



Targeted Real-time Early Warning System (TREWS) for hospitals

Early detection of sepsis with the help of an AI system



Sepsis, a life-threatening, systemic, toxic bodily reaction to infection, is often difficult to detect in its early stages. Its symptoms, including fever, shortness of breath, rapid heart rate, and confusion, are associated with many medical conditions of hospitalized patients. But if not treated rapidly, a patient may die. The Targeted Real-time Early Warning System (TREWS) for sepsis detection is proving to be a highly effective, lifesaving high-precision bedside early warning system.



In Europe, North America, and Australia, the average 30-day rate of sepsis shock mortality is 34.7% and sepsis mortality 24.4%, according to a 2020 meta-analysis of 170 studies published in Critical Care. Automated artificial intelligence (AI) sepsis detection systems in use and in development confirm that alerts at the first indications of sepsis do save lives. But many are criticized for lack of sensitivity and generating too many inaccurate alerts, to the point where they are ignored. TREWS is based on its use for two years monitoring 590,736 inpatients at Johns Hopkins Hospital in Baltimore, Sibley Memorial Hospital in Washington, D.C., and three affiliated area community hospitals. This early warning system has reduced mortality of sepsis patients by nearly 20%.

automatically and continuously monitors disparate clinical data, including vital signs, laboratory data, medication history, procedure and clinical history, and physician notes. It generates a continuous real-time "sepsis score" that can trigger an alert to healthcare staff. Clinical caregivers can analyse why the TREWS alert was generated, accept or dismiss it, and initiate

timely treatment on patients confirmed to be septic.

During the study time period, caregivers evaluated 89% of all alerts, 53% within 60 minutes. The researchers attribute this high rate of utilization in part to the fact that the system was tuned to achieve the highest possible performance without generating excessive inac-

curate alert warnings. It became trusted by clinical staff.

'Our results showing high physician adoption and associated mortality and morbidity reductions are a milestone for the field of AI,' comments Saria. 'They are the culmination of nearly a decade of significant technological investment, deep collaboration, the development of novel techniques, and rigorous evaluation. Further, what's most exciting here is that this approach is applicable not just to sepsis but to many other critical complications.'

In an accompanying commentary, Harvard Medical School Professor David W. Bates, MD, an internationally renowned expert in patient safety and use of IT to improve patient care, and Ania Syrowatka MD, PhD, a postdoctoral research fellow specializing in AI applications in medicine, laud the studies as "pivotal" in showing that sepsis detection systems can work well at multiple sites and with a near

90% clinical adoption rate. They caution about the challenges facing widespread adoption of such alert systems. They cite the difficulties of implementation across diverse health systems, the expense and difficulty of hospitals adopting multiple AI technologies, and limitations of some EHR systems that do not allow real-time queries of patient EMRs or the capability to route an alert – such as a sepsis notification – to the most appropriate clinical provider to respond.

But they are positive as well, writing, 'Overall, these technologies have great potential to improve care and rapidly identify patients who are deteriorating, especially those with sepsis – which could help prevent deaths and reduce costs for large number of patients.'

Report: Cynthia E. Keen

When Sterility is Indicated...

Visit us at stand 9D41

Give us your opinion and you could WIN \$125 Visit www.parkerlabs.com/sa100q.php



There's Only One Choice:

Sterile Aquasonic® 100 Ultrasound Transmission Gel.

The World Standard for sterile ultrasound transmission.

- Easy-to-open *Tyvek® overwrap Guarantees sterility of the inner foil pouch and the gel within
- Consistent quality Aqueous, non-staining
- Acoustically correct
- Non-injurious to transducers
- Available in 20 gram overwrapped foil pouches, 48 sterile pouches per box

ISO 13485:2016

*Trademark of Dupont®



Parker Laboratories, Inc.

The sound choice in patient care.™

973.276.9500

parkerlabs.com

© 2019 Parker Laboratories, Inc.

The sound choice in patient care is a trademark of Parker Laboratories, Inc.

MKT-0101-2 REV 3

Monitoring clinical data

Suchi Saria, PhD, director of the Machine Learning and Healthcare Lab at Johns Hopkins, who led this work, explains that TREWS

Visceral imaging

Endosonography: AI takes on the "supreme discipline"

Endosonography poses unique challenges for medical professionals, because two demanding disciplines have to be mastered at the same time. The use of artificial intelligence (AI) could help speed up the notoriously slow learning curve of the procedure, says Prof Dr Christoph F. Dietrich. At the Visceral Medicine Congress in Hamburg, the expert explained how AI can help endosonography achieve faster and better diagnoses, standardisation of images and better verifiability of findings – and which hurdles still stand in the way of introducing the technology into clinical practice.

'In a way, endosonography is the supreme discipline, as it combines endoscopy and ultrasound at the highest level,' says the head physician of the Department of General Internal Medicine at the Hirslanden Beau-Site, Salem and Permanence hospitals in Bern, Switzerland. 'The procedure is not easy to learn, because many parameters are not standardised and the assessment criteria for some diseases – especially concerning the pancreas – are difficult. Artificial intelligence could help to set standardised sections and establish quality parameters for presentability and assessability.'

One example is decision support for diffuse abnormalities in pancreas imaging: Here, early forms of fibrosis with inflammation can indicate degenerative processes in the sense of chronic pancreatitis. However, these changes are hardly visible to the naked eye. AI could provide valuable additional information to identify and classify such findings at an early stage.

A watchful eye on elasticity and perfusion

Other potential areas of application concern elastography, where the AI registers unusual stiffness in the tissue and specifically points out these suspicious areas to the physician. An analysis of vascularity and perfusion behaviour in contrast-enhanced sonography could also benefit from algorithms, Dietrich explains – and gives some examples: 'A lower accumulation of the contrast agent in the pancreatic parenchyma might point towards a ductal adenocarcinoma, as this usually has only one third of the normal vessel density. On the other hand, greater vascularisation usually indicates an inflammatory or benign neoplastic process, as these are associated with dilated or additional vessels.' Incidentally, the elastography indicators do not only apply to the pancreas, but can in principle be used for all organs, from the thyroid to the mamma and the liver, the expert adds. Soft tissue serves as an exclusion marker of pancreatic carcinoma.

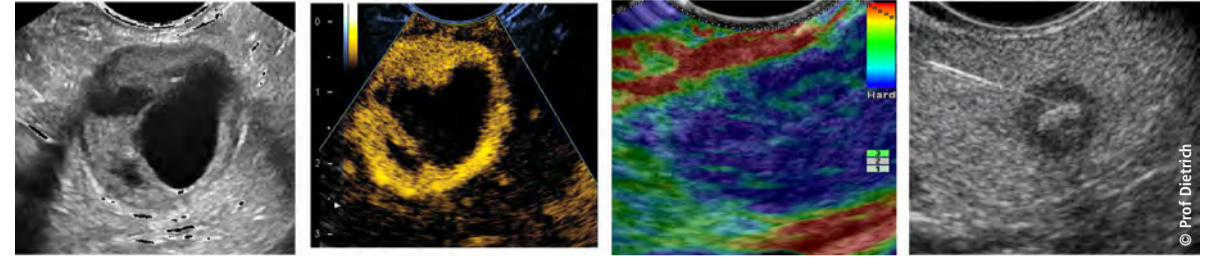
AI could also be a valuable aid for inexperienced diagnosticians:

for example, an automatic assessment of the setting parameters could ensure that the ultrasound signal achieves sufficient penetration depth and improved validity. AI-supported segmentation of anatomical structures could serve as a navigation aid and specifically point out structures that deviate from the norm.

Overcoming reservations

Currently, these applications are still in the experimental and research stages. However, Prof Dietrich is confident that in the future, medical practitioners will be able to benefit from the assistance provided by AI: 'Currently, we are still at the very beginning. Still, it is important to look at the possibilities of the technology at this point, to approach the methods of independent learning, pattern recognition and what added value they can have for our patients.'

This process will likely be subject to reservations, the expert predicts; especially seasoned physicians who have been using endosonography with conventional methods for many years tend to be sceptical

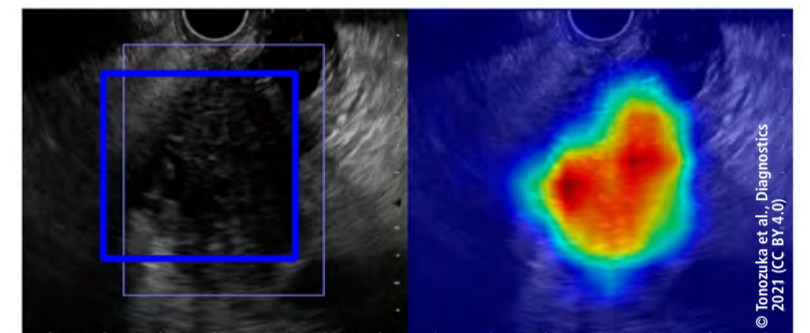


Endoscopic Ultrasound (EUS) is considered a "supreme discipline" in imaging, requiring great diagnostic skill. From left: B-mode EUS, contrast-enhanced EUS, elastography, EUS fine-needle aspiration.

about AI assistants. In order to put the discussion about the pros and cons of the new technology on a solid foundation, Dietrich is currently working together with a group of 25 experts on a 'position paper' of the World Federation for Ultrasound in Medicine and Biology (WFUMB) – a document intended to guide the handling of the new technology in an orderly manner: 'On the one hand, it is a matter of overcoming limits with the help of AI and being open to the new possibilities.'

