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November- December 2021

Obesity

The carbohydrate-insulin model. It's what you eat, not how much

Climate Change

Countries commit to develop climate resilient, low carbon health systems at COP26

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New building simulation framework shows full environmental impact pre-design

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Prognosis

A new perspective

According to the World Health Organisation, around 2.8 million people worldwide die from overweight and obesity-related diseases every year. It's a huge problem and it's getting bigger. But there may be a new way to manage weight, which has been put forward by scientists writing in *The American Journal of Clinical Nutrition* recently. Their perspective challenges the current 'energy balance' model which states that weight gain is caused by consuming more energy than we expend. They point out that despite decades of public health messaging exhorting people to eat less and exercise more, rates of obesity and obesity-related diseases have steadily risen. They propose the 'carbohydrate-insulin' model, which places emphasis on *what* people eat, rather than how much they eat, and how this affects the body's metabolism. Although this model is not new, this recently published perspective is the most comprehensive formulation of this model to date. Authored by a team of 17 internationally recognized scientists, it has radical implications for weight management. You can read more about this perspective in this issue.

There have been some hopeful developments at the recent COP26 global climate change conference where countries have agreed to increase their efforts to reduce carbon-emissions, one of the main causes of atmospheric warming. Importantly, the conference also looked, not only at mitigation, but also adaptation to climate as we are now starting to experience the effects of it. This was borne out in a show of 50 countries – including the UAE, Oman and Jordan – who have committed to develop climate resilient and low-carbon health systems. Health systems around the world account for a significant proportion of the total carbon emissions, so this is a welcome move on the part of these governments. Hopefully more will follow suit soon. You can read more about this commitment in this issue.

Stay healthy.

Callan Emery
Editor
editor@MiddleEastHealth.com

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Publisher
Michael Hurst
Michael@MiddleEastHealth.com

Editor
Callan Emery
editor@MiddleEastHealth.com

Editorial Consultants
Dr Gamal Hammad, Dr Peter Moore, Harry Brewer

Middle East Editorial Office
PO Box 72280, Dubai, UAE
Telephone: (+9714) 391 4775
editor@MiddleEastHealth.com

Marketing Manager
Foehn Sarkar
Telephone: (+9714) 391 4775 ▮ Fax: (+9714) 391 4888
marketing@MiddleEastHealth.com

Subscription & Admin Manager
Savita Kapoor
Telephone: (+9714) 391 4775 ▮ Fax: (+9714) 391 4888
Savita@MiddleEastHealth.com

Advertising Sales
PO Box 72280, Dubai, UAE
marketing@MiddleEastHealth.com

Americas, France
Joy Sarkar
P O Box 72280, Building No.2
2nd Floor, Dubai Media City
Dubai, United Arab Emirates
Tel: +971 4 391 4775 Fax: +971 4 391 4888
Joy@MiddleEastHealth.com

Japan
Mr Katsuhiro Ishii
Ace Media Service Inc
12-6, 4-chome, Adachi-ku, Tokyo 121-0824, Japan
Tel: +81-3-5691-3335 ▮ Fax:+81-3-5691-3336
Email: *amskatsu@dream.com*

China
Miss Li Ying
Medic Time Development Ltd,
Flat 1907, Tower A, Haisong Building, Tairan 9th Road,
Futian District, Shenzhen, China 518048
Tel: +86-755-239 812 21 ▮ Fax: +86-755-239 812 33
Email: *medic8@medictime.com*

Taiwan
Larry Wang
Olympia Global Co Ltd
7F, No.35, Sec 3, Shenyang Rd, Taichung
Taiwan 40651 ▮ P O Box: 46-283 Taichung Taiwan 40799
Tel: +886- (4)-22429845 ▮ Fax:+886- (4)-23587689
Email: *media.news@msa.hinet.net*

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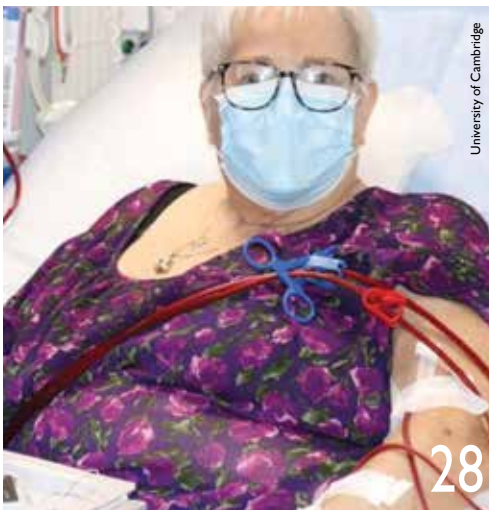

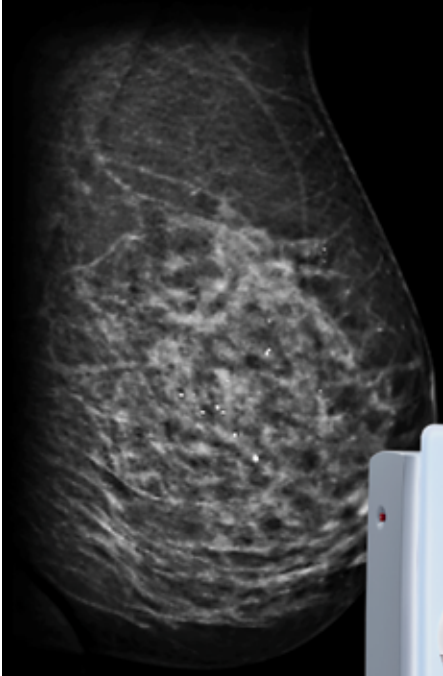

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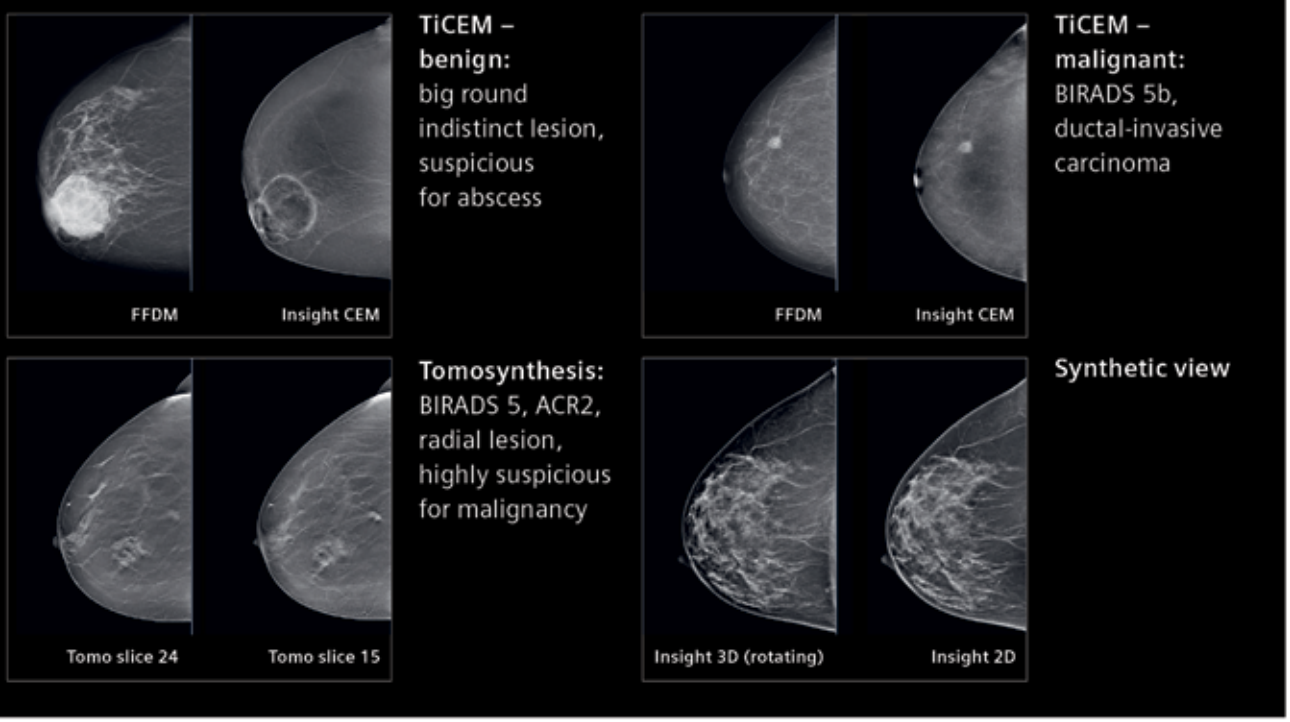

Courtesy of Dr. Ilse Vejborg, Prof. Dr. Detlev Uhlenbrock, and Prof. Dr. Luis Pina

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middle east monitor

Update from around the region

Al Jalila Children's Specialty Hospital launches one-of-a-kind animal-assisted therapy programme for children

Al Jalila Children's Specialty Hospital, a specialised paediatric hospital in UAE, has launched a one-of-a-kind animal-assisted therapy programme in collaboration with Reading Dogs, a programme of The Animal Agency, a UAE-based organisation.

