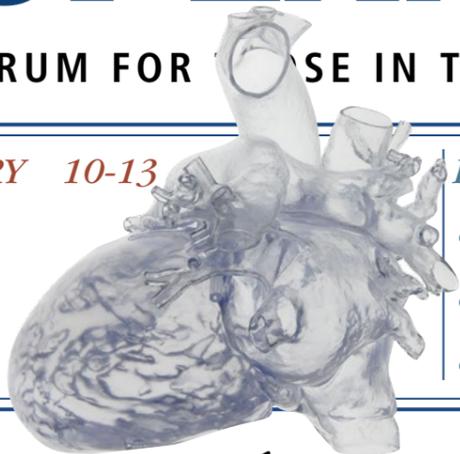


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England's harsh slash at cancer drugs list

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; Cetuximab 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 re-think 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 benefits, the cost has risen to £340m 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

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

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



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.

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.

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



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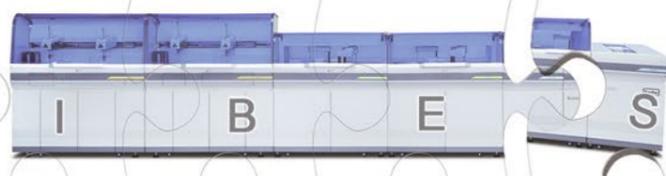
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Where pain relief is a matter of luck

Western Europe can choose from a variety of opioid preparations

Report: Michael Krassnitzer

Access to pain relieving medication varies greatly within Europe. 'The availability and reimbursement of certain pain relieving medications for patients depends less on medical criteria than luck – living in the right country,' declared Professor Hans Georg Kress, past president of the European Pain Federation EFIC, speaking in Vienna this September at the 9th EFIC Congress.

A new EFIC study, first presented at the congress, examined the gap in supply of pain-relieving medications in Europe, using oral opioid analgesics as an example. According to the study, the number of different opioid preparations available to pain patients is – as a rule – higher in Western Europe than in Eastern Europe. Germany heads the list with 47 approved oral opioid analgesics, the costs of which are assumed entirely by health insurers. Italy lies second with 42 approved and reimbursed opioids, followed by Denmark, with 37 on the market, of which only 22 are reimbursed and Sweden with 35 approved and paid medications.

The tail end includes Kosovo (four approved none reimbursed), Russia (4/4), Bosnia- Herzegovina (3/0) and the Ukraine where not a single oral opioid is available.

In some European countries the health insurers or public purse reimburses opioid costs 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



Professor Hans Georg Kress heads the clinical department for special anaesthetics and pain therapy at the Allgemeine Hospital, Vienna. He is also a past president of the European Pain Federation EFIC



Dr Wolfgang Jaksch DEAA is senior physician at Vienna's Wilhelminen Hospital and president of the Austrian Pain Society (ÖSG)

procedure that takes some one and a half hours and therefore must offer it free of charge. Result: practically no physician is willing 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 cri-

sis in recent years,' according to Dr Wolfgang Jaksch, 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 being cut constantly, that is just where they are being reduced.'

Jaksch named two other countries, which, in his view, act as models of supplying patients with pain medication. In 2010, Italy adopted a law (*Legge 38*) in which the foundation for a major structural improvement in pain medical care was laid. It grants citizens the right to palliative and pain medical care and obliges the Italian regions to provide a comprehensive selection of pain and palliative medical care. Among 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, 34 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 of sub-acute – pain both on an out- and inpatient basis. In addition to such highly specialised facilities, every Belgian hospital has been obliged to create interdisciplinary pain teams, which will be remunerated in the context of the regular hospital financing.

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 eas-

ily 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, 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 €10 billion per year. In Hungary this number reaches 1.2% related to the total expenditure of public financed healthcare. Patients want to access cross-border health services when 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's report on 'Cross-Border Healthcare in Europe' the volume of patient mobility within 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.'

In the majority of cases, the medical treatment had not been planned: 3% just happened to have received treatment in another 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



Dr Attila Bodnár is Director of the Bajcsy-Zsilinsky Hospital and Out-patient Clinic, Budapest, Hungary

healthcare systems, some of which struggle to provide care within 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 repartition process is happening. The Hungarian central government faces the same challenge as other governments: total public annual expenditure on the healthcare system is very low in terms of GDP. However, thanks to serious EU funding, the infrastructure and equipment in most state-owned medical institutions and even private sector providers has revived. Actually, Hungary's power to struggle for a bigger market share of the healthcare market may also be strengthened by the of public sector institutions, because better conditions enable them to provide such



England's harsh slash at cancer drugs list

Continued from page 1

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

Albumin Bound Paclitaxel for advanced pancreatic cancer
Bendamustine for Chronic Lymphocytic Leukaemia
Bendamustine for relapsed mantle cell non-Hodgkin's lymphoma
Bevacizumab for first line treatment of recurrent or metastatic cervical cancer
Bevacizumab for advanced breast cancer
Bevacizumab for second or third line treatment of advanced colorectal cancer
Bosutinib for refractory chronic phase Chronic Myeloid Leukaemia
Bosutinib for refractory accelerated phase Chronic Myeloid Leukaemia
Bosutinib for accelerated phase Chronic Myeloid Leukaemia

Brentuximab for refractory systemic anaplastic lymphoma
Brentuximab for relapsed or refractory CD30+ Hodgkin's lymphoma
Cetuximab for third or fourth line treatment of metastatic colorectal cancer
Cetuximab for third or fourth line treatment of metastatic colorectal cancer (with response to previous Cetuximab)
Dasatinib for treatment of chronic phase chronic myeloid leukaemia
Everolimus for metastatic renal cell carcinoma
Ibrutinib for treatment of relapsed/ refractory Chronic Lymphocytic Leukaemia
Ibrutinib for treatment of relapsed/ refractory Mantle Cell Lymphoma

Lenalidomide for second line treatment of multiple myeloma
Panitumumab for third or fourth line treatment of metastatic colorectal cancer
Panitumumab for third or fourth line treatment of metastatic colorectal cancer (with a response to previous Cetuximab)
Pegylated Liposomal Doxorubicin for named sarcomas
Peptide Receptor Radionuclide Therapy (Lutetium177 Octreotate or Yttrium90 Octreotide/ Octreotate) for advanced neuroendocrine tumours
Pomalidomide for relapsed and refractory multiple myeloma
Radium-223 Dichloride for prostate cancer
Trastuzumab Emtansine for breast cancer

Continued on page 6

A challenging shift from cure to care

John Brosky meets Yann-Bourgueil

Healthcare systems need to move beyond reform 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 to 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 counseling, 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.

Training in new skills and aligning incentives to reward coordinated care become critical to transforming chronic care delivery.

'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.'

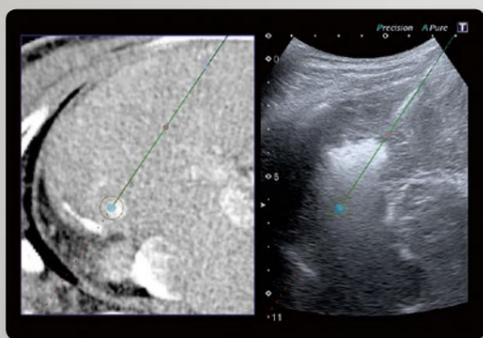
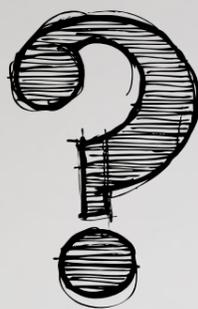


Yann Bourgueil, Director of the Institute for Research and Information in Health Economics (IRDES), Paris, France

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A road to purchasing equality must be built

Dying for equal access to drugs

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 Krassnitzer sought answers from Dr Stanimir Hasurdjiev, Board Member of the European Patients' Forum

'Today, we see innovative new treatments for diseases that had once been untreatable; there is also personalised medicine that seeks individual approaches for each patient. Such advances come with a price tag,' Dr Hasurdjiev underlined. 'Even wealthier countries struggle to meet the costs. Therefore, the time has come in Europe to act and to establish a pricing system that is really fair, based on solidarity and on the fact that all European citizens have the right to innovation.'

Where is access to new medicines good and where is access to new drugs limited?

'Traditionally, there are some countries in Europe where patients and citizens have very early access to medicines, for example in Germany, the United Kingdom or France. However, in others, mainly in Central and Eastern Europe, the time span between approval of a new drug and accessibility for patients is far longer – it can take two years, or even more, before the patients and citizens can benefit from an innovation. For example, in Bulgaria, where I live, the law says that the costs for a new medicine will only be reimbursed when five other countries already do that. Then the local reimbursement process starts, but it can take months before a decision is made. Moreover, new medicines are reimbursed only from 1 January of the year following the year of the positive decision for reimbursement. You can imagine that it can take really long before patients can benefit from the innovation.'

Is that for monetary reasons?

'It's a complex problem, but money is definitely a big obstacle – especially for countries with a lower gross domestic product (GDP), where the pressure on the healthcare budget is really high. The European pricing

system keeps the prices more or less at the same level for all European countries – which is not always fair because of the substantial differences in GDP between the wealthier and the poorer countries – but the people in poorer countries have to pay similar prices because of the external reference price system.'

How does this external reference price system work?

'An external reference pricing system means that each country can compare prices in other countries. In Bulgaria, for example, each producer or importer of pharmaceuticals has to offer the lowest possible price of all EU-countries. However, Bulgaria is a reference country for Spain. Thus, even if a pharmaceutical company acknowledged the economic situation and the constraints and offered Bulgaria a lower price, it would immediately influence the bigger and more profitable market in Spain; and, from Spain, this price could spread to any other European country.'

'This was a very good mechanism to reduce prices as long as there were fewer members of the European Union and the Member States were

similar in economic development. Today, there are so many Member States that are economically not as highly developed – and that creates definitely problems.'

Could this system change?

'This debate is on-going in Europe. I can see a shift to more openness to discuss the issue. One option to consider is the so-called differential pricing system. In other words: tailored pricing depending on a country's ability to pay – based on GDP – and its willingness to invest in healthcare. But it's tough because it would need a fundamental change in European legislation.'

What kind of change do you mean?

'First, the wealthier countries have to agree that poorer countries have the right to pay less. Secondly, and that's a bit more difficult, there has to be a guarantee that cheaper medicines from a poorer country won't appear in more wealthy markets. In Europe, we have the fundamental rule of free movements of goods: Everyone can buy cheap medicines in Bulgaria and sell them on wealthier markets, such as Germany or France. This is one of the reasons why most of the



Dr Stanimir Hasurdjiev (also Hasardzhiev) is a board member of the European Patients' Forum as well as a member of several other 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

companies keep 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.'



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The EU

Today we search in vain for

Report: Mark Nicholls

Two of the core tenets underpinning the European vision – the euro and the Schengen agreement – are coming under unprecedented threat through financial challenges and the impact of the refugee crisis across the continent.

It is these critical issues that keynote speaker Professor Martin McKee tackled during the opening plenary session at the recent European Health Forum in Gastein in Austria.

Within the main theme of this year's Conference, 'Securing health in Europe – Balancing priorities, sharing responsibilities', the intricacy posed to the capacities of European Health Systems by those fleeing conflict-torn home countries will be high on the agenda.

Professor McKee said the global financial crisis had 'exposed the fault lines in the design of the European stability mechanism'.

In addition, he feared the refugee crisis has placed the Schengen agreement – among the 26 European countries that had abolished passport and other border controls – under extreme pressure with examples of some governments taking actions to reduce free movement.