Ethical and legal aspects

On the other hand, it is important to consider the ethical and legal aspects that arise from the use of this technology, especially in terms



AI-based analysis as shown in a gradient-weighted class activation mapping (Grad-CAM): The left image is a representative original endoscopic ultrasound image. The right is a Grad-CAM image displaying the regions recognized as being important.

of data security. In short, we need to know the game this game is played by.' ■

Report: Wolfgang Bebrends

DON'T MISS! Connected Healthcare Forum

Monday

11:00-13:00: Connected medical things – IoT technologies

- Smart connected medical things – from wearables to medtech devices to implants
- Interoperability in the Internet of Medical Things infrastructure
- Connectivity options – 5G, low power connectivity and more
- Cybersecurity and data privacy

13:00-15:00: 14th Healthcare Innovation World Cup pitch

- Top12 Health Techpreneurs 2022 pitching their solutions
- Categories: IoMT devices, wearables, digital biomarkers, smart patches, smart implants
- Panel discussion: HealthTech trends 2022 – What's next?
- Award ceremony – Announcement of the Top3 Health Techpreneurs 2022

15:00-17:00: AI & Big Data

- AI-guided medical devices
- Real-time analytics
- Precision medicine
- Personalization of treatment with AI

Tuesday

11:00-12:00: Robotics

- Autonomous robots
- Robot-assisted surgery
- Robotic solutions in hospitals and care centers

12:00-13:00: Healthcare accelerators

- Scaling up future health innovations

13:00-15:00: 11th MEDICA Start-up competition pitch

- Top12 Medical Start-ups 2022 pitching their solutions
- Categories: AI in healthcare, health apps, lab diagnostics, robotics & others
- Panel discussion: Successful health innovations – Key drivers and disruptors 2022
- Award ceremony: Announcement of the Top3 Medical Start-ups 2022

15:00-17:00: MEDICA DISRUPT – Preventing chronic diseases

- Diagnostics and health monitoring
- Mobile health

Wednesday

11:00-12:20: Future hospitals and care centers

- New tech for hospitals and care centers
- Decarbonization in healthcare

12:20-14:00: Health metaverse

- Immersive environments for educational, assistive and therapeutic purposes
- AR/VR/Mixed reality
- Digital twins for new insights into health decision making

14:00-15:00: MEDICA DISRUPT – future of therapy

- Therapeutics and new treatment approaches
- Chronic disease treatment
- Tech to watch

15:00-15:30: Digitalization of the German Federal Health Ministry

- Electronic patient record
- European Health Database
- DiGA

15:30-16:20: Certifications & market access

- Access to healthcare markets
- Certifications and regulations

16:20-17:00: Tackling future pandemic

- Covid-19 learnings in digital health
- Best practice in tech
- Solutions for prevention and control

Thursday

11:00-12:00:

- MEDICA DISRUPT - Taiwanese Start-up showcase

12:00-14:00:

- MEDICA DISRUPT - Pushing the frontiers of diagnostics

14:00-15:00:

- MEDICA DISRUPT - Understanding the brain and mental health

15:00-17:00:

- MEDICA DISRUPT - Improving health equity of vulnerable populations



Rehabilitation technology

Robots help restore mobility after surgery

Innovative robot systems are being designed to help patients regain mobility and rehabilitate after undergoing surgery. In addition, robotics can also be deployed to help older people stay active and fit so they retain their independence for longer.



The role of robotics for advancing surgery and rehabilitation will be the focus of a MEDICA MCHF session on November 15. Among the speakers is Anke Mayfarth, managing director of robotics company Tediro, who will highlight her organisation's systems for rehabilitation, and in particular a vision for robotic applications for gait training to support patients in clinics using crutches. Speaking ahead of her presentation "Mobile robots for patient mobilisation", she outlined how the current skills shortage within hospital rehabilitation departments can lead to delays in helping patients recover from knee, hip or ankle surgery. However, this shortage can potentially be addressed with robot systems. 'Mobilisation is very important,' said Mayfarth. 'After operations patients need to become mobile again.'

undergone surgery on the knee, ankle joint and hips. 'The therapists can individually define the training for each patient,' she said. 'Due to pain after surgery, patients avoid certain movements; they are unsure whether they are doing the movements correctly and are worried about falling. The robot accompanies them during their self-training, gives recommendations for corrections and motivates them to train.' Importantly, all training results are

documented, and both patients and therapists can refer to, and learn from, this documentation.

Mayfarth said the next major step is to get through the regulatory process to enter the market with the robot to support patient rehabilitation.

Report: Mark Nicholls

Monitoring and evaluating movement patterns

Tediro specialises in robots for therapy and diagnostics and offers solutions and different applications for post-surgery and mobility of the elderly, via a universal robotic platform, which is about 1.5m high and moves on wheels in front of the patient. 'The robot adapts to the patient's speed and maintains a constant distance from the patient during the training session,' she explained. 'Meanwhile, cameras capture the exercise, analyse all deviations, and give audio-visual advice to improve movement patterns step by step.' The focus is on intelligent software to deliver the evaluation of the movement patterns, analysis and physiotherapeutic feedback. The company is continuing research in that area for the development of further applications and studies.

Individual patient training

The robotic support at this stage is focused on patients who have



Anke Mayfarth

Anke Mayfarth is managing director and co-founder of Tediro. With degrees in physiotherapy and management, she has several years of experience as a physiotherapist in the specialist areas of neurology, surgery and orthopaedics.

Real-time audio and video connection

AR for medical services

Eye4Care is a frontline healthcare staff support service, based on a proprietary platform, which enables real-time audio/video connection between healthcare specialists and the staff treating patients.

home patients who receive remote assistance and support.

Eye4Care is also available on smartphones via a mobile app designed

It allows healthcare staff to perform:

- Supervision of nurses' activity through remote support, with the aim to reduce the number of specialist medical personnel in the ward
- Distance learning and real-time distribution of new procedures to frontline medical staff to speed up their learning curve
- Hands-free pre-triage via an infrared camera integrated within the smart glasses to measure temperature
- Hands-free collection of vital parameters of patients, and certification of individual procedures



© HeadApp Srl

Thanks to the use of voice-controlled, PPE-compatible smart glasses devices, doctors, nurses, and caregivers can make a diagnosis and prescribe therapies to

to support patients at home or in isolation, who can receive remote assistance from a specialist doctor at any time. Eye4care allows:

- Real-time interaction between doctor and patients/citizens
- Direct and autonomous check of vitals by patients
- Health status assessment and management of Level 1 remote assistance

Eye4Care relies on augmented reality and artificial intelligence to provide remote care to frontline physicians, patients and home care staff.



MCHF: "Robotics – Advancing surgeries, rehabilitation and processes to the next level" is on November 15 (11.00-12.00) and also features presentations on: how soft materials are changing the perception of wearable assistive technology and human augmentation; medical robotics from the view of an industrial robotics supplier.



Hall 15 / E32-41

Please Visit us at Medica 2022
Booth No. **7.0E23**

Since 1980
KIMES 2023
www.kimes.kr

KIMES
38th Korea International
Medical & Hospital
Equipment Show
**23 - 26. March
2023**
COEX, Seoul, Korea

Concurrently held with

Medicomtek 2023
Medical Component & Material Technology Korea

Organizers Korea E & Ex Inc. / KMDICA / KMDIA
Contact Korea E & Ex Inc. Tel. +82-2-551-0102 Fax. +82-2-551-0103 E-mail. kimes@kimes.kr

Tissue-engineered glioblastoma model shows proliferation and drug resistance of malignant cells

3D brain tumour in a dish to personalize cancer treatment

It is the size of a common pencil eraser, but it could have a huge impact on the therapy of glioblastoma: Scientists in Virginia have developed a novel 3D tissue-engineered model of the brain tumour microenvironment, which can be used to assess how the glioma cell invades healthy tissue, proliferates, and reacts to chemotherapy drugs.



Gabriela Mendes, a postdoctoral associate in the Jennifer Munson lab of the Virginia Tech Fralin Biomedical Research Institute, holds an example of the 3D model of the glioblastoma tumour microenvironment the lab developed to study how different people's cancers respond to different therapies.

Glioblastoma, the most common and most malignant form of brain cancer, is notoriously difficult to treat, due in part to its invasion into surrounding tissue where the tumour cells become more resistant to therapy. Median patient survival is five months.

Tumour microenvironments (TMEs) – the tissue that surrounds a tumour – are known to contribute to cancer progression. The brain TME contains cells specific to the central nervous system, including astrocytes and microglia. Understanding how TME functions and how glioblastoma tumour cells grow, and being able to control, manipulate, and tune its elements, may help enable the development of more effective, individualized therapies for glioblastoma patients. The 3D model developed by Jennifer M. Munson, PhD, an associate professor of biomedical engineering at the Fralin Biomedical Research Institute of Virginia Tech

in Roanoke, is an accurate recreation of TMEs: It contains cells unique to the central nervous system, in ratios based on those found in patients, as well as glioblastoma stem cells and interstitial fluid flow, the movement of fluid between and around cells in tissues. Dr Munson and a multi-institutional team of researchers describe the model's detailed composition and what they learned from it in an article published in NPJ Precision Oncology (<https://doi.org/10.1038/s41698-022-00290-8>). 'Our goal is ultimately to develop a personalized medicine approach in which we can take a patient's tumour, build a model of that tumour in a dish, test drugs on it, and tell a clinician which therapy will work best to treat it,' said the expert.

