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Technology applications

Medical 3D printing: from niche to mainstream



Cranio-maxillofacial plates have been among the first medical implants to benefit from 3D printing technology at scale.

From personalized medical guides and implants to advanced surgical planning solutions: 3D printing and visualization has grown considerably over the past years and is already making a significant impact in healthcare. AI, cloud, and virtual reality technologies show promise to further advance the number of applications. However, many hospitals find it challenging to implement these technologies into their established clinical workflows and structures.

At the 3D Printing in Hospitals Forum in Leuven, Belgium, hosted by Materialise, we spoke with Koen Peters, Executive Vice President Medical, and Sebastian de Boodt, Business Line Director Medical Software, about the potential for growth and barriers that need to be overcome for more patients to benefit from this technology.

Orthopaedics was the first medical specialty to utilize 3D printing at scale, starting with customized guides for knee implants, Peters re-

calls. 'This was still a far cry from the personalized healthcare we know today – but the benefits were already obvious: Ultimately, every person is different, and the better a medical product fits their individual anatomy, the greater the chance of achieving a positive outcome.' It was already at this early stage that the importance of 3D visualisation software became apparent, De Boodt adds: 'Seeing how a personalized device fits within a patient, and planning the necessary cuts in advance can greatly contribute to shortening surgery times and reduce complication rates.'

The rocky, but rewarding road to clinical implementation

While personalized 3D technology saw its first applications in complex cases, it has now become common, especially in orthopaedic and cranio-maxillofacial procedures. The improving accessibility of the software has been a key contributor to this development, Peters says. 'With a growing awareness about the benefits of this kind of personalized approach, many institutions have started adopting the technology.' Since the advent of the technology, Materialise has developed around 600,000 patient specific guides and implants, the expert estimates. Including cases where patient scans were analyzed with its software, this number rises to about 10 million.

As became clear during the 3D printing forum's presentations however, implementation is not always straightforward. 'One major challenge is finding the right staff,' explained De Boodt: 'An important starting point is having an engineer with good medical knowledge or

at least medical affinity. Close collaboration between these fields is essential to make sure that the technology fits within the established clinical workflows and structures.' Quality management is another important aspect, he adds: '3D printing effectively means that the hospital is creating medical devices, and this needs to be done in a way that is safe and in compliance with medical regulations.'

Last, but not least, successful implementation of the technology hinges on integration into funding and reimbursement structures, the experts point out. For one, establishing a 3D printing lab can be a significant investment, De Boodt points out. 'Often, this is achieved using research grants and seed funding. However, after this initial period, hospitals are usually expected to cover for the running costs themselves. 'The added value is in many ways very obvious, but it does not always translate in how hospitals manage their billing,' Peters says. While it may be simple to submit a CT scan into the system for reimbursement, this option is often absent for procedures involving 3D printing. 'I think this is a bit of a missed opportunity.' Therefore, departments utilizing the technology should make sure to raise awareness about how it provides cost savings and find ways to integrate it into established reimbursement structures.

Beyond printing: advancing personalization with AI and VR

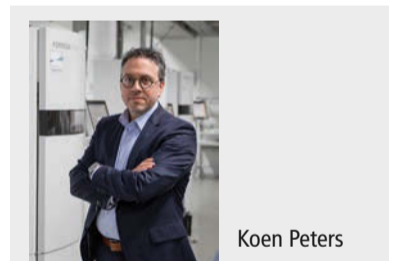
Looking ahead, Peters sees artificial intelligence as a key technology to complement and advance 3D printing and planning: 'AI will certainly accelerate the process of creating personalized solutions for patients,' he predicts. It enables automation of certain steps during the planning phase, which lowers the learning curve for new users and streamlines the finalization of designs, reducing both manual work and costs. 'AI addresses some of the greatest challenges in personalization,' De Boodt says. 'Certain applications, which were just not viable before – due to time constraints, design limitations or financial aspects – suddenly become realistic options.' This in turn increases the appeal of 3D technology within a hospital's business structure, potentially serving as a catalyst, the expert argues.

He also sees great promise in virtual and augmented reality (VR/AR) technologies, although their time has not come quite yet: 'There is a lot of innovation happening at

the time, but actual usage in the clinical practice is still relatively limited, mainly due to hardware limitations. The true value of this technology will become apparent once we find technically realistic applications as navigation tools during procedures.'

Despite the many people who already benefitted from the use of 3D technology, Peters sees a wealth of yet-untapped potential: 'There are so many more people that would be better off with a personalized approach,' Peters explains. 'As we have seen during the presentations, many patients who were treated with conventional methods could have a fundamentally different life. And of course, we hope to play a major role in that development, like we have been doing over the past few decades. We really want to be at the forefront of that innovation that will drive that acceptance towards the future.' ■

Article: Wolfgang Behrends



Koen Peters

Koen Peters is Executive Vice President Medical at Materialise and a member of the company's Executive Committee. Since January 2025, he has overseen global Operations, R&D, Sales, and Marketing for the Medical Unit, focusing on sustainable growth and performance. An alumnus and external PhD researcher at Tilburg University, Koen is a remarkable data scientist.

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Medical Taiwan 2025

Accelerating the journey of medical AI



Medical Taiwan has long been a showcase for cutting-edge healthcare solutions, but this year marked a pivotal moment. Visitors of the latest edition of the medical, health and care expo in Taipei witnessed a particularly noticeable step forward: the definitive transition of medical AI from promising research to actual clinical practice. Organized by the Taiwan External Trade Development Council (TAITRA), the show featured more than 300 Taiwanese and international companies, ready to pioneer this new chapter in medical technology.

'AI is not the future – it is already here.' With this statement, TAITRA Chairman James C.F. Huang made it clear just how far the technology has come in healthcare within the last few years. Unlike previous years that highlighted AI's potential, Medical Taiwan 2025 demonstrated working solutions already transforming patient care. To get ready for this paradigm shift, the TAITRA Chairman invited his audience to enter a 'profound dialogue about the future of health' – an invitation that was eagerly accepted by the attending companies, who took the opportunity to present their market-ready solutions, from AI-assisted X-ray diagnostics of conditions like lung cancer, to hospital ward management support systems. According to the organizers, 15,000 visitors attended this year's show, reflecting the immense interest in the presented healthcare topics and solutions.

Shift from treatment to prevention

With advances in medical technology, the industry is placing a greater emphasis on prevention. GKT's Winback radiofrequency systems exemplified this pre-

ventive approach, targeting pain reduction and tissue regeneration before conditions worsen.

Focusing on the potential of digitalization, the telemedicine and smart medical devices pavilion was home to promising solutions such as the LinguaFlex system from TMU startup FlexMed, which uses gamification to encourage tongue muscle training, to treat obstructive sleep apnea, dysphagia, and speech impairments. Another university startup, DMolution, presented a data-driven approach to diabetic foot care. Their AI-supported system evaluates information gathered by a sensor to early detect patterns of impaired circulation in the feet due to diabetes, preventing permanent damage.

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Enhancing patient comfort was in the spotlight at the booth of Ya Hai International. The company showcased a wide range of medical products, including advanced mattress toppings, sensor mats for non-intrusive patient position monitoring, and smart bed lighting systems. Further, highly customizable care lifters, patient transfer solutions and gait trainers were presented, designed to reduce the workload of care staff and adapt the systems to the individual needs of each patient, the exhibitors pointed out.

Generative AI to assist pre-consultation

With the first wave of medical AI tools entering the market, the next iteration is not far behind. AI-based large language models (LLM), popularized by ChatGPT, are showing particular promise. Pioneering this approach, Taiwanese company Intowell Biomedical, presented "Dr. AI", an LLM-based platform for medical pre-consultation. As the

company's CMO Jack Huang explained, patients simply speak into a wearable device such as a smart ring, and the AI provides preliminary health assessments in 38 languages across twelve medical specialties. The system can assist in booking an appointment with a doctor based on the symptoms described in the recorded conversation, and can also generate a record for the doctor to use.

The company envisions "Dr. AI" to become an all-round companion for patients on their medical pathway. 'For example, when you scan a prescription, it turns into a pharmacist,' Huang said, providing easy-to-understand information on the prescribed drugs, helping with medical terminology and deciphering instructions in small font sizes.

'The system is not designed to replace doctors,' the CMO emphasized, but to serve as an intelligent assistant, handling routine tasks so doctors can focus on complex patient care.

Regenerative solutions and digital twins

The field of regenerative medicine was also well-represented at Medical Taiwan. Notably, Acro Biomedical showcased its "ABCcolla" collagen ophthalmic matrix for corneal transplants, as well as upcoming solutions for alopecia. 'Our vision is to address the global shortage of transplantable tissues and organs,' said Dr DJ Hsieh, the company's Chairman and CEO.

Present with one of the largest booths at the event, BenQ Group led the showcase with 13 affiliated brands – including BenQ Materials Corporation – and presented a comprehensive range of healthcare solutions covering prevention and beyond. From AI-powered imaging evaluation systems and "digital twin" platforms for health data analysis to consumables such as professional hygiene materials, disinfectants, protective garments, wound care solutions and mobile dialysis systems, the company provided an overview over their extensive product portfolio, attracting a great number of visitors.