As Professor of European Public Health at the London School of Hygiene and Tropical Medicine, he continued: 'In both these cases, the measures that must be taken are obvious, except, it seems, to European governments.'

'It is also clear that we need a fair system to distribute refugees across the European Union, regardless of race or religion, yet we have the remarkable situation, in the 21st century, of one member state refusing to take Moslems and others refusing to participate at all.'

'This is happening at a time when the ordinary people of Europe are opening their arms to welcome those who are fleeing conflict and persecution, adding a new word – Wilkommenkultur – to our vocabulary.'

Professor McKee, who established the European Centre on Health of Societies in Transition (ECOHST)

Death risk rises over weekends

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 database to which 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 in the heightened risk of death in Australia.

'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 under-

stand 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 Trusts 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 a 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 call for hospital 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-

ing levels and services, and patient safety and that changes to how the NHS provides weekend and out of hours care 'will be an ideal opportunity to evaluate their impact on the weekend effect'.

The UK government has confirmed that plans for seven-day services will focus on the delivery of urgent and emergency care, rather than seven-day elective care.

Dr Mark Porter, the BMA (British Medical Association) council chair, said: 'The BMA agrees that seven-day urgent and emergency care should be the priority for investment. This will ensure the sickest patients have access to excellent care, around the clock. The focus should be on bringing this up to the same high standard across the week before looking at whether the NHS can afford to expand routine, elective care. 'More detail is now needed on how seven-day services will be provided at a time when existing staff and ser-

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)

vices are under enormous pressure, including how additional weekend care can be delivered without weekday services being affected.’

Secrecy surrounding the Transatlantic Trade and Investment Partnership currently being discussed by the EC and USA is posing ‘a serious threat to the ability of governments to implement healthy public policies.’

With Europe failing to train enough health workers, Professor McKee points out that [health workers among] refugees from Syria, Iraq

and Afghanistan entering a Europe with its falling birth rate and ageing populations can ‘make a major contribution to the delivery of health and social care over the years to come’.

‘Unfortunately, this means that they will no longer be able to provide much-needed care for those who remain in the countries from which they have departed,’ reflected Professor McKee, who is also research director of the European Observatory on Health Systems and

Policies. His over-riding concern is that the political structures in Europe to tackle these current issues are not being effectively used. With a ‘frightening vacuum of leadership in Europe at present’ and some politicians seeking to exploit the current divisions within Europe, there is a greater need for transparency within the Council of Ministers and parts of the European Commission, he concluded.

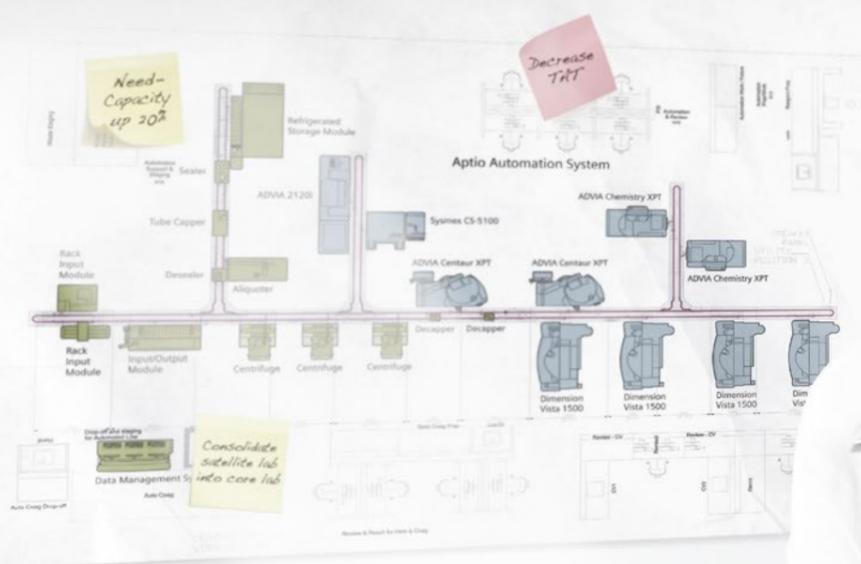
‘The idea of Europe was created by political giants, such as Adenauer



Martin McKee is Professor of European Public Health at the London School of Hygiene and Tropical Medicine

and Schumann,’ McKee emphasises. ‘We now search in vain for anyone with that vision.’







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HCV prevalence could decrease by 45% due to revolutionary antiviral treatments

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 past decade and, according to Dr Miguel Angel 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 VHC 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 1,093 liver transplants in Spain were attrib-



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uted to VHC alone in 2013. New research shows that the virus transmission modes have also changed. Nosocomial transmission could be responsible for 73% of cases diagnosed in tertiary hospitals, especially when multidose tubes are used, Simón explained. 'Out of 131 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 200,000 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 VHC+ 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 30-60% 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 85-95% 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 '...asvirs', which are NSSA inhibitors blocking the replication complex formation; the '...buvirs', NS5B polymerase inhibitors; and the '...previrs', NS3/4 protease 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 tradi-



Following his role as head of the Digestive Hospital Miguel Servet, in Zaragoza, Miguel Angel Simón became head of the Gastroenterology department at Lozano Blesa University Hospital, Zaragoza. He is also Associate Professor at the Faculty of Medicine, University of Zaragoza, where he had gained his bachelor of medicine and gastroenterology specialist qualifications in 1980 and 1985. In 1990, he also received a medical degree from the University of Navarra. Today, Dr Simón's main interests lie in advanced endoscopy, endoscopic therapy and hepatology – especially viral hepatitis

tionally did not respond to treatment, for instance patients with renal insufficiency or HIV,' he explained. 'Daclatasvir combined with sofosbuvir in HIV co-infected patients has a similar efficiency to mono-infected treatment.'

The next step – screening the population

Efficacy has a price. Sovaldi, for instance, costs \$1,000 per day, or \$84,000 for the typical 12-week course. It will be critical for healthcare providers to prioritise patients according to the acuteness of their case in a first stage, Rodríguez Baño stressed.

The next step would be to screen the population. 'First we must treat patients with liver disease and cirrhosis, then we will treat HCV+ 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 very 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-financed – 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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Microbubbles reach into the cracks and crevices

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 Birkin 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 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



StarStream is a new technology that delivers a gentle stream of cold water through a nozzle to generate ultrasonically produced tiny bubbles that 'scrub' surfaces

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 duodenoscope, 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



Tim Leighton, FEng FRS, is founder and chair of Southampton University's Network for Anti-Microbial Resistance and Infection Prevention (NAMRIP) Strategic Research Group, which hosts over 100 members. He is also founder and chair of Health Effects of Ultrasound in Air (HEFUA), and Professor of Ultrasonics and Underwater Acoustics at the Institute of Sound and Vibration Research within the Faculty of Engineering and the Environment at the University of Southampton

Details: www.southampton.ac.uk/engineering/research/projects/starstream.page

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 ultrasonic 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.

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Shrouded in secrecy: a non-venous blood sampling system

Drawing blood from capillaries

Report: Cynthia E. Keen

It hasn't happened yet, but the laboratory testing industry in the United States is bracing up for a day when venous blood draws may become more of the exception than the rule. For the past two years, Theranos, a Palo Alto, California-based start up and its founder Elizabeth Holmes, the world's youngest female billionaire, have disrupted this industry with finger-prick technology and laboratory testing offered at a fraction of the price of its established competitors like Laboratory Corporation of America (LCA) and Quest Diagnostics.

Theranos has developed a novel, proprietary blood-testing platform that uses a few drops of blood obtained via finger-stick, or with very small needles. The firm posts its prices for tests online and delivers results rapidly to ordering physicians and patients themselves who have downloaded the company app. The website also offers integration with electronic health systems (EHRs) to its customers.

How Theranos' proprietary technologies work are shrouded in secrecy, although the company did

receive the USA's Food and Drug Administration (FDA) clearance for a laboratory test to detect herpes simplex 1 in July 2015. However, the FDA's detailed 29-page memo

in the laboratory testing industry, in an effort to the FDA to grant formal clearance to its novel methodology.

Also in July, Theranos signed strategic partnership agreements with mega-pharmacy chain Walgreens, with AmeriHealth Caritas, a national Medicaid managed care organisation, and with Capital Blue Cross, Central Pennsylvania's largest health insurer. All of these deals are based on the low cost and rapid turnaround of Theranos' laboratory testing services.

Tasso, a medical technology start-up company headquartered in Seattle, Washington, is developing HemoLink, a device for self-collection of blood samples. Information about the product has been explained in more detail by journalists rather than by the company itself. Neither its website nor its anonymous spokespersons – the Tasso Team – offer any information.

Journalist Patricia Kirk of *Dark Daily* describes HemoLink as a small device the diameter of a golf ball, which when placed against an arm or abdomen for two minutes will draw blood from capillaries into a small container.

Gizmag reports that, by using capillary action, HemoLink leverages microfluidics to create a slight vacuum that pulls blood from capillaries through tiny channels in the skin and into a small tube. The device collects 0.15 cubic centimetres of blood.

In April 2015, Tasso received a \$2.6 million grant from the US Department of Defense's Defence Advanced Research Projects Agency (DARPA) to continue work to develop the device commercially. Its development partner GenTegra received \$1.3 million for technology that dries blood samples so that they can be shipped and stored without refrigeration.

Currently, the companies are working together to develop an integrated device that is able to collect blood easily from patients and stabilise biomarkers at ambient temperatures without requiring cold chain transportation.

Once the FDA clears these products and technologies in development, they are expected to be used by consumers in their homes, rural areas and war zones. However, when this will happen is not yet known. Media reports suggest that HemoLink will be submitted to the FDA in 2016.

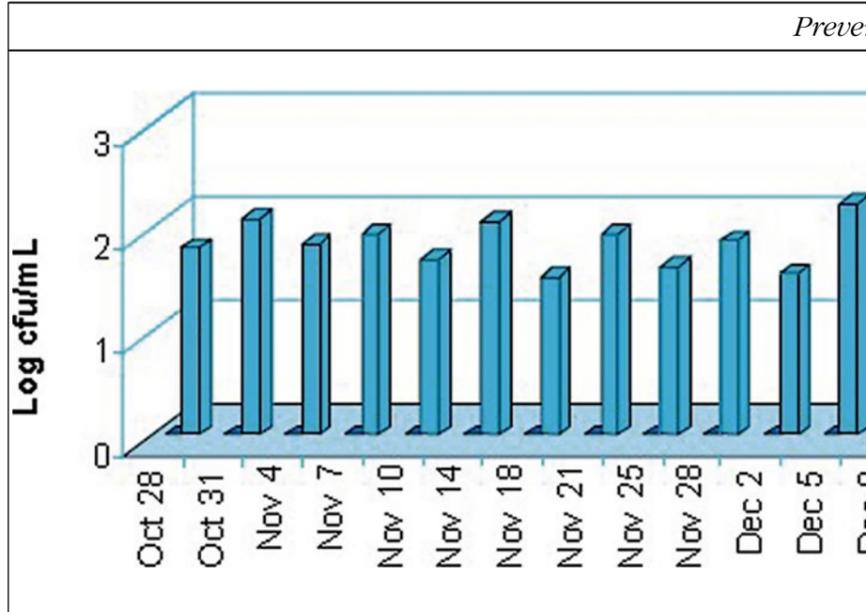
When contacted, the Tasso Team stated in an email that '... it has no quoted timeline for this effort'.