Inter-patient differences have huge impact

The research team examined individual and synergistic effects of the cellular and biophysical glioblastoma microenvironment on patient-derived glioma stem cell outcomes, bidirectional intercellular communication between glioma and glial cells, and the effectiveness of various chemotherapy drugs on destruction of tumour cells. They determined that:

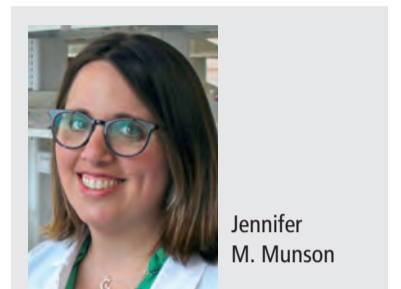
- Invasive regions primarily contain neural astrocytes and microglia;
- Glioma cell invasion is patient specific and depends on the TME context. Inter-patient differences are the greatest contributor to invasion. The addition of glial cells or a combination of glia and interstitial fluid flow can mean-

ingfully influence glioblastoma stem cell invasion either positively or negatively;

- The proliferation of tumour cells is highly dependent upon a patient's glioblastoma stem cell line(s) and how a specific cell line interacts with fluid flow;
- CCL2, a chemokine which guides a variety of immune/inflammatory cells to the site of a tumour, plays a role in TME-driven enhancements to glioma malignancy and may impact individualized cancer responses;
- Therapeutic drug response exhibited in the model could partially predict responses seen in in-vitro tests on laboratory mice. Further testing is required to expand on these findings and incorporate other important factors, such as the blood-brain barrier (BBB), which impacts drug transport and provides important pro-tumour signalling.

'Results of our testing varied widely,' Munson said. 'This highlights the importance of a personalized medicine approach to glioblastoma and the value of being able to recreate an individual patient's tumour microenvironment.'

The team is working to obtain more patient data and establish more academic-clinical collaborations to better identify which model components and metrics are needed to establish transformative



Jennifer M. Munson

Jennifer M. Munson, PhD, is an associate professor in tissue engineering in the Biomedical Engineering and Mechanics Department of the Virginia Tech College of Engineering. She is director of the Munson Lab at VT's Fralin Biomedical Research Institute, and a co-director of the Virginia Tech Cancer Research Alliance. Munson began to develop 3D tissue-engineered models for cancer research in 2014. She collaborates with engineers and biologists throughout the world.

predictive power in glioma therapy. Munson told European Hospital that the team is also leveraging the tunability and ease of implementation of this system to use it to identify new therapeutic targets and to understand the complex interactions between the cells in the brain and tumour cells in disease.

Report: Cynthia E Keen

Sponsored · 3D single-port surgery and 3D endoscopic sleeve gastropasty

Keep 2D endoscopy but see 3D vision

One of the world's leading endoscopic imaging system companies, MedicalTek (MDTK) from Taiwan, launches its brand new endoscopic visualization system, Darwin MS-301. While keeping the main feature – conversion of 2D endoscopic images to 3D – from its predecessor MonoStereo, Darwin delivers the twice-better performance, more intuitive control, and Rigid and Flexible scope modes.

The conversion feature, called "Keep-2D-See-3D", has become an acceptable and efficient method to help doctors gain spatial vision during surgery and gastrointestinal endoscopic procedures

for years. The system has been installed in hospitals around the world since 2017. Two of the hundreds of Darwin 3D Endoscopic Visualization System users, Dr Miguel Afonso from Portugal and Dr Cheng-Ming Peng from Taiwan, share their unique experiences with the Darwin 3D system.

Application in Portugal

Dr Miguel Afonso from Gastroclinic in Lisbon, Portugal, applies the Darwin 3D Endoscopic Visualization System in every endoscopic sleeve gastropasty to obtain the better visualization and depth perception, without the 3D effect causing nausea. 'It's not possible

to drive our car with only one eye. In fact, it is the binocular vision or two-eye vision that gives us depth perception. Being able to see the inner side of a stomach in 3D helps us understand not only the distance, width, and length, but also the depth. 3D view is already available for laparoscopy. The novelty of the Endoscopic Visualization System is that the gastroenterologists can now have an identical system in endoscopy. This is really a great progress in gastroenterology,' said Afonso.

Experiences from Taiwan

In Asia, Dr Cheng-Ming Peng from Chung Shan Medical University Hospital in Taiwan is amazed by the 3D vision brought by MedicalTek's Darwin system during single-port laparoscopy with a scope of 5 mm diameter and 46 cm length. He states that before the operation, he thought the image would be too dark since the light source usually does not project far enough through such a long and thin scope for him to observe the deeper tissues in patient's abdomen; with an added darkening effect from the 3D glasses. The gamma correction function, which enhances both the brightness and contrast of the image, in the Darwin system, compensates the disadvantage of

the thin laparoscope and brings clearer sight for him to conduct the single-port laparoscopy with depth perception.

Peng has sought 3D solution with longer and thinner telescopes for single-Port and NOTES (Natural Orifice Transluminal Endoscopic Surgery) for long; for him, the operation with big dual-lens 3D scopes proved is challenging due to collisions between the scope and surgical tools. Now, thanks to the depth perception brought by the Darwin 3D vision available for the long and narrow space, single-port surgeries are easier to conduct and less time-consuming. Patients also benefit from the scarless surgeries with less pain and faster recovery. The Darwin system does improve the way that Peng conducts single port and port-less laparoscopy. Apart from that, MedicalTek's newly-launched

Lascaux (MS-300) 4K/3D/HD Recorder supports dual-inputs, allowing not only single-signal but also dual-signal 3D recording, e.g. during robotic surgery. With this new device, the audience in the conferences can now watch the live 3D robotic surgery image.

MedicalTek was incubated by IRCAD-Taiwan. Prof Jacques Marescaux brought many brilliant ideas during the product development. Furthermore, in order to bring a better 4K3D image to doctors, MedicalTek is in partnership with the world-famous display manufacturer, AUO Display Plus. MedicalTek is planning to launch its own 4K3D medical monitor. With this integration, the Darwin 3D Endoscopic Visualization System will be more affordable while taking the quality to next level, the company announces.



 Hall 10 / B03

Lab in Utrecht

3D printed implants on demand

A custom-made new hip, a knee or maybe a piece of bone? The technology and possibilities for 3D printing are (almost) there. And such an implant from a 3D printer has many advantages, not only for the patient, but also for the surgeon who has to perform the operation. Koen Willemsen, physician, and medical engineer at the University Medical Center Utrecht (UMCU), was at the cradle of the 3D lab at the UMCU where 3D implants, as well as surgical drilling and sawing jigs, are printed on demand.

3D printed implants have a large benefit to both physicians and patient. For patients for whom standards implants don't work, the very precisely calculated technology of creating a 3D model sometimes literally makes the difference between not walking or walking again. The advantage for doctors is that by using a 3D template of the affected area, they know exactly where to make the incision during surgery and what the exact location of the implant will be. This accuracy is further enhanced by the application of augmented reality (AR), in which Willemsen's 3D lab is also a pioneer.

Enhanced accuracy

Doctors place an order for the 3D/AR visualization. Willemsen: 'Using AR glasses in the lab, doctors are able to see on a computer screen exactly what a patient's inside looks like. We guide then through the operation. They can "walk around" the 3D model of the patient, and practice implant placement. This also helps to prepare before surgery, saves quite some time and is an assurance for quality. Therefore, we sell this as a sustainability option. We have been working with AR for six months now and our intern students are developing the protocols, conditions and are looking into how to make it even more accurate. Everything has to be placed correctly because mistakes are easy to make. For instance, in another center, they had made a 3D model, but measured it incorrectly. The surgeon therefore used the wrong cut-off point because the aneurysm was actually smaller than calculated. Accurate measurements and requirements could have prevented this. And that's why quality management and risk analysis are so important.'

Safety measures and guidelines

Users also need to be aware of the legal boundaries, cautions Willemsen: '3D printing opens a lot of possibilities, but must comply with all kinds of safety measures. Here too, we play a pioneering role because at the moment, only few hospitals are able to produce 3D prints in compliance with the current Medical Device Regulation legislation (MDR) that's in place for just over a year now. We co-developed the requirements for the MDR, which now describes techniques and safety issues in a well-founded system. Before 2021, there were really only advisory guidelines for developing medical

implants and devices. Ignoring those guidelines was not punishable, and things went wrong quite often. For example, even tangerine packing nets could be approved as pelvic floor mats.'

Such questionable practice was among the reasons for Willemsen to take 3D printing to a safe level in their lab for both the procedures and the materials used. 'In our hospital, we take the international ISO standards for quality management (ISO 13485) as a starting point so that everything is done properly and safely. MDR is a dynamic system, because of ongoing developments, for example in the use of materials. Until 2016, titanium was the most common material for 3D printed implants. Now there are many more materials, like PEEK (polyetheretherketone), which is a powerful thermoplastic material with very low moisture absorption and good dimensional stability. We make all the implants ourselves according to the International ISO 13485 standard. Because research into bone replacement materials is ongoing, users need to go a step further in the quality of the management system and prove the safety of the new materials before they may be used in a patient.' The 3D model is created from the MRI scan by selecting and

segmenting the appropriate organ on each slice, which determines how and where operations can be performed best. A 3D model can also be of great help in paediatric surgery. Willemsen: 'For example, the scan of a child shows that there is a fistula somewhere behind the heart. The 3D model of the scan shows the exact location, allowing to operate in a much more focused way and determine the exact spot of the fistula.'

