Leading Spanish experts presented the latest developments in hepatitis C management in their country during the May meeting of the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC) in Seville.

Report: Mélisande Rouger

The global hepatitis C epidemic is constantly evolving – its prevalence, incidence, contamination mode and genotype distribution have altered considerably over the last decades. Current estimates suggest that up to 180 million individuals are infected with the hepatitis C virus (HCV) worldwide.

In Spain, the incidence and prevalence have decreased significantly over the last decade and, according to Dr Miguel Ángel Simón from Lozano Blesa University Hospital in Zaragoza, just 1% of the population is now HCV positive. "We estimate that about 467,000 people are HCV positive, but only 162,049 of them have actually been diagnosed.

Liver disease prevalence is expected to rise

Diagnosis in those patients is crucial because HCV can trigger liver cirrhosis in 10 to 40% of cases and, at worst, liver failure and hepatocellular cancer (HCC). The prevalence of these diseases is expected to rise in the near future. "Compensated cirrhosis is expected to rise by 55% by 2030; decompensated cirrhosis should also rise by 60%, HCC associated to HVC by 105% and hepatic mortality by 95%," Simón said.

The burden of the disease on the healthcare system is already significant. Thirty percent of all 1,095 liver transplants in Spain were attributed to HVC alone in 2013. New research shows that the virus transmission modes have also changed. "Nosocomial transmission could be responsible for 75% of cases diagnosed in tertiary hospitals, especially when multidose tubes are used," Simón explained. "Out of 151 cases of acute hepatitis C between 1989 and 2010, 40% could have had nosocomial origin, according to studies published in 2008 and 2012." Sexual transmission is not an efficient transmission mode, but is possible. "Fairly uncommon in stable heterosexual couples, HCV prevalence is high and rising in HIV co-infected homosexual males. Cases of reinfection are also more common in this population."

HCV is currently the first cause of death in HIV patients, a 250,000 strong population in Spain. As many as 30 to 40% of HIV patients are HCV+ and complications of HCV can be lethal. Prevalence is also higher among prison inmates, as much as 20-30 times more than in the rest of the population. Finally, intravenous drug use is responsible for about 10% of the infection and 80% of intravenous drugs users are HVC in Spain.

New drugs start a revolution in treatment

Prevalence of HCV, however, is expected to decrease by 45%, thanks notably to revolutionary antiviral treatments. There has been a complete revolution in hepatitis C treatment. New drugs are very effective and well tolerated. One year ago, we had drugs with an efficacy of 50-60% that were very badly tolerated; most of the patients could not end the treatment. Now it's completely different, and it all happened within the past twelve months," said Jesús Rodríguez Baño, President of the SEIMC Scientific Committee.

Efficacy of the new antivirals is 95-95% within 12 weeks. The drugs target specific strains (or genotypes) and are designed to generate a strong T-cell immune response against HCV T cells are found to be important in those patients who can clear the virus naturally.

Three big families of antivirals are currently being developed: the ‘…avir’, which are NSSA inhibitors; the ‘…buvir’, which are NS3/4a protease inhibitors; and the ‘…cuvir’, which are NS5B polymerase inhibitors.

Their power has changed the perception of their patients by epidemiologists, according to Dr Javier Crespo from Marques de Valdecilla University Hospital in Santander. "There's been a great change in the perception of patients who traditionally followed their doctor's lead. Now it's completely different. Patients can now decide if they want to go with new drugs or not."

Viral load is a key factor in HCV treatment. "It's not just about the treatment, but also about the prevention. ‘Prevention is better than cure,’" Simón said.

One year ago, we had drugs that were very costly, with side effects, and patients had to restart treatment after a year. "Now, we have a new generation of drugs that are very effective and well tolerated. Patients who previously refused treatment are now starting treatment." And the patients are really happy with new drugs.

New treatments for hepatitis C are currently being developed by pharmaceutical companies. "There are new drugs in development that are expected to be more effective and less toxic," Simón said. "But it will take time before they are available for all patients." 

The next step – screening the population

Efficiency has a price. "Sovaldi, for instance, costs $1,000 per day, or $44,000 for the typical 12-week treatment. The country could spend much more on other treatments for patients who don't have a serious disease, and finally we should screen patients to look for new populations. This has to be discussed soon."

A question of...

Continued from page 2

Qualified services that patients seeking private sector treatment want. This is a pertinent question, because – above infrastructural developments over recent years – the costs spent on operation do not support services development, and do not even make the system sustainable. According to these facts, nowadays Hungary ranks behind most European Countries in aspects of quality and sustainability.

Despite Hungary's benefits in circumstances and human resources in healthcare, the country has been losing its market share position for European healthcare business. Hungary has to use up its national – public-funded – assets more intensively, and re-join the competition for patients willing and able to pay for healthcare services. The country needs to find the answer to 'How do we do it?' instead of 'How can we reject the participation of public sector in the competition?'

Assuring the rights of patients for Hungarian citizens, the country can realise more revenues from the increasing market share, and – depending on the sum and political intent – the country could spend more on the public financed healthcare system, improving the quality and the overall accessibility of the system for everyone. 

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EUROPEAN HOSPITAL Vol 24 Issue 5/15
New ultrasound system cleanses instruments

UK-based researchers have shown how a pioneering ultrasonic device can significantly improve the cleaning of medical instruments and reduce contamination and risk of infection.

Report: Mark Nicholls

Called StarStream – a new ultrasonic device makes water more efficient for cleaning by sending a gentle stream of water through a nozzle that generates ultrasound and creates tiny bubbles that automatically scrub surfaces. The system is reported to improve the cleaning power of water and reduce the need for additives and heating.

Currently, StarStream is built into a hairdryer-type device for manual cleaning, but could be fixed onto robot arms for other applications, such as for cleaners that can access hard-to-reach areas.

Whilst ultrasonic cleaning is a recognised technique, the inventors of StarStream point to that flexibility and adaptability as offering significant benefits in a healthcare environment.

Invented and patented by Professor Tim Leighton and colleague Dr Peter Binkin from the University of Southampton – and in commercial production by Ultrawave Ltd – recently published studies have demonstrated the effectiveness of the system.

Using just cold water, StarStream has been shown to be capable of removing biological contamination, including brain tissue, from surgical steel. It was also able to remove bacterial biofilms that typically cause dental disease and was effective at removing biological contamination, as well as being highly effective at removing soft tissue from bones, which is necessary before transplants to prevent rejection of transplanted material by the recipient’s immune system.

Professor Leighton, from the University’s Institute of Sound and Vibration Research, said: ‘In the absence of sufficient cleaning of medical instruments, contamination and infection can result in serious consequences for the health sector and remains a significant challenge. Our highly effective cleaning device works with cold water and without the need for chemical additives, or the high power consumption associated with conventional strategies. It has the potential to meet this challenge and transform the sector.’