Hiwin Healthcare presented an AI-enhanced robotic gait training system for rehabilitation. The device monitors the patient's movement to generate a personalized training regimen. 'The algorithm detects whether the patient is performing the correct movement, and adjust the programme accordingly,' explained the company's Senior General manager Sophie Lin. 'This way, the optimal level of exercise is provided.' The system is already used in 21 hospitals across Taiwan.

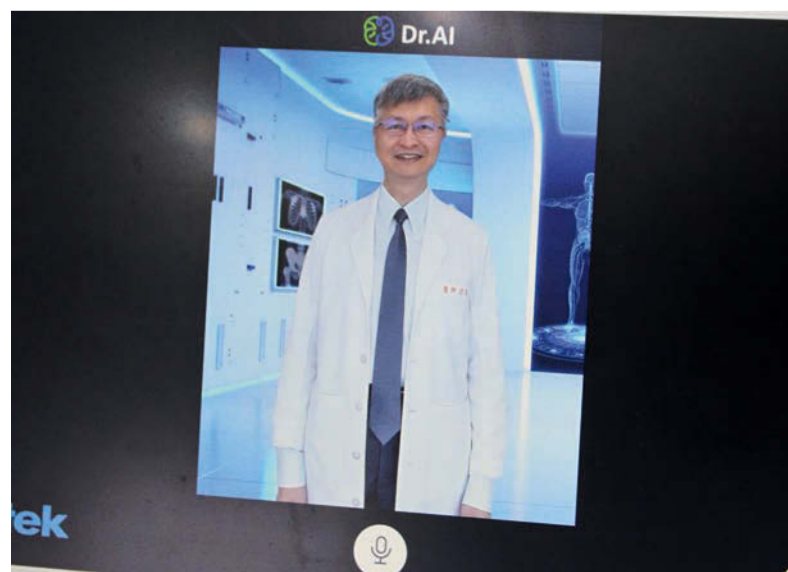
Smart medical devices to address medical staff shortage

A staple of any Medical Taiwan event, the Smart Medical Pavilion was home to high-tech applications. The special zones gave manufacturers opportunity to exhibit their combined solutions in a context resembling actual clinical configurations. Notable examples include a setup consisting of a smart surgical table and OR lighting from BenQ, complementing a robotic system for precision neurosurgery from Eped.

When commercially available AI tools do not fit the specific needs of a hospital, institutions may try to create customized algorithms for themselves. To facilitate this effort, QOCA aim from Quanta Computer Inc. provides a medical cloud platform, which covers the entire process from AI development to clinical application. The solution is web-based and user-friendly, but since the data is hosted in the hospital's internal network to address data privacy concerns.

Medical Taiwan 2025 provided testament to AI in healthcare moving beyond proof-of-concept to practical reality. After witnessing three days of medical devices, health technology and care solutions, the show's organizers and exhibitors looked back on another successful iteration of Medical Taiwan, and forward towards the show's return in 2026. ■

Article: Wolfgang Behrends



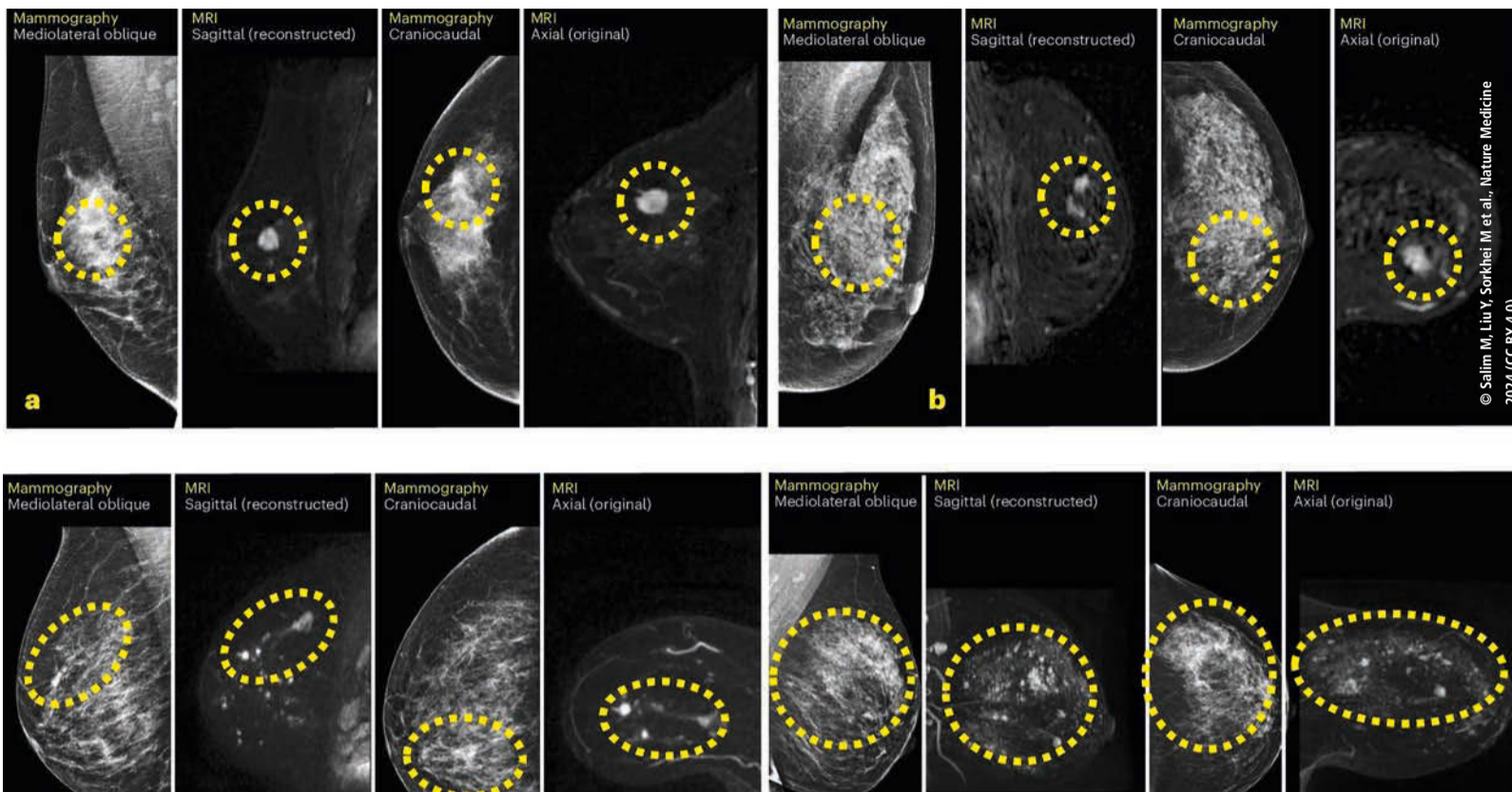
"Dr. AI", an LLM-based platform for medical pre-consultation. ©Wolfgang Behrends



Scan for the extensive article on the Healthcare in Europe website.

Risk stratification initiatives in Europe and UK

Future breast imaging: a date with density



Cancers detected by supplemental MRI after negative mammography: a) A 13-mm large BI-RADS 4 finding on MRI that corresponded to a 13-mm large invasive cancer as diagnosed in the surgical specimen. b) A 9-mm large BI-RADS 4 finding on MRI that corresponded to an 8-mm invasive cancer and 14-mm ductal cancer in situ. c) Three suspicious lesions within a total area of 60 mm, BI-RADS 5 finding on MRI, that corresponded to a 50-mm multifocal invasive lobular cancer. d) Two suspicious lesions, the largest 13 mm, BI-RADS 3 on MRI, which corresponded to a 10-mm invasive lobular cancer with 85-mm extent including ductal cancer in situ.

About 60% women in Europe enrolled in a national breast cancer screening programme who have a screening mammogram can feel reasonably confident that radiologists will be able to diagnose early-stage breast cancer. But what about the 30% categorised as having dense breasts, and the 10% who have extremely dense breasts? At the 2025 SBI (Society of Breast Imaging) Breast Imaging Symposium held in Colorado Springs, USA, Prof. Ruud Pijnappel, MD, PhD, discussed current clinical trials addressing breast screening of dense-breasted women.

For these women, detecting early-stage breast cancer on mammographic images can be challenging. They may need additional types of breast imaging, but which technologies are most effective? Clinical trials in Europe are underway to determine the most beneficial and most cost-effective screening methods for high-risk women. They are needed to convince governments to fund supplemental breast imaging to screen for cancer in women at average risk with dense breast tissue.

Pijnappel, Professor of Breast Radiology at the University Medical Centre (UMC) Utrecht, the Netherlands, and chief executive officer of the Dutch Expert Centre for Screening in Nijmegen, started off with a transatlantic overview: 'Research in Europe on this subject differs slightly from that being undertaken in the United States,' he said. 'One imaging methodology does not fit all, and protocols for more personalised screening are needed. Research in Europe is especially focussed on risk profiling so that interval cancer rates can be reduced, and to make screening frequency and modality based on

an individual woman's risk assessment.'