The future

Future plans include printing bones, cells and various tissue types. Bones consist mainly of calcium and phosphate and are relatively easy to recreate via 3D printing. Because of this, application in humans is already waiting in the wings. The composition of cartilage is much more complex, let alone printing a kidney or heart. Willemsen: 'We already have the first results of tissue prints, now being done in animal research. Next, we need to translate that to humans. I expect to see the first results in the next few years.' He emphasizes that removing, of spreading open the bone, is the main treatment. 3D Bone implant placement is secondary and can speed up recovery. 'Because we also make drilling and sawing jigs of the affected bone, the surgery,



3D print of a hip cup

both the removal and placement of an implant, can be much more successful and accurate. The cost of 3D printed bone replacement structures is significantly below the price tag of actual bones. For example, the Dutch bone bank charges € 5000 for a femur.'

Willemsen: 'We are at the beginning of these developments and are setting up a European Special Interest Group for 3D devices. The first meeting has already taken place in the summer of 2022. We need to make 3D printing rationally applicable to other hospitals by properly defining design rules and rationales. Ensuring safety, sharing records. We want to prevent cowboy behavior, which is why requirements and protocols are so important. At the moment, we can only treat the

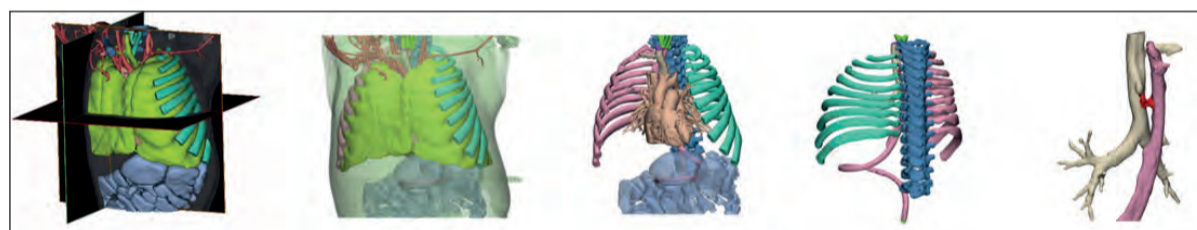
happy few with 3D models, but with wider adoption it will become available to many more people.' ■

Report: Madeleine van de Wouwe



Koen Willemsen

Koen Willemsen started his medical studies at the Vrije Universiteit in Amsterdam. After graduation in 2016, he was awarded a PhD position and worked as a medical doctor and PhD student as part of a large consortium in which novel 3D-printed implants and MRI-based diagnostic tools were developed. In 2019, he co-founded the UMCU's 3D lab. In 2020, he started a post-graduate traineeship as a Qualified Medical Engineer at the Technical University Eindhoven next to his work as 3D lab coordinator to further professionalize the 3D lab and work towards his Doctor of Engineering degree.



Workflow of the 3D print.

ASAP-approved for facilitating Standard-ANTT®

VISIT US AT
STAND 9D41

DRESS FOR SUCCESS

Introducing the World's First Barrier and Securement Dressing

Minimize cost and eliminate secondary cleaning procedures with UltraDrape® from Parker Laboratories. UltraDrape is cost-efficient compared to the alternative use of sterile gels and covers, while its inventive design allows an aseptic, no touch procedure. UltraDrape is manufactured with a film layer which provides an effective barrier against all viruses and bacteria as small as 20nm.

UltraDrape... the first-of-its-kind, sterile barrier and securement dressing uniquely designed for UGPIV.

ULTRADRAPE®
UGPIV Barrier and Securement



To learn more about UltraDrape visit
parkerlabs.com/ultradrape



Patent parkerlabs.com/ultradrape

ISO 13485:2016



Parker Laboratories, Inc.

The sound choice in patient care.™

973.276.9500

parkerlabs.com

©2022 Parker Laboratories, Inc.

UltraDrape and The sound choice in patient care are trademarks of Parker Laboratories, Inc.

AD 34-15-3 REV 6

Overheard at AACC

The complexities of drug testing in urine and hair

Urine screening tests using only immunoassays are the most common procedures used to identify drug abuse. They are inexpensive, automated, and produce rapid results. But they may generate false-positive or false-negative results, which vary based on the drug, drug class, and the assay used. Hair toxicology analysis is another form of drug testing which, unlike urine tests, enable analysis of drug use over a period of time. Hair toxicology tests complement urine tests but can be just as challenging to interpret.

Mass spectrometry, specifically liquid chromatography with tandem mass spectrometry (LC-MS/MS), is a powerful tool for toxicology analysis. Although more labour intensive, more time consuming, and much more expensive than hair and urine tests, LC-MS/MS is recommended for drug confirmation testing following a positive or inconclusive immunoassay screen. It is highly complex and requires significant expertise but provides definitive results due to its superior sensitivity and specificity.

At the 2022 AACC Annual Scientific Meeting in Chicago, Joe M. El-Khoury, PhD, director of the Clinical Chemistry Laboratory at Yale-New Haven Health, discussed the challenges of interpreting complex urine toxicology cases.

'When in doubt, mass spec it out'

El-Khoury discussed a routine urine test ordered for a patient prescribed opioids and other medications for multiple, chronic, and complex medical problems. Her physician wanted to verify that this patient was not taking additional types of painkillers. The test results were positive for heroine, but other findings were contradictory and confusing. 'Immunoassay screening may not produce accurate results, because antibodies used in the assays for the targeted



drug may exhibit cross-reactivity toward other closely related compounds,' said El-Khoury. 'Patients maintained on chronic opioids are often at risk of false positives. The LC-MS/MS test determined that the patient was only taking exactly what she'd been prescribed. When in doubt, mass spec it out.'

He noted that patients taking Suboxone, a drug widely used for treatment of patients with opioid use disorder, are high-risk, and may attempt to stimulate compliance by spiking the pill in urine to pass the screening test. Immunoassays are not specific enough to detect this sample adulteration and patients may get away with it. El-Khoury recommends that quantitative LC-MS/MS testing be the only method used for assessing adherence in patients taking Suboxone. When concentrations of drugs in urine are high, he advised the audience to make sure to rule out pharmaceutical impurities, and to rule out enzyme inhibitors when metabolite patterns are unusual.

Jacqueline Hubbard, PhD, the Laboratory Director of Three Rivers Diagnostics in Pittsburgh, Pennsylvania, gave deeper insights into hair toxicology analysis. Hair grows an average of 1 cm each month. When hair samples are segmented into sections, it is possible to obtain a detailed historic profile

of an individual's drug exposure over a specified amount of time. However, the accuracy of the analysis may be impacted by ultraviolet light exposure and diffusion of sweat, which may occur at any time. Cosmetic hair treatments may strip analytes or increase environmental contamination.

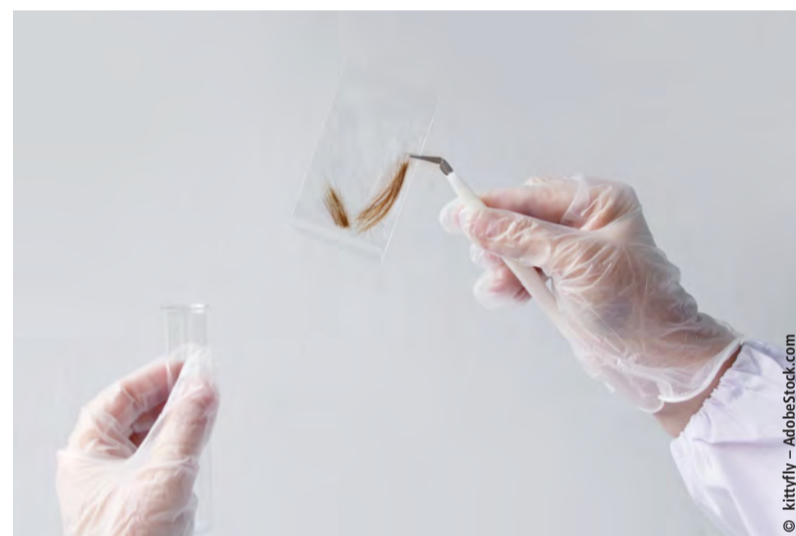
Melanin must be considered

A person with higher melanin may show a greater accumulation of drugs compared to a person with low melanin, so this needs to be considered when testing dark hair. Hubbard explained that the Society of Hair Testing (SHT) recommends that hair first be segmented prior to decontamination. The Society recommends use of aqueous washes and an organic solvent to remove oil and external contaminants from the hair. But these processes may still be insufficient. Recent research has suggested that such procedures may lead to the swelling of the hair and may promote incorporation of analytes into the hair itself. Cleansed hair samples need to be cut, ground, and pulverized before they are analysed. 'When drugs are detected in a panel, I recommend metabolite detection to confirm ingestion,' she said. 'The detected presence of drugs in hair may be due to ingestion, incidental exposure from contaminated surfaces, impurities found in the drug,

and/or decomposition products of drugs.'