‘Cracks, crevices, contoured surfaces and intricate architectures, like small tools, are normally difficult to clean because brushes and wipes do not penetrate these architectures well. Leighton added: ‘StarStream is very good at cleaning in cracks and crevices, because the interaction of the crevice with the sound field creates “acoustic radiation forces” which actively draws bubbles into the crevices to clean them. These bubbles are like microscopic scrubbing machines, removing contaminants from surfaces.

‘The range of contaminants that it removes is extensive although, if necessary, the water can be heated and chemicals such as a bleach or biocide added. StarStream helps these chemicals penetrate cracks and crevices much more quickly than mere passive diffusion would allow.’

‘Designed as a ‘clean in place’ tool, it can be used with minimal training and runs without special facilities. ‘It could provide a quick rinse of a number of items, for example the tools at the end of a duodeno-scope, to remove the bulk of tissue clumps,’ Leighton suggested.

‘This might become increasingly important as the economic recession causes more Sterile Services departments to close at weekends. If tools used on a Friday afternoon were to be allowed to dry all weekend, before attempts are made to clean them on a Monday, the hazard of infecting the next patient increases greatly.’

Professor Leighton has been interested in the interaction of sound and bubbles since 1984 but that interest evolved into examining what would happen if you projected ultrasound at a bubble.

‘Realising the ‘wobble’ induced in the bubble by ultrasound caused effective cleaning, with the bubbles turned into microscopic scrubbing machines, he assembled a team to make these ideas a reality and has been supported by the Royal Society Brian Mercer Award for Innovation, which provided £250,000 to conduct the necessary research.

That was also underpinned by increasing concerns about hospital cleaning challenges, reducing contamination and water usage, as well as the disadvantages of ultrasound cleaning baths.

The sound and vibration expert not only believes StarStream has clear benefits for hospitals but there are also applications for wounds in combat zones and he believes ambulances and other rescue vehicles could effectively carry such devices.

StarStream is being refined for a growing range of applications as it moves into commercial production.

Disinfection and cleaning of medical instruments with ultrasound

DIGITEC®, SONOMIC® and TRISON®

SONOREX DIGITEC
- Ultrasonic baths with pushbuttons
- Disinfection and cleaning – gentle and in shortest time

SONOMIC
- Space-saving built-in bath or compact version
- Disinfection and cleaning of standard and/or rinseable MIS instruments – gentle and in shortest time

TRISON®
- Modular compilation of system as required and type of instruments
- Time optimized and coordinated cleaning processes depending on the type of instruments
- Disinfection and cleaning – gentle and in shortest time
- Robotic and rinseable MIS instruments: safety by the rinsing of single channel and examination
Drawing blood from capillaries

Theranos’ blood-testing platform needs only a few drops of blood obtained via a finger-stick.
such assays are performed using calf intestine (CIP). Bacterial ALP released following the proliferation of bacterial species on pure water can create interferences with CIP in enzyme immunoassays, where it is used to generate signals. UV/visible light, fluorescence, or chemiluminescence.

Generation of turbidity – Bacteria in high concentrations can behave as particles, interfering in turbidimetric assays, and affecting detection at 340 nm.

Increased equipment maintenance – Both analysers and water purification systems that also incorporates robust and reliable technologies, such as reverse osmosis (RO) and electrode ionisation (EDI) (see water purification system diagram).

Ultraviolet germicidal lamps – Ultraviolet (UV) treatment is powerful purification technology. Germicidal UV lamps inactive bacteria in pure water and thus avoid the formation of biofilm. Treatment with UV alters the bacteria’s DNA structure, preventing the growth of microorganisms.

To minimise the risk of bacterial growth, UV lamp treatment typically occurs before water is stored, and in some cases, in the storage tank, as well as during recirculation.

Protection from bacteria: effective system design and intermittent recirculation

Combined purification technologies – In the biomedical laboratory, effective water purification systems typically use a combination of purification technologies. This approach efficiently reduces contaminant levels (ions, organics, bacteria, particulates, silica) and also ensures that the water dispensed to the clinical analyser is of constant quality.

To specifically target the presence and effects of bacteria, a number of purification techniques are available. In this article, only those that specifically influence bacterial control are discussed.

However, for use with a clinical analyser, it is highly recommended to select a water purification system that also incorporates robust and reliable technologies, such as reverse osmosis (RO) and electrode ionisation (EDI) (see water purification system diagram).

A sanitary sampling valve can provide easy and reliable microbiological testing of analyser feed water produced by the water purification system.
3-D printed hearts

The CSI Congress (Congenital, Structural and Valvular Interventions) is one of the major fixtures for catheter therapy of congenital and structural heart defects. Key moments in this high profile event are live broadcasts and the audience can not only to listen to but also interact with the teams in the cath labs involved.

At this year’s CSI gathering, three live interventions – one case of mitral valve insufficiency, a degenerated bioprosthetic tricuspidal valve and a transcatheter aortic valve implantation, performed in Frankfurt/Germany in late June – demonstrated how patient-specific 3-D printed heart models can be used for surgical planning.

Belgium-based manufacturer Materialise offers software solutions and services for 3-D imaging and 3-D printing. Just before he began to enable the first live case, Dr Sameer Gafoor of the Cardio-Vascular Center, Frankfurt summarised his experiences with the firm’s HeartPrint models. To see the model means to change strategies,’ he said.

Based on CT, MRI and/or 3-D ultrasound image data, the transparent silicone models show the individual anatomy in amazingly realistic detail. This allows a physician in the pre-operative planning phase to literally get his hands on the structures he is going to see – down to the different tissue thicknesses of muscles and vessels, including calcifications! This kind of haptic exploration of the intervention site helps to decide whether catheter access will in the leg or the neck. In turn, that decision informs the choice of instruments to be used. In complex cases, interventional cardiologists and cardiac surgeons can test their actual operating theatre strategy on the model, adapt their procedure, if needed, and even discuss it prior to the intervention, during the multi-disciplinary cardiology board. Thus, the entire team knows what’s in store.

‘Basically open heart interventions cannot be repeated,’ Dr Gafoor explained, pointing at two further advantages of 3-D print models for planning purposes – high surgical success rates and markedly improved patient outcomes. Even more, the ‘test runs’ with the 3-D models reduce intervention time, which in turn has several positive side effects: shorter anaesthesia times, reduce health risks for the patient resulting in faster recovery. For the hospital this translates into quicker turn around-times and shorter length of stay. In short: significant cost savings.

3-D models are not only used for intervention planning, they also support patient information very effectively: now the patient may better understand why the intervention is necessary and how it is going to be done. This should deepen trust in the physician and intervention acceptance – an important psychological factor, positively impacting on a patient’s attitude before, during and after the intervention.

Obviously learning by 3-D model is not limited to physicians, patients and families – it is also a perfect tool for training medical students and junior cardio-surgeons.