Photo: Theranos

Theranos' blood-testing platform needs only a few drops of blood obtained via a finger-stick

does not explain how the Theranos system works. The company claims that it is working to obtain regulatory clearance for at least 120 different tests, not a standard practice



Ensure quality: your clinical ana

Report: Stephane Mabic PhD and Maryse Gauthy Baraou

In busy biomedical laboratories high quality, well-maintained analysers and professional competent lab personnel are two ways to ensure consistently accurate results and maximise clinical analyser uptime. Another less obvious – but nonetheless very important factor – is the quality of reagents, including water used to feed the analyser. Several types of contaminants must be removed from potable tap water, however, in order to attain a suitable grade of purity for use with assays. In particular, achieving a low bacteria count in pure water is critical, because bacteria can contaminate the analyser and generate numerous interferences in biochemistry and immunochemistry assays.

Multiple effects of bacteria
Gram-negative bacteria, such as *Ralstonia pickettii*, *Sphingomonas paucimobilis*, *Caulobacter crescentus*, and *Pseudomonas aeruginosa* can reproduce and contaminate the

clinical analyser. These grow in the tubing, on-board reservoir, manifolds, as well as in samples and reagent needles.

Bacteria release enzymes and small organic acids, such as oxalate and pyruvate, which interfere with several assays, causing unstable calibrations, high absorbance of blanks, reference drifts and errors on mean patient values.

Interferences in chemistry assays – In the calcium Arsenazo assay, the bacterial proteins bind to Ca, modifying the concentration of the analyte dosed in the serum. In the potassium potentiometric assay, high coefficients of variation (CVs) and the need for recalibration were observed following a stand-by mode of the instruments; these faded away after rinsing and use of the instrument for some time.

Interferences with enzyme immunoassays (EIAs) – Alkaline phosphatase (ALP) is commonly used as a detection enzyme in numerous biomedical methods, including enzyme immunoassays and ALP-labelled nucleic probes. Mostly

Trial pitches M against Clostri

Clinical trials of a new drug to treat C-Diff infections are underway in the United Kingdom. Mark Nicholls reports

Scientists at the University of Strathclyde in Glasgow have been working to identify compounds with important anti-infective activity and suitable for treating serious infectious diseases caused by bacteria and parasites, such as *Clostridium difficile*. Their work has led to the creation of the new drug known as MGB-BP-3 (MGB = minor groove binder).

Now, the university's research and development partner MGB Biopharma has begun a Phase 1 clinical trial in healthy male volunteers to assess the safety and tolerability of the oral formulation of MGB BP-3 to treat C-Diff infections.

Professor Colin Suckling, from Strathclyde's Department of Pure & Applied Chemistry, who is the

Principal Investigator in the DNA MGB (minor groove binder) technology, said: 'Drug discovery is a major research theme at Strathclyde and we are now beginning to see real benefits by reaching the clinical trials for MGB BP-3.'

'MGB-BP-3 is a member of a family of compounds we call S-MGBs, or Strathclyde MGBs. Different S-MGBs target different infectious organisms – some against other infectious bacteria and others against trypanosomes – the microbes that cause sleeping sickness.'

'We have been able to tune the properties of these compounds, so that pathogens can be targeted without harming the patient, and look forward to taking these potential



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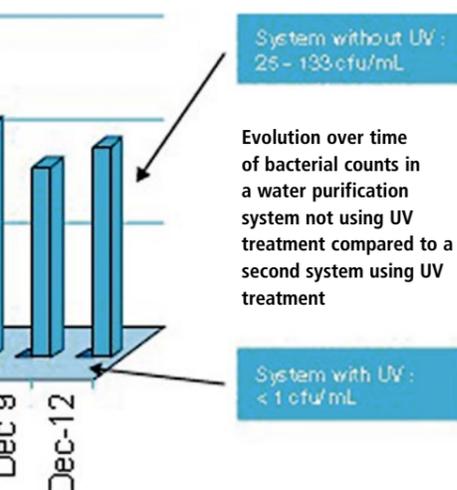
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conting problems caused by bacteria



clean up analyser

such assays are performed using calf intestine (CIP). Bacterial ALP released following the proliferation of bacterial species in 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 units must be decontaminated to reduce bacterial interferences. This results in a loss of time for biomedical laboratory personnel, analyser downtime, as well as the risk that traces of sanitising agents could remain in analyser fluidics and later interfere with assays.

Protection from bacteria: effective system design and intelligent storage

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, particles, 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).

Ultraviolet germicidal lamps – Ultraviolet (UV) treatment is powerful purification technology. Germicidal UV lamps inactivate 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.



A sanitary sampling valve can provide easy and reliable microbiological testing of analyser feed water produced by the water purification system

tion in the water distribution loop. The importance of storage tanks – A modern, intelligently designed water storage tank can also help reduce bacterial growth and degradation of water purity over time. A strict choice of quality storage tank materials, associated with careful design and appropriate protection against airborne contaminants, can ensure consistent water quality during storage.

Virgin ion-exchange resins and automatic recirculation – Depending on the assays, the clinical analyser and the laboratory, water temporarily stored in the reservoir can be directly used to feed the analyser, or further purified.

Additional purification to reach Clinical and Laboratory Standards Institute (CLSI) clinical laboratory reagent water (CLRW) quality involves the use of virgin ion exchange resins (IEX), which remove ions to a very low level. The use of these high-quality resins, as well as intermittent recirculation, both help avoid bacterial growth on resin beads over time.

0.22 µm filtration – In the water purification chain, screen membrane filtration (0.22 µm) can also be used in bacteria control. Usually, a 0.22 µm membrane filter is placed at the purification system outlet to ensure a constant low bacterial count (< 10 CFU/mL) in water delivered to the analyser.

Ultrafiltration to remove bacterial by-products (ALP) – To efficiently remove alkaline phosphatase potentially released by bacteria, an ultra-filter can be installed at the outlet of the purification unit, right before water is distributed to the analyser.

Conclusion

Correct water purification system design, an adequate and effective sanitisation procedure, as well as selection of an efficient final filter can help keep bacteria under control and maximise clinical analyser uptime.

Contact for authors: Millipore S.A.S. Lab Water Business Field, Lab Solutions Business Area, Saint-Quentin-en-Yvelines, France.

MGB-BP-3 Clindium difficile

treatments forward to trials as well. There has been a significant decline in deaths involving C-Diff in recent years in Scotland and across the UK, but figures from the National Records of Scotland statistics still reveal 160 deaths there from C-Diff in 2013.

In England and Wales, the number of C-Diff related deaths fell from 8,324 in 2007 to 1,646 in 2012, with much of the improvement down to improved hospital hygiene during that period.

However, with the growing threat from antibiotic resistance, Professor Suckling said, 'New, powerful treatments are urgently needed.'

MGB BP-3, discovered as a result of research collaboration between the Strathclyde chemists and biologists, represents a new class of drugs, with a new mechanism of action that could transform the treatment of

common, and potentially fatal, infectious diseases.

MGB Biopharma has allowed the Strathclyde developed S-MGB platform exclusive worldwide licensing rights for all anti-infective fields.

This platform provides an opportunity to develop various compounds, with a completely new mode of action, which are distinct from the antimicrobial drugs used in clinical practice today.

Drug discovery is a major research theme at Strathclyde, with Health Technologies a key area of expertise within the University of Strathclyde's new £89 million Technology and Innovation Centre, opened in July.

Trial results are expected by the end of 2015, with high expectation within the research team that the new antibiotic MGB-BP-3 will enter clinical use.



Colin Suckling has been Freeland Professor of Chemistry at the University of Strathclyde since 1989, and also served as Dean of the Faculty of Science, Deputy Principal, and Vice Principal of the university. His work on the development of inter-institutional and interdisciplinary research partnerships gained him an Order of the British Empire (OBE) from Queen Elizabeth II in 2006. His research focus lies on the synthesis and properties of heterocyclic compounds designed as molecular probes for biological systems, or as drugs. Particular progress has been made in fused pyrimidine compounds with anti-cancer and anti-parasite activity and in minor groove binders for DNA with antibacterial activity.

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Cardiac surgery gains an excellent planning tool

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

Report: Ralf Mateblowski

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 Centre Frankfurt summarised his experiences with the firm's HeartPrint models. 'To see the model means to change strategies,' he said.

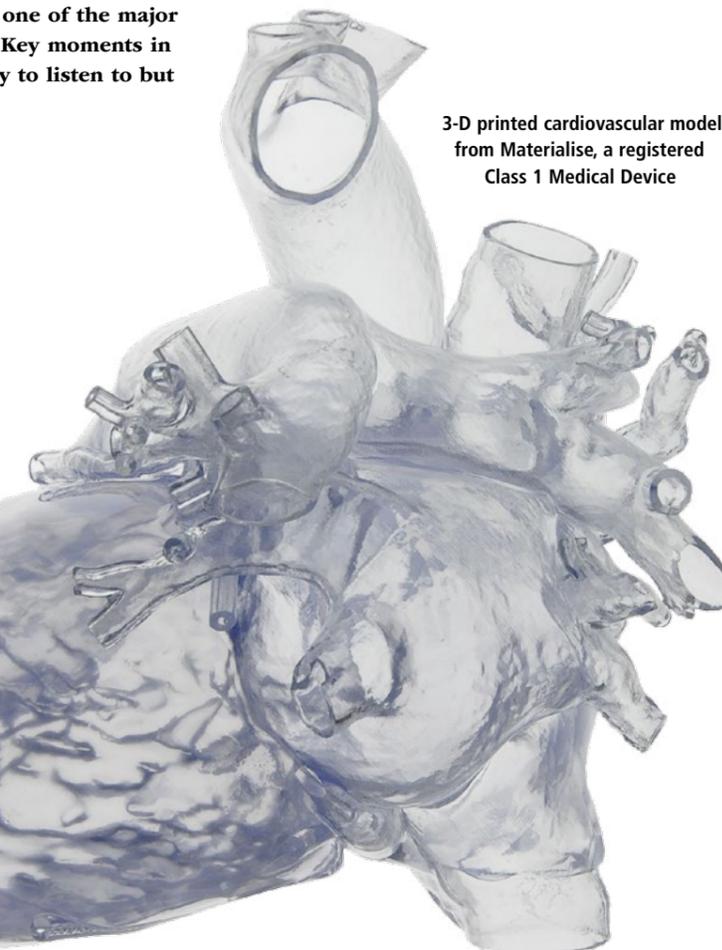
Based on CT, MRI and/or 3-D ultrasound image data, the transparent silicone models show the individual anatomy in amazingly realistic detail. This allows a physician in the pre-operative planning phase to literally get his hands on the structures he is going to see – down to the different tissue thicknesses 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 cardio 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 theatre 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.



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

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, throughout pre-clinical trials to product marketing. While the use of 3-D models in cardiology, as described above, is more or less

still in the beginning cranio-maxillofacial surgery and orthopaedic patients already receive 3-D printed implants. In these disciplines the innovation potential of 3-D print 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.

Suitable for coun

A highly surgical I

StarLED3 NX, a lamp produced by ACEM Me generation LED technology '... assuring col consumption,' the manufacturer reports. 'It's both for surgery and the operating theatre - dermatology, general medicine and surgery

'StarLED3 NX grants a homogeneous and shadow-less light thanks to its special LED optics created by ACEM that directs light beams at best according to the needs,' the firm continues. 'The visual area is perfectly illuminated assuring both excellent visual comfort and working conditions. Its next generation LEDs produce an unparalleled quality of light with a colour temperature (CCT) of 4.500 °K and a colour rendering index (CRI) of 95.'

With light intensity of 130.000 lux the lamp also has a with a low energy consumption of 69W.