'Hair toxicology interpretation to determine the frequency of use and if a person used specific drugs is not that simple. The amount of drugs detected in hair may not be equivalent to the actual concentration present in hair, and the relationship between the concentration in hair and the amount ingested is not well established,' cautioned Hubbard. 'Drugs in hair are indicative of repeated use and/or exposure, and not of a single use or recent use. Hair as a matrix for toxicology testing has implicit biases, including seeing higher drug concentrations in pigmented

toxicology analysis showed that the child had ingested two drugs, including methamphetamine. A two-year-old boy was admitted to a hospital emergency department with acute encephalopathy and seizures. His urine and lab tests were negative, but when the hair toxicology reports became available 30 days later, they had tested positive for exposure to oxycodone and methamphetamine 'Hair toxicology helped identify an unstable home situation from drug use for both children. For the boy, whose parents were separated, it provided definitive evidence that the mother of the child was a drug abuser, enabling the child to stay with his



versus non-pigmented hair after the same systemic exposure. This test frequently has a longer turnaround time compared to urine tests. But it may be useful to identify if children who have unexplained conditions or may be experiencing developmental delays are living in unhealthy situations,' she said. Hubbard described two cases that demonstrate the utility of hair toxicology testing. A malnourished two-year-old girl showing signs of neglect and developmental delays had a negative urine drug screening test for 11 drugs. However, hair

father. These tests can be invaluable in help keeping vulnerable children safe,' she concluded.

Report: Cynthia E. Keen

mgo^o fachverlage

Publisher

Mediengruppe Oberfranken –
Fachverlage GmbH & Co. KG
E.-C.-Baumann-Str. 5
95326 Kulmbach/Germany
Phone +49 9221 949-311
Fax +49 9221 949-377

Editor and Production Manager:
Sonja Buske (SB)

Editorial team:
Wolfgang Behrends (WB)
Sascha Keutel (SKE)

Managing Directors:
Walter Schweinsberg, Bernd Müller
Founded by Heinz-Jürgen Witzke
ISSN 0942-9085

Correspondents

Austria: Michael Krassnitzer (MK)
France: Jane MacDougall (JMD)

Germany:

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

Great Britain:

Mark Nicholls (MN)

Spain:

Mélanie Rouger (MR)

The Netherlands:

Madeleine van de Wouw (MvW)

USA: Cynthia E. Keen (CEK)

Subscriptions

Simone Sesselmann
kundenservice@mgo-fachverlage.de
Subscription rate
8 Euro

Printed by: mgo360 GmbH & Co. KG,
Bamberg, Germany

Representatives

Germany, Austria, Switzerland:

Ralf Mateblowski

Phone: +49 201 1775094

E-Mail:

r.mateblowski@mgo-fachverlage.de

France, Italy, Spain: Eric Jund

Phone: +33 493 58 77 43

E-Mail: jund@european-hospital.com

GB, Scandinavia, BeNeLux:

Simon Kramer

Phone: +31 180 6200 20

E-Mail: kramer@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

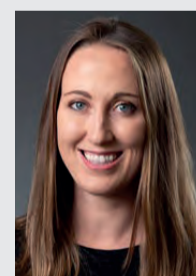
Maria Kaiser

Phone: +1 250 726 4007

E-Mail: mkads@mac.com

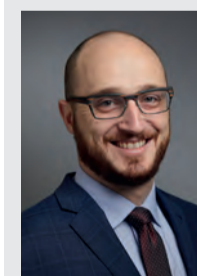
All company, brand and product names in this publication are the property of their respective holders.

Users must obtain permission from those holders before copying or using the owner's trademarks, product and company names or logos.



Jacqueline Hubbard

Jacqueline Hubbard, PhD, joined QualiTox Laboratories, now Three Rivers Diagnostics, in 2022 as its Laboratory Director. Her interests include toxicology interpretations, test utilization, and mass spectrometry. She also serves as an MSACL Practical Training scientific committee member and is actively involved in training new users on mass spectrometry. Her research has also focused on developing and validating drugs of abuse assays, driving under the influence of marijuana, and Covid-19 serology research.



Joe El-Khoury

Joe El-Khoury, PhD, is Director of the Clinical Chemistry Laboratory at Yale New Haven Health in New Haven, Connecticut, and Associate Professor of Laboratory Medicine at Yale University School of Medicine. A fellow of the AACC Academy, his research interests include indicators for monitoring clinical laboratory performance, investigating biomarkers of acute kidney injury and chronic kidney disease, and development of new mass spectrometry-based methods for the measurement of markers in biofluids.

An overview

DON'T MISS: Talks and panel discussion at the Labmed forum



Monday: Regulations and quality

The motto of the opening day will be 'Regulations and quality'. This day of the forum is dedicated in particular to the European In vitro Diagnostics Medical Devices Regulation (IVDR), which aims to markedly improve the standards of quality within the area of diagnostics to increase patient safety. As of May 2022, these regulations now apply to laboratory diagnostics as well and pose enormous regulatory challenges not only to manufacturers, but also to medical laboratories using proprietary assays – for example for specialised parameters – in practical patient care. 'A statement such as 'We've always been doing it like this' will be unacceptable in the future,' says Prof Dr Astrid Petersmann, Medicine and Health Sciences at Oldenburg University.

In the same sense, this applies to quality assurance methods which have been established for many years, but the requirements of which have so far been formulated more from a perspective of technical feasibility than from a perspective of medical necessity.

This is to change in the future, and Prof Dr Matthias Nauck, Greifswald University Department of Medicine, will present the first steps that have been established.

Other than that, information about the quality of the examinations carried out by medical laboratories must become more transparent and concrete for the attending doctors. This aspect will be discussed in the part of the event titled 'Quality assurance in patient-oriented laboratory medicine'.

Tuesday: Trends in laboratory medicine

The second day of the event is dedicated to short lectures and interactive stage discussions about the newest trends in laboratory medicine.

Referred to as liquid biopsy or liquid profiling, diagnosis through nucleic acids circulating in the blood (CNAPS) has been talked about now for years. According to Prof Dr Stefan Holdenrieder, who will lead the session on "New insights in circulating nucleic acid diagnostics", this diagnostic tech-

nique is quickly taking the leap from a scientific research method to clinical practice – from 'bench to bedside'.

The 'perpetual issue' of Covid-19 will have its own session this year, titled 'Covid-19: The challenge remains'. Current challenges include the ongoing, astounding evolution of perpetually new virus variants and the resulting necessity for adapting diagnostics, therapy and the development of vaccines accordingly.

As another challenge both for individuals and for society as a whole, long Covid syndrome is also slowly beginning to gain attention. To better understand and treat this slowly spreading 'disease after the disease' which affects millions of people worldwide – including those who had a mild course of acute illness – and which can cause long-lasting physical and psychological disability, a deeper understanding of the pathophysiology, new molecular diagnostic tests and specialised treatment centres for affected patients are necessary.

Wednesday: Emerging biomarkers in laboratory medicine

On November 16, recently discovered biomarkers take central stage. The morning will be dedicated to technologies the potential of which for medical diagnostics and therapy is still under evaluation. This includes new methods of sequencing genomes and detecting complex epigenomic changes.

Dr Verena Haselmann from the University Hospital Mannheim and a team of young, dedicated scientists will shine a light on the 'rising stars' among the new biomarkers.

Another topic is the application of these methods on single cells (single-cell omics) and the examination of blood samples by magnetic resonance imaging (MRI); a method which so far has only been routinely used for diagnostic imaging. In the afternoon, there will be an introduction of methods which are already closer to being ready for the market, but still subject to heavy discussion. Speakers will talk about detecting genetic aberrations of the embryo in the maternal blood through noninvasive prenatal testing (NIPT) or immune response assays on the cellular level, which are of importance right now when assessing the status of immunity during the Covid-19 pandemic.

Thursday: Innovative developments in the life sciences

The closing day will showcase innovative developments within the life sciences. Dr Peter Quick, head of the Life Science Research work group at VDGH e.V., the German association of the diagnostics industry, will bring researchers



and developers on stage whose work on RNA technologies, highly important for the development of vaccines, has gained widespread recognition.

Dr Christian Dohmen, Ethris GmbH, Senior Director Formulation & Aerosol Research, will present the 'mRNA Therapeutics for Lung Diseases' project, one of the RNA technologies discussed. The project advocates for a novel class of mRNA products to be used as therapeutics in the treatment of respiratory and infectious diseases. The Ethris technology platform will pave the way for a protein replacement therapy for rare lung diseases and for antiviral therapies.

Gene therapy, genome editing and diagnostics – where does the journey lead? Toni Cathomen, professor for cell and gene therapy at Freiburg University and director of the Institute for Transfusion Medicine and Gene Therapy at the University Medical Center, will also look at the future. Programmable nucleases like CRISPR-Cas have hailed a new era within personalised medicine. Prof Cathomen will explain the principles of gene therapy and genome editing, present examples of successfully applied gene therapies for diseases of the blood and the immune system, and discuss new technologies for editing the genome, which have

noticeably enlarged the application spectrum of gene therapy. He will end his presentation with a closer look at diagnostic assays used to assess, and where appropriate ameliorate, the risks of genotoxicity. The audience is invited to join the discussion about the future of this field.

Hall 1 / G37



**More than just
MRI accessories**



www.allmri.com

Multi-cancer early detection

New MCED blood tests could shake up cancer screening

New tests can identify over 50 types of cancer and boost detection of traditionally elusive cancers from tumour DNA in blood, researchers showed at the ESMO congress in September. These multi-cancer early detection (MCED) tests in development can spot common cancer signals across over 50 types of cancer and predict where the signal comes from in the body, results from a prospective investigation reported at the conference suggest.

In the study, MCED testing, which collects the signal arising from small sequences of circulating tumour DNA in the blood, detected a cancer signal in 1.4% of participants aged 50 years and over who were not known to have cancer. Carcinoma was confirmed in 38% of those with a positive test. The researchers also found that 99.1%

of the 6,290 participants who were cancer-free received a negative test result. The time to reach a diagnosis for those with a positive test result was an average of 79 days. For 73% of participants with a positive screening test, that time was only three months.