Last, but not the least, the medical technology manufacturers benefit from 3-D models from the development phase to product marketing. While the manufacturers benefit from 3-D models to optimise patient-specific care is already being realised and the results indicate immense potential awaits exploration in cardiology – above all in paediatric patients, since a baby’s heart can be merely the size of a walnut.

3-D printed cardiovascular model from Materialis, a registered Class 1 Medical Device

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**3-D printed hearts**

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**Cardiac monitor achieves good pilot study results and CE approval**

**Biotronik’s BioMonitor 2 has received CE mark approval after pilot study results confirmed its reliability. Involving patients in Australia, the study showed that the device can be inserted in less than two minutes, and provides high R-Wave amplitudes and a greater than 90 percent success rate for daily Biotronik Home Monitoring transmissions. In addition, the device has a capacity of over 60 minutes of EGG recording time and can transmit up to six sECGs (subcutaneous EGG) daily via Home Monitoring.**

The results of the pilot study confirm the deliverability of the device and excellent sensing amplitudes afforded by the increased sensing...
Real-time MR images of the beating heart

Today, magnetic resonance imaging (MRI) allows more gentle, precise, and cost-effective heart disease diagnosis. However, up to now, using MRI to diagnose cardiovascular diseases has been limited – image acquisition is not fast enough to monitor cardiac movement due to breathing and heartbeat interference. Patients have to hold their breath during an electrocardiogram (ECG) – the only way to match the separate images to the appropriate heartbeat phase during subsequent image reconstruction.

Small children who cannot control their breathing must be sedated for the procedure. In addition, for those patients with cardiac arrhythmia, the ECG simply cannot deliver reliable data for an image reconstruction.

The CaFuR (Cardiac Function in Real Time) project, a recently completed joint venture of the Fraunhofer-Institute for Medical Image Computing (MEVIS), in Bremen, and the Biomedizinische NMR Forschungs GmbH at the Max Planck Institute for Biophysical Chemistry, in Göttingen, provides a remedy for these problems. Göttingen experts, working under Professor Jens Frahm, developed a method for real-time MR imaging. ‘Images with extremely shortened measurement time enable acquisition of films of the beating heart with 50 to 50 images per second, free breathing, and no use of ECG.’

This method allows physicians to observe the heart muscle or blood flow reactions under physiological strain directly,’ Frahm explains. Fraunhofer MEVIS developed the required image analysis methods, including an algorithm that automatically identifies the breathing and heart contraction phases in the data independent of the ECG information.

‘One challenge we had to overcome was the substantial amount of data,’ says medical engineer Dr Anja Hennemuth, project manager at MEVIS. ‘Up to eight gigabytes of image data can be acquired during an examination, which is impossible for doctors to manually analyse.’

BioMonitor 2 is designed for highly accurate and reliable long-term continuous remote monitoring of patients with atrial fibrillation, syncope, bradycardia and tachycardia,’ the manufacturer reports. With the device to be available in Europe soon, Manuel Ortega, Senior Vice President at Berlin-based Biotronik said: ‘Its accurate sensing and detection, combined with its transmission success and data capacity will provide doctors with more useful information on a patient’s condition over time.’

SCHILLER’S CARDIOVIT AT-170

Robust design and high-performance

NEW HIGH-END ELECTROCARDIOGRAPH

- Wide high-resolution touch screen for easy ECG review
- Full-size keyboard with a durable cover keeping dust, dirt and liquids away, making it highly hygienic
- ETM Sport, the first automated interpretation of athletes’ ECGs based on the Seattle Criteria
Tomorrow’s operating theatre

Previously known as a provider of high quality, high-end monitors, Eizo is developing into a systems solutions supplier. The company’s new division for operating theatre (OT) solutions is aimed at advancing technological networking in the OT. Matthias Lubkowitz, the company’s Vice President of this division, reports on the new requirements for intelligent operating theatre technology.

Speaking of the multitude of data generated in today’s hospitals – data from MRI and CT scans, endoscopy videos and electronic patient files – Matthias Lubkowitz pointed out that many hospitals ‘... make do with PCs on mobile technology trolleys, with the respective logistics, space and hygiene problems this causes.’

Eizo GmbH, OR Solutions, offers monitors, video management and data transmission technology from one source,’ he explains. ‘The CuratOR surgical panels are central pieces of the installations. They facilitate the administration of patient data, control of external devices or the transmission of image- and sound signals. The user or clinician respectively perceives the surgical panels as wall-mounted monitors with PC systems. Additionally, so-called monitor suspension systems or satellite monitors stream the required information to all relevant locations in the operating theatre or elsewhere.’

How do the surgical panels work?

‘The user decides what can be seen on the monitors. The CuratOR Caliop software, named after one of the nine muses in Greek mythology, allows the user to select the information required for each monitor. Not only that – the screen can be divided into several segments, so that all image sources, ranging from MRI or CT scans and digital X-rays, from the patient file to live images from the endoscope, ultrasound or surgical cameras to the display of vital parameters, can be displayed in selected combinations. During surgery an operating theatre nurse usually controls the surgical panels. Depending on instructions received from the surgeon the nurse selects images for display on the monitors. The documentation can also be done via the surgical panels, such as information about which material is being used or whether complications occurred. A nurse usually loads the data into the hospital information system.’

‘A flexible system is achieved through the technology that runs in the background. The central element of control is known as the large monitor manager. This important yet unimposing piece of equipment will be located in the technology room.

‘We differentiate between front and back end, with the customer mostly exposed to the front end. The entire system is independent of modalities and therefore compatible with equipment from different manufacturers, and it can process all known analogue and digital signals.’

Why has Eizo entered the systems solutions field?

‘Our company has been known as a provider of high end monitors for more than 50 years,’ Lubkowitz reflected, and listed some of their presence in renowned design agencies, air traffic control centres, aerospace setups and the automotive industry. ‘In 2002 we made the move into the sensitive world of medicine and developed high quality monitors in cooperation with doctors, IT specialists and specialists in medical technology. With the CuratOR, Eizo is now moving into the field of solution providers.

‘We offer system solutions for the operating theatre or, put even better, for the operating theatre of tomorrow. With our modular structure we are not only able to equip new settings with a complete infrastructure but also to adapt to existing environments. We have seen that the requirements in the operating theatre have changed in the world of medicine as a whole, including all the IT networking, have become more complex. Whilst other large providers often feature complete solutions in their range we have designed our software very flexible so that individual elements also can be easily adapted around the interfaces.’

How does this new division fit into the company?

‘Flexibility is something that’s also a feature of the corporate structure at Eizo. The company was founded in Japan in 1968, but is active worldwide. Our individual companies can act relatively independently of one another and are particularly adept at reacting promptly in project business. This is part of the reason behind our company’s success. The different mainstays deliver their expertise, allowing us to fall back on a multitude of competencies for high-end monitors and information technology as well as for customised solutions and the industry. ’This,’ he concludes, ‘is very helpful when new ventures such as ours are being launched.’