'The life cycle of its LEDs is about 50.000 hours,' ACEM points out.

Composed of three reflectors, these produce a well-blended and intense cone of light focusable through the automatic adjustment of the light spot diameter. The firm also points to assets in the lamp's slim, practical and compact and ergonomic design and suitability for the laminar flows of the operating theatre.

The ENDO function (light for endoscopy) also adds the value of using this lamp for minimally invasive surgery.

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Cardiac monitor achieves good p

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The subcutaneous insertable cardiac 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 ECG recording time and can transmit up to six sECGs (subcutaneous ECG) 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



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and easy-to-clean I-SENSE control panel,' the manufacturer confirms, and lists attributes that include light intensity adjustment; DoF - depth of field - for a deep light; Endo - for endoscopy; Size - light spot diameter adjustment to focus the operating area; Sync - an optional function to synchronise controls of the combined lamps: StarLED3 NX double (twin dome configuration) and StarLED3 NX with StarLED5 NX or StarLED7 NX.

The lamp also can be ceiling, wall or trolley mounted (with ABPS battery on demand).



...pilot study results and CE approval

lighter, cardiac monitor

vector length,' said Dr Sze-Yuan Ooi, at the Prince of Wales Hospital, in Sydney. 'I'm hopeful that future trials will show that this translates into improved diagnostic abilities.'

'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.'



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 30 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 physical strain directly,' Frahm explains. Fraunhofer MEVIS developed the

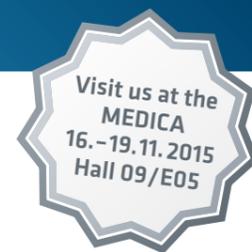
required image analysis methods, including an algorithm that automatically identifies the breathing and heart contraction phases in the data independent of the ECG information.

'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.'

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The Art of Diagnostics

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 centre-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



CuratOR Caliop is an all-in-one software to be controlled centrally

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.

'The customer normally decides on specific settings for different operating theatre situations, so-called pre-sets. These pre-sets can be selected based on the type of surgery, the location and even on the individual. Indeed, the system can even be configured according to an individual surgeon's ideas.'

How many different sources can the system include?

'The system can receive and transmit the most varied types of media signals. It's so flexible that we can configure it specifically around our customers' desires and requirements. All this is made possible by 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, and in the world of medicine as a whole, including all the IT networking, have become very complex. Whilst other, larger providers often feature complete solutions in their range we have designed our software very flexibly 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

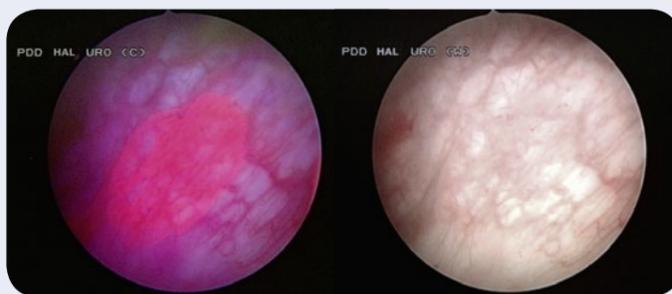
PHOTODYNAMIC DIAGNOSIS-ASSISTED TURB IN A REAL-LIFE SETTING

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%.¹ 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.^{2,3} 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.⁴

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.⁵ 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 hexaminolevulinat (HAL)-guided cystoscopy identified a vital number of additional CIS lesions (+25%, $p < 0.0001$). Additionally, in 10.0% of patients with NMIBC, ≥ 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^{6,7} 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



CIS lesion, blue-light vs. white-light, copyright of Professor Dirk Zaak, Traunstein, Germany

sponsored feature



Matthias Lubkowitz is Vice President of the Eizo GmbH | OR Solution division. With a diploma in media technologies he worked as a research assistant at the Fraunhofer Institute, followed by a role at Bosch and later Panasonic, before entering the medical sphere in which he continues to operate today

1 Van der Heijden et al., 2009 Eur Urol Suppl (8):556-62. 2 Jocham et al., J Urol. 2005 Sep;174(3):862-6. 3 Hermann et al., BJU Int. 2011 Oct;108(8 Pt 2):E297-303. 4 Sanson-Fisher et al., Am J Prev Med. 2007 Aug;33(2):155-61. 5 Burger et al., Optimized photodynamic diagnosis for Transurethral Resection of the Bladder (TURB) in clinical practice - Results of the Non-Interventional Study (NIS) OPTIC III (V 38.8, DGU 2015). 6 Palou et al., BJU Int. 2015 Jul;116(1):37-43. 7 Lykke et al., Scand J Urol. 2015 Jun;49(3):230-6.

Spine ops terrorise surgeons no more

'Spinal 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 minimalisation 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 Speising 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. ■



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Work in progress

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 Stroszczyński, 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. Stroszczyński 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 prac-

tice. 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 doctors check 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



Christian Stroszczyński 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 disease, cancer and vascular medicine

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 at the contrast agent stage. By the 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.

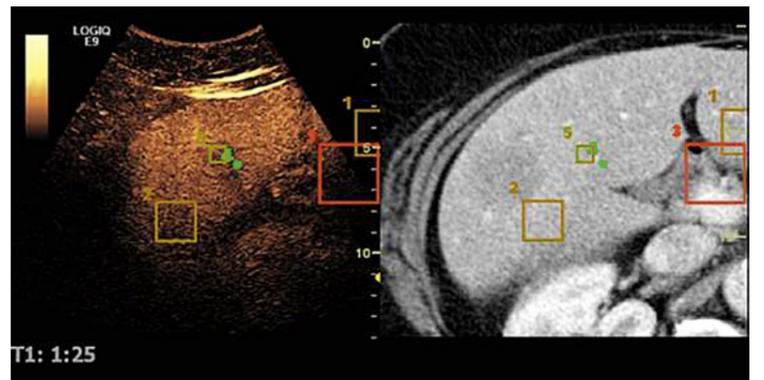
One big challenge in oncology is assessing if and how a patient responds to treatment. The most important factor is clearly tumour size, but conventional measuring procedures are not precise enough.

Further development of volumetric procedures for precise and reproducible tumour measuring 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 technical problems 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 CTs simple. Thanks to further developments in multi-slice



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



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

CT, we can now image the entire liver and determine the perfusion,' Stroszczyński 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.'

LI-RADS (Liver Imaging Reporting and Data System) is a further innovation. It is hoped that, by using

standardised assessments in oncology that can also be internationally compared, the system will standardise reporting and data collection. Stroszczyński 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.'

European paediatric imaging issues take central stage

The International Day of Radiology

Paediatric 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 and 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 endangered in some countries, 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 specialty in Paris.

Today's French radiologists view paediatric radiology as not as lucrative as other subspecialties, with punitive daily schedules and on call arrangements, all exacerbated by staffing shortages. Dealing with children is more time consuming than general adult radiology, especially in areas such as paediatric MR, where sedation and anaesthesia 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

Continued on page 16

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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 preventive 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: Sascha 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. In other words, many painful tests establish results that are often inaccurate creating stress and physical inconvenience for the patient without providing diagnostic safety.

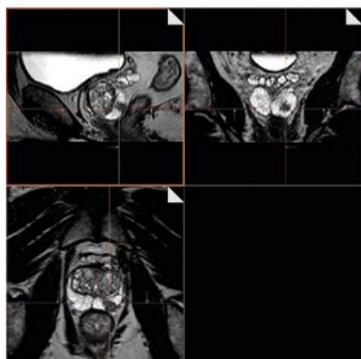
Improved accuracy

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. The new technology is



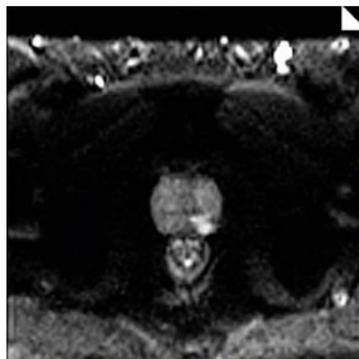
New Body 60 coil for optimised coverage of the pelvis and improved signal

known as mpMRI, which stands for multi-parametric MRI – because it uses several parameters. mpMRI enables physicians to probe tissue parameters such as cellular density



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



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

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: SEEit, 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 programme for men above a certain age, questions: 'If this is done for



Jelle Barentsz is Professor of Radiology and Head the Prostate MRI Reference Centre of the Radiology and Nuclear Medicine of the Radboud University Medical Centre in The Netherlands. He received his medical degree from Utrecht University in 1980 and his doctorate in 1990 for his research on MRI of the bladder. As an internationally recognised expert and renowned speaker he has been awarded many international prizes, inter alia in 2008 the Koningin Wilhelmina Research Prize: an award of two million euros for his research into using MRI for the diagnosis and treatment of prostate cancer. Recently, he was also knighted for the societal impact of his work

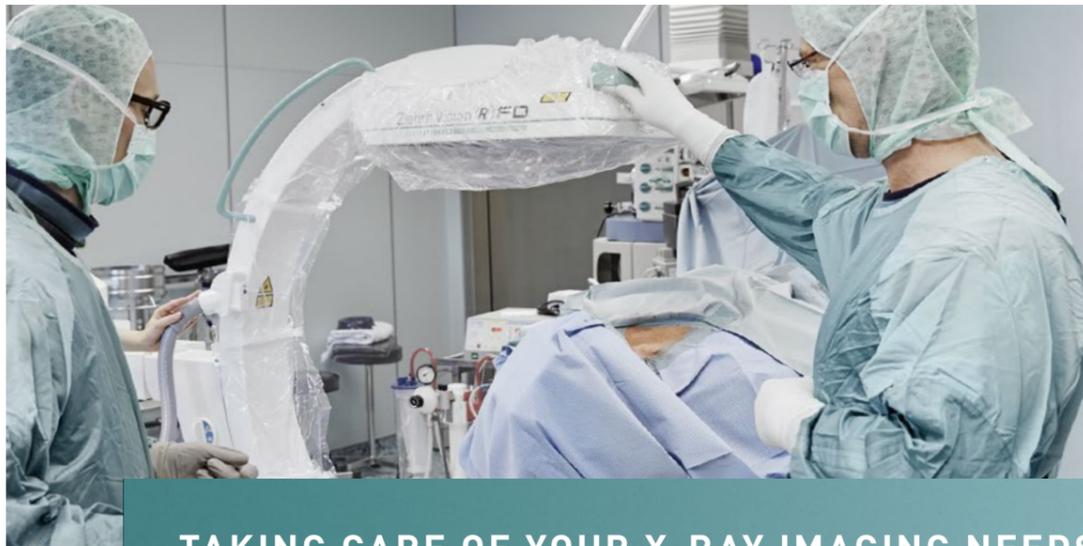
breast cancer which afflicts 1 in 7 women, then why isn't it done for prostate cancer, where 1 in 6 men is affected? Why don't we have a "mammography" yet?

MRI scans could radically change the diagnosis and treatment of prostate cancer and halve the number of unnecessary biopsies. 'My 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 scan!'

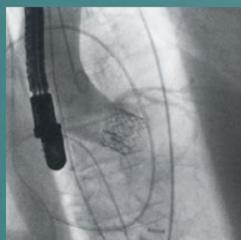


Catherine M Owens MD is a Consultant Radiologist and Reader at the University College London (UCL) and Consultant Paediatric Radiologist at Great Ormond Street Hospital for Children (GOSH), where she has worked since 1996. Her specialist interests are cardio-respiratory radiology, radiology in cystic fibrosis, computed tomography and radiology in immune-compromised patients. In 2008, she was appointed as UCL Reader and has written more than a hundred peer-reviewed articles and over 20 chapters focusing on cardiothoracic CT, radiation protection in CT and radiology in the immune-compromised patients and in cystic fibrosis. The radiologist has lectured at over 150 national and international congresses and supervised higher degrees and diplomas, acting as liaison/host for the European School of Radiology fellowships. Dr Owens is also current President of the European Society of Paediatric Radiology.