Between impressive evidence and financial challenges

The DENSE clinical trial (NCT01315015) involves over 40,000 women ages 50 to 75 with extremely dense breasts living in the Netherlands who had normal results on screening mammography. It is evaluating if supplemental breast MRI can minimize the number of interval cancers in a two-year screening round. Participants were randomly assigned in a 1:4 ratio. For the MRI group, the interval-cancer rate was 0.83 per 1000 screenings compared to 5.06 per 1000 in the mammography-only group in the first round.

'This solid scientific evidence was impressive, but costs and breast MRI scanner availability made this very difficult for EU countries to implement,' explained Prof. Pijnappel. 'Only Estonia adopted supplemental MRI screening for extremely dense breasted women to its national screening programme protocol. So, three clinical trials investigating individual screening optimisation were initiated.'

Ongoing clinical trials

Launched in November 2024, the DENSE 2 (NCT06636370) is enrolling 36,000 women aged 49–72 with density D category to determine if either contrast-enhanced mammography (CEM) or an abbreviated breast MRI (AB-MRI) exam supplementing a "normal results" at mammography performed at UMC Utrecht are more effective in reducing interval cancers than mammography alone. CEM is less costly and easier to implement than a conventional breast MRI. Secondary outcomes of the study include cancer detection rates and false positive rates. This trial in-

cludes two screening rounds and is expected to conclude in April 2029.

In the United Kingdom, mammography breast cancer screening is offered to women ages 50 to 75 every three years. The Breast Screening-Risk Adaptive Imaging for Density (BRAID) randomised clinical trial (NCT04097366), led by Prof. Fiona J. Gilbert, MD, of the University of Cambridge, recruited 9,361 women with C and D dense breast categories who have had a normal screening mammogram at one of 10 locations. Participants were randomised to a control group without supplemental testing, or to receive a CEM, an AB-MRI scan, or automated whole breast ultrasound (ABUS). The first supplemental exams were performed within six months of the screening mammography. Begun in 2019, the primary endpoint of the study is to measure both the primary and interval cancer detection rate over 42 months, recall and biopsy rates, tumour size, and grade of cancer.

Prof. Pijnappel explained that the interim results presented at ECR 2025 revealed that 85 cancers were diagnosed with supplemental screening: 73 invasive cancers and 12 ductal carcinomas in situ (DCIS). The cancer detection rate was 19.2 per 1000 examinations for CEM, 17.4% for AB-MRI, and 4.2% for ABUS. The invasive tumour size identified by AB-MRI and CEM was half the size of those found with ABUS.

The ScreenTrustMR (NCT04832594) prospective clinical trial being conducted at Karolinska University Hospital in Stockholm, Sweden, is evaluating the ability of an AI tool (AISmartDensity) to identify women with the highest probability of having a delay in cancer detection from a false negative

screening mammogram, and who would benefit from a supplemental breast MRI exam. The AI tool assesses mammographic breast density, potential masking, suspicious cancer signs, and other risk factors.

The AI tool analysed data of 1,211 women to whom it had assigned high risk scores to mammography exams performed at Karolinska. Principal investigator Fredrik Strand, MD, PhD, advised that the cancer detection rate of participants who had a supplemental MRI was 64.4 cancerous lesions per 1,000 exams, according to a report published in Nature Medicine.


Because the AI tool only selected 6.9% of over 59,300 women, Dr Strand and colleagues state that the cost per cancer detected with supplemental MRI is four times more efficient than conventional mammography. Additionally, it is comparable to the cost of screening mammography for this very high-risk population. In a future study, the researchers will investigate if an additional review of mammograms flagged as high risk by the AI tool will yield an increased cancer detection rate.

Appeal for a more personalised approach

Prof. Pijnappel predicts that breast cancer risk stratification by traditional density measurement is going to become less important, and that AI tools have great potential to identify at-risk women. 'Not every woman with dense breast tissue will develop cancer. And you know that breast cancer occurs in women with average tissue density and fatty breasts. Women at low risk may only need mammograms at four- or five-year intervals. This may offset the cost of offering exams annually to high-risk women. Breast cancer screening should become more personalised, not the "one size fits all" frequency of today,' he concluded. ■

Author: Cynthia E. Keen


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Respiratory health

Pulmonary embolism in pregnancy: diagnostic pathways under scrutiny



Radiation safety and legal framework

CTPA, when optimized, typically exposes the fetus to less than 1 mGy – well below the 100 mGy threshold for teratogenic risk. Dose parameters such as the dose-length product (DLP) and computed tomography dose index (CTDI) must be recorded in the radiology report. In France, these figures must also be communicated to the IRSN if the fetus is in the scan field.

'The fetal dose is often negligible, particularly for thoracic exams where the uterus is outside the radiation field,' Dehaene said. 'Nevertheless, radiation safety regulations and informed consent procedures must be strictly followed.'

Role of scintigraphy and diagnostic limits

Scintigraphy remains an acceptable alternative when chest radiograph is normal, offering diagnostic performance comparable to CTPA. However, it lacks the ability to identify alternative diagnoses and may also be inconclusive in some cases.

CT, in contrast, provides broader diagnostic coverage and allows for evaluation of embolic burden. 'Still, artefacts and suboptimal contrast enhancement can reduce image quality,' she acknowledged.

Optimizing safety and certainty

Clear protocols, tailored imaging, and adherence to legal requirements are key to ensuring safe and effective diagnosis of PE in pregnant patients. For Dehaene, the message is clear: 'Know the algorithms, justify the indication, adapt the protocol, and document everything.'

By aligning clinical vigilance with technical precision, radiologists play a central role in improving maternal outcomes in suspected PE. The stakes are high – but with informed strategy, risks can be controlled. ■

Author: Mélanie Rouger

Pulmonary embolism (PE) remains one of the leading causes of maternal mortality. At the French Thoracic Society Spring Days in May, Dr Aurélie Dehaene, radiologist at European Hospital in Marseille, France, reviewed diagnostic strategies for suspected PE during pregnancy, with a focus on clinical algorithms and optimized imaging protocols.

'Venous thromboembolic disease is common in pregnancy and peaks during the postpartum period,' she said. 'Physiological changes associated with gestation significantly increase the risk of thrombosis.' These include vascular compression due to uterine enlargement, hormone-induced vasodilation, and hypercoagulability – elements that align with Virchow's triad: endothelial injury, stasis, and a pro-thrombotic state.

Additional pregnancy-related factors such as preeclampsia, in vitro fertilization, postpartum haemorrhage, or caesarean section further increase this risk, alongside general risk factors like obesity, smoking, and advanced maternal age.

Clinical overlap and diagnostic hesitation

The overlap of PE symptoms with normal pregnancy complaints complicates clinical evaluation. 'Dyspnea and peripheral oedema are common and non-specific,' Dehaene said. This contributes to diagnostic uncertainty and reluctance to prescribe radiation-based imaging, despite the severity.

Yet both underdiagnosis and over-treatment carry significant risks. 'Missing a PE is dangerous, but so is unnecessarily anticoagulating a patient,' she warned.

To support diagnostic accuracy, clinicians now rely on structured algorithms. The two most referenced models were developed in 2019 by the European cardiology and respiratory societies and the Artemis group. Both integrate pre-test clinical scoring, D-dimer assessment, and imaging protocols.

Adapting clinical probability tools

The European approach proposes a modified Geneva score adapted for pregnant patients. Criteria include age, recent immobilization or surgery, unilateral leg pain, history of PE or DVT, haemoptysis, leg swelling or tenderness, and tachycardia. A score above seven indicates high clinical probability.

In combination, D-dimer levels help stratify risk. 'If D-dimers are low and clinical suspicion is low, PE can be safely ruled out without imaging,' Dehaene explained. However, the test's performance decreases in the third trimester due to physiologic D-dimer elevation.

A prospective study involving 141 pregnant women validated this algorithm, though it showed better performance when supplemented with venous compression ultrasound and CT pulmonary angiography (CTPA).

Imaging: structured and stepwise

When further workup is needed, a chest X-ray is typically performed first, to rule out alternative diagnoses. If signs of deep vein thrombosis (DVT) are present, lower limb Doppler ultrasound is indicated. 'A positive Doppler result confirms venous thromboembol-

ism and eliminates the need for thoracic imaging,' Dehaene said.

In the absence of clear DVT findings, either CTPA or ventilation/perfusion (V/Q) scintigraphy may be used depending on local expertise and radiographic results. Scintigraphy is preferred when chest X-ray is normal; otherwise, CTPA is recommended.

CTPA optimization for pregnancy

'Pregnancy increases cardiac output by up to 50%, creating specific imaging challenges,' Dehaene stated. Protocols must be adapted to reduce fetal exposure while ensuring diagnostic quality.

Scanning should cover only from the aortic arch to the diaphragmatic dome, omitting apical regions. Contrast injection should use 120 mL of iodinated agent at 4–6 mL/s, with a concentration of 350–360 mg iodine/mL. Bolus tracking is triggered in the pulmonary artery, with thresholds between 120 and 150 HU. 'A simple breath-hold – not deep inspiration – is preferred to limit motion artefacts,' she advised.