The programme, which will be piloted over three months, will treat children with human-animal interaction therapy sessions with specially trained dogs.

The programme builds on evidence of the benefits of human-animal therapy that has been shown to decrease stress and depression by increasing the levels of feel-good chemicals – specifically, serotonin, oxytocin, and dopamine – in the brain, alongside enhancing relaxation, building trust and empathy.

Dr. Mohamed Al Awadhi, Chief Operating Officer at Al Jalila Children's Specialty Hospital said: "Our world-class teams of highly qualified medical experts and paediatricians are setting new standards for paediatric healthcare excellence on a local and regional level. Our hospital is a place where SMART technology and design converge to enhance patient care and outcomes. The hospital also aims to foster clinical innovations, astute learning and development programmes. Our innovative partnership with Reading Dogs is a natural extension of this."

Karalynn Thomson, Founder of the Animal Agency and Reading Dogs, added: "The launch of the dog-assisted therapy programme with Al Jalila Children's Specialty Hospital builds on the hospital's commitment to bringing innovative care to children. We look forward to supporting that mission and helping children on their recovery journeys.

"Animal-assisted therapy offers patients positive human-animal interactions in a clinical setting, bringing emotional support at a vulnerable time. The human-animal bond is a mutually beneficial relationship that positively influences the health and well-being of both." MEH

Mediclinic City Hospital earns Comprehensive Stroke Centre certification

The stroke programme at Mediclinic City Hospital in Dubai has been recognised by the Middle East and North Africa Stroke Organization (MENASO) and the American Stroke Association (ASA).

A team of expert reviewers evaluated Mediclinic City Hospital for compliance with Comprehensive Stroke Centre standards and requirements including advanced imaging and treatment capabilities, 24/7 availability of specialised treatments, participation in research and staff and physicians with the unique education and competencies to care for complex stroke patients. The reviewers found the hospital met or exceeded all required standards. Comprehensive Stroke Centres must document and demonstrate how their organisation has committed to providing quality care for stroke patients.

"Worldwide, stroke is the second leading cause of death and the third leading cause of disability, but rapid, appropriate treatment is key to improving survival, minimising disability and speeding recovery times," said Suhail Al-Rukn, M.D., president of MENASO. "Comprehensive Stroke Centre certification recognises healthcare organisations that are committed to fostering continuous quality improvement in patient safety and quality of care."

The American Stroke Association uses its stroke certification model to assist hospitals with a framework to manage and deliver quality care by standardising and increasing the adherence to scientific guidelines and access to acute care for patients who experience a stroke.

This certification programme is based on standards developed independently and overseen by two mission-driven organisations, reflecting decades of science and clinical expertise.

"Mediclinic City Hospital is honoured to be recognised by the American Stroke Association and MENASO for our

dedication to helping our patients have the best possible chance of survival after a stroke," said Dr. Andrew McCombe, Medical Director at Mediclinic City Hospital . "Providing consistent, evidence-based care to our patients is a priority – this certification shows our commitment to save lives and reduce disability for our patients who suffer a stroke." MEH

Cleveland Clinic Abu Dhabi initiates Emirati breast cancer study

Three studies underway at Cleveland Clinic Abu Dhabi aim to offer insights on the awareness, genetic profile and demographics of Emirati women with breast cancer, which can have a significant impact on the detection and treatment of the disease.

Initiated in September, the three studies are being led by the Oncology Institute's multidisciplinary team and will rely on voluntary participation as well as retrospective data collected from hospital records over the last five years.

Dr. Stephen R. Grobmyer, Chair of the Oncology Institute at Cleveland Clinic Abu Dhabi, said that these studies will gather specific data that will enable tailored care and targeted awareness programmes for UAE Nationals.

"These studies will give us an important starting point to understand how breast cancer affects Emirati women, what are the unique characteristics and risk factors of the disease in the UAE population, and the level of knowledge about family and personal health history among patients. This approach will not only enable us to personalize care for our patients but has the potential to inform public health policy and protocols that benefit the population," said Dr. Grobmyer.

The first study on breast cancer health awareness and genetics among Emirati women will provide essential baseline knowledge about breast health history and seek new information about the spectrum of genetic mutations among patients with breast cancer.

Divided into two parts, 100 women having a screening mammography done at Cleveland Clinic Abu Dhabi will be surveyed to understand their breast health literacy. Another 50 newly diagnosed Emirati breast cancer patients will be invited to take a genetic panel testing to determine the rate and spectrum of genetic mutations among this population. The study is estimated to be concluded in 2022.

"We've known for a long time that family history is an important part of a woman understanding her risk of breast cancer. The reason is that breast and ovarian cancer has been found in multiple generations of certain families. If a patient knows her family and personal health history, there are several things we can do to help her and her family members. This strategy would include extensive genetic testing, increased frequency of imaging, and prescribing hormonal medications to reduce her apparent risk. However, if a woman does not have that knowledge, it is hard for us to help her make an informed decision on the best treatment plan," Dr. Grobmyer said.

"The second part of this study will aim to find the percentage of patients with known genetic mutations and the patterns of mutations for a comparison between the Emirati and Western population."

The second study will look at the demographics and tumour characteristics of breast cancer among Emirati patients treated or evaluated at Cleveland Clinic Abu Dhabi from May 2015 until June 2021.

Dr. Grobmyer said that this study will help them assess if their anecdotal evidence on the demographics and characteristics of tumour in breast cancer patients can be backed by data.

"We are seeing a larger percentage of young Emirati patients with breast cancer at our clinic. This contrasts with the age at which women in the US are diagnosed with the disease. We will assess the age at which these patients developed breast cancer, and the types of cancer, whether invasive or noninvasive, that are more common."

Dr. Grobmyer said the outcome will help them make recommendations for new screening protocols and work on different ways to target and educate the population.

The final study will evaluate the hospital's time to treatment initiation (TTI) among cancer patients treated or evaluated at Cleveland Clinic Abu Dhabi from January 2018 until January 2020.

Highlighting the importance of this study, Dr. Grobmyer said that the purpose is to evaluate their adherence to the US-based National Comprehensive Cancer Network (NCCN) cancer staging guidelines. A recent observational study <*https://doi.org/10.1245/s10434-021-10116-9* > of 28,000 breast cancer patients in America, which was conducted by researchers at Cleveland Clinic in the U.S. and co-authored by Dr. Grobmyer, found a decrease in patient survival rates when treatment options – surgery, chemotherapy and radiation – are completed more than 38 weeks from the time of diagnosis.

"This study will help us identify what is currently happening when our patients are first diagnosed with breast cancer and how long it takes for them to complete treatment. Sometimes, patients in the UAE have to visit multiple specialists or want to seek multiple opinions, which prolongs their treatment. We want to identify all the challenges within the patient journey." MEH

Fakeeh University Hospital signs MoU with Siemens Healthineers to establish Innovation Think Tank laboratory

Dr. Fatih Mehmet Gul (left), Chief Executive Officer, Fakeeh University Hospital, and Ole Per Maloy, Managing Director, Siemens Healthineers Middle East and Southern & Eastern Africa, sign an MoU to enhance their collaboration.

Fakeeh University Hospital (FUH), a world-class healthcare and academic centre in the UAE, has signed a Memorandum of Understanding with Siemens Healthineers to further enhance collaboration across several areas with a special focus on medical excellence, improvement of productivity, and innovation in healthcare delivery.

Brought to the UAE by pioneering Saudi healthcare provider group, Fakeeh Care, FUH is committed to delivering medical excellence and championing outstanding research in the UAE, building on four decades of healthcare legacy. Equipped with cutting-edge technology and with the support of its partnership with Siemens Healthineers, its systems are set up to treat an estimated 700,000 patients a year.

In the most recent collaboration with Siemens Healthineers, FUH will see the institutionalization and facilitation of the Middle East's first Innovation Think Tank (ITT) laboratory. It will create a local innovation infrastructure connected to global Innovation Think Tank locations, focusing on improved patient experience, disease pathways advancement and workflow optimization. The FUH-ITT lab will act as a physical and virtual centre for research, clinical excellence, and training, where staff, students and researchers can apply their real-world expertise towards the development of medical innovations, from new practices to breakthrough technologies.