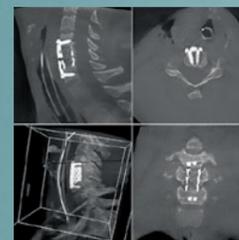
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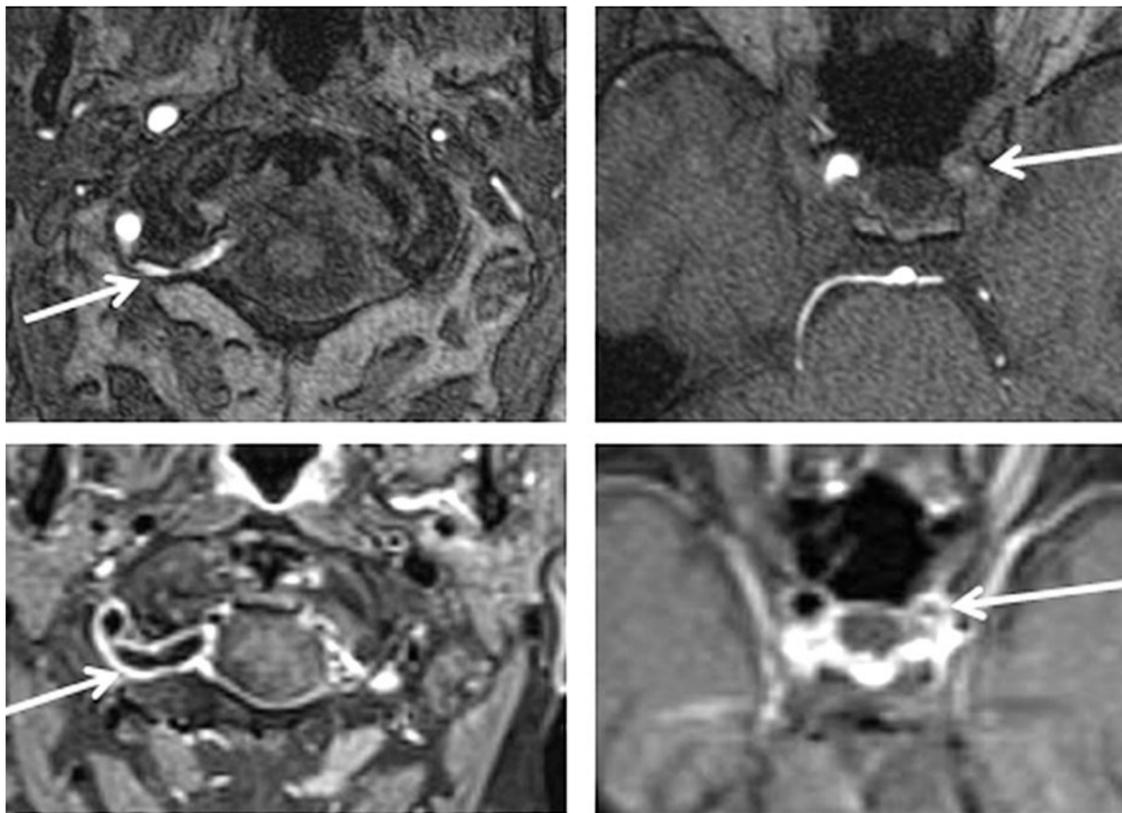
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Sensitive MRI procedures

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 resolution make 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



Benefits for young patients - '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

In the upper row the source images of the TOF-MR angiography show the constricted vessels (A. vertebralis right and A. carotis interna left), which are mainly affected. In the row below, the dark blood sequences correspond with significant contrast agent accumulation in the vessel walls

this technology for clarification of a diagnosis. 'The additional sequence probably takes about eight minutes,' the neuroradiologist explains. 'When vasculitis is suspected, the diagnostician should therefore examine the respective areas in the brain before

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 occurs in large infarctions, but to an inflammation of the vessel walls. Previously, the diagnosis was difficult to confirm, because of available technology limitations; it required

the more invasive catheter angiography, along with clinical and laboratory tests. 'An important differential diagnosis is required to clarify whether the patient has had an embolic stroke, or whether they are suffering vasculitis,' Gizewski points out.

'In principle, the procedure works like vessel wall imaging; however, we don't look at the large vessels, such as the aorta, but at the, in parts, very small vessels in the brain. In neuroradiology the procedure is still carried out comparatively infrequently and currently requires further evaluation.'

Contrast agents help to determine those affected

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. T-1 weighted sequences that help to

'darken' blood. However, for the neuroradiological diagnosis of vasculitis, a double suppression of both light blood signals and signals from adipose tissue is carried out because many of the basal cerebral vessels are located within adipose bone structures that impair the view of the inflamed vessel walls.

Treatment makes the difference

In addition to the neurological results, which mostly will already point towards a diagnosis, this technology can help to differentiate between vasculitis and embolic stroke without invasive examinations, which has a great effect on treatment. 'Patients diagnosed with vasculitis are treated with immunosuppressant drugs, such as cortisone, or others, depending on the extent of the disease and on which vessels are affected,' the specialist explains. It has now emerged that the accumulation on the vessel walls is not actually 100% specific for vasculitis. 'However, through process monitoring we can determine whether improvements develop,' Gizewski points out.

'If the accumulation in the vessel walls decreases during treatment we know we are on the right track.' The procedure can definitely be utilised as a follow-up marker.' ■



Professor Elke Ruth Gizewski has directed the University Clinic for Neuroradiology at the Medical University of Innsbruck since 2012. Alongside her other commitments the professor is an assessor for multi-centre studies and specialises in functional and structural MRI, (Ultra-) High Field MRI and interventional neuroradiology

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The International Day of Radiology

Continued from page 14

attractive to trainees. The situation in France and Germany is particularly alarming. Both countries having had a very strong history of excellence within paediatric radiology; it is very sad to see desperation within the French and German speaking groups,' she declares.

Another particular problem is a substantial shortage of MR equipment, leading to long waiting lists. French patients have to wait 30.3 days to undergo an MR examination, according to a report published last summer by the Imaging Health Future (Imagerie Santé Avenir, ISA) and France remains far behind its European counterparts with 11.9 MRI devices per million inhabitants, compared to an average of 20 across the rest of Europe, according to 2014 statistics.

However, Owens insists that MR shortage and lack of trained expertise within optimising and reporting paediatric examinations is a global situation, as these examinations take longer and demand significant adaptation of sequences and are chal-

lenging in young patients. 'Children often require sedation, or anaesthesia input, so MR exams take longer,' Owens points out. 'Not every imaging centre provides MR examinations under anaesthesia. MR access is a problem everywhere, with perhaps few exceptions, such as perhaps Switzerland and Luxemburg, which in terms of GDP spend more on healthcare.'

Furthermore, beyond neuroimaging, the quality of magnetic resonance scans is not always optimal in young patients because they are small; real knowledge is needed of the fundamental physical principles that must be optimised on site by an expert MR radiologist and physicist.

Therefore, unless there is an expert in paediatric MR imaging to supervise protocol and to read the MR images, the quality of the examinations can be suboptimal, indeed poor.

Nonetheless, MR is a really critical tool in paediatric imaging because it does not expose patients to ionising radiation, unlike conventional

X-rays or CT. Radiation effects are more hazardous in children, due to the immaturity of the tissues and longer expected life span. Moreover, repeated examinations over their lifetime causes cumulative radiation dose

Radio-protection is therefore essential within paediatric radiology, and avoiding unnecessary irradiating examinations remains the best protection. When these examinations need to be performed, and are deemed of benefit to the individual patient, radiologists should use appropriate child-friendly techniques and low dose technical settings.

Unfortunately, the level of knowledge of child-focused imaging is heterogeneous amongst radiologists, many of whom are not sufficiently trained (being in adult centres) and not always adept at optimisation of their adult departmental equipment for children.

Several guidelines on low-dose protocols exist, including from the ESPR, and ESR. But the diversity

Black and white medical displays switch to colour and higher resolutions

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

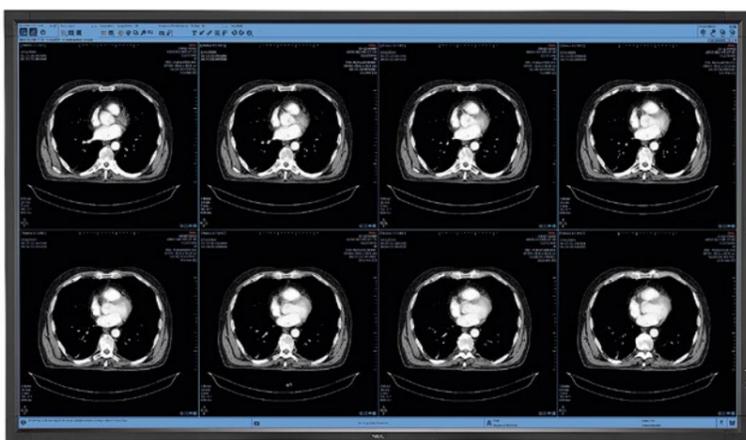
Together with even better displays, the need for a centralised quality control arises. Particularly in big hospitals, it is time consuming to control and calibrate each display at the workspace. Software tools that connect all workstations and their connected displays together mean you can access displays 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 line-up have a small front sensor for calibration. All monitors come with a free client software licence for GammaCompMD QA.

Better displays – better treatment

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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

of the existing equipment in, for example, paediatric CT, challenges the redaction of common guidelines.

'Each company markets multiple CT scanners, so it's very difficult to try and issue generic parameters for wide scale implementation. The machinery varies from very old to brand new, and the more recent scanners are particularly adept at producing excellent quality images at lower doses in fast acquisition times, so less motion artefacts. All of these are fantastic for use in children,' Owens points out, adding: 'The problem is that these new CT scanners are not often available as they are very expensive and some institutions have out-dated equipment because they can't afford to buy new machines.'

A study conducted by the European Society of Radiology, during ECR 2015, warned of looming equipment obsolescence in the European Union and notably revealed that the public hospitals in Croatia invest only 11 percent of all CT equipment budgets in new scanners.