There is no established contraindication for iodinated contrast during pregnancy. Although potential fetal thyroid risks are often cited, no evidence of clinical hypothyroidism has been demonstrated. 'Paediatric teams may monitor thyroid function as a precaution,' Dehaene stated. Regarding breastfeeding, only a few agents require temporary interruption, and usually no longer than four hours.



Dr Aurélie Dehaene during her presentation.

Hospitalists explore diagnostic and therapeutic adjustments

Dual challenge: Managing critical care of the pregnant inpatient



Hospitalists face a dual challenge when a critically ill pregnant patient is admitted to a hospital: providing safe and effective treatment for both mother and fetus. Pregnancy causes physiologic changes as well as anatomical ones, which complicates the assessment and medical management of pregnant women. At the annual meeting of the Society of Hospital Medicine (SHM) in Las Vegas, an expert discussed why hospitalists must draw on a variety of skills when treating pregnant inpatients.

Pregnancy causes physiologic changes as well as anatomical ones, which complicates the assessment and medical management of pregnant women. Hospitalists must play a critical role verifying the accuracy of clinical information, such as the comprehensiveness of patient-provided drug lists, analyzing the possible impact on pregnancy of lifestyle and pre-existing conditions, and answering questions posed by pa-

tient and family that are both general and fetal risk-related. They also need to be knowledgeable about how physiologic changes impact laboratory results and prescription medications.

Speaking at SHM Converge, Courtney Bilodeau, MD, Associate Professor of Medicine and Clinical Educator in Obstetric Medicine and Breastfeeding Medicine at the Warren Alpert Medical School of Brown University in Providence, Rhode Island, stated that essential qualities include:

- Clinical expertise and knowledge
- Diagnosing and treating a wide range of medical conditions
- Staying updated on current medical advancements
- Problem-solving and critical thinking
- Strong interpersonal communication and teamwork skills; and
- Empathy and compassion.

Considering that this is the 21st century, the maternal death rate in the United States is shocking, she

remarked. The National Vital Statistics System recorded 18.6 deaths per 100,000 live births in 2023. This is an improvement from 2020, when 23.8 deaths occurred, according to the US Centers for Disease Control and Prevention (CDC). By comparison for that year, the most recent for comparative multinational statistics, the next highest rate in comparable European industrialised countries were much lower, with the highest being France, at 8.7 deaths. Factors in US mortality range from pre-existing conditions (e.g., obesity, hypertension), and unhealthy lifestyle (e.g., alcohol, smoking, illegal drug use), to pregnancy and birth related complications, including pre-eclampsia, gestational diabetes, peripartum hemorrhage, and venous thromboembolism (VTE).

2017–2019 CDC data reveal that 66% of pregnancy-related deaths occur in the postpartum period: 22% during pregnancy, 13% on the day of delivery, 12% one-to-six days postpartum, and 30% from 43 to 365 days. In many countries, including the US, there is a shortage of primary care physicians to provide after-birth medical treatment.

Considering extensive changes

Because fetal well-being depends upon maternal well-being, the pregnant body works harder to meet the needs of the developing fetoplacental unit. Hospitalists must consider the normal physiologic changes in pregnancy and determine if changes in the patient are pathologic. 'It's important to think what a diagnosis might be if a patient was not pregnant,' she said. 'Then consider how pregnancy physiology impacts these disorders.'

Pulmonary changes include the increase in the angles of a rib, changes in arterial blood gas measurements, lower esophageal sphincter tone, increases in upper airway edema, increased Mallampati score which predicts ease of intubation, increased risk for as-

piration, decreased gastric emptying, and increased intra-abdominal pressure.

Kidneys hyper-filter during pregnancy. Renal blood flow increases by 50%. Creatinine clearance increases to levels of 120–160 ml/min, and levels of serum creatinine are decreased to 0.4 to 0.7 mg/dl.

Changes in the cardiovascular system include an up to 30% to 50% increase in cardiac output, potentially worsening pre-existing cardiac comorbidities. Compression of the aorta can result in hypotension. Total blood volume increases by 25% to 40%, and plasma volume by 40% to 50%. Pregnant patients are at greater risk of coagulation, causing anaemia. Elevation of the diaphragm and uterus enlargement contributes to the risk of hypoxia. All pregnant patients also become insulin resistant.

'Hospitalists need to consider what tests and imaging exams they order for a non-pregnant patient,' Dr Bilodeau advised. 'Can these diagnostic investigations be done safely in pregnancy, or is there another way by which to obtain the information needed? Are the lab tests changed by physiologic changes? Assess the risk of either not doing the work-up or delaying it until after delivery.'

Advice on radiation and medication

Although radiation dose exposure to the fetus should be avoided, if possible, there is no clinical evidence of adverse effects from doses of less than 0.05 Gy, said Dr Bilodeau. Almost all commonly used diagnostic imaging using radiation involves exposure well below 0.01 Gy. Imaging for pulmonary embolism is both safe and accurate, including a V/Q scan, a chest X-ray, and a chest CT if necessary. She warned that gadolinium contrast agent should not be used.

'Make certain that a patient who is about to deliver has not received

prophylactic dose anticoagulant medication within 12 hours, or therapeutic dose anticoagulant medication within 24 hours of undergoing regional anaesthesia. The patient needs to be eligible for regional epidural or spinal anaesthesia if needed during delivery,' she advised.

Additionally, medications should be ordered only if they are approved for pregnant patients and patients who are breastfeeding. Any medication risks should be discussed with patients in the context of risks that could occur if a patient does not take the prescription drug.

'Don't trust the medication list on a patient's hospital chart,' Dr Bilodeau said. 'Ask the patient if she is or has been taking "recreational drugs". Ask about over-the-counter medications and supplements, especially herbal supplements, including dosage and frequency of use. The patient may not realize that any of these could impact testing and treatment.'

Lactation and breastfeeding: 'Don't assume anything'

'Lactation periods are also sensitive. Medications are more likely to be transferred into breast milk during the first to fourth day of lactation. Some women breastfeed their children for two years or more. Don't assume anything,' she said.

'Finally, help a patient realize that her own health is most important,' Dr Bilodeau counselled. 'Patients will ask what risk they have. Make time to explain this in understandable terms. Advise that in any natural pregnancy, there is a 3% to 5% risk of congenital anomalies.' ■

Author: Cynthia E. Keen

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Publisher
mgo fachverlage GmbH & Co. KG
E.-C.-Baumann-Str. 5
95326 Kulmbach/Germany
Phone +49 (0) 9221 949-311
Fax +49 (0) 9221 949-377

Managing Directors:
Eva-Maria Bauch, Stephan Behrens

Editor and Production Manager:
Tim Hofmann (TH)
Phone: +49 (0) 9221 949-176
E-Mail: redaktion@european-hospital.com

Editor: Wolfgang Behrens (WB)

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Correspondents
Austria:
Michael Krassnitzer (MK)

Germany:
Cornelia Wels-Maug (CWM)
Dr Christina Czeschik (CC)

Great Britain:
Mark Nicholls (MN)

Spain:
Mélisande Rouger (MR)

USA:
Cynthia E. Keen (CEK)

Subscriptions
Simone Sesselmann
kundenservice@mgo-fachverlage.de

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Representatives
Germany, Austria, Switzerland:
Diana Thümmel
Phone: +49 9221 949-407
E-Mail: d.thuemmel@mgo-fachverlage.de

Europe:
Eric Jund
Phone: +33 493 58 77 43
E-Mail: jund@european-hospital.com

Taiwan:
Charles Yang
Phone: +886 4 232 236 33
E-Mail: medianet@ms13.hinet.net

USA & Canada:
Hanna Politis, Media International
Phone: +1 301 869 66 10
E-Mail: hanna@media-intl.com

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Digital support for the women's health agenda

Bridging the gender health gap



Karen Kirkham, Claire Riley, Misbah Mahmood and Tulsi Patel (left to right) at the Digital Maturity Forum Keynote Session

Digital technology is being harnessed to support the women's health agenda in the UK and address issues of equity and access to healthcare through a range of innovative initiatives. Delegates to the HETT (Healthcare Excellence Through Technology) North conference in Manchester heard how digital is being leveraged to support women's health hubs – which tailor care to meet women's needs while helping reduce pressure on secondary care – and midwifery services.

The keynote session was chaired by Karen Kirkham, partner and Chief Medical Officer from the professional services network Deloitte, who opened by highlighting the definition of health equity as a 'fair and just opportunity of everyone to achieve their full health potential' that includes social, emotional, physical and non-medical social determinants of health.

A former GP with a strong interest in women's health, Kirkham also pointed to a recent Deloitte report, which highlighted four tenets for improving health:

1. helping organisations understand what health equity is;
2. how to break the barriers to improve health equity, particularly through data;
3. how to embed health equity in every organisation with use of data, analytics, digital inclusion and workforce training, and;
4. how to close the health equity gap.