Eizo’s individually configurable wall consoles for operating theatres

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PHOTODYNAMIC DIAGNOSIS-ASSISTED TURB IN A REAL-LIFE SETTING

Recently published data confirm previous study results in daily clinical use and demonstrate that HAL-guided blue-light cystoscopy is an effective tool for improving NMIBC detection and management.

Non-muscle-invasive bladder cancer (NMIBC) is characterised by a high-risk of recurrence after transurethral resection of an initial tumour; the 1-year recurrence rate is 15 to 61%, and the 5-year recurrence rate is 31 to 78%. In particular, early recurrence after transurethral resection of the bladder tumour (TURB) is most probably associated with missed lesions or inadequate resection at the time of initial TURB. Photodynamic diagnosis (PDD)-assisted TURB has been shown to reduce the risk of early recurrence compared with white-light TURB in several randomised controlled trials. The randomised trial represents the most rigorous method of getting to the truth as to whether an intervention causes an outcome. However, these trials do not necessarily translate into real-life experience in a non-experimental setting.

At this year’s DGU (German Society of Urology) congress in Hamburg, Professor Maximilian Burger presented the results of a prospective, non-interventional study (OPTIC III), investigating optimised photodynamic diagnosis for TURB. From May 2013 to April 2014, 403 patients with suspected non-muscle-invasive bladder cancer undergoing TURB in daily clinical practice were involved in assessing the additional detection of bladder cancer using PDD-assisted TURB at 30 German sites. It was shown that hexaminolevulinate (HAL)-guided cystoscopy identified a vital number of additional CIS lesions (≥1 positive lesions were detected with PDD only and 2.2% of NMIBC patients would have been missed with white-light cystoscopy). These results are in line with previously conducted randomised clinical trials demonstrating that HAL-guided cystoscopy significantly improves the detection of bladder cancer and provides a diagnostic benefit to patients with suspected NMIBC in daily clinical practice. Moreover, the findings of the OPTIC III trial are also in accordance with other recently published real world data (RWD) studies, showing the ability of PDD to reduce the risk of recurrence of NMIBC significantly under routine conditions.

The results of the OPTIC III study confirm previous data from controlled trials. Nevertheless, the OPTIC III data is data from daily clinical routine use and the results still demonstrate an advantage for blue-light cystoscopy. This is very exciting because we still have a higher rate of detected papillary tumour lesions compared to white-light cystoscopy. And we still do have a 25% difference in favour of blue-light cystoscopy with regard to CIS detection compared to white-light cystoscopy.’

Professor Dirk Zaak during the DGU congress in Hamburg 2015

Spine ops terrorise surgeons no more

'Spine surgery has become even gentler and more effective in the past years,' says Professor Claudius Thomé MD, director of the Neurosurgical Clinic at the Medical University Innsbruck (Austria). Increasing attention is being given to preserving the anatomical structures, such as in the discs or even the muscles surrounding the spine. 'In particular, minimally invasive procedures involving tiny incisions to provide relief of the spinal canal, or fusion, are increasingly common,' emphasised Thomé, who is also president of the Austrian Society for Spinal Surgery (ÖGW). Applying minimal access spine technology (MAST), the target area is usually reached gently by means of trocar systems (puncturing instruments that enable and maintain an entry).

'Thus such interventions involve significantly fewer complications than in the past and are no longer so terrifying,' Thomé explains. In combination with the continuous improvement of anaesthetic techniques such operations are possible even at advanced ages. This is good news in view of the demographic development and the growing demands of older patients regarding quality of life and mobility.

Technical progress in the operating theatre was and is decisive to establish gentle surgery techniques. Surgical microscopes or camera-supported visualisation permit continuous minimisation of the access with an ever-improving detail depiction of the surgical area.

Spinal navigation enables high precision for the computer-aided insertion of implants. With the aid of intraoperative imaging, the result can still be checked on the 'open' patient. 'This improves the results and prevents re-operations,' the neurosurgeon explains. Screws and other implants become more technically advanced and can be inserted using minimally invasive methods. Ultimately, all these factors lead to better outcomes.' Of course all this demands that surgeons gain the skills necessary to keep in step with these developments.

In the same line, Professor Michael Ogon at the Spinning orthopaedic hospital in Vienna, who became President of the Spine Society of Europe (EuroSpine) in September, added. 'Due to new insights, new surgical techniques, and technological progress, specialised training in spinal surgery becomes even more important.' Ogon was speaking during the 'Summer University' in Vienna, one of the annual professional congresses organised by medical technology supplier Medtronic and the International Group for Advancement in Spinal Science (IGASS), and attended by 300 specialists this year. Ogon refers to the European Spine Diploma issued by EuroSpine, which is intended to assure that the initial training in spinal surgery in Europe is uniform and that the same standards apply everywhere.

Returning to spinal surgery itself, Thomé reported on the state of the art to journalists in Vienna: 'The knowledge with regard to the statics and biomechanics of the spine has progressed in recent years. Whereas little attention was paid in the past to the placement of screwed connections in fusions, today we are aware of the important role the vertical profile plays for the spine.' However in Thomé's view the future of spinal treatment lies in regenerative therapy strategies. 'The aim must be to prevent, or at least retard, the natural deterioration of the disc respectively in the spine. Molecular biological discoveries such as those pertaining to stem cells and growth factors will allow us to influence the aging processes in the future.'

In a new clinical study at the Medical University Innsbruck disc cells from slipped disc incidents are currently being cultivated and injected again into patients after three months. Initial results are expected within one to two years.
CT procedures in oncology

Over the last few years CT scanner manufacturers have introduced numerous hardware and software innovations to the market. CT diagnostics benefit from this unbroken trend towards ever faster scanning and from the new reconstruction procedures that require a significantly smaller signal to generate clear images. The lower radiation dose, smaller amounts of contrast media needed and reduced tube voltage all help to make the examination less invasive – resulting in an increased use of the procedure. But the progress in CT technology has not yet reached the end by far. It’s more like a work in progress,’ observes Professor Christian Stroszczynski, director of the Institute for Diagnostic Radiology at the Regensburg University Hospital.

One important development is hybrid imaging. Hybrid scanners, i.e. equipment that can generate both morphological (CT or MRI) and functional (PET) data during one examination, produce merged image data records, which provide complementary information. These procedures have distinctive advantages and deliver a more precise diagnosis than the individual procedures separately, particularly for whole body examinations of cancer patients. PET scanning can often detect primary tumours and metastases clearly, whilst CT and MRI facilitate an anatomically accurate localisation of these lesions.

Stroszczynski points to the growing importance of another new procedure, which he summarises with the term fusion. The combination of CT or MRI images respectively with ultrasound is likely to become of great significance for clinical practice. The procedure involves feeding the CT and MRI image data records into the ultrasound scanner via a USB stick and then overlaying the ultrasound images accurately over the CT- and MRI images.