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Training is necessary to work competently with this highly specialised technology

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 Tamborrini, Medical Director, rheumatologist and specialist for musculoskeletal ultrasound at the Ultrasound Center of Bethesda Hospital, Basle, Switzerland, explains sonography is so important in rheumatology

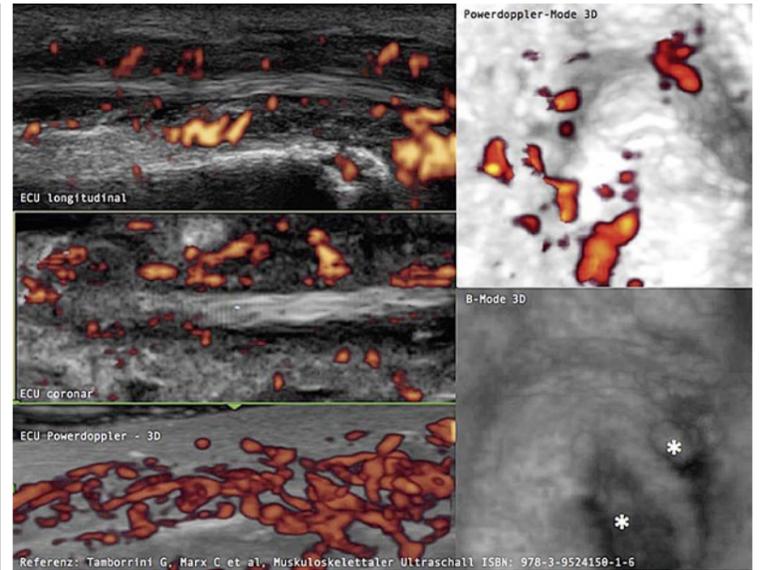
In Switzerland, as in most other countries, the first stop for patients is usually a general practitioner (GP) – and the GPs decide when to refer patients to a rheumatologist. ‘We drafted guidelines for the early diagnosis and management of rheumatoid arthritis that define when and for which purpose an ultrasound exam should be performed,’ explains rheumatologist Dr Giorgio Tamborrini. ‘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,’ Tamborrini 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 rheu-

matologist stresses. With patients who present with suspected rheumatoid arthritis, generally both hands, elbows, knees and feet are examined to detect inflammations as well as existing damages to the cartilage or bones. According to Tamborrini, ‘all examination data are collected and documented in order to optimise patient management, as well as for research and quality assurance in the context of registry studies.’

‘Additional imaging modalities are used as required or when, for example, the carpal bones might be involved,’ he adds. In the latter case ultrasound is limited in its diagnostic capabilities and an MRI scan of the hand is indicated – performed



Tenosynovitis of ECU tendon in rheumatoid arthritis (left) and active synovitis (right top) with erosions (right bottom) in the MCP joint

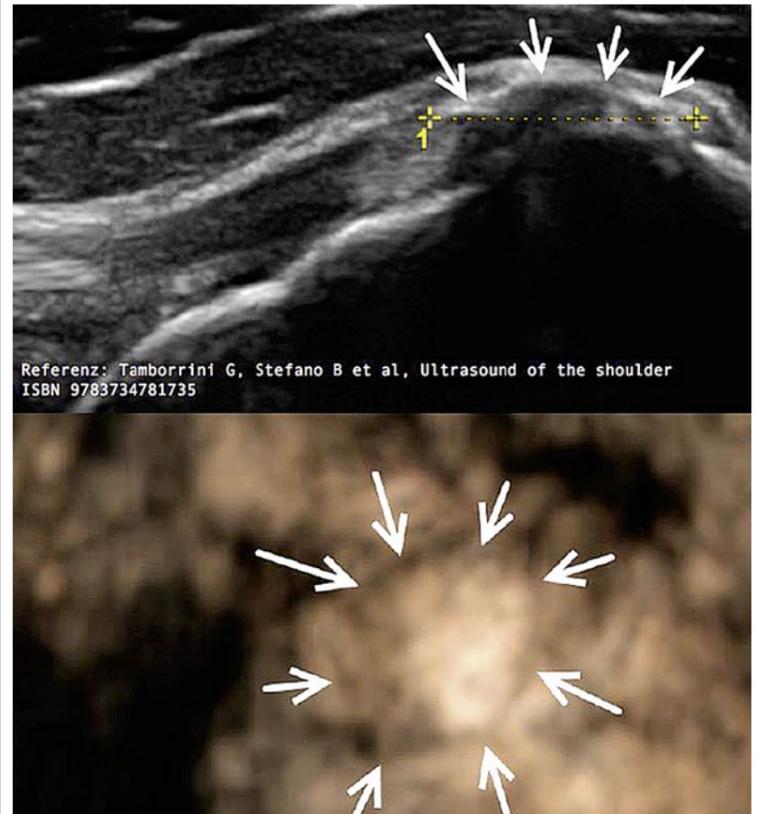
in a radiology department that has proven experience in diagnostic imaging of the musculoskeletal system. ‘The majority of patients requiring diagnostic imaging for arthritis can be successfully examined with high-resolution ultrasound; a slice imaging modality is not required,’ Tamborrini points out.

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 dif-

Calcification in the infraspinatus tendon (arrow) shown in the posterior-transversal plane (top) and in 3-D (bottom)



New convention dates and location

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:

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Giorgio Tamborini MD is Medical Director of Musculoskeletal Ultrasound und Rheumatology at the Ultrasound Center in Bethesda Hospital, Basle, Switzerland. The rheumatologist specialises in general and inflammatory rheumatology as well as diagnostic and interventional ultrasound of the musculoskeletal system, and focuses on ultrasound imaging of inflammatory conditions (e.g. peripheral spondyloarthritis, rheumatoid arthritis or crystal deposition diseases), as well as ultrasound of degenerative or trauma-related conditions, above all in the shoulder. Actively involved in several national (SGUM, Sonar) and international societies, he has also been an ultrasound trainer for many years and authored several books, web tools and scientific articles on ultrasound.

ferential diagnosis. 'Physicians with adequate knowledge of sono-anatomy and sono-pathology can tell with certainty whether a patient suffering from inflammatory arthropathy is dealing with rheumatoid arthritis or psoriatic arthritis, or a crystal deposition disease of the type gout or pseudogout,' and,' Tamborini explains, inflammatory activity can be easily assessed with Doppler ultrasound.

A type of exam, routinely performed in hospitals, is functional ultrasound of the shoulder. This highly specific imaging technique is requested by rheumatologists, internal medicine specialists or shoulder surgeons when concrete questions need to be answered that MRI diagnostics cannot resolve. 'For example, we do a high-resolution dynamic ultrasound when complex ruptures of single tendons, or of stabilising tendons in the rotator cuff interval, are present. These ultrasound scans complement the MRI scan and provide the shoulder surgeon with relevant data that help him to plan surgery,' Tamborini explains.

Shoulder ultrasound supports PMR diagnosis

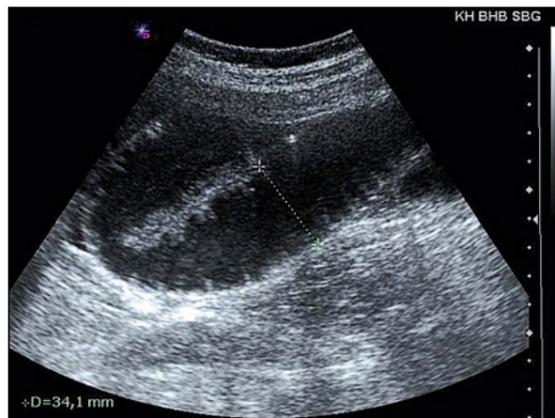
Polymyalgia rheumatica (PMR) is another frequently occurring inflammatory rheumatic disease where ultrasound of the shoulder supports diagnosis as well as classification of the disorder. 'Polymyalgia is often accompanied by bursitis or inflammations in the joint,' says Tamborini. 'Because the musculoskeletal system and rheumatic diseases are such a complex field, over the past few years we've been drafting guidelines and recommendations that are published in different journals and ultrasound text books.' (<http://dgrh.de/9399.html>).

With clinical and ultrasound technology being highly specialised the European League Against Rheumatism (EULAR) launched an international training network (http://www.eular.org/musculoskeletal_imaging_network_centres_list.cfm). Physicians from domestic and foreign hospitals can sign up for training courses in these centres. 'In recent months we've had colleagues from different countries here to watch and learn,' Tamborini reports, 'for example, England, Australia and Germany.'

Ileus diagnosis is a long-running debate – perhaps without end

Controversy surrounds intestinal obstructions

The guidelines – the Bologna Guidelines on the Diagnosis and Management of Mechanical Intestinal Obstructions as well as the respective guidelines from the American College of Radiology – recommend a plain abdominal X-ray and/or CT scan when an ileus is suspected. There is no mention at all of ultrasound in these guidelines. However, many clinicians do not agree with this. 'In our hospital we haven't actually carried out plain abdominal X-rays for patients with acute abdominal pain for the last 20 years,' emphasises Dr Alois Hollerweger, Consultant in the Department for Radiology and Nuclear Medicine at the Hospital of the Brothers of Mercy in Salzburg. 'For us, the primary imaging modality for these cases is always ultrasound. The plain abdominal X-ray is not sensitive enough for to diagnose acute abdominal pain.'



Sample images for a mechanical obstruction of the small intestine: Fig. 1: Fluid-filled and dilated loops in the upper small intestine



Fig. 2: Next to the dilated intestinal loop is the contracted colon (white arrow)

In most cases, an ultrasound scan can confirm the presence of the three most important criteria for ileus - dilated, fluid-filled intestinal loops, active peristalsis (early stage) and sudden change of the lumen (sudden change in diameter). A plain abdominal X-ray on the other hand does not help with the assessment of the peristalsis in the intestine, and other impending complications cannot be captured, either, Hollerweger 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 differentiated 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,' Hollerweger 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:



Fig. 3: Coronary reconstruction. The loops in the small intestine are dilated and fluid-filled, the large intestine (white arrows) is largely contracted

'A plain X-ray can be carried out at any time during the day and night without the presence of a radiologist. For smaller hospitals this is a simple way of carrying out an initial, basic diagnosis outside the standard times of operation. Interestingly, the abdominal X-ray is something surgeons still insist on, in large hospitals as well.' Another reason for ignorance about ultrasound in the guidelines is most probably the situation in the United States, where it is not clinicians, but members of a specifically named profession, i.e. sonographers (radiographers) who carry out ultrasound examinations.

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 emphasises. 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



Alois Hollerweger is a Consultant in the Department for Radiology and Nuclear Medicine at the Hospital of the Brothers of Mercy in Salzburg. The key focus of his work is ultrasound diagnostics, particularly ultrasound of the gastrointestinal tract. He has 44 scientific publications on this topic to his name. Born in Upper Austria, the radiologist, who read medicine in Innsbruck and specialised in Salzburg, is a much in demand instructor: Hollerweger holds ÖGUM courses and also regularly runs courses in ultrasound for the abdomen, gastrointestinal tract as well as for Small parts

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 also recommends a clear system for the examination. 'Firstly, you should check via the side and spleen whether or not the stomach is full. Secondly, you need to check the upper small intestine via the left lumbar region, and check whether the adjoining large intestine is contracted.

'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!'

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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 the overall group were assessed

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.

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

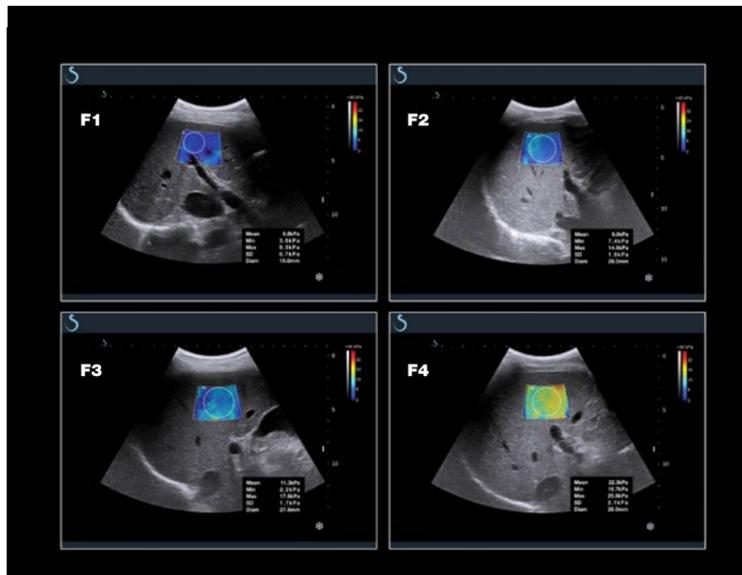


Mireen Friedrich-Rust is a consultant at the Centre for Internal Medicine, University Hospital Frankfurt am Main. Having read medicine in Münster, Heidelberg, New Haven and New York, Professor Friedrich-Rust wrote her habilitation treatise at the Johann Wolfgang Goethe University Frankfurt am Main and was awarded an extracurricular professorship in 2014

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 the quality criteria are taken into consideration the superiority for the diagnosis of a moderate liver fibrosis persists, and this is frequently the threshold used to decide on whether treatment should begin.