Innovation Think Tank is a global infrastructure of co-creation labs and programmes at Siemens Healthineers locations, universities, and hospitals. ITT empowers partner institutions to create self-sustaining infrastructures and proactively drives innovation to improve human life. ITT has established a network of 56 activity locations, consisting of ITT laboratories and certification programmes. It is also responsible for more than 2,500 product definitions, R&D and strategy projects and continues to offer 200 ITT fellowships annually to programme participants from more than 150 universities in 38 countries.

In addition to the laboratory space at its state-of-the-art facility, the flagship ITT Certification Program will be organized in a hybrid format, engaging key healthcare stakeholders in the region and focusing on defining new designated projects in the FUH-ITT lab. A dedicated digital engagement platform will be launched on FUH's website which will showcase the most outstanding projects and potential engagement options with the global community on research and innovation. The laboratory space itself will strengthen the hospital's education arm by providing opportunities for doctors and staff to undergo specialized training sessions to further enhance patient care capabilities. FUH will be the reference site for technology and innovation solutions, with the establishment of the Siemens Healthineers Academy for clinical training of healthcare professionals from across the Middle East.

Dr. Fatih Mehmet Gul, Chief Executive Officer, Fakeeh University Hospital said: "This is an exciting moment for us as we further establish ourselves as a leading centre of academic excellence and patient-centric care in the country and region. As a globally recognized stamp of expertise, the ITT certification allows us to ensure that we continue to train and retain some of the best minds in medicine at our hospital. We look to Siemens Healthineers as our natural partner, to help us continue to pave the road towards innovation and quality care. Together, we can address the biggest healthcare challenges in the UAE and wider region."

Ole Per Maloy, Managing Director, Siemens Healthineers Middle East and Southern & Eastern Africa said: "In addition to our existing multifaceted partnership, Fakeeh University Hospital is now among the growing number of prestigious institutions worldwide that have undertaken the Innovation Think Tank program. Building on their impressive expertise, this program will allow participants to explore their intrinsic creativity and diversity to encourage out-of-the-box thinking, ultimately creating an innovation ecosystem and addressing local challenges in our region as well that will improve the lives of patients." MEH

All Abu Dhabi-based hospitals now connected to Malaffi HIE

Dr. Hamed Ali Al-Hashemi, Advisor to the Chairman of Department of Health – Abu Dhabi.

The Department of Health – Abu Dhabi (DOH), announced in October that all public and private hospitals in the Emirate are now connected to Malaffi, the region's first Health Information Exchange (HIE) platform. This is a major milestone in the ongoing efforts to improve the quality of healthcare and patient outcomes in Abu Dhabi, and a strategic initiative of the platform. The platform allows healthcare providers to safely exchange important patient health information in real-time, creating a centralised database of unified patient records.

All 59 hospitals, 1,100 clinics and medical centres and 380 pharmacies in the emirate are now connected to the platform. This enables more than 39,600 doctors, nurses and other members of staff across Abu Dhabi to have secure access to Malaffi and to make better-informed and more efficient decisions.

Malaffi collates 559 million unique clinical records of medical information such as patient visits, medical conditions, allergies, procedures, lab results, radiology reports, vaccination records, vital signs, and medications.

Dr. Hamed Ali Al-Hashemi, Advisor to the Chairman of DOH, said: "Malaffi is one of the most prominent and innovative programs launched by Abu Dhabi to advance the healthcare sector as it continues to adopt digital technology and achieve the highest levels of efficiency and effectiveness regarding the sector. This pioneering healthcare system is in line with the most advanced systems in the world. We will continue to work according to the Abu Dhabi Economic Vision 2030 to achieve a healthy society and consolidate the emirate's position as an incubator for innovation and distinguished digital initiatives, which will positively affect the health and well-being of all members of society."

Atif Al Braiki, the Chief Executive Officer of Abu Dhabi Health Data Services, the operator of Malaffi, said: "Connecting 100% of hospitals in Abu Dhabi to be able to access and share important patient data through Malaffi in under three years is a major accomplishment. Our mission to enable a safe and secure exchange of patient health information across the entire sector is now closer than ever. I am glad to see the wide recognition of the value of connected healthcare for the delivery of better care, especially during the pandemic. We are grateful for the support of the DOH and the entire healthcare sector that have been crucial to this success. We look forward to further supporting the communities of the emirate on their journey to good health, happiness and prosperity."

The DOH continues to lay a solid foundation for a future based on technology, innovation and Artificial Intelligence in the emirate's healthcare sector through a series of initiatives and programmes such as The Artificial Intelligence (AI) Lab, TIP Healthcare Innovation programme Awards, Abu Dhabi's Workforce Health Management System, Population Risk Management, COVID-19 Predictive Modelling and Capacity Planning Tool along with other digital platforms.

Mediclinic Middle East announces plan to attract 1,000 Emiratis into its workforce

Mediclinic Middle East, one of the UAE's leading private hospital groups with seven hospitals and more than 20 outpatient clinics across Dubai, Abu Dhabi and Al Ain, has announced an initiative to attract 1,000 Emiratis into its workforce to achieve targeted UAE national representation in the private and semi-government sectors.

Mediclinic Middle East already has a number of Emirati employees in both clinical and non-clinical roles, and actively seeks to attract Emiratis in a range of medical and allied health positions

David Hadley, CEO, Mediclinic Middle East

through established educational affiliations with institutions such as the Mohammed Bin Rashid University of Medical and Health Sciences, Fatima College of Health Sciences, United Arab Emirates University, Al Ain University and Abu Dhabi University. The new scheme, however, will be broadened to include a learning academy for young UAE nationals to develop and prepare themselves for a variety of roles across the group, with visible career progression linked to performance standards, a customised mentorship and orientation programme for Emiratis, and the establishment of new internship programmes in areas such as Pharmacy, Nursing and Dentistry.

David Hadley, Chief Executive Officer of Mediclinic Middle East, said: "Mediclinic has worked hard over the past few years to ensure that Emiratis view a career at Mediclinic as long-term and sustainable, but we are now better positioned to recruit and retain UAE nationals in the private sector than ever before. I am confident that we can deliver on our target of a workforce of 1,000-plus UAE nationals and I am excited that Mediclinic can continue to give back to the country in which it has played an active and integral part for many years."

Mediclinic is initially seeking UAE national applicants in the clinical areas of nursing, laboratory, pharmacy, medical imaging, physiotherapy and medical doctors. Non-clinical opportunities are available to UAE nationals in the areas of general healthcare administration, client engagement, finance, insurance and human resources. Emiratis wishing to apply, can register their CV on the following link: *https://bit.ly/3bgyzwR*

Dubai-based Aviv Clinics provides hyperbaric oxygen therapy to treat Alzheimer's

Dubai-based Aviv Clinics is offering a programme using hyperbaric oxygen therapy (HBOT) to treat age-related cognitive and physical decline.

Gulf countries, such as UAE, Saudi Arabia, Kuwait and Qatar, are expected to see a significant increase in their older populations. The World Health Organisation warns that such a shift in population demographics can result in an increase in the number of people who may develop Alzheimer's disease.

In response, Aviv has developed its pioneering medical programme with a unique protocol of Hyperbaric Oxygen Therapy (HBOT) at its core – a non-pharmaceutical, non-invasive method that involves administering patients with a hundred per cent pure oxygen in a pressurised environment to promote normal organ function and accelerate tissue repair.

The programme also includes a series of comprehensive assessments to holistically evaluate a patient's health, a personalised cognitive training plan, a fitness plan and nutrition coaching, with the aim of enhancing the patient's cognitive and physical performance, and improving their quality of life.

Studies by Sagol School of Neuroscience in Tel Aviv and Tel Aviv University have shown that HBOT can be effective in reversing early symptoms of Alzheimer's disease.

Dr. Shai Efrati, director of the world-leading Sagol Center for Hyperbaric Medicine and Research at Shamir Medical Center and Chair of Aviv's Medical Advisory Board said: "Age should never be a factor in determining how mentally or physically fit a person is. HBOT can be used as a viable drug-free and non-invasive solution to treat the decline in age-related cognitive and physical performance, and we are pleased to be able to offer our unique programme to patients in the UAE and across the region."

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Update from around the globe

Countries commit to develop climate-resilient, low carbon health systems at COP26 UN climate conference

A group of 50 countries, including the UAE, Oman and Jordan [1], have committed to develop climate-resilient and low-carbon health systems at the UN Climate Change Conference in Glasgow (COP26), in response to strong evidence of the impact of climate change on people's health.