This has several advantages, specifically in oncology. It allows improved comparability for process monitoring. An example: If a doctor checks the size of a metastasis after two weeks they can compare the current ultrasound scans with the old CT scans. Process control is carried out with ultrasound, reducing both radiation exposure and cost. This can also make treatment easier, for hepatocellular carcinoma, for instance. During contrast with a CT or MRI scan the lesion will be only visible to the doctor for a short time. I carry out a scan and see a lesion. If I’m then asked to puncture the lesion there is no benefit to seeing it for longer. The next time I’ll have positioned the needle the lesion will no longer be visible. However, now I can take these CT data records and feed them into the ultrasound scanner and then use ultrasound to locate and puncture the lesion based on the data records,’ the specialist explains.

One big challenge in oncology is assessing if and how a patient responds to treatment. The most important factor is clearly tumour size, but conventional measuring procedures are not precise enough. Further development of volumetric methods for precise and reproducible tumour measurement in all organs is therefore an important step. The opportunities provided by imaging, such as perfusion imaging, also play an important part here. However, this procedure initially had to be simplified. For mobile organs, such as the liver, the images have to be produced in the same layer within a period of 40 seconds to measure perfusion; but, nobody can hold their breath for 40 seconds, which means there have always been unacceptable compromises with eliminating respiratory motion artefacts.

‘When you are particularly unlucky the metastasis, or tumour, will literally slip off the image. Now we have the opportunity to make volume perfusion measurements. Thanks to further developments in multi-slice CT, we can now image the entire liver and determine the perfusion.’ Stroszczynski continues. ‘We now have special drugs which help to impair or block tumour perfusion, resulting in it dying off. When you want to see how patients respond to this medication volume perfusion, CT is a good instrument that can be used at an early stage to help with treatment decisions.’

Hybrid imaging of CT and contrast enhanced ultrasound provides new options for clinical application

Christian Stroszczynski has held the chair of Radiology and been Director of the Institute for Diagnostic Radiology at the University Hospital of Regensburg (UKR) since October 2010. Prior to this he was Assistant Director and Senior Consultant at the Institute for Diagnostic Radiology at the Carl Gustav Carus University Hospital in Dresden for four years. The core areas of his work are image guided diagnosis and treatment procedures for liver diseases, cancer and vascular medicine.

In perfusion studies, dynamic CT facilitates differentiated imaging of perfusion parameters, such as blood volume, mean transit time and time-to-peak imaging.

European paediatric imaging issues take central stage

The International Day of Radiology

Paeidiatric imaging will be in the spotlight on 8th November, as celebrations for the International Day of Radiology (IDoR) aim to raise public awareness on the role radiology plays in detecting and treating diseases in children, Mélisande Rouger reports.

Whilst the International Day of Radiology initiative will inform patients and families about what they can expect when visiting a radiology department, it will also help to relieve anxiety regarding what will happen to their little ones, it will also highlight critical issues within the field and how radiology department personnel and equipment allocation varies across Europe.

Paediatric radiologists, subspecialists recognised as such only in a few countries worldwide, are a relatively rare species within some areas of Europe; actually they’re almost exclusive in Eastern Europe, according to Dr Catherine Owens, President of the European Society of Paediatric Radiology (ESPR). ‘There’s a dramatic lack of paediatric radiologists across the EU, especially in Eastern Europe,’ she explains, ‘but more recently within countries like France and Germany, who are going through a real crisis.’

Membership of the ESPR, a well-established society, is a good barometer to assess interest for the discipline on the continent. The UK has a healthy number of ESPR members, but there are still unfilled paediatric radiology posts in the country. The situation is much worse in Eastern Europe and huge countries such as Russia. Many of these countries have a very young population, yet few trained specialists, of whom even fewer are ESPR society members.

The society now has very few members from France, where, ironically, the ESPR dug its roots half a century ago, when Professor Jacques Lefèbvre initiated the first international meeting of the speciality in Paris.

Today’s French radiologists view paediatric radiology as not as lucrative as other subspecialities, with punitive daily schedules and on call arrangements, all exacerbated by staff shortages. Dealing with children is more time consuming than general adult radiology, especially in areas such as paediatric MR, where sedation and anesthesia are required to engage the child’s cooperation during the examination.

There is increasing difficulty with the economic and financial compensation for these procedures being limited. In some countries, adult radiologists earn more money than paediatric radiologists and have more opportunity for private practice. Therefore, paediatric radiology can be sometimes considered less standardised assessments in oncology that can also be internationally compared, the system will standardise reporting and data collection. Stroszczynski uses a practical example to explain this: ‘Some doctors talk about massive tumours, others will describe the same tumours as large. It’s therefore important to agree on size specifications. This structured reporting is currently in vogue and is likely to become more and more integrated into the diagnosis process.’

Continued on page 16
One in six men will develop prostate cancer

Mr. Prostate’s MRI dream: ‘Yes, we scan!’

One in six men will develop prostate cancer. This disease is the second leading cause of cancer death among men in the USA as well as the EU. Definite diagnosis, at an early stage, is vital for survival and early treatment minimises the risk of adverse effects, such as incontinence, erectile dysfunction, or impotence. While there is no preventative screening there is a ray of hope. With his team, Jelle Barentsz, Professor of Radiology and Head of the Prostate MRI Reference Centre of Radboudumc, has established new MRI techniques that can quickly confirm or dismiss suspected aggressive prostate cancer as well as accurately determine the aggressiveness of the disease and stage it.

Report: Sacha Keutel

Latest studies show that many patients with mild forms of prostate cancer (known as indolent carcinoma) appear to undergo excessive treatment, a consequence of inadequate staging before therapy with the commonly used diagnostic tools. This current diagnostic work-up has several disadvantages. Patients with an elevated prostate-specific antigen (PSA) levels usually undergo a transrectal ultrasound (TRUS)-guided biopsy, which typically involves sampling tissue from twelve (sometimes six or as many as 24) points in the prostate, in accordance with an established pattern. However, the probability of detecting a carcinoma using this method is only about 50 percent, since ultrasound shows the prostate itself but often does not reveal the position of a carcinoma. Therefore, leading urologists are calling for a non-invasive and reliable method to detect or rule out prostate carcinomas. MRI has been shown to be the most promising method to this end.

New Body 60 coil for optimised coverage of the pelvis and improved signal

Non-invasive 3-D morphology imaging of the prostate in 4:58 minutes

Non-invasive diffusion-weighted imaging of the prostate in 4:20 minutes

(With diffusion-weighted imaging) in addition to depicting the anatomical features and vascularity. It significantly improves accuracy of diagnosis and has the potential to save men pain, discomfort and infection. The latest clinical data suggest a sensitivity of more than 89 percent, which means a patient with a negative MRI result does not need to undergo any further biopsy. Therefore it is currently the most reliable procedure available to confirm and stage a prostate carcinoma or to rule it out.