These results are an encouraging first step for early cancer detection tests, according to study senior author Deb Schrag, MD, MPH, a medical oncologist at Memorial Sloan Kettering Cancer Center, New York, USA. 'The study showed a good detection rate for people who had cancer and an excellent specificity rate for those who did not have it,' she said. 'In people with a positive test, it took less than two months to confirm the diagnosis if they had cancer and a bit longer if they didn't have cancer primarily, because physicians opted to perform imaging studies and then

repeat them a second time several months later to investigate the possibility of a cancer diagnosis.'

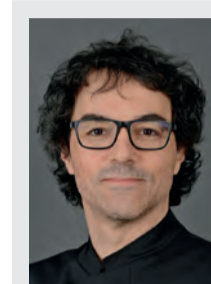
Screening options for previously unscreenable cancers

Another important aspect was that only few participants with a false positive screening test required multiple invasive procedures such as endoscopies and biopsies, Schrag pointed out. 'This finding should help to allay concerns that these tests could cause harm by generating unnecessary procedures in people who are well,' she said. Schrag stressed the importance of continued standard screening for cancers such as breast and colorectal cancer, while MCED tests are being refined and validated for cancers such as pancreatic, small bowel and stomach cancer, where there are currently no screening options. 'This study indicates that hope is on the horizon for detecting cancers that are currently unscreenable, but of course much more work is needed, and, with experience and larger samples, these assays will improve,' she said.

Impact on future cancer screening programmes

The PATHFINDER study is the first prospective investigation to show that an MCED test can detect cancer in patients with undiagnosed cancer, as previous studies used tests only in patients already known to have cancer.

The new results may have major implications for future cancer care



Fabrice André

Fabrice André, MD, PhD, is Director of Research at Gustave Roussy Cancer Center, Villejuif, France, and the newly elected future president of the European Society of Medical Oncology (ESMO) for the 2025–2026 term. Prof André is a medical oncologist specializing in breast cancer and a Professor of Medicine at Paris-Saclay University.



Deb Schrag

Deb Schrag, MD, MPH, is Chair of the Department of Medicine and George J. Bosl Chair at Memorial Sloan Kettering Cancer Center, New York, USA. Dr Schrag is a medical oncologist and health services researcher at the Dana-Farber Cancer Institute. She is Chief of the Division of Population Sciences and a Professor at Harvard Medical School in Boston and has a longstanding focus on gastrointestinal cancers, particularly colorectal cancer.

provision, according to Professor Fabrice André, ESMO 2022 Scientific Co-Chair. 'Within the next five years, we will need more doctors, surgeons and nurses, together with more diagnostic and treatment infrastructure, to care for the rising number of people who will be identified by multi-cancer early detection tests,' he explained.

All stakeholders must be involved in deciding new pathways of care and must agree on who will be tested and when and where tests will be carried out, André added. 'We need to anticipate the changes that will happen as a result of these tests, for example in the diagnosis and treatment of people with pancreatic and other cancers that are usually diagnosed at a much later stage,' he said. Comparative trials

across all types of cancer are needed to find out if having an early detection test affects morbidity and mortality and how the procedure benefits patients, he suggested. 'In addition, we need to know more about the small proportion of false positive tests (...) We need some of these answers before we can calculate the cost impact of introducing MCED tests in routine clinical practice,' he concluded.

Report: Mélanie Rouger



Stereoscopic viewing and virtual work

Passive 3D stereo monitors in medical applications

Volumetric 3D images and 3D models are becoming increasingly important in medical technology. Schneider Digital's high-resolution 3D PluraView stereo monitors are a perfect fit for 3D stereo display of medical data, especially from CT and MRI scanners.

The 3D PluraView monitor is compatible with all leading 3D-enabled medical software applications, such as Siemens Syngo, Brainlab Stereotaxy, Virtual Vert, Forsina, Vived Anatomy, Vesalius 3D, Paskal 3D, ThermoFisher Amira or 3D Slicer.

Compared to other 2D and 3D monitors, PluraView systems have two screens with passive 'BeamSplitter'

technology that provide a realistic 3D experience, but with brightness suitable for daylight. Combined with the appropriate medical software and a powerful graphics card, they provide turnkey 3D workstation solutions that analyze and present volumetric medical data comfortably and efficiently – in the highest resolution, flicker-free, even in normal, bright workstation environments.

Areas of use and application:

- Surgery planning and preparation
- 3D computed tomography (CT)
- 3D imaging (MRI, ultrasound)
- Preparation for medical 3D printing
- Evaluation of visual medical data
- Education & Training



Hall 10 / C45

At Boston area hospitals

Managing the CT contrast media shortage with clinical decision support tools

On March 31st, 2022, a city-wide lockdown to curtail the spread of the Covid-19 virus in Shanghai, China, shuttered the GE Healthcare manufacturing facility that produces 80% of the global supply of iodinated contrast media agents iohexol (Omnipaque) and iodixanol (Visipaque). Although the plant was able to operate at 50% capacity by mid-May, the shutdown resulted in a substantial contrast media shortage that has had worldwide impact.

To deal with the shortage, hospitals implemented strategies to conserve contrast media supplies for urgent or non-deferrable CT exams. Strategies included methods to reduce administered contrast media volume, use of a single vial for multiple patients, use of alternatives to non-ionic contrast media when clinically appropriate, and performing alternative imaging exams in lieu of contrast-enhanced CT, such as MRI, ultrasound, and PET/CT.

In addition to the recommended strategies, Brigham and Women's Hospital, Massachusetts General Hospital, seven community hospitals, three specialty hospitals, and multiple affiliated ambulatory care centres utilized a clinical decision support (CDS) tool embedded in the electronic health record (EHR) to alert clinicians about the contrast media shortage and to encourage them to modify their imaging exam orders for their patients whenever possible. Researchers assessed the impact of two EHR order entry-based interventions, reporting in the American Journal of Roentgenology that over a 90-day period beginning April 1st, the mean number of orders for contrast enhanced CT per weekday decreased by 15.2%. Additionally, a mean 12% fewer patients had these scans every weekday.



Principal investigator Daniel I. Glazer, MD, Assistant Professor in Radiology at Harvard Medical School and a member of the Center for Evidence-based Imaging of Brigham and Women's Hospital, and colleagues assessed the impact on contrast enhanced CT utilization and ordering patterns of the CDS-triggered EHR intervention. CT utilization and ordering patterns were compared prior to and following two consecutive, individual EHR interventions. The study data included 79,259 patients having 41,433 exams in the pre-intervention period, 6,157 in the first post-intervention period, and 50,989 in the second one.

Prior to the contrast media shortage, the existing protocols for

ordering CT exams through the EHR interface in the multi-facility hospital system enabled referring physicians to order exams with and without contrast media, with the use of contrast media at the radiologist's discretion, or not to specify at all. Additionally, ordering physicians could enter free-text clinical information about the reason for the exam as part of the order.

Intervention #1 and #2

Beginning May 10th (intervention #1), when a referring physician ordered a contrast-enhanced CT of the neck, chest, or abdomen and pelvis, an alert was displayed advising of the contrast media shortage, and recommending specific alternative exams. Also, an email blast was sent to all practitioners

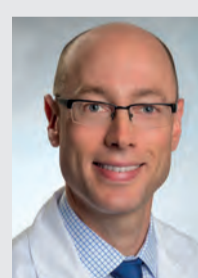
in the healthcare system advising of this. Beginning May 16th (intervention #2), it became necessary for a physician ordering a contrast-enhanced CT to enter detailed clinical information in the free-text box. Radiologists reviewed this information to determine if a non-contrast CT exam could be substituted, and did so if clinically feasible.

There was a small steady decline in the total number of patients having CT exams performed during the study period. The average number of patients having CT exams of any kind on a weekday was 1,350 pre-intervention, 1,323 first post-intervention, and 1,314 second post-intervention, a modest decline. However, the number of patients having contrast-enhanced

CT exams performed on weekdays declined significantly, averaging 727 daily pre-intervention, 689 first post-intervention, and 639 second post-intervention, or 53.8%, 52.1% and 48.7% percent of the total, respectively.

'The findings support the role of EHR order entry-based changes to achieve rapid impact on ordering clinician behaviour and subsequent clinical practice within a large health system,' concluded the authors.

Report: Cynthia E. Keen



Daniel I. Glazer

Daniel I. Glazer, MD, is an abdominal radiologist at Brigham and Women's Hospital (BWH) as well as the Medical Director of CT and Cross-Sectional Interventional Radiology for Brigham Health. He is an assistant professor of radiology at Harvard Medical School as well as faculty at BWH's Center for Evidence-based Imaging (CEBI). CEBI is dedicated to achieving measurable improvements in the quality, safety, and efficiency of care delivery, using innovative information technology solutions and change management strategies.

MEDICAL TAIWAN

INTERNATIONAL MEDICAL, HEALTH & CARE EXPO

The Healthcare Market is Booming: Medical Taiwan 2022 Visitors Increased by 13%

Medical Taiwan 2022 attracted more than 6,000 visitors, an increase of 13% over the previous year, demonstrating the healthcare industry's huge development potential. Decision makers came to transact business and to understand market trends, proving that Medical Taiwan is an ideal venue for business matching and exchange.