The governments of these 50 countries, which include some of those most vulnerable to the health harms caused by climate change as well as some of the world's biggest carbon emitters, have committed to take concrete steps towards creating climate-resilient health systems.

Forty-five of these countries have also committed to transform their health systems to be more sustainable and low-carbon. Fourteen have set a target date to reach net zero carbon emissions on or before 2050.

The commitments were made as part of the COP26 Health Programme [2], a partnership between the UK government, the World Health Organization (WHO), the United Nations Framework Convention on Climate Change (UNFCCC) Climate Champions and health groups, such as Health Care Without Harm.

"The future of health must be built on health systems that are resilient to the impacts of epidemics, pandemics and other emergencies, but also to the impacts of climate change, including extreme weather events and the increasing burden of various diseases related to air pollution and our warming planet," said Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization.

"Health systems must also be part of the solution, by reducing carbon emissions. We applaud those countries that have committed to building climate-resilient and low-carbon health systems, and we hope to see many others following their lead in the near future."

Countries that have committed to achieving low-carbon, sustainable health systems include Argentina, Fiji, Malawi, Spain, the United Arab Emirates, the United States of America and 39 others. Countries that have committed to enhance the climate resilience of their health systems include Bangladesh, Ethiopia, the Maldives, the Netherlands, and 45 others.

The government of Fiji, for example, is responding to the increase in cyclones, flash floods, and rising sea levels causing lack of drinking water due to saltwater intrusion, by building more climate-resilient health infrastructure, strengthening the health workforce, and providing healthcare facilities with sustainable energy services.

"The message from WHO and health professionals around the globe is clear: climate change is a huge health challenge and we need to act now. I'm really pleased to see so many countries prioritising this issue through the COP26 Health Programme and their level of ambition. Strong leadership from the health sector is vital to make sure we protect our populations from the impacts of climate change by enhancing the climate resilience of health systems, and by reducing emissions from the health sector," said Wendy Morton, Minister for Europe and Americas, in the United Kingdom's Foreign, Commonwealth and Development Office.

The country commitments come off the back of a recent WHO survey, which shows that the majority of countries now include health in their national climate plans to the Paris Agreement, but that plans often still lack detailed health actions or support mechanisms.

"These government commitments exemplify the growing global health movement for climate action. Around the world doctors, nurses, hospitals, health systems and ministries of health are reducing their climate footprint, becoming more resilient and advocating for a just transition that puts health at the centre of a decarbonized civilization," said Josh Karliner, International Director of Program and Strategy of Health Care Without Harm.

Health systems must also be part of the solution, by reducing carbon emissions. We applaud those countries that have committed to building climate-resilient and low-carbon health systems, and we hope to see many others following their lead in the near future.

In addition to the national commitments, 54 institutions from 21 countries representing more than 14000 hospitals and health centres have joined the UNFCCC Race to Zero [3] and committed to achieving net zero emissions.

References

[1] Country commitments *https://www.who.int/initiatives/cop26-health-programme/country-commitments*

[2] COP26 Health Programme *https://www.who.int/initiatives/cop26-health-programme*

[3] UNFCCC Race to Zero *https://healthcareclimateaction.org/racetozero*

Cervical cancer rates reduced by 87% in women vaccinated against HPV, study confirms

Cervical cancer rates are 87% lower in women who were offered vaccination against human papillomavirus (HPV) when they were between the ages of 12-13 than in previous generations confirms a new study published in *The Lancet*[1].

The researchers also found reductions in cervical cancer rates of 62% in women offered vaccination between the ages of 14-16, and 34% in women aged of 16-18 when vaccination was introduced. This is the first direct evidence of prevention of cervical cancer using the bivalent vaccine, Cervarix.

HPV vaccination has been introduced in 100 countries as part of efforts by the World Health Organization (WHO) to eliminate cervical cancer.

"Although previous studies have shown the usefulness of HPV vaccination in preventing HPV infection in England, direct evidence on cervical cancer prevention was limited," says Professor Peter Sasieni, King's College London, one of the authors of the paper. "Early modelling studies suggested that the impact of the vaccination programme on cervical cancer rates would be substantial in women aged 20-29 by the end of 2019. Our new study aims to quantify this early impact. The observed impact is even greater than the models predicted."

Dr Kate Soldan from the UK Health Security Agency and co-author, sadi: "This study provides the first direct evidence of the impact of the UK HPV vaccination campaign on cervical cancer incidence, showing a large reduction in cervical cancer rates in vaccinated cohorts. As expected, vaccination against HPV was most effective in the cohorts vaccinated at ages 12-13 amongst whom the uptake was greatest and prior infection least likely. This represents an important step forwards in cervical cancer prevention. We hope that these new results encourage uptake as the success of the vaccination programme relies not only on the efficacy of the vaccine but also the proportion of the population vaccinated."

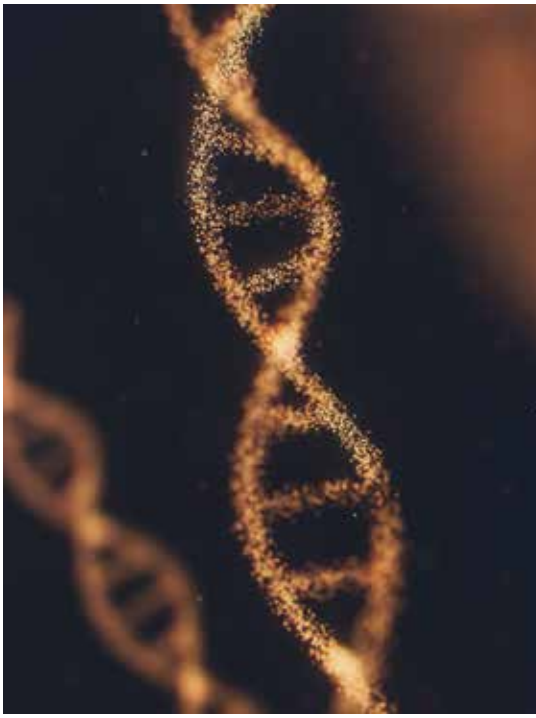
Lucy Elliss-Brookes, Associate Director for Data Curation at NHS Digital and one of the authors of the paper said: "The findings of this study are hugely important in encouraging those eligible to take up the vaccine, but also in demonstrating the power of data in helping medical researchers and the NHS to understand what causes cancer and how best to diagnose, prevent and treat it."

Writing in a linked comment, Professor Maggie Cruickshank from the University of Aberdeen, who was not involved in the study, says: "The scale of HPV vaccination effect reported by this study should stimulate vaccination programmes in low and middle-income countries where the problem of cervical cancer is a far greater public health issue than those with well-established systems of vaccination and screening. The most important issue, besides the availability of the vaccine, is the education of the population to accept the vaccination, as an increase in the rate of immunization is a key element of success."

Reference:
[1] *https://doi.org/10.1016/S0140-6736(21)02178-4*

NIH providing $185 million for research to advance understanding of how human genome functions

The U.S. National Institutes of Health is providing approximately $185 million over five years to the Impact of Genomic Variation on Function (IGVF) consortium, initiated and funded by NIH's National Human Genome Research Institute (NHGRI). NHGRI will fund 25 awards across 30 U.S. research sites. IGVF consortium investigators will work to



understand how genomic variation alters human genome function, and how such variation influences human health and disease.

The genome sequences of two different people are more than 99.9% identical. But those 0.1% genetic differences combined with the environment and lifestyle ultimately shape a person's overall physical features and disease risk. Researchers have identified millions of human genomic variants that differ across the world, including thousands of disease-associated ones. By integrating experimental methods with advanced computer models, the IGVF consortium will identify which variants in the genome are relevant for health and disease – information that will be of critical importance to clinicians.

"Biomedical researchers have recently made remarkable advances in the experimental and computational methods available for elucidating genome function," said Carolyn Hutter, Ph.D., director of the NHGRI Division of Genome Sciences. "The IGVF consortium will include world leaders in these areas, and together they will leverage these advances to tackle an incredibly challenging and important series of questions related to how genomic

variation influences biological function."

The IGVF consortium will develop a catalogue of the results and approaches used in their studies. All information generated by the consortium will be made freely available to the research community via a web portal to assist with future research projects. Because there are thousands of genomic variants associated with disease, and it is not possible to manipulate each variant individually and in each biological setting, consortium researchers will also develop computational modelling approaches to predict the impact of variants on genome function.