Economic viewpoint

However, there is a problem: This technique is not yet widely available. As it is considered very time consuming and demanding it tends to be restricted to centres of excellence. Due to the complexity of the images and the data volume that needs to be processed, evaluating the results is a very complex task for the treating physician, and the results are often difficult to interpret for the referring urologist. Barentsz disappointedly confirms: ‘Ignorance, legislation and cost accounting mean that a mpMRI is not the first option in the case of suspected prostate cancer.’ Nonetheless the expert points out that even ‘From an economic viewpoint the new MRI techniques are also favourable: they clearly lower the costs of diagnosis and treatment throughout the entire course of care, and improve the quality of life.’

For example: SEER, a new prostate MRI solution by Siemens, makes this examination as comfortable as possible: powerful coil technology (Body 60 and Tim 4G) and unique applications (RESOLVE) allow a non-invasive examination in less than ten minutes.

Mr. Prostate’s dream

Barentsz, who has often been called ‘Mr. Prostate’, advocates for the future a general screening program for men above a certain age, questions: ‘If this is done for breast cancer which affects 1 in 7 women, then why isn’t it done for prostate cancer, where 1 in 6 men is affected? Why don’t we have a “manography” yet? MRI scans could radically change the diagnosis and treatment of prostate cancer and halve the number of unnecessary biopsies. Mr. Prostate’s dream is that MRI screening becomes standard practice if somebody comes to his or her GP with an elevated PSA level,’ he explains.

However, the introduction of new medical services always depends on decisions by the national healthcare authorities. Barentsz has a clear opinion about the use of prostate MRI: ‘I hope that we – government, health insurers, specialists, GPs and patients – will increasingly be able to work together to give men with suspected prostate cancer the benefits of a modern MRI scan. Yes we can!’

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Vasculitis in the brain

Vasculitis in the brain, an inflammation of the vessel walls resulting from autoimmune disorders, as yet has been difficult to diagnose with imaging procedures. Now, however, new and more sensitive MRI procedures and higher image resolutions allow it possible to visualise micro-infarction as well as the thickening of the vessel walls typical for vasculitis, even in the smaller cerebral vessels. This can be of great advantage specifically for younger patients, as Professor Elke Gizewski, neuroradiologist and Medical Director at the Department of Radiology at the Medical University of Innsbruck reports:

"Especially for younger patients who, measured by their age, present with too many micro-angiopathic changes in the brain, it makes sense to carry out further investigations into the presence of vasculitis with additional MRI sequencing," Gizewski advises. As some patients do not even notice such micro-infarctions and are not admitted to hospital, but present as out-patients or in GP surgeries, it is particularly important to use this technology for clarification of a diagnosis.

The administration of contrast agents enables confirmation of changes to the vessel walls, which indicate an inflammation. If only the right side of the brain is affected, the vessel walls on the right side will accumulate the contrast agent; those on the left will not. Thus it is possible to determine precisely which vessels are actively affected.

In such cases, diagnosis and carrying out process monitoring during treatment is easy. Vessel wall imaging is a procedure already commonly used for other body areas, especially black-blood sequences, i.e. T1 weighted sequences that help to:

- determine precisely which vessels are actively affected;
- determine those affected and after administration of a contrast agent;
- determine those affected and after administration of a contrast agent.

**Vessel wall imaging for smaller vessels**

Vasculitis does not lead to the complete occlusion of the vessels that occur in large infarctions, but to permeation of the vessel walls, which indicate an inflammation. If only the right side of the brain is affected, the vessel walls on the right side will accumulate the contrast agent; those on the left will not. Thus it is possible to determine precisely which vessels are actively affected.

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84-inch 8MP displays strengthen consultations

More is better – when it comes to medical display technology a higher resolution is a desirable feature of next generation displays. Today, the number of pixels alone is just one of many factors that distinguishes a display developed specifically for diagnostic purpose from those designed for regular use. Shinji Nohara, Product Manager for Pro/Colour/Medical Desktop Display at NEC Display Solutions Europe, gives this report.

Medical displays: More than in any other sector, high contrast is essential. Only with outstanding capabilities can a radiologist distinguish between different structures in an image and detect even the smallest irregularities like a metastasis.

Higher resolution is the future
Apart from the introduction of colour the resolution has also changed, so that 3-megapixel with the same quality is possible without any problems. Assistant tools offered by software – such as those used for measuring the size of tissue – are easier to spot in colour, which makes the software easier to operate and another person reviewing the results can find marked portions of the image better.

Another trend is to combine two 3-megapixel monitors into one 6-megapixel installation. With this resolution it is possible to review the huge amount of images of modern diagnostic tools in a more efficient, ergonomic way.

The importance of quality control
Together with even better displays, the need for a centralised quality control arises. Particularly in big hospitals, it is time consuming to control and calibrate each display at the workspace. Software tools that connect all workstations and their connected displays together mean you can access displays any time and check the live status, such as temperature or backlight hours. It is therefore a tool to maintain displays and see the last calibration reports and conformance test reports. Overall, the better the IT infrastructure is in a hospital the more features can be used from the software.

To make the software work, most medical display models in the NEC lineup have a small front sensor for calibration. All monitors come with a free client software licence for GammaCompMD QA.

Better displays – better treatment

Trends in displays such as 4K have reached the medical area and will continue to change the way details in radiology can be viewed. Large 84-inch 8MP (4K UHD) displays, compliant to the DICOM Part 14 standard are starting to replace traditional projectors in hospital meeting rooms. At group diagnosis meetings, doctors from different disciplines, e.g. radiology and oncology, can discuss medical images in far better quality. As medical imaging technology progresses with new generations of MRI and CT, display technology makes its contribution. The better the image, the better physicians can detect and cure diseases. NEC Display Solutions is proud to be part of a technological revolution that has a direct impact on many people’s quality of life.

Details: www.medical.nec-display-solutions.com

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Rheumatology depends on ultrasound

Switzerland is among few European countries that require extensive supervised ultrasound training as a mandatory component in medical specialist training for rheumatologists. Ultrasound is an important tool for many rheumatic diseases because it suits diagnostic and therapy monitoring needs as well as targeted efficient ultrasound-guided interventions. Dr Giorgio Tamborini, Medical Director, rheumatologist and specialist for musculoskeletal ultrasound at the Ultrasound Center of Bethesda Hospital, Basel, Switzerland, explains sonography is so important in rheumatology.

In Switzerland, as in most other countries, the first stop for patients is usually a general practitioner (GP) – and the GPs decide when to refer patients to a rheumatologist. ‘We drafted guidelines for the early diagnosis and management of rheumatoid arthritis that define when and for which purpose an ultrasound exam should be performed,’ explains rheumatologist Dr Giorgio Tamborini. ‘The guidelines were published in a journal for internal medicine (Swiss Med Wkly. 2013;143:w13861), for internal medicine specialists to develop a feeling for the right time to do such an exam.’