What women want (in healthcare)

Following up, Claire Riley, Chief Corporate Services Officer for the NHS North East and North Cumbria Integrated Care Board (ICB),

detailed how her region in the north of England had invested in women's health hubs and surveyed 5000 women on what their priorities are. 'We can look at the data and also look at what services women are accessing,' she said, 'but we don't always ask women what they want. We wanted to make sure that the patient voice was at the heart of our plans going forward. If we are going to make a sustained difference to how women access services and the care they receive, we need to start with what they want.'

The expert pointed out the importance of acquiring data on deprivation, ethnicity, and economic activity was pivotal in offering a holistic approach to women's care. Women's health hubs – which were established under the Women's Health Strategy for England – are having a major impact by offering appointments covering 3–5 issues, rather than one appointment for one area of care, she added.

'We are starting to see real benefits of that joined up care focused on women's health to the point where we are now extending some of those services in our hubs to include diagnostics.'

Unmet demand for mental health support

With the majority of women's health funding still going into a hospital environment, Riley added that data can identify where the investment needs to be spent in the community. She said that data can identify gaps in service and where improvements can be made by assessing health trends alongside patient feedback.

Links to the NHS app enable medics to provide more personalized treatment pathways. However, the expert added that those

who are not yet able to access the technology should be supported as 'any technology that is activating individuals to take control of their own health and wellbeing has to be a positive.' Still, she remained concerned that while tech companies are heavily promoting solutions in areas such as fertility or menopause, a similar focus on mental health is absent. 'But that is an area that women are accessing services for,' she said, explaining that anxiety and depression are among the conditions associated with the most GP consultations, only surpassed by urinary tract infections.

Help patients take ownership of their condition

The audience also heard from Misbah Mahmood, Deputy Chief Midwifery Information officer at Leeds Teaching Hospital NHS Trust, who outlined how the electronic patient record (EPR) has standardised collection of data and led to the creation of a health inequalities dashboard. In an example, she said: 'The platform tells us that 50% of women who give birth at Leeds are from a deprived background and that 10% are gestational diabetic.' That data, she continued, enabled her team to offer relevant and timely interventions and support.

Mahmood explained how technology had been harnessed in maternity services in Leeds by having online notes on a web-based system that women can access as well as health information. In areas such as blood pressure monitoring or diabetes, she said it helped women understand and take ownership of their condition and make lifestyle changes. The number of women accessing online notes is monitored and where gaps are identified, teams can reach out to communities. Mahmood said the introduction of

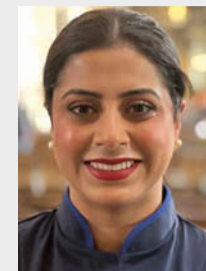
online self-referral to maternity services had enabled information capture and the ability to identify and see women with the greater needs sooner.

Generational shift

Tulsi Patel, Director of Product at women's health technology company Hertility, emphasized that data forms the cornerstone of their operations. She highlighted that 600,000 women have completed the company's online health assessments, which generate GP-ready reports on women's health conditions, facilitating expedited referrals when necessary. Noting a 'generational shift' in technology and wearables, she pointed out a trend towards higher prioritization of healthcare in general and women engaging 'sooner in their healthcare journey'. Patel emphasized the importance of user-friendliness of health technology and emphasized the role of consumer input to achieve this.

The panel also expressed concern about the levels of inappropriate and inaccurate information being offered on social media channels and the need to support families that cannot afford technology to benefit their health. ■

Author: Mark Nicholls



Misbah Mahmood

Misbah Mahmood is Deputy Chief Midwifery Information officer at Leeds Teaching Hospital NHS Trust, and has been a qualified midwife for 10 years. She has led several projects across maternity services, including an end-to-end electronic patient record and secure online notes portal. She is a member of the Digital Midwives Expert Reference Group.



Tulsi Patel

Tulsi Patel is Director of Product at Hertility where she leads the Product Management and Design operation, which is spearheading the future of reproductive healthcare by pioneering diagnostic testing, and providing data-driven and advanced insights into all aspects of women's health.



Karen Kirkham

Karen Kirkham is a partner and the Chief Medical Officer at Deloitte and a member of the HETT Steering Committee. She previously worked as a GP in south of England with an interest in women's health. Her areas of interest are healthcare operations and consultancy.

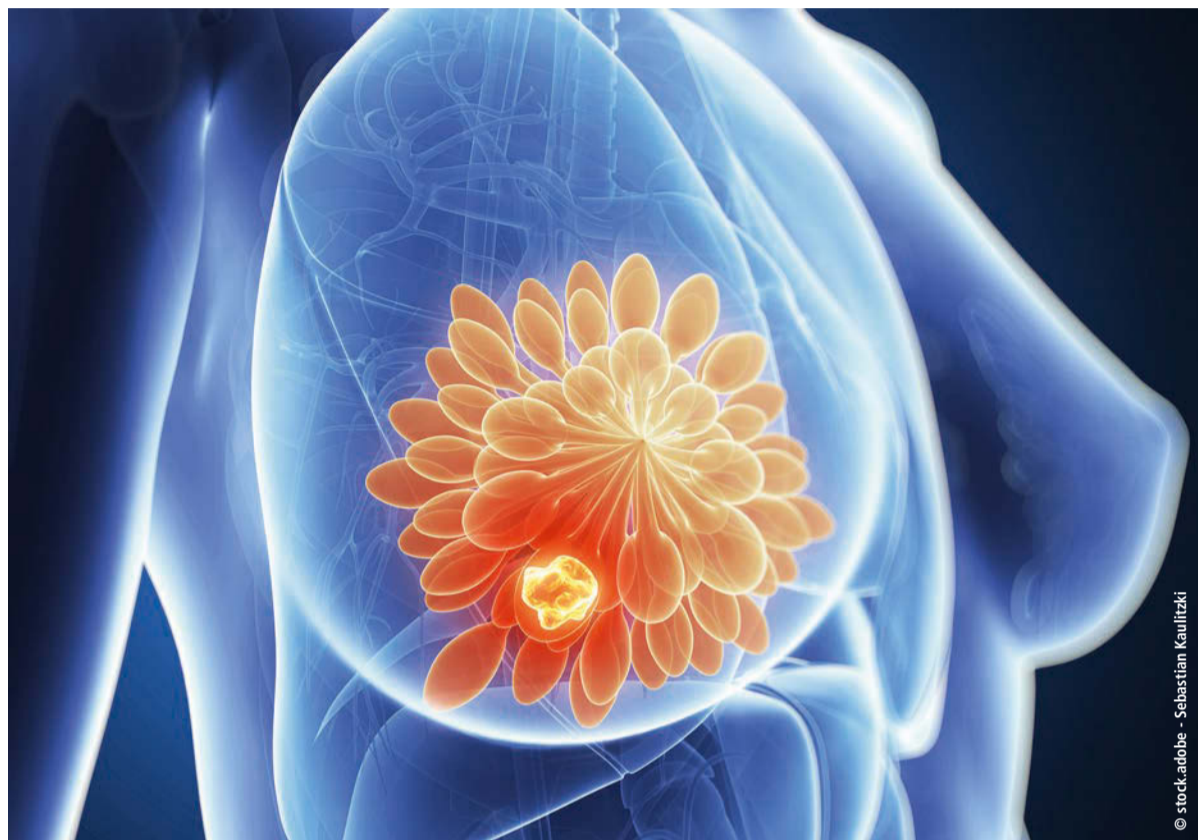


Claire Riley

Claire Riley is Chief Corporate Services Officer for North East and North Cumbria Integrated Care Board (ICB) and Executive Lead for Women's Health, Research and Innovation. She was previously the Executive Director of Communications and Corporate Affairs at Northumbria Healthcare NHS Foundation Trust.

AI-powered prediction

Machine learning identifies cardiotoxicity risk in breast cancer patients



Researchers have developed a machine learning algorithm that uses cardiac MRI images to help identify breast cancer patients who may be at risk of cardiotoxicity during cancer treatment. The research, led by cardiologist Dr Paaladinesh Thavendiranathan from Toronto General Hospital University Health Network, was presented at the European Society of Cardiology's Cardio-Oncology Conference in Florence in June.

The study addressed the challenge of predicting cancer therapy-related cardiac dysfunction (CTRCD), which the researchers noted "remains a challenge." According to the research paper, clinical risk models and conventional cardiac magnetic resonance (CMR) analysis 'are limited' in predicting HER2+ targeted therapy (HER2-TT) CTRCD risk.

Dr Thavendiranathan, who is also a Professor of Medicine at the University of Toronto, explained that current techniques for risk stratification 'are not very effective.'

Promising study performance

The Canadian study aimed to determine if deep learning (DL) approaches using CMR cine images pre or early during cancer therapy can predict CTRCD better than clinical risk scores or conventional quantified imaging measures.

Women with early-stage HER2+ breast cancer receiving sequential anthracyclines and trastuzumab from three prospective studies were included. Patients were seen pre- and post-anthracycline and sequentially during treatment with repeated cardiac imaging (echocardiography and CMR) to create various machine learning models to predict CTRCD.

"This model performed better than clinical risk factors, echocardiography measures, and traditional cardiac MRI measures or biomarkers," Dr Thavendiranathan said. "When we validated our findings in a separate cohort, the model continued to perform well."