The IGVF consortium includes five components: Functional Characterization Centers, Regulatory Network Projects, Mapping Centers, a Data and Administrative Coordinating Center and Predictive Modeling Projects. MEH

NIH, FDA and 15 private organizations join forces to increase effective gene therapies for rare diseases

The National Institutes of Health, U.S. Food and Drug Administration, 10 pharmaceutical companies and five non-profit organizations have partnered to accelerate development of gene therapies for the 30 million Americans who suffer from a rare disease. While there are approximately 7,000 rare diseases, only two heritable diseases currently have FDA-approved gene therapies. The newly launched Bespoke Gene Therapy Consortium (BGTC) <*https://www.nih.gov/research-training/accelerating-medicines-partnership-amp/bespoke-gene-therapy-consortium*>, part of the NIH Accelerating Medicines Partnership (AMP) program and project-managed by the Foundation for the National Institutes of Health (FNIH), aims to optimize and streamline the gene therapy development process to help fill the unmet medical needs of people with rare diseases.

"Most rare diseases are caused by a defect in a single gene that could potentially be targeted with a customized or 'bespoke' therapy that corrects or replaces the defective gene," said NIH Director Francis S. Collins, M.D., Ph.D. "There are now significant opportunities to improve the complex development process for gene therapies that would accelerate scientific progress and, most importantly, provide benefit to patients by increasing the number of effective gene therapies."

A single rare disease affects small numbers of people, but rare diseases collectively affect millions. Most rare inherited diseases stem from a specific gene mutation that is already known, making gene therapy a promising therapeutic approach. However, gene therapy development for rare diseases is highly complex, time consuming and expensive. Moreover, the development process is stymied by limited access to tools and technologies, lack of standards across the field, and a one-disease-at-a-time approach to therapeutic development. A standardized therapeutic development model that includes a common gene delivery technology (a vector) could allow for a more efficient approach to specific gene therapies, saving time and cost.

"Rare diseases affect 25 to 30 million Americans, but because any given rare disorder affects so few patients, companies often are reluctant or unable to invest the years of research and millions of dollars necessary to develop, test and bring individualized gene therapy treatments for a single disease to market," said Joni L. Rutter, Ph.D., acting director of NIH's National Center for Advancing Translational Sciences (NCATS). "The BGTC aims to make it easier, faster and less expensive to pursue bespoke gene therapies in order to incentivize more companies to invest in this space and bring treatments to patients."

"By leveraging on experience with a platform technology and by standardizing processes, gene therapy product development can be accelerated to allow more timely access to promising new therapies for patients who need them most," said Peter Marks, M.D., Ph.D., director of FDA's Center for Biologics Evaluation and Research. "FDA is committed to developing a regulatory paradigm that can advance gene therapies to meet the needs of patients with rare diseases."

A primary aim of BGTC is to improve understanding of the basic biology of a common gene delivery vector known as the adeno-associated virus (AAV). BGTC researchers will examine the biological and mechanistic steps involved in AAV vector production, vector delivery of genes into human cells and how therapeutic genes are activated in target cells. These results will provide important information for improving the efficiency of vector manufacturing and enhancing the overall therapeutic benefit of AAV gene therapy.

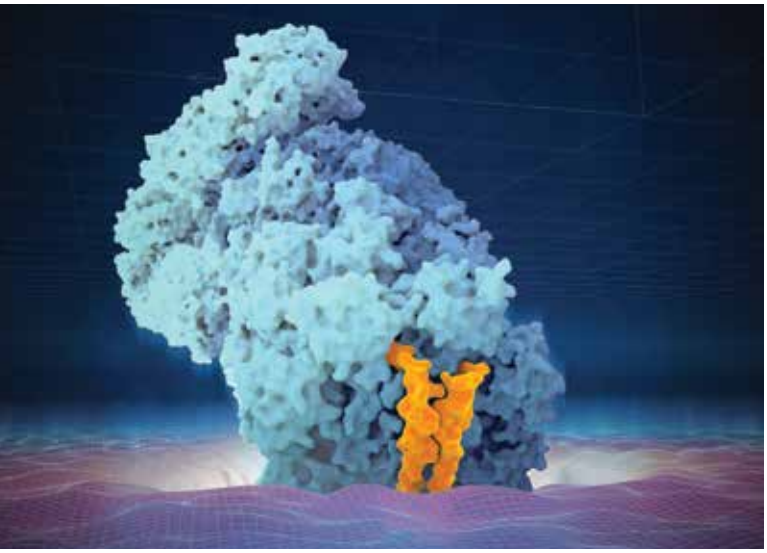
To improve and accelerate gene and vector manufacturing and production processes, the BGTC program will develop a standard set of analytic tests to apply to the manufacture of viral vectors made by consortium researchers. Such tests could be broadly applicable to different manufacturing methods and make the process of developing gene therapies for very rare conditions much more efficient.

NIH and private partners will contribute approximately $76 million over five years to support BGTC-funded projects.

Private partners include Biogen Inc., Cambridge, Massachusetts; Janssen Research & Development, LLC, Raritan, New Jersey; Novartis Institutes for BioMedical Research, Cambridge, Massachusetts; Pfizer Inc., New York, New York; REGENXBIO Inc., Rockville, Maryland.; Spark Therapeutics, Philadelphia, Pennsylvania; Takeda Pharmaceutical Company Limited, Deerfield, Illinois; Taysha Gene Therapies, Dallas, Texas; Thermo Fisher Scientific Inc., Waltham, Massachusetts; and Ultragenyx Pharmaceutical, Novato, California. Several non-profit partners also are involved, including the Alliance for Regenerative Medicine (ARM), Washington, D.C.; the American Society of Gene and Cell Therapy, Milwaukee, Wisconsin; CureDuchenne, Newport Beach, California; National Organization for Rare Disorders (NORD), Quincy, Massachusetts; and The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), Newark, Delaware. MEH

the laboratory

Medical research news from around the world



IMP

Artist's interpretation of AKIRIN2's role in the import of the proteasome into the nucleus. The two 'fingers' of AKIRIN2 (in orange) carry the proteasome (light blue) into the nucleus.

How cells keep their nucleus clean: a fundamental discovery

Scientists at the Research Institute of Molecular Pathology (IMP) in Vienna have developed a CRISPR-Cas9 screening assay that allows to systematically pinpoint regulators of any gene of interest, including cancer-related genes. Using this approach, they discovered how cells transport their clean-up machinery, the proteasome, into the nucleus to maintain protein balance and get rid of unwanted nuclear proteins. The results of this study are now reported in the journal *Nature*.

At the Research Institute of Molecular Pathology (IMP) in Austria, scientists in the lab of Johannes Zuber are on the hunt. They are searching for cellular switches that could turn off genes associated with cancer. One of their targets is the gene MYC and its associated protein, which is overly expressed in tumour cells and underlies boosts of cell division.

In a healthy cell, MYC is one of the most short-lived proteins: as soon as its work is done, it needs to be destroyed, or it may cause unwanted cell proliferation. Such is the function of the proteasome, a complex of proteins that acts as the clean-up machinery of the cell. Once a protein is no longer used, the proteasome breaks it apart into smaller peptide pieces.

"The healthy functioning of our organs, tissues, and cells relies on the rapid production and turnover of tens of thousands of proteins. Each protein is controlled by 'gas pedals' and 'brake pedals', and both can be exploited for the development of drugs," explains Johannes Zuber, senior scientist at the IMP. "The goal of our study was to pinpoint the gas and brake pedals of cancer-related genes such as MYC, and we found a regulator that we hadn't expected."

Two PhD students in Zuber's lab devised a CRISPR-Cas9 screening assay that allows to eliminate, or 'knock out' any gene in the genome in a time-controlled manner, and to see if it affects the abundance of MYC. Should a knocked-out gene result in a decrease in MYC, it could represent a potential drug target for cancer.

Because MYC is essential for cancer cells to grow, its regulation is challenging to study. "Deleting essential genes leads to very quick cell death. However, our screening method allows us to initiate the gene knockout at any chosen moment, so that we can study the immediate consequences of this knockout before the cells start dying," explains Melanie de Almeida, co-first author of the study and a Vienna BioCenter PhD student.

With their innovative method, the team was able to get a comprehensive view of the regulators of MYC. One of these regulators was a protein they had never heard of.

"In every screen we ran, we found a small protein called AKIRIN2 that appeared to be essential for switching off MYC. Without AKIRIN2, cells showed a strong increase in MYC levels, which was very similar to what we saw when we disrupted the proteasome." says Matthias Hinterndorfer, co-first author and Vienna BioCenter PhD student. "It was like the first piece of a puzzle that we wanted to solve."