The Swiss model has a crucial advantage: it ensures a patient with a suspected inflammatory rheumatic disease receives a complete diagnostic work-up by a trained and certified rheumatologist (SGUM, EFSUMB, EULAR, etc.), including high-resolution ultrasound. This procedure allows us to diagnose arthritis in the joints that are most commonly affected, with high sensitivity and specificity, Tamborini explains. Additionally, Doppler ultrasound shows ‘active’ rheumatoid arthritis, which plays a crucial role in therapy and prognosis of the disease. A further advantage of ultrasound is the opportunity to view joints dynamically and in several planes. Moreover, the technology allows us to assess many joints in a short period of time; the rheumatologist stresses. In the latter case ultrasound is limited in its diagnostic capabilities and an MRI scan of the hand is indicated – performed in a radiology department that has proven experience in diagnostic imaging of the musculoskeletal system. ‘The majority of patients requiring diagnostic imaging for arthritis can be successfully examined with high-resolution ultrasound; a slice imaging modality is not required,’ Tamborini points out.

Conditions need differentiation via ultrasound

The word ‘rheumatism’ is used to describe 200 different disorders. About 100 of them can cause joint pain or inflammation, he explains. Thus the rheumatologist must be familiar with all variants and be able to tell them apart. Inflammatory conditions must be differentiated from degenerative disorders, or from pathologies caused by post-traumatic changes. The combination of a thorough anamnesis and a differentiated exam by an ultrasound specialist can produce highly sensitive and highly specific findings that help to rule out or rule in specific disorders in a differentiated imaging modality.

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The America Institute of Ultrasound in Medicine (AIUM) is returning to New York City for its 2016 Annual Convention. The Convention will now take place:

March 17-21, 2016
New York Hilton Midtown
Training is necessary to work competently with this highly specialised technology. "Watch and learn," Tamborrini reports, from different countries here to EULAR, an international training network. "Technological advances are such a complex field, over the past few years we've been drafting guidelines and recommendations cannot be captured, either, often explained," Tamborrini explains. Furthermore, intestinal obstructions can be diagnosed around 6-12 hours earlier with ultrasound than with plain abdominal X-rays because, in the early stage, the intestinal loops are not yet strongly dilated but already filled with fluid, which can only be seen on the ultrasound scan. Ultrasound also facilitates a more differential diagnosis. "The ultrasound image also shows possible other causes of acute abdominal pain, such as renal congestion or biliary colic. The X-ray on the other hand makes no contribution to a differential diagnosis," Tamborrini stresses. He does not accept the oft-cited argument that the abdominal X-ray visualises the fluid level in the intestines well. "This may be the case - but the level is only an indirect sign that there may be air and fluid in the intestines. Ultrasound allows the direct detection of the fluid." Hollerweger believes that the reason why so many hospitals carry out plain abdominal X-rays when an intestinal obstruction is suspected is mostly organisational is gas in the intestines. "Therefore, it’s very important to apply the transducer in the lumbar region."

He also recommends a clear system for the examination. "Initially, you should check via the side and spleen whether or not the stomach is full. Secondly, you need to try and ascertain whether or not the abdomen is contracted. Whether congestion continues to the adjoining large intestine is questionable. Finally, you must check in the right, lower abdomen whether the lower small intestine has collapsed, or whether congestion continues to the large intestine."

"Afterwards you need to try and narrow the site of the obstruction down even more precisely." Hollerweger advises all colleagues to regularly update their knowledge of the gastrointestinal tract. "Practice makes perfect!"

The guidelines and ultrasound examiners agree on one thing: the follow-on examination procedure of choice to establish a diagnosis should be CT. "When an ultrasound scan does not deliver a result in cases where an intestinal obstruction is highly suspected, then the next diagnostic step should be a CT scan," Hollerweger emphasizes. A CT scan is also indicated for obstructions of the large intestine, not least because the most common cause of these is cancer. 

In conclusion, this experienced ultrasound trainer offers some practical tips. In most cases of ileus there is gas in the intestines. When the patient lies on his back this rises to the front. Therefore, it’s very important to apply the transducer in the lumbar region.

He recommends checking the abdomen and gastrointestinal tract as well. "Another reason for ignorance is that surgeons still insist on, in large hospitals, without the presence of a radiologist. A plain X-ray can be carried out at any time during the day and night whereas the presence of a radiologist makes no contribution to a differential diagnosis. A CT scan is also indicated for obstructions of the large intestine." Hollerweger advises all colleagues to regularly update their knowledge of the gastrointestinal tract. "Practice makes perfect!"

\[\text{ISO 13485:2003} \]

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2-D Shear-wave elastography

The advantages of a larger examination area

How good is 2-D shear-wave elastography for the diagnosis of cirrhosis of the liver, and does it offer any advantages compared to transient elastography? This was the subject of a study carried out at the University Hospital Frankfurt am Main under joint leadership of statistics expert Prof. Dr. Eva Hermann and gastroenterologist Prof. Dr. Mireen Friedrich-Rust. The study was first introduced in Vienna at the 50th Annual Congress of the European Association for the Study of the Liver (EASL) in April this year and is due to be published shortly. It comprises clinical data of 1,340 patients in 13 centres.

120 patients for this meta-analysis came from the University Hospital Frankfurt itself. For each patient, the histological grade of fibrosis determined by the liver biopsy was correlated with the elastography results, as Prof. Dr. Mireen Friedrich-Rust, Consultant at the Centre for Internal Medicine, reports. 972 patients out of those examined were assessed for the entire range of patients and stages of fibrosis as long as the quality criteria are taken into consideration. The results are less precise. The present meta-analysis confirms a slight superiority of the 2-D shear-wave elastography across the entire range of patients and stages of fibrosis as long as the quality criteria of transient elastography are disregarded, says Friedrich-Rust. If only a smaller, random area is selected the results are less precise. The region of interest is larger, and particularly in the early stages of fibrosis the histological changes are often distributed inhomogeneously, explains the consultant. If only a smaller, random area is selected the results are less precise.

Better differentiation in early stages

Based on current data, 2-D shear-wave elastography achieves a better differentiation, particularly in the early stages of fibrosis, interprets Friedrich-Rust. Her explanation is that 2-D shear-wave elastography facilitates the examination of a larger area and sends multiple shear waves into the tissue. "The region of interest is larger, and particularly in the early stages of fibrosis the histological changes are often distributed inhomogeneously," explains the consultant. If only a smaller, random area is selected the results are less precise. The present meta-analysis with transient elastography in addition to the 2-D shear-wave elastography. The patient population consisted of patients with Hepatitis C (470), Hepatitis B (420), non-alcoholic fatty liver disease (172) and other types of liver disease. No fibrosis, or only mild fibrosis, was diagnosed in 40.8% of patients; 19.3% had a moderate fibrosis, 14% severe fibrosis and 26% were suffering from cirrhosis of the liver.