June 8-10, 2023
Taipei Nangang Exhibition Center, Hall2 (TaiNEX 2)

LIVE TOUR

SOURCING MEETING

PRODUCT LAUNCH

INDUSTRY FORUM

Exhibition Review

Booth Application

Medical Taiwan 2023 Opens for All Kinds of Healthcare Companies.

TAITRA
 medicaltaiwan@taitra.org.tw
 www.medicaltaiwan.com.tw

Implementing the electronic patient record in the hospital

Step by step into the digital future

In Europe, Germany has been bringing up the rear in implementing the electronic patient record (EPR) for years. While the EMRAM score of German hospitals continues to be negligible – on the international as well as on the European level – there are signs of progress that give reason for hope.

Far too often, paper records still dominate daily routine in German hospitals despite the fact that the EPR is the linchpin of digitalisation. Under the new so-called Future of Hospitals law in Germany, substantial funding is earmarked for EPR implementation. Financial support is provided above all for the digitalisation of documentation (clinical and care) and medication as well as for linking patients to a digital portal before and after their hospital stay. An analysis by Curacon shows that 54 percent of the grant applications aim at expanding digital documentation. The fact that suddenly EPR is becoming top priority can be easily explained: in the future, hospitals that do not introduce EPR will be sanctioned.

By 2023, implementation progress has to be shown via the so-called digital radar. Since this is a rather tight time frame for such a complex project, hospitals are under severe pressure. Experience shows that the introduction of the EPR is a demanding task, mostly because almost all members of the clinical and care teams are involved. Moreover, in the different departments and wards different documentation standards have evolved which have to be harmonized when introducing the EPR. Most importantly, however, the documentation process itself will have to change since maintaining paper records is very different from maintaining electronic ones. Case in point: Much data will be transferred from the medical devices or from the lab directly into the EPR and no physical records have to be searched for or picked up. On the other hand, digital documentation can be more time consuming, e.g. with medication, since the product has to be selected and the dosage has to be determined in detail. Last but not the least, a technical infrastructure has to be put in place that gives everybody access to the EPR

from anywhere. The following four steps help to successfully implement the EPR:

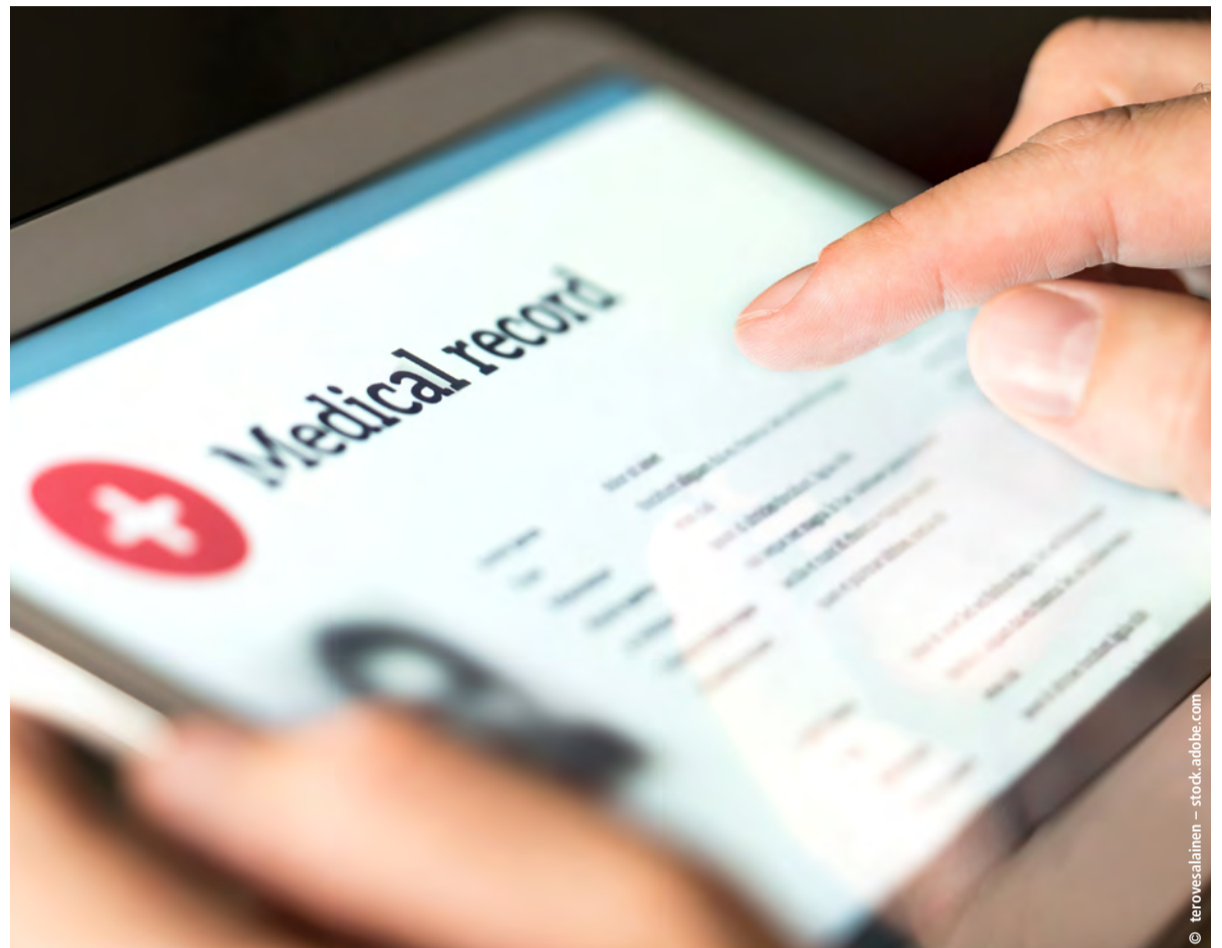
1. Create the technological foundation

In many German hospitals, the infrastructure is outdated and not all institutions are equipped with WiFi, which is a basic requirement for using mobile peripherals such as tables, carts, as well as smartphones and mobile medical devices. Updating the infrastructure with WiFi, however, is expensive since cabling and access points have to be installed. These basic technology and network structures have to be created prior to any EPR implementation. Since this time-consuming task cannot always be handled by the internal technical and IT teams in addition to their other responsibilities, external service providers might have to be contracted.

In a next step, all medical devices have to be integrated into the network either by cable or WiFi in order to be able to transfer all diagnostic results of the medical equipment directly into the EPR. Obviously, it needs to be ascertained that all medical devices are indeed network-enabled. If not, modern replacements need to be purchased – an investment item which has to be included in the budget. Moreover, since the necessary peripherals are part of the technological foundation, the provider of the hospital information system (HIS) has to be consulted as to the most suitable tablets, smartphones and carts.

2. Develop a documentation standard

Parallel to creating the technological foundation, a common documentation standard should be developed. Many hospitals simply follow their hospital information system but each HIS uses its own documentation philosophy. Many systems are configurable which means the customer has to set the parameters. This is often done by pilot departments and pilot wards which – consciously or not – create the rough frame for the documentation standard. When EPR implementation is planned, many hospitals are tempted to simply transfer the paper record 1:1 into



the digital version. This is a crucial mistake since many of the existing structures and processes are shaped by the paper approach and are unsuitable for digitalisation. It is therefore strongly recommended to establish a multi-disciplinary team of clinical and nursing staff to define a single, unified documentation standard for the entire institution. It makes little sense to task the IT department with the leadership and control of such a project. Rather, the documentation standard, which includes patient vital signs, medication and the clinical and care documentation, has to be shaped by the professions and professionals who will use it on a daily basis.

3. Clear project organisation and responsibility

The objective of implementing the EPR is the full digitalisation of all patient data. In order to achieve this goal, all documentation processes have to be re-thought since a 1:1 transfer of analogue processes will never bring about the EPR's potential increase in efficiency and reduction of work load. With the focus being on the processes, the project should not be led by the IT department unless that department is in charge of process development across the institution. If the hospital has a dedicated department responsible for process development, it should be in charge of the implementation project. If no such department exists, a specialist for documentation and clinical and care processes needs to be identified. If there is no person with this specific job profile, experienced nursing or clinical staff with a strong interest in IT and in such an implementation project are a good choice.

It is important to squarely place the project in a transparent project organisation. We recommend a 3-level approach encompassing three subprojects, project manage-

ment and a steering committee. One subproject is tasked with creating the technological/IT preconditions, a second one with developing the documentation standards. These two subprojects should work in parallel. When they have reached a certain point, the third subproject – implementation – can start.

The project manager should be a person who is familiar with the documentation processes and the documentation contents. The task is to manage the project and control project progress.

The steering committee, which is made up of representatives of the core decision-making units of the hospital or the hospital group, will be regularly informed about progress and problems and decide on important measures to be taken in case there is a deviation from the plan. With such a structure, the implementation process can be controlled and enforced.

4. Migration and schedule

Very often, EPR is implemented as a pilot on a single ward or in a single department. Then, implementation is expanded step by step across the institution. The underlying idea is that specific documentation requirements can thus be integrated step by step as well. While this approach is frequently chosen because no unified documentation standard has been established prior to the implementation, it exposes the project to two risks: Firstly, when new requirements regarding more and more topics are constantly added, the unified documentation standard is weakened and the entire process tends to develop into a 1:1 transfer of the analogue patient record. Secondly, the step-by-step approach becomes problematic when a patient is moved from an already digitalised ward to a non-digitalised one. At that point, all documents have to be printed

out and turned into a paper-based record. In view of these risks we strongly recommend to establish a comprehensive documentation standard prior to implementation. This standard can then be tested on one or two wards/departments. In a next step, it is implemented in all other departments. The EPR is adjusted only when urgently needed data have not yet been saved. These changes have to be approved by the subproject team in charge of the documentation standard. In order to reduce the complexity of the implementation and training processes, the different modules can be implemented one after the other. Such an approach ensures that all wards and departments are at the same stage throughout the process and can support each other.