AKIRIN2: two fingers pulling the proteasome into the nucleus

The scientists found that AKIRIN2 was consistently associated with the proteasome and not only required for the regulation of MYC, but of many more short-lived proteins. To their surprise, they found that AKIRIN2 only affected nuclear proteins, which accumulated freely in its absence. Thus, they hypothesised that AKIRIN2 might help the proteasome to enter the nucleus to break down unwanted nuclear proteins.

To test their idea, the team harnessed the IMP's broad expertise in molecular biology and teamed up with David Haselbach, group leader at the IMP and expert in proteasome biology.

"With our biochemical analyses, we characterised the structure of AKIRIN2, and confirmed that it binds to the proteasome: it forms a dimer that looks a bit like two fingers, which attach to the proteasome and carry it from the cytoplasm into the nucleus," explains Haselbach. "This process is particularly important after each cell division, where AKIRIN2 quickly imports proteasomes from the cytoplasm into the newly formed nuclei of daughter cells."

"Our work highlights the power of interdisciplinary research and the collaborative spirit at the IMP. We have this unique setting that brings together researchers from different fields of molecular biology, who then build on each other's expertise to tackle scientific problems from different angles," says Zuber.

Exploiting AKIRIN2 to develop selective proteasome-inhibiting drugs

Inhibitors that block the activity of the

proteasome are already applied to treat various types of cancer. However, existing drugs affect proteasomes in all the cells of our body, which can lead to unwanted side-effects in healthy cells.

"Our study shows that AKIRIN2 is required for bringing proteasomes into the nucleus after each cell division. Drugs blocking the interaction between AKIRIN2 and the proteasome could therefore provide a strategy to selectively inhibit nuclear proteasomes in rapidly dividing cells, such as cancer cells," says Matthias Hinterndorfer.

To develop such selective proteasome inhibitors, scientists need to better understand how AKIRIN2 functions and how it is regulated. Luckily, the assay that the team pioneered in this study is applicable to virtually any gene – and now can be used to uncover the factors that regulate AKIRIN2.

"Our paper represents a fundamental discovery for biology, but it's also a major technical advancement for the study of gene regulatory networks," says de Almeida. "Our assay may allow scientists to study essential regulators of any protein of interest, including proteins that are related to cancer."

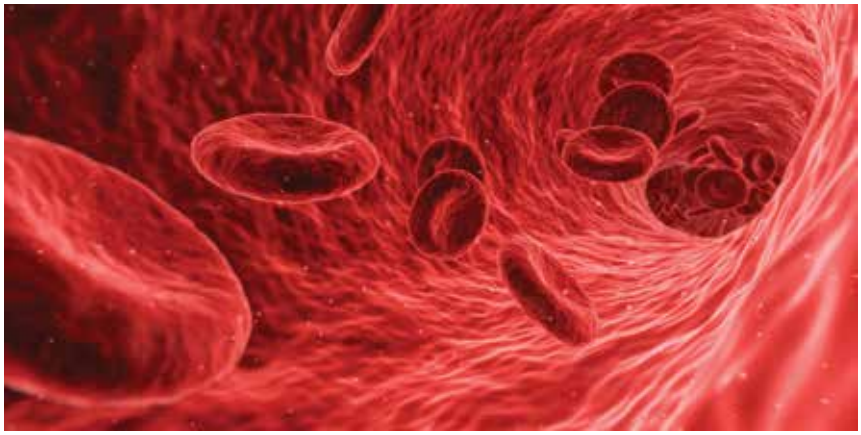
The ground-breaking study combines the development of a novel assay to study essential regulatory pathways in the cell, the discovery of an essential regulator of nuclear proteins, and the characterisation of its 3-dimensional structure.

Reference:
Frazer, J., Notin, P., Dias, M. et al. Disease variant prediction with deep generative models of evolutionary data. *Nature* (2021). *https://doi.org/10.1038/s41586-021-04043-8*

Discovery of red blood cells acting as micro-electrodes opens new doors in medical research

A first of its kind study demonstrates voltage outside of biological cells, with potential implications for cardiovascular disease, cancer and fertility treatment.

In a paper published in *Scientific Reports*, academics at the University of Surrey have discovered that biological cells generate an electric field voltage that appears outside and not just within, meaning each cell acts as a tiny electrode. Since this voltage impact show cells interact with their environment, including the way cells stick to one another, this has significant potential implications for future medical treatments.



Since the 1790s, scientists have known that electricity plays a role in the function of life, with the discovery in the 1940s that every cell contains a voltage that controls many of its functions. This is particularly the case in muscle and nerve cells but has also been shown to play an important role in diseases such as cancer.

However, until now, this voltage has always been understood to be contained within the cell. Through intricate experiments with red blood cells, the Surrey-led research team has shown that the voltage appears outside the cell as well. This means that cells effectively act as tiny transmitters, electrically changing the environment around them. Similar results in other types of biological cells could play a significant role in determining new types of medical treatment.

Circadian rhythms

The paper also demonstrates that the electrical characteristics of red blood cells exhibit circadian rhythms, the natural 24-hour cycle followed by most living things, with peaks coinciding with the time of day when most cardiovascular disease events occur, such as heart attacks and strokes, presenting an important area for further research.

Commenting on the study, Professor Mike Hughes said: "Biology is often reduced to interactions between big molecules, but cell-scale science is an essential area of study. By reintroducing the electrical element, we are looking for – and finding – a whole new way to understand how the bodyworks."

The study was led by engineer Professor Mike Hughes and biologist Dr Fatima Labeed, both at the University of Surrey. The work is part of a broader study on how cells work as electrical, rather than just biochemical, entities.

Reference:
Hughes, M.P., Kruchek, E.J., Beale, A.D. et al. Vm-related extracellular potentials observed in red blood cells. Scientific Repors 11, 19446 (2021). *https://doi.org/10.1038/s41598-021-98102-9*

New research points to better targeted therapies for treatment-resistant leukaemia

New research from Johns Hopkins Kimmel Cancer Center investigators shows why some drugs in clinical trials for treating a form of acute myeloid leukaemia (AML) often fail and demonstrates a way to restore their effectiveness.

The preclinical study, published in September in *Blood Cancer Discovery*[1], potentially clears a pharmacologic hurdle in developing molecularly targeted therapies for AML.

About one-third of patients with AML have a mutation in the gene FLT3. Normal FLT3 genes produce an enzyme that signals bone marrow stem cells to grow and replenish. When mutated, FLT3 causes rapid growth of leukaemia cells, leading to

higher rates of relapse following treatment and lower survival overall.

FLT3-mutated AML is particularly sensitive to a class of drugs called e-family tyrosine kinase inhibitors (TKIs), making them prime candidates for drug development, says first author David Young, M.D., Ph.D., who conducted the study while at the Johns Hopkins Kimmel Cancer Center. Dr. Young is now at the U.S. National Heart, Lung and Blood Institute of the National Institutes of Health.

However, these TKIs and others often fail and patients relapse. In a series of experiments with human leukaemia cell lines and mice, the team demonstrated that the human alpha(1)-acid glycoprotein (AGP) binds the drug, effectively preventing it from reaching its intended FLT3 mutation target and killing the cancer cells.

Donald Small, M.D., Ph.D., director of the Division of Pediatric Oncology and the Kyle Haydock Professor of Oncology at the Johns Hopkins Kimmel Cancer Center, and colleagues treated mutant FLT3 cell lines grown in human plasma from healthy donors or standard laboratory conditions with lestaurtinib, TTT-3002 or midostaurin a drug approved by the U.S. FDA that targets FLT3 – at various concentrations. They found that adding human plasma reduced the ability of TKI to inhibit FLT3, unlike blood components from other sources. Further testing identified human AGP as binding the three drugs and inhibiting their ability to kill leukaemia cells.

To demonstrate clinical relevance of the findings, the researchers collected blood samples from adults newly diagnosed with AML and looked at the effect of their plasma on midostaurin. In the presence of high inflammation, like in newly diagnosed patients with leukemia, AGP levels are elevated. As expected, the drug lost potency in the human plasma assay from these cases.

"Midostaurin is very specific and potent, and we've seen about a 10% improvement in patient outcomes since the FDA approved its use in adults with AML in 2017," says Young, "but we never got the 'home run' we were looking for because it's bound by AGP."

In another set of experiments, the team showed that this plasma protein inhibition could be reversed by adding an agent that also binds to AGP. Mifepristone is known to bind to AGP with an affinity comparable to or greater than that of the three drugs in the study. Researchers ran the FLT3 assay with human protein plasma, midostaurin and mifepristone. They found that mifepristone displaced the AGP-bound midostaurin, restoring its anti-FLT3 activity. Testing the concept in mice, they had similar results.