Liver stiffness measurement with 2-D-ShearWave Elastography.
acquired pneumonia. This is normally diagnosed with conventional X-rays taken in two positions. Things are different with children. Although chest X-rays (for reasons of radiation protection taken only in one position) are also used here, there should be a discussion as to whether a suspected diagnosis should not initially be confirmed via ultrasound instead. There are cases of pneumonia that can be detected on a chest X-ray and CT, but not with ultrasound; these are mostly atypical changes to the lungs. Historically, chest X-rays were the first imaging procedure used to diagnose TB, which is why, in Austria, all asylum seekers still have to undergo chest X-rays. Replacing these with ultrasound scans would make no sense in my view, because many changes caused by TB cannot be seen on an ultrasound scan. We need to individually differentiate which type of infection is likely to be present, which patient is affected and when there is a good reason to use ultrasound.‘

Are there guidelines for ultrasound of the lungs?

‘As far as I’m aware there are no S3 guidelines for community acquired and/or nosocomial types of pneumonia that stipulate the use of ultrasound for diagnosis. Pneumonia is a common, and specifically for older patients, serious disease. If we insisted on carrying out the initial diagnosis with ultrasound for all patients affected this would make no sense because there would likely be a large number of cases that we wouldn’t be able to detect. From an organisational viewpoint this would not be feasible either, both for in- and out-patient settings. If the objective is a comprehensive diagnosis for a patient suffering from severe pneumonia, we need to establish for prognostic reasons alone how many pulmonary lobes are affected and whether the pneumonia is necrotising or abscess forming. It isn’t always possible to determine this clearly with ultrasound. The same applies to changes to the bronchi, such as tumours or bronchiectasis, which lead to pneumonia.’

You mention X-rays, CT and ultrasound… why not MRI?

‘There are currently several working groups looking into the use of MRI to monitor children with congenital diseases such as mucoviscidosis (cystic fibrosis), for reasons of radiation protection. However, MRI does not have as good a spatial resolution as modern CT. Furthermore, the lung diagnosis is made more difficult because of movements caused by breathing and the beating heart. The lungs, which are mostly filled with air, appear on MRI more or less as black holes but, despite this fact, there are still concerted efforts to utilise MRI for functional diagnosis of the lungs. The results achieved by these working groups remain to be seen.’

ULTRASOUND

53-year-old male with suspected pneumonia. Chest X-ray (a) shows a consolidation bottom right and a pleural effusion on the right. The CT (b) soft tissue image shows a pleural effusion with an air pocket on the right and a thickening of the pleural layer; the consolidation shows the start of necrosis. The CT lung image (c) shows an infected infiltration in the left lower lobe, which can hardly be seen on the X-ray (a). Diagnosis of pathogens: Pneumococci. Clinical diagnosis: abscess-forming bilateral pneumonia with pleural empyema on the right.

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New atlas will redefine OB/GYN imaging

Using Superb Microvascular Imaging

In its first year of routine use, the new Apio Platinum Series has won praise from leading clinicians worldwide

Impacting on clinical decisions.
Accelerating clinical routine.
Following the release of its new Version 6 software upgrade for the Apio Platinum Series ultrasound system, Toshiba has received high marks for the enhanced functions and performance from practitioners, each offering specific insights into how they are applying the technology.

In a whirlwind world tour, here’s what they say:

Superb Microvascular Imaging

"Estimated very conservatively, I’d say that in around 20% of cases a different approach to treatment results from the use of Superb Microvascular Imaging (SMI)," reports Professor Thomas Fischer MD, Head of Ultrasound Diagnostics at the Institute for Radiology at the Charité Mitte Hospital in Berlin.

"SMI is a Doppler imaging procedure that reacts a lot more sensitive to low flow speeds than normal Doppler imaging – with the added benefit of increased spatial and temporal resolution. The new version of the software has also reduced clutter artifacts that can affect the visualisation of perfusion. SMI can be used with contrast agents, can be visualised in 3-D and is compatible with more transducers."

In clinical diagnostics SMI has proved to be a game changer.

Fischer suggests this functionality can be used wherever the objective is the diagnosis of vascularisation and he sees a particular advantage for the diagnosis of liver disease and, specifically, cancers. After the wash-in and wash-out phases of contrast agent, the examiner can switch to SMI, now optimised
An essential innovation of the Aplio Platinum series was the introduction of the shear-wave elastography with propagation mode, also making it possible to visualise the propagation of the shear-wave generated in the tissue as a colour-coded image, while simultaneously measuring the absolute value of elasticity in a chosen region.

‘Having these available in twin view allows a greater degree of confidence in selecting reliable regions of interest for elastography measurement,’ Gibson said. Elastography mapping in general has been enhanced with the Version 6 upgrades to the Aplio platform, he added, with propagation map cleaner than ever.

‘The Aplio 500 can indicate whether an elasticity measurement was successful, or not, because of the propagation mode, and the new version has even further improved this,’ Fischer said. ‘The examination procedure used to be a case of guessing the region of interest in a certain section of the image, starting the measurements and hoping that shear-wave signals were actually being measured. Now we can actually see whether or not the quality of the shear-wave propagation is adequate and then measure where propagation lines occur most evenly within the region of interest.’

‘This enhanced functionality carries clinical impact,’ he pointed out. ‘It will lead to long-term changes for the diagnosis of liver disease. Whilst it is possible to diagnose fibrosis with the help of a biopsy, shear-wave measurements can document much larger sections of the organ. To me this makes more sense than examining just a small sample.’

Fusion imaging and real-time 3-D needle tracking

Three rooms are equipped for interventional radiology at the University Hospital of Strasbourg in France and, according to the department chairman Afschin Gangi MD, ‘they are packed with patients, completely full, because we are asked to do so many interventions.’

‘The majority of our cases are for biopsies, but patients are lined up for ablations, as well.’ When the upgraded needle-tracking capability arrived for the Aplio Platinum system, ‘it was like adding a fourth room for biopsies and interventions,’ he said. ‘Once I have the image fusion and know where the tumour is situated, I can do the intervention anywhere I can correctly position a needle, with propagation map.’

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Bone biopsy in a haemangioma after 15s. The use of SMI to visualise vascularisation with contrast agent after 1:12 minutes. The characteristic vascular pattern can be viewed at any point after the administration of contrast agent without the need for a new bolus administration.

50-year-old patient has Hepatitis C and histologically confirmed stage three fibrosis. Shear-wave propagation on the left image. The ROI is determined within the area outside the vessels, which is free of artefacts and is simultaneously visualised on the B-image on the right to standardise the measurement.
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