Friedrich-Rust phrases the summary of the results seen so far very carefully 'The results of the study definitely confirm that 2-D shear-wave elastography is at least as good as transient elastography.' One advantage for her is the fact that the 2-D shear-wave elastography is integrated into a routine ultrasound scanner, so there is no need for the purchase of additional specialist equipment which puts pressure on budgets. 'An ultrasound scanner with this additional tool is a gain for all clinicians.'

Liver stiffness measurement with 2-D-ShearWave Elastography.



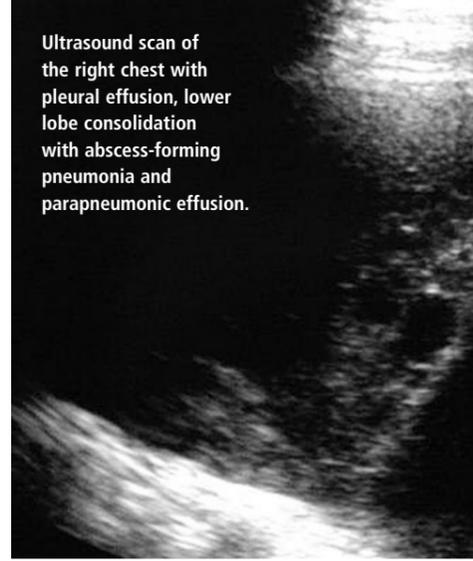
Pulmonary and pleural infections

Using every examination

In Germany, Austria and Switzerland ultrasound is performed by doctors from different areas of expertise. However, for pulmonary and pleural infections many specialists refer patients to radiologists rather than make their own diagnosis via ultrasound. One reason is that only a few doctors have expertise in all aspects of ultrasound. A further reason is that ultrasound has its limitations when it comes to lung diseases, explains Professor Gerhard Mostbeck, radiologist at the Wilhelminen Hospital and Otto-Wagner Hospital in Vienna.

Asked why so many clinicians refer patients to radiologists to diagnose pulmonary and pleural infections, rather than perform the examinations themselves, Professor Gerhard Mostbeck explained:

'It's not only knowledge, i.e. theoretical knowledge that's required here, but also practical skills and a lot of practical experience with clinical ultrasound. Ultrasound is a great procedure – but it's of no benefit unless you know a lot about it. Any doctor, be they emergency medics or specialists in lung disease or internal medicine, should be familiar with ultrasound. However, in clinical practice only a small proportion of doctors are actually competent in all aspects of clinical ultrasound, and it's mostly those who have developed a particular interest in this technology. Ultrasound goes far beyond real-time applications. Nowadays, contrast-enhanced ultrasound, elastography and other new procedures also facilitate multiparametric examinations; but, even though all this may be taught over the course of a medical degree, not everyone will become an expert in this technology



Ultrasound scan of the right chest with pleural effusion, lower lobe consolidation with abscess-forming pneumonia and parapneumonic effusion.

at the highest level. 'There's also the issue of time. Examinations of the pleura and lungs require a lot of time spent with both the patient and the technology. Ultrasound is particularly suitable to diagnose pleural effusion and pneumothorax, and for clinical monitoring of pneumonia, and specifically to monitor pneumonia in children. For pleural effusions, ultrasound is the method of choice for diagnosis and for US-guided puncture, and is far superior to 'blind' puncture of pleural effusions.

'This, of course, does not mean that conventional X-rays or CT are bad; however, they require a medical indication and their use must be justified, based on the medical radiation protection guidelines.'

What about chest X-rays, as used to detect tuberculosis (TB)?

'We need to differentiate between different types of infection, here. If you are healthy, middle aged, and working and you suddenly develop a cough, fever and phlegm, chances are that the diagnosis is CAP, i.e. community-



Gerhard Mostbeck heads the Institute for Diagnostic and Interventional Radiology at the Wilhelminen Hospital and the Institute for X-ray Diagnostics at the Otto-Wagner Hospital, Vienna. Having qualified as a radiology specialist at the Medical University of Vienna, he wrote his habilitation treatise in 1990 on an ultrasound-related topic. From 2002-2005 he was President of the Austrian Society for Ultrasound in Medicine (ÖGUM) and 2006-2008 he presided over the Austrian Roentgen Society. In 2000 he was president of the congress of the ultrasound societies of the Dreiländertreffen – the three German-speaking countries in Vienna, and of the WFUMB-EFSUMB and the Dreiländertreffen on Ultrasound in Vienna in 2011, as well as of the ESGAR Annual Meeting in Salzburg in 2014

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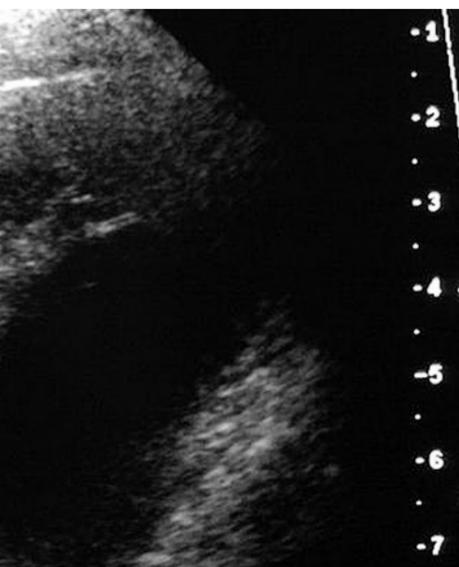
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a procedure for diagnosis

and ctions



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.'

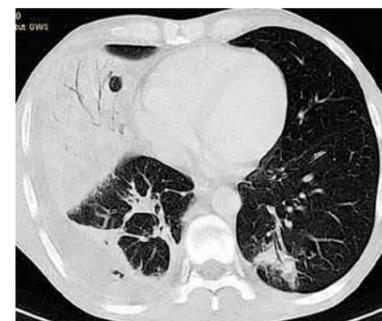
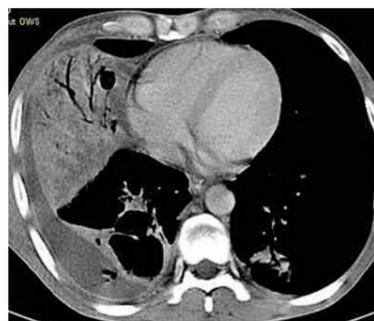
Are there guidelines for ultrasound of the lungs?

'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

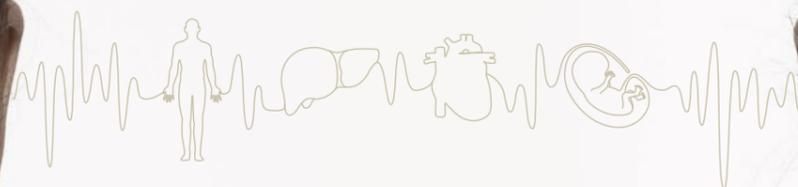
fibrosis), for reasons of radiation protection. However, MRI does not have as good a spatial resolution as modern CT. Furthermore, the lung diagnosis is made more difficult because of movements caused by breathing and the beating heart. The lungs, which are mostly filled with air, appear on MRI more 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.



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 layers; 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



Real-time virtual ultrasound turns fusion imaging on its side with a dynamic synchronisation of ultrasound with MRI

Using the Arietta V70 from Hitachi, a French diagnostic imaging team is rewriting the book on obstetrics and gynaecology. Entitled the 'Atlas d'échographie de fusion en gynécologie obstétrique', the new edition by Jean-Marc Levaillant MD, and colleagues from the diagnostic imaging centres at the Bicêtre and Créteil hospitals in Paris, will be published before the end of 2015.

Driving the excitement behind the new atlas are unique double views of anatomy acquired using the Real-Time Virtual Sonography (RVS) feature on the Hitachi Aloka Arietta V70 ultrasound system, according to Laurence Gitz MD at the Prenatal Diagnostic Centre at Bicêtre. 'Here we have a synchronisation of images rather than superimposing one image on top of the other, as with the usual fusion imaging. This means that we have a dynamic comparison with side-by-side viewing, which allows us to focus more clearly on a zone of interest and scrutinise better the anomaly,' Gitz explained during a presentation at the French Radiology Congress.

The new atlas will include what she described enthusiastically as side-by-side views of a foetal cranium where the Hitachi echo images confirm a suspicion raised on the MRI images.

During the workshop, Naïma Chaïbi MD noted that there could be uncertainties and disagreements about a diagnosis among clinicians when the MRI and ultrasound imag-

es are viewed separately. 'In such cases where the condition is not clear on one modality, there is an advantage to bringing them together, in having both examinations simultaneously displayed,' she said.

Chaïbi currently leads a project to create a scoring method that will relate visualisations acquired by the Arietta V70 using RVS with an evaluation of risks for a patient.

Originally developed for interventional radiology applications, Hitachi Aloka combined this new approach to fusion imaging with the company's deep experience in OB/GYN examinations to develop the new application for the Arietta V70.

After a scanner sequence is loaded onto the platform, a clinician clips a mini-sensor to the ultrasound probe that is tracked in a magnetic field projected from an antenna. According to Senior Product Manager Frédéric Philippe, the registration of the patient's anatomy with the scanned data set is so robust that it can maintain the accuracy of a synchronised ultrasound exam even where there has been a shift of organs, or a foetus has moved.

The lightweight and ergonomic design of the Arietta platform has been accelerated for the top-of-the-line V70 with the addition of high performance processing power that Philippe said is more than three-times more powerful than earlier versions.

The clinical advances Hitachi Aloka brings are the result of maintaining a horizontal, global approach to development that crosses ultrasound specialties, he added. 'We bring to OB/GYN advanced tools

and technologies originally developed in other clinical specialties. For example, the speckle tracking developed for cardiology has been applied to obstetrics for tracking a foetal heart. In bringing fusion developed for the liver and kidneys from radiology applications, we were able to show for the first time the foetal brain and have since shown the clinical relevance of echo fusion exams for diagnosing placenta abnormalities. Studies are now exploring cervical and ovarian cancers,' he said.

'We have stayed focused on a fundamentally different approach oriented to improving the clinical value of our technology. Sometimes ultrasound is used for clever marketing techniques, such as showing a snapshot of the unborn baby's face. But this does not have a lot of clinical value. Our goal is to precisely monitor the development of the foetus or organ and detecting any abnormalities as early as possible,' he said. 'As a result of this commitment, starting in the first trimester of pregnancy, a clinician can see a level of information with an image quality that has never been available before. Clinicians have told us they are now able to see specific conditions of a foetus several weeks earlier in its development by using our probes and imaging platforms.'

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Using Superb Microvascular Imaging and...

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

Fast. Efficient. Precise. Sharp.