Using information from the whole heart

The research concluded that 'in women with breast cancer receiving anthracyclines and HER2-TT, a DL model using CMR short axis cine images pre-anthracycline had higher discrimination for future CTRCD than clinical and conventional imaging quantification models.'

Dr Thavendiranathan's key finding was that a machine learning algorithm applied to a single set of cardiac MRI images could identify patients at high risk of cardio-

toxicity. He suggested this 'may be due to the ability to potentially use information from the whole heart with the ML algorithm to risk stratify patients, as opposed to single chamber information as we do traditionally.'

The expert outlined potential clinical benefits of identifying at-risk patients before treatment begins: "This would provide opportunities for clinicians to cater their cancer therapies to minimize risk or to add cardioprotective medications or to modify the surveillance strategies to pick up early cardiac dysfunction during cancer therapy," he said.

"If patients at risk for cardiotoxicity can be identified even before cancer therapy, preventive strategies can be instituted to reduce the risk of cardiotoxicity. This will reduce the chance of the patient subsequently developing heart failure or having their life saving cancer therapy interrupted."

Transforming risk stratification

The next step, according to Dr Thavendiranathan, is validation of findings in larger cohorts and to consider applying similar methods to more readily available imaging tests in patients with cancers, such as echocardiography.

He expressed hope that further research could potentially lead to a baseline test for use prior to cancer therapy that may identify patients at risk of developing cardiotoxicity. "This has the potential to transform the way that we risk stratify patients as current techniques are not very effective and hopefully, by early treatment, have an impact on the cardiovascular prognosis and overall survival of these patients," Dr Thavendiranathan concluded.

The session at ESC Cardio-Oncology 2025 also included presentations on non-uniform cardio-

vascular risks of tyrosine kinase inhibitors, left atrial strain in multiple myeloma patients undergoing carfilzomib therapy, cardiovascular adverse events with cdk4/6 inhibitors, cardiac function following anti-BCMA CAR-T therapy, and cardiovascular safety of modern radiotherapy techniques in breast cancer. ■



Dr Paaladinesh Thavendiranathan

Dr Paaladinesh Thavendiranathan is a cardiologist at the Toronto General Hospital University Health Network, and a Professor of Medicine at the University of Toronto, Canada. With a background in advanced cardiovascular imaging and an international expert in the field of cardio-oncology, his research is in the use of advanced cardiac imaging techniques for detection and management of cardiac toxicity. He is Director of the Ted Rogers Program in Cardiotoxicity Prevention which focuses on cardiac toxicity from systemic therapies including cancer therapy.

EIS shows promise to advance cancer cell monitoring

A new study unveils a method to non-invasively monitor cell spatiotemporal dynamics involved in cancer progression in a real-time and label-free manner, which can provide new insights for cancer diagnosis and treatment.

The new methodology combines the use of micro-electrode arrays, electrical impedance spectroscopy (EIS) that measures the characteristics of tissue surrounding the sensor, and predictive algorithms. The use of predictive algorithms allows for faster prediction, better resilience to noise, and recognition of complex data patterns when compared to tradi-

tional EIS analysis approaches. This new methodology is believed to be the first-ever use of EIS to enable quantitative real-time monitoring of cell spatiotemporal dynamics, or cell changes over time.

In the study, the team at École Polytechnique's Hydrodynamics Laboratory (LadHyX) leveraged Sensome's technology and exposed it to normal and cancerous breast epithelial cells, where it was able to accurately predict the spatiotemporal evolution of cell density, cell substrate coverage, mean cell diameter, and cell type in agreement with microscopy findings. It also enabled real-time tracking of spatial heterogeneities in breast

cancer cell growth and the competition between normal and cancerous cells based on the EIS measurements alone.

"This technology has the potential to obviate the need for microscopy imaging in cancer cell monitoring in various settings and significantly advance our understanding of cancer cell behavior and interactions," said co-author Abdul Barakat, CNRS Director of Research and Professor at École Polytechnique. "Assessing how cells organize in space and time is essential to elucidating cancer progression. Live-cell fluorescence microscopy is the predominant method for tracking these dynamics today but

is often limited by cytotoxicity induced by the fluorescent dyes, by cellular photo-damage during extended periods of microscopic imaging, and by restrictions in optical access in the case of opaque clinical samples. This methodology using Sensome's technology demonstrates a non-invasive, label-free method enabling long-term monitoring of cancer-related cellular spatiotemporal dynamics with minimal disruption of natural cellular processes."

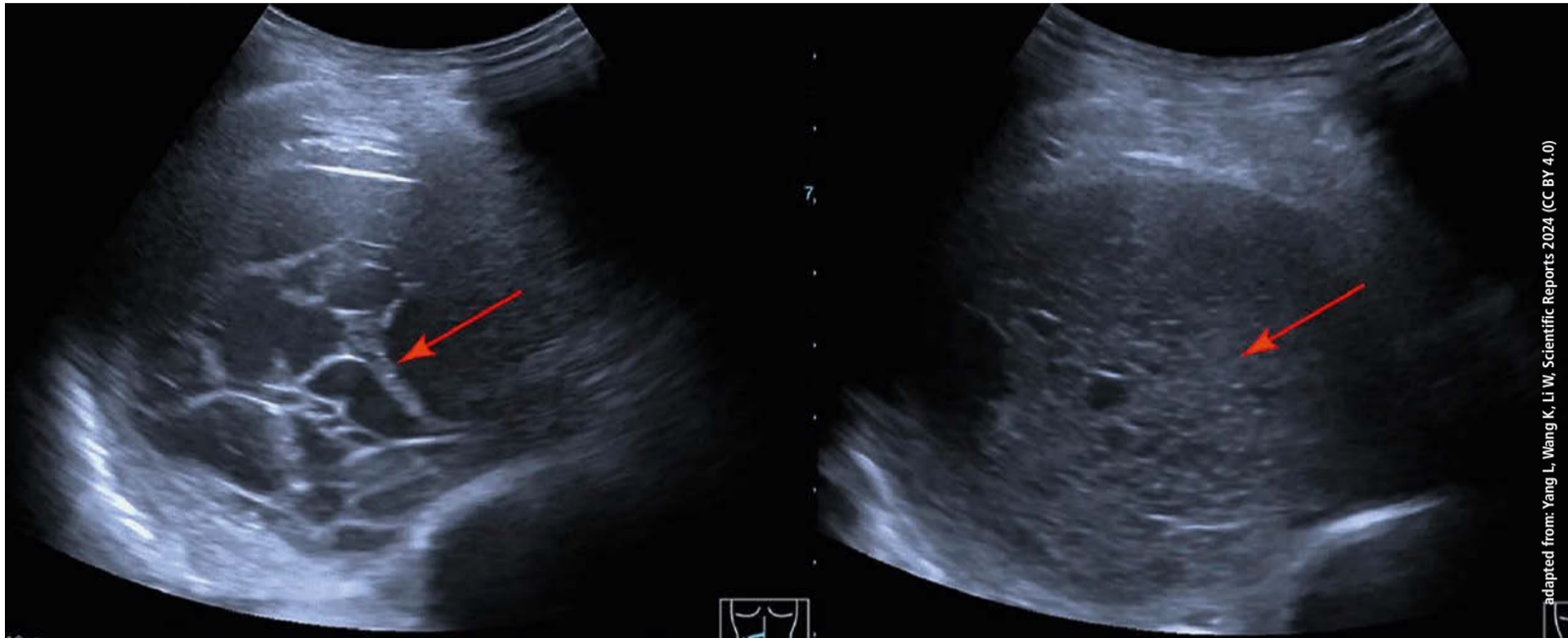
"This study shows that the proprietary signal processing and machine learning algorithms involved in our technology can empower a method to successfully monitor

cancer cell differentiation and evolution over time," said Franz Bozsak, CEO and co-founder of Sensome. "This breakthrough is the first step in exploring the use of our tissue-sensing technology in monitoring cancer-related phenomena, such as tumor growth. It complements the work we are currently doing in lung cancer—where in-situ cancer detection is crucial—which is one of several applications where we are applying our mastery of electrical impedance spectroscopy to novel uses in medicine."

Source: École Polytechnique – Institut Polytechnique de Paris

Utilizing new strengths, fixing old weaknesses

Ultrasound update for organ imaging



adapted from: Yang L, Wang K, Li W. Scientific Reports 2024 (CC BY 4.0)

Illustration of multiple septations in a pleural effusion on ultrasound.

Has organ imaging using ultrasound arrived at the same level as cross-sectional imaging? At the annual conference of the German Society for Internal Medicine (DGIM), PD Dr Corinna Trenker presented new technological developments and their diagnostic significance. Despite numerous innovations such as multiparametric protocols and AI support, she made it clear that the human factor remains one of the greatest strengths of sonography over other modalities.

The examination of neck and soft tissue as well as organs in the near-field – testicles, thyroid or breast – has traditionally been one of the strong suits of ultrasound, reported the expert from the Clinic for Haematology, Oncology and Immunology at Marburg University Hospital: ‘With a lateral image resolution of up to 0.1 to 0.2 millimetres, sonography simply exceeds the resolution of CT and

MRI.’ This is also reflected in the S3 guidelines – ultrasound is the method of choice for both testicular cancer and the detection of thyroid masses.