Outlook and challenges ahead

In view of the sanctions for failing to implement the EPR, the HIS software providers will most likely face short-term bottlenecks. The shortage of IT professionals will further exacerbate the problem since all hospitals will try to meet the compliance deadline. At the same time, the hospitals might have to conduct complex public tenders in order to be able to spend the funds that were made available for EPR implementation. In addition, introducing the EPR will temporarily increase the work load of the hospital staff. Institutions that are already struggling with staff shortages and teams that are already putting in extra hours will suffer. Nevertheless, introducing the EPR is vital since it will improve patient care and will enable a more effective control of the processes in the hospital. And: digitalisation is an important factor that makes a hospital attractive for new staff. ■

Report: Dr Christian Heitmann and Dominik Weis, Curacon

SPOT ON INNOVATION



Arvato Systems turns TI into a service

To connect to the telematics infrastructure (TI), the digital healthcare network in Germany, a connector is required. Until now, this was located on-site in doctors' offices, pharmacies, etc. With flexTI, Arvato Systems is moving the connectors to its own secure data centers. This offers

users more flexibility in their daily work and a low-cost, low-threshold entry option. In addition, higher availability is achieved – an indispensable quality feature for service providers who are working around the clock. Arvato Systems is thus taking another important step toward telematics infrastructure 2.0.



Hall 10 / G20

Developing a sustainability calculator

Tackling the eco-footprint of healthcare

There is a growing awareness of the healthcare sector's adverse impact on the environment due to its emissions of greenhouse gases (GHG). A recent report from the non-profit organisation Health Care Without Harm (HCWH) finds that globally, healthcare is responsible for 4.4% of total net GHG emissions.

If the health sector were a country, it would be the fifth largest GHG emitter on the planet, says the same study. According to Dr Alina Herrmann from the Institute of Global Health at the University Hospital Heidelberg (UKHD) in Germany, the contribution of the health sector to climate change globally is about twice that of air traffic worldwide.

According to HCWH's 2019 study "Health Care's Climate Footprint", healthcare in Europe accounts for an estimated 5% of the European carbon emissions. Consequently, healthcare has been facing more regulatory requirements to mitigate these negative effects, especially with a view to its contribution in achieving the European 2030 climate and energy targets. However, healthcare institutions themselves are seeking to decarbonize the provision of healthcare and hospitals of varied sizes have taken up environmental stewardship efforts to this effect.

In a first step, healthcare institutions – with the focus on hospitals – need to quantify their own GHG emissions. For this, they can use the framework developed as part of the Greenhouse Gas Protocol. This allows healthcare institutions to measure their carbon footprint with the help of various levels of so-called "scopes", which reflect to which extent an institution controls GHG emissions. The protocol distinguishes between three types: **Scope 1** emissions are mostly directly controlled and are emitted on the premises of an institution (e.g. anaesthetic gases); **Scope 2** emissions represent energy (electricity and heat) used by an organisation but produced by a different organisation (like district heating, electricity producers); and **Scope 3** emissions are indirectly influenced by the organisation and usually include the embedded carbon emission in the production and supply of all the goods and services purchased by the organisation.

According to the Health Care's Climate Footprint report, globally healthcare's Scope 1 emissions represent 17% of overall GHG discharge, with Scope 2 accounting for 12% and Scope 3 representing 71% respectively. The report revealed that the majority of GHG emissions are indirect (Scope 3), with healthcare's supply chain being a large offender. The worst emitters being pharmaceuticals at 12%, followed by business services at 10.7%, then food, catering, and accommodation at 7.2% of global healthcare's GHG emissions. There are few emitters unique to the healthcare sector, most notably anaesthetic gases, and metered dose inhalers.

Decarbonisation efforts within German healthcare

The Health Care's Climate Footprint report also shows that Germany's healthcare sector accounts for 5.2% of national GHG emissions. Its annual climate footprint is equivalent to 14 coal-fired power plants, 754,572 tanker trucks' worth of gasoline or the emissions of 12,101,911 passenger vehicles.

In 2020, 232 of 1,925 German hospitals (12%) reported their Scope 1 and 2 GHG emissions; but none reported Scope 3 emissions, partly because these are difficult to measure. This is about to change, as the UKHD has started on a project to tackle Scope 3 emissions. This is part of the UKHD's overarching sustainability strategy: 'As an institution that is committed to the health of the population in clinic and research, we see it as our responsibility to actively support climate protection. Because climate protection is health care,' says Professor Dr Ingo Autenrieth, Executive Medical Director of the UKHD.

The KliOL project

Funded with about € 320,000 by the Federal Ministry for the Environment, Nature Conservation Nuclear Safety and Consumer Protection, the project "Climate Protection in Hospitals by Optimizing Supply Chains" – or KliOL for short – targets the reduction of Scope 3 emissions by at least 7% or 6,000 tonnes of carbon dioxide equivalents.

The project, which will run over a three-year period, started in the

last quarter of 2021. It is conducted by the Institute of Global Health at the UKHD in cooperation with the Institute for Energy and Environmental Research Heidelberg (ifeu). In the first year of the project, both institutes developed a first version of a carbon footprint calculator for hospitals with a special focus on emissions from supply chains (Scope 3). However, it will also assist in measuring Scope 1 and 2 emissions. To create this calculator, the collaborators did not have to start entirely from scratch. They used the framework of the GHG Protocol as well as a GHG calculator developed by ADEME, the French Environment and Energy Management Agency, and adapted those for the German healthcare system. In parallel, interviews with selected stakeholders of the UKHD were conducted to uncover how they perceive potential GHG reduction measures for the UKHD.

In a next step, UKHD's newly developed calculator was used to determine the hospital's own GHG emission profile: The preliminary results show that in 2019, the UKHD generated 226,500 tons of CO₂-equivalents, whereby 2.6% were Scope 1, 22.2% Scope 2 and 75.2% Scope 3 emissions. Medical products (24% of the total carbon footprint), pharmaceuticals (13%), patient transport (7%), staff transport (5%) and food supply (3%) accounted for the bulk of Scope 3 emissions. For the calculation, KliOL applied a bottom-up as well as a top-down approach. Claudia



Quitmann, Scientific Coordinator of KliOL, recounts that interviewed stakeholder were taken by surprise by the extent to which pharmaceuticals contribute to GHG emissions.

Based on these results, the UKHD will identify effective and feasible GHG reduction measures. They will be implemented and evaluated in terms of their impact on the GHG balance, financial aspects, and health effects.

By the end of the funding period, KliOL aims to provide a low-threshold GHG calculator along with a manual to make the use of the calculator as user friendly as possible for other hospitals.

En route to a more climate friendly healthcare delivery, this tool will also help to raise the awareness of employees and patients to sustainability issues within health-

care. Furthermore, the operation of "greener" hospitals will require a redirection of resources towards data procurement and data handling to measure GHG emissions as well as the management of measures to implement initiatives to cut the emission footprint. At the UKHD, there is a willingness among its employees to rethink some processes with a view to make them more sustainable. As a result, some departments have already taken small steps like a different choice of internet browsers or the use of recycling paper. This bottom-up and top-down approach is a good start for the implementation of sustainability measures, the experts conclude. ■

Report: Cornelia Wels-Maug

DON'T MISS! Health IT Forum

Monday: virtual and hybrid care

11:00-12:00

- Digital patient journey – Tech talk

12:00-13:00

- Blended care – Tech talk

13:00-14:00

- How to connect connected care – Expert panel

14:00-15:00

- Hybrid care models – Tech talk

15:00-16:00

- The merging of digital health & biomedicine – Expert panel

16:00-17:00

- Med delivery revolution – Deep dive session

Tuesday: AI in healthcare

11:00-12:00

- Assist-as-needed – smart assistance in rehabilitation – Tech talk

12:00-13:00

- Predictive care – Tech talk

13:00-14:00

- AI in pharma – Expert panel

14:00-15:00

- Smart glasses 2.0 – Tech talk

15:00-16:00

- Digital health analytics – Expert panel

16:00-17:00

- AI-based therapy planners – Deep dive session

Wednesday: Green health & sustainability

11:00-12:00

- Green hospitals – Tech talk

12:00-13:00

- Circularity in the healthcare industry – Tech talk

13:00-14:00

- How healthcare can become more sustainable with digital help – Expert panel

14:00-15:00

- Climate change-indicated health issues & digitization – Tech talk

15:00-16:00

- Health environment research in Europe – Expert panel

16:00-17:00

- Nutrition & tech – Deep dive session

Thursday: fields of innovations

11:00-12:00

- The future of photonics in healthcare – Tech talk

12:00-13:00

- Gender-sensitive medicine – Expert panel

13:00-14:00

- New work & occupational health – Tech talk

14:00

- Open Mic

Hall 12 / E19



Member of  MEDICAlliance

**SEE YOU
AGAIN**

13-16 NOVEMBER 2023

Messe Düsseldorf GmbH
Postfach 10 10 06 _ 40001 Düsseldorf _ Germany
Tel. +49 211 4560-01 _ Fax +49 211 4560-668
www.messe-duesseldorf.de



Messe
Düsseldorf