"We wanted to free up enough midostaurin to allow the drug to do its thing," Young explains. "If we give human AGP, and give midostaurin plus mifepristone, it kills the leukemic cells. Mifepristone acts like a decoy that prevents midostaurin from binding to the glycoprotein."

Although more testing and validation is needed, the researchers say mifepristone or other agents with similar AGP-binding properties could be tested in future clinical trials of combination TKI therapies, or developed as protein plasma "decoys" to increase the effectiveness of molecularly targeted therapies.

Screening of the Johns Hopkins Drug Library has offered tantalizing promises of more drugs that may function like mifepristone to restore anti-FLT3 activity and might synergize with TKI therapies in other ways.

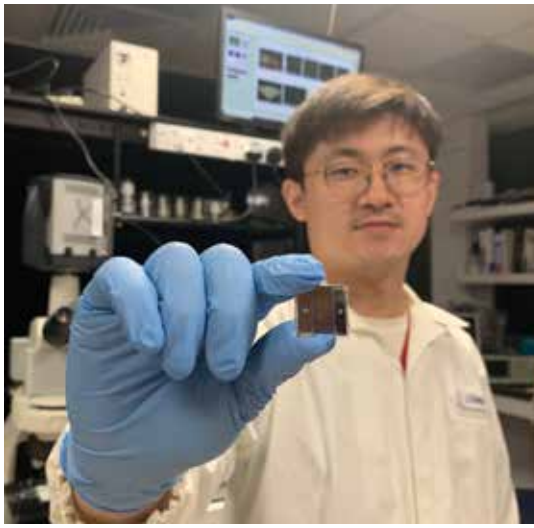
"There may be ways to affect the pharmacology of the human body to give these old drugs new life," Young says.

References:
[1] doi: *https://doi.org/10.1158/2643-3230.BCD-20-0119*

Scientists create device that uses 'light tweezers' to trap and move viruses

A team of scientists led by Nanyang Technological University, Singapore (NTU Singapore) has created a laser-powered device that can trap and move viruses using light.

The device, which has the ability to manipulate light to act as 'tweezers', would aid in the development of new approaches to



disease diagnosis and the study of viruses, as the device can precisely 'move' a single virus to target a particular part of a cell.

It would also aid in vaccine development, as the device allows scientists to separate damaged or incomplete viruses from a group of thousands of other specimens in under one minute, compared to current processes which are tedious and lacking in precision, said the scientists.

Associate Professor Eric Yap, from NTU's Lee Kong Chian School of Medicine, a medical geneticist who co-led the research, said: "The conventional method of analysing viruses today is to study a population of thousands or millions of viruses. We only know their average behaviour as an entire population. With our laser-based technology, single viruses could be studied individually.

"As well as diagnosing diseases, our device could be used to spot the outliers – the rare individual virus that has the potential to evolve and create the next wave of an epidemic, for instance. This brings us into an era where we can contemplate precision diagnostics at the single virus level."

The researchers tested their device known as a digital virus manipulation chip on adenoviruses, which is a group of common viruses that can cause cold-like symptoms, measuring 90 to 100 nanometre (nm) in diameter. Although not yet tested on coronaviruses, it has the potential to be used for research on SARS-CoV-2 virus, which causes COVID-19, as it is similar in size, between 80 to 120 nm in diameter.

Professor Liu Aiqun, from NTU's School of Electrical and Electronic Engineering, who led the research, said: "Our invention uses light to manipulate viruses in a certain size range and we have proven that it works with adenoviruses. We believe our device could also be used to trap and concentrate SARS-CoV-2 for research and diagnosis."

The findings of the study were published in the peer-reviewed scientific journal ACS Sensors in September.

Measuring 2 cm by 2 cm, about the size of a thumbnail, the device consists of a chip that is made from a wafer of silicon oxide and silicon nitride, with nanometre sized cavities to contain the trapped viruses. Above the chip is a laser directing highly focused light beams with the right amount of energy to act as a pair of 'tweezers' that can isolate and move viruses.

The device works by loading a fluid that contains viruses, such as blood, into the chip (see video: *https://youtu.be/xGqNHUQTYN8*). After which, a laser beam is directed on to it, forming spots of light. As the intensity of the light is highest in the centre of the spots, this creates a strong force that attracts and traps the virus in designated c

By shifting the locations of the spots of light, viruses can be freely moved to other parts of the chip. This allows for the easy sorting and concentrating of viruses of different sizes, ranging from 40 nm to 300 nm. MEH

Scientists make sperm from mouse pluripotent stem cells and produce healthy, fertile offspring

For species that rely on sexual reproduction, including mice and men, offspring can only happen if sperm from the male fertilize eggs from the female. Even artificial fertilization techniques depend on donors for both of these cells. However, a new study led by researchers at the Institute for the Advanced Study of Human Biology (ASHBi) at Kyoto University shows that mouse pluripotent stem cells can differentiate into functional sperm. These sperm were successfully used to produce healthy, fertile offspring and provide the most comprehensive model yet for generating male germ cells in a test tube.

Pluripotent stem cells have allowed scientists to study how each and every cell in the body is formed. Brain cells, heart cells, and livers cells are just some examples of the cell types made from these stem cells and now being used in patients as experimental cell therapies. However, some cell types remain difficult to make from pluripotent stem cells, particularly sperm cells.

Among all cell types, germ cells are unique for many reasons. First, unlike all other cells, which carry 46 chromosomes, germs cells only have 23 chromosomes, with the egg having all its chromosomes from the mother, and sperm having all its chromosomes from the father.

Furthermore, they are the only cells that parents actually pass to their offspring, which makes them, according to ASHBi Director Mitinori Saitou, one of the authors of the study, "the driving force that sustains and evolves a species".

Although more research is needed, scientists have made significant strides in producing sperm cells from pluripotent stem cells, at least for mouse. The process is generally broken into three stages that mimic natural development. First, the stem cells are differentiated into primordial germ cells, then into spermatogonia stem cells, which is when the male sex is determined, and finally sperm.

Spermatogonia stem cells are what allow the male to produce sperm for a lifetime, but this second stage has proven to be the most difficult to recreate in the laboratory.

Mouse spermatogonia stem cells can be made, but inefficiently, which is why Dr. Yukiko Ishikura, another contributor to the study, concluded that optimizing the differentiation process was needed.

"The differentiation rate is about one week slower than in the mouse body and the contribution of the spermatogonia stem cells to spermatogenesis is low," she said.

Beginning with mouse pluripotent stem cells, she and colleagues prepared primordial germ cells and examined over 10000 of them in 8 different conditions using what they call a "new reconstituted testis method".

To validate the best conditions for manufacturing spermatogonia stem cells, they confirmed that the cells shared several properties with those in mouse testis, including the expression of key genes, epigenetics, and the transient upregulation of retrotransposons, which Saitou was especially unexpected.

"Retrotransposon control was recaptured. Retrotransposon regulation is a mechanism to control the effects of retrotransposons on key genes by randomly repeating their regulation," he said.

The identical epigenetics was also crucial. While genes are made of DNA, their expressions depend on epigenetic factors like DNA methylation. Germ cells show distinct DNA methylation patterns during their development, patterns that are considered crucial for their ability to produce offspring.

To confirm the spermatogonia stem cells behaved just as those produced in the body, the researchers injected their laboratory-made spermatogonia stem cells into mouse testes, where the cells were allowed to develop into spermatids. These spermatids were harvested and injected into eggs to grow embryos. The embryos were then used to impregnate mice, which went on to give birth to healthy offspring that were also fertile.

The findings provide the most comprehensive reconstitution of male germ cell development yet starting from pluripotent stem cells.

"This is the first study to reconstitute functional sperm from mouse pluripotent stem cells in a test tube. This open new possibilities for male germ cell differentiation," said Saitou.

Reference:

Yukiko Ishikura, et. al. In vitro reconstitution of the whole male germ-cell development from mouse pluripotent stem cells. *Cell Stem Cell*, 2021. **doi:** *https://doi.org/10.1016/j.stem.2021.08.005* MEH

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Call for urgent IHR reforms to reduce risk from future pandemics

As work is underway to reform global governance of pandemic preparedness and response, a new paper published in *The Lancet*[1] offers comprehensive and specific ideas for legal reform. This is based on a careful mapping and analysis of the Independent Panel's authoritative COVID-19 chronology.

Through analysis of the meticulous timeline, the authors, including many members of the Independent Panel Secretariat, sought to understand how and when the existing legal regime – the International Health Regulations (IHR) – helped or hindered rapid alert and response. The Independent Panel for Pandemic Preparedness and Response[2] released the authoritative chronology at the time of its main report in May 2021.