Even though the results of lymph node detection are consistently convincing, the technique has not yet been included in the guidelines, Dr Trenker summarised. Nevertheless, she said that multiparametric imaging using elastography and contrast-enhanced ultrasound (CEUS) is an exciting new tool for assessing lymph node hardening and vascularisation¹ – ‘however, this is not relevant for the primary assessment of malignancy,’ the expert added.

In thoracic examinations, another advantage of ultrasound imaging comes into play: ‘Sonography clearly has the edge because examinations can be performed in real-time,’ explained Dr Trenker. Particularly when assessing thoracic wall infiltration in bronchial carci-

nomas, ‘the decisive factor is the respiratory-dependent fixation of the tumour, and here the sensitivity and specificity of ultrasound is clearly superior to CT imaging.’² Ultrasound also remains the method of choice for the detection and differentiation of pleural effusions in 2025. ‘Not only can pleural effusions of just a few millilitres be detected, but they can also be differentiated more accurately,’ said the expert.³

AI opens new possibilities

When it comes to deeper anatomical structures, ultrasound quickly reaches its limits, and the physical limitations of air-filled structures remain unchanged, Dr Trenker pointed out. The high level of examiner dependency also continues to be an issue – but this could change in the future: New publications suggest, for example, that artificial intelligence (AI) could support the traditionally demanding screening for hepatocellular carcinoma (HCC).⁴ Con-

sidering the growing issue of staff shortages, which also affects experienced sonographers, this is a promising development, the expert pointed out – even if there are still a lot of unsolved questions regarding data protection.

Dr Trenker illustrated the amazing diagnostic potential of AI in ultrasound by looking at a recent meta-analysis from China: here, researchers used AI to analyse the sonograms of more than 11,000 breast cancer patients – and, based on this alone, predicted their HER2 receptor status with a high degree of accuracy.⁵ ‘This is a little hard to grasp, but, at least in initial studies, it is possible. I believe that many more applications in this field will emerge in the future.’

Patient contact: not just ‘nice to have’

Despite the general enthusiasm for technological progress, the expert reminded her audience of one of the key advantages of ultrasound:

personal contact with the patient. Studies have shown that this not only creates a more pleasant atmosphere during the examination, but also improves the quality of the diagnosis⁶, she emphasised. ‘This is where we really have a big advantage over other cross-sectional imaging techniques – and this should not be underestimated,’ she concluded. ■

Author: Wolfgang Behrends

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Quantum mechanics to remove noise from medical images

The math describing how particles move in space can apply to stray pixels, removing noise from images.

Medical imaging methods such as ultrasound and magnetic resonance imaging (MRI) are often affected by background noise, which can introduce blurring and obscure fine anatomical details in the images. For clinicians who depend on medical images, background noise is a fundamental problem in making accurate diagnoses. Methods for denoising have been developed with some success, but they struggle with the complexity of noise patterns in medical images and require manual tuning of parameters, adding complexity to the denoising process.

To solve the denoising problem, some researchers have drawn inspiration from quantum mechanics, which describes how matter and energy behave at the atomic scale. Their studies draw an interesting analogy between how particles vibrate and how pixel intensity spreads out in images and causes noise. Until now, none of these attempts directly applied the full-scale mathematics of quantum mechanics to image denoising.

In a paper in *AIP Advances*, by AIP Publishing, researchers from Massachusetts General Hospital, Harvard Medical School, Weill Cornell Medicine, GE HealthCare, and Université de Toulouse took translating the particle-pixel analogy to the next level.

‘While quantum localization is a well-established phenomenon in physical materials, our key innovation was conceptualizing it for noisy images – translating the physics literally, not just metaphorically,’ author Amirreza Hashemi said. ‘This foundational analogy didn’t exist before. We’re the first to formalize it.’

A central concept in the math describing matter and energy, localization is used to explain how particles vibrate in a space. Vibrations that stay confined are considered localized, while vibrations that spread out are diffused. Similarly, pixel intensity, or brightness, in a clear image can be considered localized, while noisy patterns in an image can be considered diffused.

The authors apply the same mathematics that describes the localization of particle vibrations in the surrounding physical space to decipher the localization of pixel intensity in images. In this way, they can separate the noise-free ‘signal’ of the anatomical structures in the image from the visual noise of stray pixels. ‘The main aspect was developing an algorithm that automatically separates the localized (signal) and nonlocalized (noise) components of pixels in an image by exploiting their distinct behaviors,’ Hashemi said.

The researchers’ direct application of the physics and mathematics of particles also eliminated the need to manually fine-tune parameters in denoising algorithms, which

Hashemi said is a major hindrance in traditional approaches. ‘Our method leverages physics-driven principles, like localization and diffusive dynamics, which inherently separate noise from signal without expensive optimization,’ Hashemi said. ‘The algorithm just works by design, avoiding brute-force computations.’

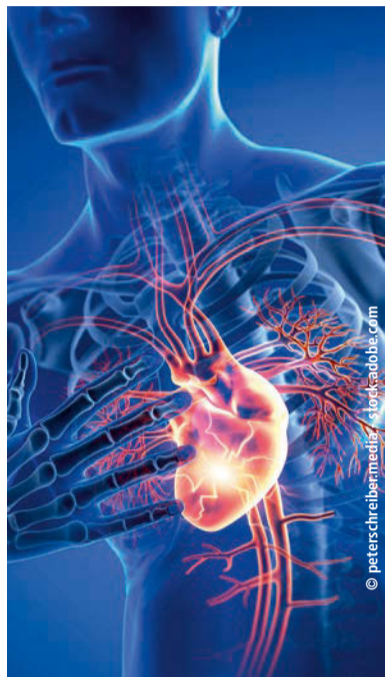
Their method has applications not only in medical image denoising, but across quantum computing, too. ‘Our physics-driven framework aligns with the computational primitives of quantum systems, offering a potential performance advantage as quantum computing scales.’ ■

Source: American Institute of Physics

SHM meeting explores complexities of doctor-patient communication

“Very rarely a chance of heart attack or death” – Wait, what?

Hospitalists frequently discuss the risks associated with tests, treatments, and/or surgical procedures with their patients. A session on the meaning of risk to patients and how to effectively communicate risk was discussed at SHM Converge 2025, the annual meeting of the Society of Hospitalist Medicine held in Las Vegas in April. ¹



‘We work with our colleagues to conduct detailed assessments of risk for a specific patient to determine the level of risk to proceed as well as the level of risk not to do so,’ said co-presenter Jeffrey L. Greenwald, MD, of the Medicine Consult Service Team of Massachusetts General Hospital in Boston. ‘We discuss risk with our patients and assume that the patient understands what we are talking about. But do they? And does this change the outcome? Almost never. The patient goes to surgery regardless, yet shared decision making between patient and physician(s) should be central to this process.’

Co-presenter Douglas E. Wright, MD, PhD, director of Mass General’s Medicine Consult Services, said he was jolted into awareness of the ambiguity of meaning of risk statements when he was reviewing a consent form for a cardiac stress test he was about to take while sitting in an empty waiting room at 6 am. The risks that could occur from taking the test included the statement: “very rarely a chance of heart attack or death”. What precisely did this mean? The technician did not know, and Dr Wright had the test without incidence.

Interpretations may vary

Dr Wright and Dr Greenwald subsequently discussed the incident and pondered how a patient would interpret the phrase “slight risk of complications” versus “10% risk of complications”. Researching the subject, they discovered that there is no easy answer. People individually define risk differently. Pre-conceived notions, shared experiences, cultural and society influences, emotional states, and

for some, innumeracy, make interpretation of even the most carefully crafted description of a specific medical risk assessment difficult and unpredictable.

As an example, they cited a study presented at the 2019 Annual Congress of the Association of Anaesthetists conducted at Sheffield Teaching Hospital NHS Trust in the United Kingdom. It evaluated how 57 clinicians and 290 patients interpreted seven probability expressions of risk relating to the occurrence of a major peri-operative complication. ²

Not only was there a wide variation among all participants, but patients tended to assign a much higher risk probability than clinicians meant. The study also confirmed the influence of education and the ability to understand numeric probability when assessing risk. Other research studies published in peer-review journals reveal that risk assessment interpretation is highly individualized.

Dos and Don’ts

Because of these and other data, the presenters recommend that hospitalists prepare in advance for a meeting with a patient and/or family.

They suggest that doctors should:

- recognize that information provided about risk of tests, treatments, or procedures may be misunderstood and that the patient may become very emotional.
- determine their patient’s understanding of the medical situation. Identify their goals and priorities, specifically what they are hoping for and what they are worried about, such as prior experience with similar situations. Identify if there are language, literacy, or numeracy issues and assume that these are present unless proven otherwise.
- not impose their own beliefs, preferences, and biases on the patient.
- select a combination of language, visual representations, and numerics (such as percentage) that they think will best convey their message in a way that the patient will understand.
- ask the patient to explain in their own words what they (the doctor) said.
- document the content of their interaction with the patient.