Impacting on clinical decisions. Accelerating clinical routine. Following the release of its new Version 6 software upgrade for the Aplio 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

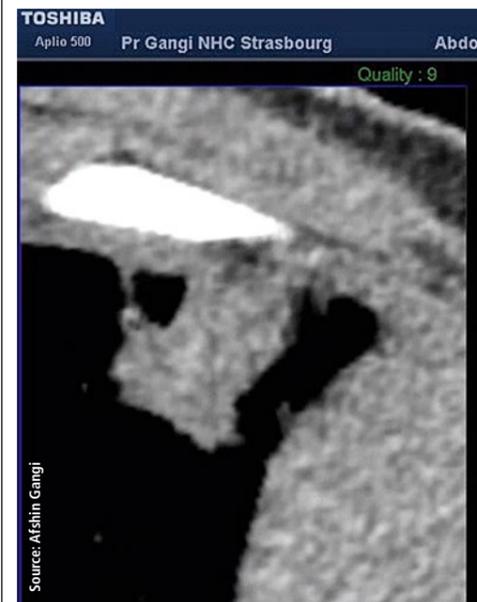
'Estimated very conservatively, I'd say that in around 20% of cases a different approach to treatment results from the use of Superb Microvascular Imaging (SMI),' reports Professor Thomas Fischer MD, Head of Ultrasound Diagnostics at the Institute for Radiology at the Charité Mitte Hospital in Berlin.

SMI is a Doppler imaging procedure that reacts a lot more sensitively 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 artefacts that can affect the visualisation of perfusion. SMI can be used with contrast agents, can be

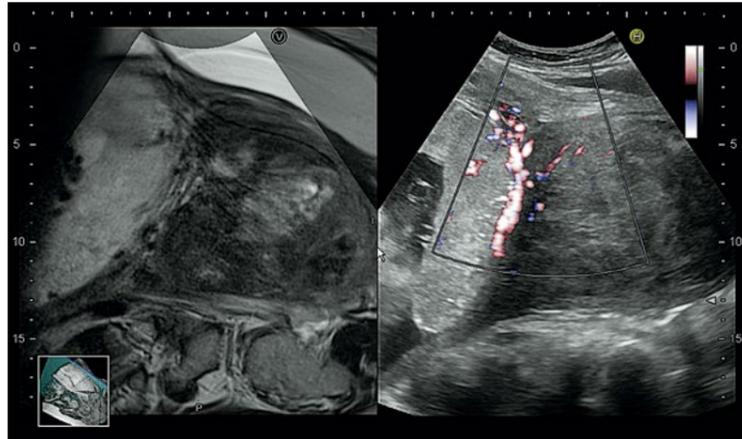
visualised in 3-D and is compatible with more transducers.

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 the contrast agent, the examiner can switch to SMI, now optimised



A suspicion of placenta accreta – detected with Hitachi Aloka's high-definition blood flow imaging (eFLOW) and illustrated with Fusion Imaging (RVS)



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Subscriptions
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Theodor-Althoff-Str. 45, 45133 Essen, Germany

Subscription rate
6 issues: 42 Euro, Single copy: 7 Euro.
Send order and cheque to:
European Hospital Subscription Dept

Printed by: WVD, Mörfelden-Walldorf, Germany
Publication frequency: bi-monthly
European Hospital ISSN 0942-9085

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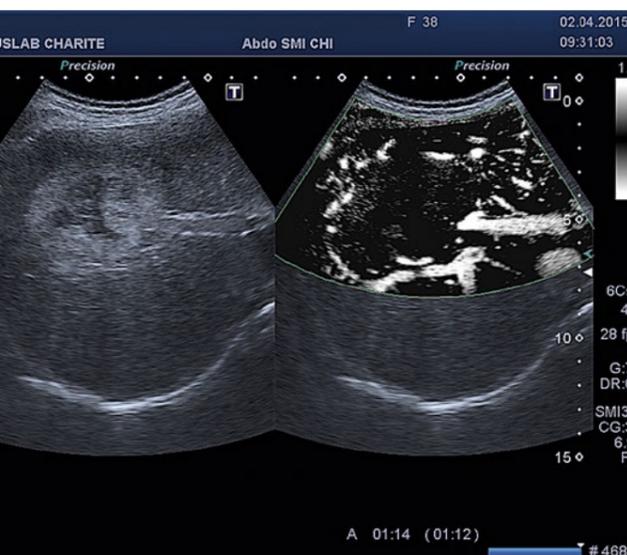
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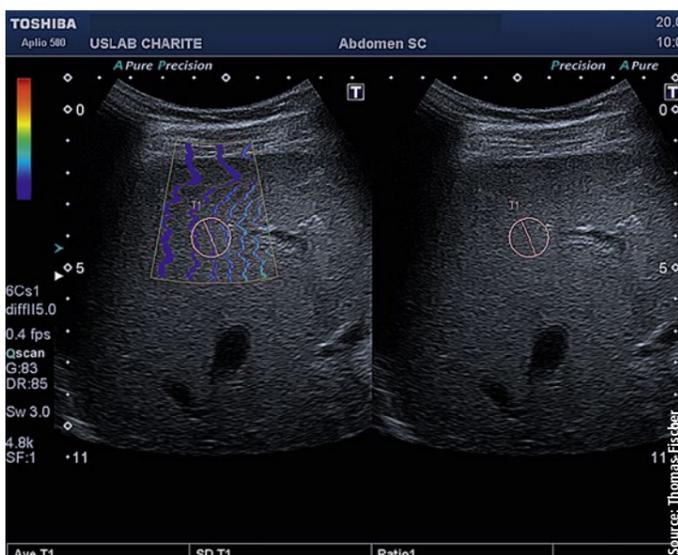
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CEUS image of a haemangioma after 15s. The use of SMI to visualise vascularisation with contrast agent after 1:12 minutes. The characteristic vascular pattern can be viewed at any point after the administration of contrast agent without the need for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



Afshin Gangi, M.D., is head of the department of Interventional Radiology at the Hospital of Strasbourg in France. He received his education in the International French School of Teheran, graduating in 1980. During the summer of 1980, he attended medical school at the University of Reims in France, receiving his Degree in 1987. He began his residency in Strasbourg in 1987, first in the intensive care unit of Pneumology where he became excited about imaging and moved to the imaging department.

erb Microvascular and more...

for use with contrast, and visualise vascular patterns, long after the bolus injection, he explained. 'It is important for the detailed diagnosis to see how vessels grow into the tumour and to visualise exactly the vascular tree of the tumour, which is now also possible in 3-D technology with SMI.'

Meanwhile, half a world away at the Royal Melbourne Hospital in Australia, Robert Gibson MD finds Version 6 enhancement on the Aplio platform to be refined SMI and simplified its use with filter controls, which, he said, 'should prove a real

clinical advance in displaying small vessel flow and vascular morphology.'

Shear-wave elastography

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 Afshin 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



In 2007, Thomas Fischer became Head of Ultrasound Diagnostics at the Institute for Radiology at the Charité Berlin. Some two years later he founded the Ultrasound Research Laboratory there. The lab, of which he is still manager, focuses on studies into new ultrasound procedures and technologies

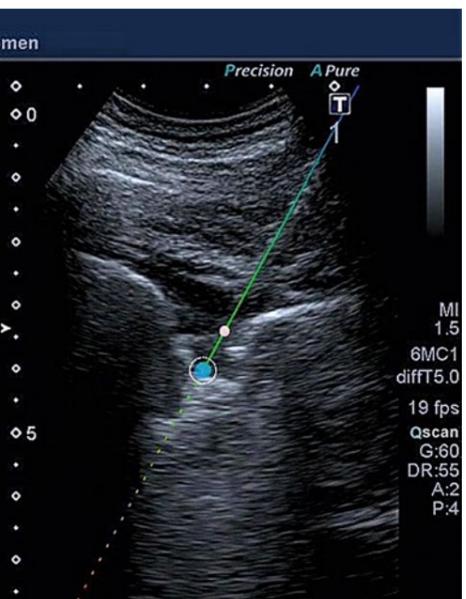
form, I don't have to wait for the CT or the MR room to be open.'

Additionally, he pointed out, 'The needle-tracking function is excellent, giving an ability to truly project the path for the needle into the lesion, and then keeping clinicians on-track, even where the actual needle cannot be visualised by ultrasound because of bone structures or body fat.'

'The system shows exactly where the tip of that needle is and, even better, tells me if I am too high or too low. We can achieve far greater precision during biopsies now – more precise every time. With the help of image fusion and needle navigation we can now use ultrasound guidance for applications we would never have considered before, such as with bone or the chest wall.'

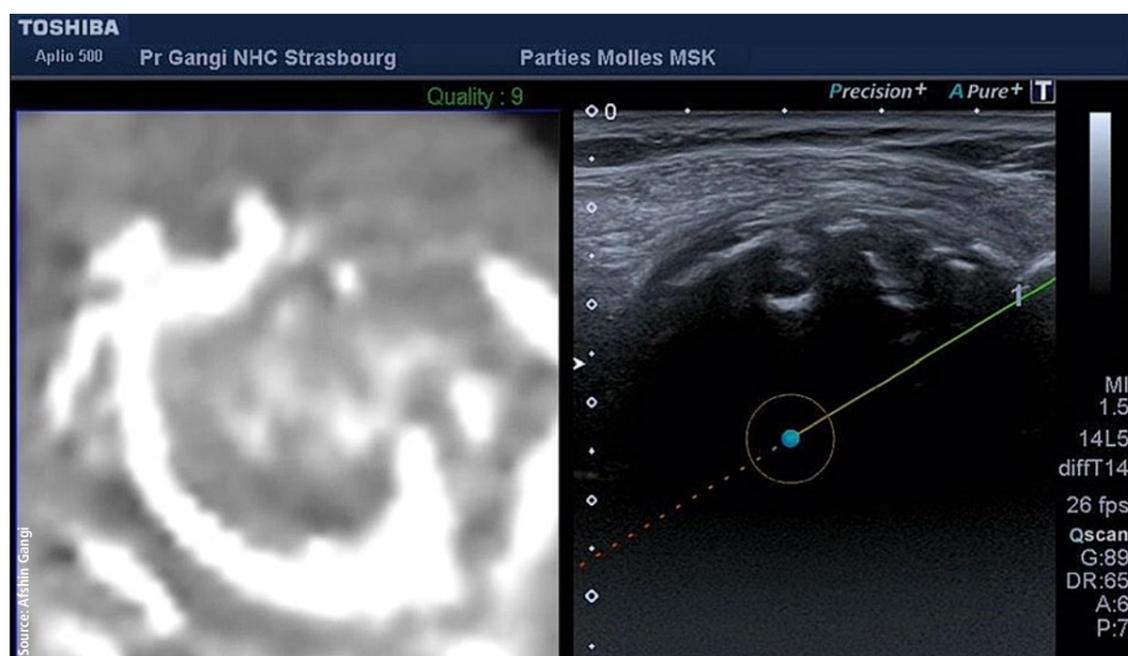
The ease-of-use and accuracy of the enhanced image fusion software has also affected clinical routine and accelerated patient throughput, Gangi explained: 'Today the technicians can do this so that when the interventionalist comes into the room, it's done. This saves a lot of time, and I can tell you this is very important for us.'

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 patient. With the Toshiba Aplio plat-



Lung biopsy with thoracic contact to rule out malignancy: Smart Fusion allows the interventionist to find the lung lesion attached to the pleura easily – and even the smaller ones. The needle navigation improves his depth targeting confidence and makes the biopsy safer for the patient

Bone biopsy in a humerus fracture to exclude a bone metastasis: Smart Fusion allows the interventionist to find the region of interest easily, which would not have been possible without this system. Needle Navigation gives an extremely precise depth control even after entering the bone surface



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