‘In situations where clinical specialists have differing opinions about a patient’s risk, be diplomatic yet frank if you are put in the position of a mediator,’ Dr Greenwald advised.

‘Hospitalists are generalists. Specialists may be experts in their field, but they may not have evaluated the “bigger picture” with respect to totality of the patient’s clinical record. That is our job,’ he commented.

When European Hospital asked Dr Greenwald what he personally experienced at Massachusetts General Hospital, a prestigious academic research hospital, he advised that most patients accept the risk information as presented. ‘I think that receptivity of risk information is based on the knowledge and trust of the physicians,’ he said. Co-author Benjamin P. Geisler, MD, a Doctoral Research

Fellow at the Department of Health Management and Health Economics at the University of Oslo, Norway, comments, ‘I definitely think that the issue exists in other countries too. Language and culture undoubtedly have an impact on these discussions. The clinician-patient relationship may be different on where you are in the world, say Scandinavia or Russia. Risk assessment discussions in Europe may have an even greater technical detail than in the US or alternatively, be discussed only very briefly with the authority and recommendations of the physician unquestioned.’

The presenters concluded with this tongue-in-cheek comment. ‘In summation, what do you tell your patients? “You’ll be fine. Probably.” ■

Author: Cynthia E. Keen

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Jeffrey Greenwald

Jeffrey L. Greenwald, MD, is a teaching hospitalist and a member of the Core Educator Faculty of the Department of Medicine at Massachusetts General Hospital (MGH) and is an Associate Professor of Medicine at Harvard Medical School. Having served as the lead physician for Mass General Brigham’s High Performance Medicine Team on Readmissions, Dr Greenwald works with the MGH Readmissions Care Redesign Committee, and was a principal developer of a novel readmission risk indicator currently used by MGH. He also works on the hospital’s Palliative Care Continuum Project, whose goal is to expand primary palliative care skills and education to clinicians.



Ben Geisler

Benjamin P. Geisler, MD, is currently a Doctoral Research Fellow at the Department of Health Management and Health Economics at the University of Oslo. He practices hospitalist medicine at Massachusetts General Hospital, and is particularly interested in cardiovascular diseases, antimicrobial prescribing, rare diseases, and diagnostic dilemmas across medical sub-specialties. Dr Geisler is also a health services research, decision-analytic modeler, and health economist.

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Blood-based biomarkers under scrutiny

BBB testing for universal Alzheimer's screening? It's complicated



Amyloid plaques in Alzheimer's disease

Laboratory tests using blood-based biomarkers (BBB) to identify the presence or risk of Alzheimer's disease (AD) in the brain are proliferating, offering the unprecedented opportunity for global population screening. Do these tests represent the next type of universally recommended screening tests, like pap smears for cervical cancer or feces analysis test kits for colon cancer? Experts curb the high expectations for this type of diagnostic tool.

They argue that it is going to take years before AD BBB tests become a mainstream health-wellness test commodity, designed to identify people at risk a decade or more before they develop AD cognitive decline.

Clinical hurdles that need to be addressed include:

- population-representative clinical validation trials
- a significant amount of clinical research to understand and quantify the impact of other diseases, medications, and combinations thereof on levels of brain AD biomarkers
- establishment of validated cut-offs and reference levels for all races and ethnicities
- extensive training of medical professionals, particularly primary care physicians, physician assistants, and nurse-practitioners, in the accurate interpretation of test results, in the counselling of patients at risk, and in patient monitoring and support protocols.

Ethical issues abound, including the question of whether a patient and/or family will benefit from knowing the test results or will be hurt by them. Government legislation is needed to protect a testee from discriminatory action that could be life-damaging.

Limited diagnostic significance

Current BBB tests that identify the presence and level of Amyloid-beta plaques and tau tangles in the brain which are symptomatic of AD are not definitive diagnoses of the disease. They are not recommended as standalone diagnostic tools. Rather, they are intended to supplement a clinical diagnosis made by a physician of patients presenting with symptomatic or subjective cognitive decline. They may be a precursor to an invasive lumbar puncture test of cerebrospinal fluid (CSF) or an expensive PET scan. BBB tests also qualify AD diagnosed patients with early-stage cognitive decline for regulatory-approved disease modifying therapies (DMT) or clinical trials.

Many BBB clinical trials testing for AD have used patient cohorts who were predominantly non-Hispanic Caucasians. As an example, the TRAILBLAZER-ALZ 2 study of donanemab, an FDA-cleared drug which significantly slowed clinical progression of AD in individuals with low/medium tau, included only 5.8% Hispanic, 4.1%, Black and 1.0% Asian patients in its 1,736 patient cohort.¹

What this means for both symptomatic and asymptomatic people of colour is that the specific findings of this clinical trial may not be as applicable to them. Until more inclusionary trials are completed, there is no way of definitively knowing.

Challenges of non-specialist physician interpretation and follow-up

Prof. Michelle M. Mielke, PhD, of the Department of Epidemiology and Prevention of Wake Forest University School of Medicine in Winston-Salem, NC, is the co-lead of a BBB Workgroup of the Global CEO Initiative on Alzheimer's Disease, tasked with providing actionable recommendations on implementing BBBs in primary and

secondary care settings in the United States. She and her colleagues express concern about the ability and confidence level of health care professionals who are not a dementia specialist interpreting BBB test results.^{2,3}

Physicians must be able to consider positive and negative predictive values of a test with validated reference standards. But this may not be as easy as it seems, especially if BBB tests adopt a two-cut-off approach. What should a physician do if a patient's test results fall between the two?

Chronic kidney disease, stroke, obesity and cardiac disease have been found to influence AD BBBs. Prof. Mielke and colleagues point out that failure to consider the impact of any of these comorbidities when interpreting BBB levels may result in misdiagnosis. Additionally, no established guidelines exist for interpreting BBB tests in patients with multiple chronic conditions.

Another factor to consider are medications which might impact test results. A clinical study conducted at the Institute of Neuroscience and Physiology of the Sahlgrenska Academy at the University of Gothenburg, in Mölndal, Sweden, revealed that a prescription drug used for treating heart failure increased plasma Amyloid-beta concentrations by approximately 30%, while another drug for the same purpose had no impact.⁴

Global resources are seriously constrained treating patients with cognitive decline, with AD or other types of dementia. What health professional resources will be needed for patients exhibiting early cognitive decline but are functional if BBB testing for AD is positive? What types of assistance are needed? Do protocols exist to follow this patient? What if the patient does not have access or re-

sources to receive and pay for AD disease modifying therapies? Will stress generate other medical conditions that require treatment?

Benefit to patient?

An essential question for a physician to consider is the benefit a BBB AD test will have for a patient, or not. Would a patient in their 60's with no symptoms of cognitive impairment but with a family history of AD benefit? Because the AD pathologies of Amyloid-beta and tau accumulate in the brain years before AD symptoms manifest themselves, and because some individuals will never develop cognitive decline in spite of significant AD pathology accumulations, would a test be more harmful emotionally than beneficial as a warning of a possible debilitating illness?

Would it be better for patients at presumed high risk be more motivated to make lifestyle changes to deal with sleep disorders or medical conditions that are associated with AD development, instead of having the test?

Would positive test results lead to discrimination impacting quality of life? Would a still cognitive individual have a driver's license revoked or denied? Would an application for a life insurance policy be rejected or would premiums of an existing one increase? And in countries like the United States with an independent health insurance payor model, would premiums soar as to become prohibitive? Legislation could prevent these scenarios from happening, but have any governments implemented legal protections?

Lawrence VandeVrede, MD, PhD, an Assistant Professor of Neurology at the Memory and Aging Center of the University of California-San Francisco, and a core team member of Prof. Mielke's group, is deeply concerned about the questions. He writes, 'Until

there is evidence that biomarker testing improves the outcomes of cognitively unimpaired patients, biomarker testing of these individuals outside of research studies or clinical trials likely has more risks than benefits.'⁵ ■

Author: Cynthia E. Keen

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Lawren VandeVrede, MD, PhD, is an Assistant Professor of Neurology at the University of California-UCSF and is a researcher and clinician at its Memory and Aging Center at the Weill Institute for Neurosciences. His clinical and research interests are in advancing the care of patients with neurodegenerative disorders, either through development of novel therapeutics or increasing understanding of the disease process. Dr. VandeVrede serves on the core team of the Global CEO Initiative on Alzheimer's Disease BBB Workgroup.

Michelle M. Mielke, PhD, is Professor of Epidemiology and Prevention and Professor of Gerontology and Geriatric Medicine at Wake Forest University School of Medicine in Winston-Salem, NC. In addition, she is Chair of the Department of Epidemiology and Prevention. She works as a translational epidemiologist to identify fluid and neuroimaging biomarkers for the diagnosis, prediction and/or progression of neurodegenerative diseases. Dr Mielke is a co-leader of BBB Workgroup 2 of the Global CEO Initiative on Alzheimer's Disease, which is tasked with providing actionable recommendations on implementing BBBs in primary and secondary care settings in the United States.