"The Independent Panel's authoritative chronology helps to pinpoint where the IHR obligations are not precise enough, or fail to encourage countries and decision makers to more proactively respond to outbreaks with pandemic potential," said Dr. Sudhvir Singh, lead author on the paper and an advisor to the Independent Panel. "COVID-19 demonstrated that losing even a few hours or days of time can have deadly consequences."

The IHR are currently the only legally binding international instrument governing countries' obligations to report and respond to pathogens that could result in cross-border disease outbreaks and potential public health emergencies of international concern.

Revised following the Severe Acute Respiratory Syndrome outbreak almost two decades ago, the IHR focus on balancing disease notification and health risks with international trade and travel considerations. They specify when and how States should notify WHO of a local disease outbreak, and broadly what actions WHO and States take following that notification.

"Despite significant focus on origin countries' obligations to rapidly report outbreaks, COVID-19 has shown that the existing obligations under the IHR are insufficient for our interdependent and digital world," said Dr. Alexandra Phelan, an Assistant Professor at Georgetown University and senior author.

"Our analysis demonstrates that collectively, countries urgently need to update our international system to respond to the potential rapid spread of a high impact respiratory pathogen. We have concrete suggestions for ways in which the IHR may be revised or amended, as well as the approach and issues that must be covered in any new legal framework, like a pandemic treaty."

The Independent Panel developed a peer-reviewed, authoritative chronology that shows the day-by-day, and at times hour-by-hour and even minute-by-minute actions taken by local, national and international actors when a novel respiratory virus was identified in December to the end of March when COVID-19 had spread worldwide.

The Lancet paper authors have established and analysed the chronology, and mapped the actions taken against IHR obligations. The authors provide analysis of five sequential phases of the emergence of the pandemic, and suggest objectives to detect and mitigate high-impact respiratory pathogens in future. These suggestions can inform those working on reforms to the IHR and a potential pandemic treaty.

The analysis also adds even more weight to the argument that a pandemic treaty, building on and complementing the IHR, would fill deadly gaps in the current system, and instil norms of equity, justice and global public goods. This includes faster and ongoing sharing of data, variant tracking and the equitable development and distribution of diagnostics, therapeutics and vaccines.

"It's clear: if a new, fast-spreading pathogen were to emerge next month, the current IHR regime would not protect people and trade as intended," said Dr. Singh. "We suggest change to the IHR and a new treaty or other instrument that would result in more information shared faster, WHO able to investigate rapidly, all countries moving immediately to assess risk, and tools – like tests and vaccines – available to all who need them."

Dr. Phelan noted: "The upcoming Special Session of the World Health Assembly is a critical opportunity for Member States to move ahead with strengthening the IHR and to agree on a process for negotiating a pandemic treaty. We must not lose this opportunity to protect global public health and future generations."

The World Health Assembly Special Session is scheduled from 29 November-1 December 2021. A new pandemic legal instrument is the sole major item on the agenda.

Reference

[1] Sudhvir Singh, et. al. How an outbreak became a pandemic: a chronological analysis of crucial junctures and international obligations in the early months of the COVID-19 pandemic. *The Lancet*. Nov 8, 2021.

doi: *https://doi.org/10.1016/S0140-6736(21)01897-3*

[2] The Independent Panel for Pandemic Preparedness and Response *https://theindependentpanel.org*

Study offers insights on why the elderly are more susceptible to Covid-19

Among the populations most significantly affected by Covid-19 are the elderly and patients with pre-existing medical conditions including diabetes, hypertension, obesity, metabolic syndrome, cardiovascular disease and chronic lung diseases like COPD and asthma.

In a new study published in the journal *JCI Insight*[1], Brown University researchers describe the cellular and molecular events that explain why these groups have a higher risk of infection as well as of severe side effects and death.

"This paper details a major discovery in Covid-19," said corresponding author Dr. Jack A. Elias, an immunologist and dean of medicine and biological sciences at Brown. "It shows that levels of a protein called chitinase 3-like-1 increase with age as well as co-morbid diseases and infection. What's more, chitinase 3-like-1 augments SARS CoV-2 infection."

The findings not only answer important questions about key mechanisms of the complex SARS-CoV-2, Elias said, but also have direct implications for the development of therapeutics to control the viral infection.

Elias is part of a National Institutes of Health-funded laboratory that focuses on the cell and molecular biology of lung injury and repair. Researchers in the lab, including lead study author Suchitra Kamle and co-author Chun Geun Lee, have recently focused on the biology of enzymes and enzyme-like molecules, called chitinases and chitinase-like proteins, respectively. Of particular interest is a chitinase-like protein referred to as chitinase 3-like-1, a molecule naturally found in blood.

"We've been studying this gene family here at Brown for a while and we know that it has a large number of biologic effects, as well as tremendously important roles in both health and diseases," said Lee, a professor of molecular microbiology and immunology.

Chitinase 3-like-1 is the cornerstone of a critical pathway that is activated during injury and inflammation. These research-

ers and others have shown that circulating levels of chitinase 3-like-1 increase during infection, especially in diseases characterized by inflammation and tissue alterations – like emphysema, asthma and COPD, some of the same co-morbid diseases that are risk factors for Covid-19.

Interestingly, Lee said, levels of chitinase 3-like-1 have also been shown to increase during normal ageing. In fact, they have been reported to be the best predictor of all-cause mortality in people in their 80s.

The researchers thought they might be able to take some of the work they've already done with this gene family and apply it to Covid-19, Elias said. They decided to examine the relationship between chitinase 3-like-1 and the receptor ACE2, the spike protein to which the SARS-CoV-2 binds to enter human cells.

In a series of studies, the researchers compared the effects of chitinase 3-like-1 on ACE2 as well as on other protease enzymes that metabolize the spike protein and contribute to infection. They examined these interactions in the lungs of mice that were genetically modified to have exaggerated levels of chitinase 3-like-1 as well as mice deficient in chitinase 3-like-1. In the lab, Kamle led experiments that examined the effects of chitinase 3-like-1 on human lung epithelial cells.

The researchers found that levels of chitinase 3-like-1 increased with age, comorbid diseases and infection. In addition, they noted that chitinase 3-like-1 was a potent stimulator of the receptor that SARS-CoV-2 uses to infect cells.

Spurred by this discovery, the researchers developed a humanized monoclonal antibody called FRG that attacks a particular region of chitinase 3-like-1 – a step that turned out to be critical. They found that this "therapeutic" antibody, as well as another small molecule, powerfully blocked the induction of the ACE2 receptor.

"So in that way, the virus cannot enter into the host system," said Kamle, a Brown investigator in molecular microbiology and immunology as well as antibody engineering. "This means there will be less infection in the presence of this therapeutic FRG antibody."

These findings could pave the way for the development of therapeutics to protect people from infection, Elias said.

Reference:

Suchitra Kamle, et. al. Chitinase 3-like-1 is a therapeutic target that mediates the effects of aging in Covid-19. *JCI Insght*. Nov. 8, 2021. doi: *https://doi.org/10.1172/jci.insight.148749*

US NIH builds large study population to research long-term effects of Covid-19

The US NIH National Institutes of Health awarded nearly $470 million to build a national study population of diverse research volunteers and support large-scale studies on the long-term effects of Covid-19. The NIH REsearching Covid to Enhance Recovery (RECOVER) Initiative <*https://recovercovid.org/*> made the parent award to New York University (NYU) Langone Health, New York City, which will make multiple sub-awards to more than 100 researchers at more than 30 institutions and serves as the RECOVER Clinical Science Core.

This major new award to NYU Langone supports new studies of Covid-19 survivors and leverages existing long-running large cohort studies with an expansion of their research focus. This combined population of research participants from new and existing cohorts, called a meta-cohort, will comprise the RECOVER Cohort.

NIH launched the RECOVER Initiative to learn why some people have prolonged symptoms (referred to as long Covid) or develop new or returning symptoms after the acute phase of infection from SARS-CoV-2, the virus that causes Covid-19. The most common symptoms include pain, headaches, fatigue, "brain fog", shortness of breath, anxiety, depression, fever, chronic cough, and sleep problems.

"We know some people have had their lives completely upended by the major long-term effects of Covid-19," said NIH Director Francis S. Collins, M.D., Ph.D. "These studies will aim to determine the cause and find much needed answers to prevent this often-debilitating condition and help those who suffer move toward recovery."

Data from the RECOVER Cohort will include clinical information, laboratory tests, and analyses of participants in various stages of recovery following SARS-CoV-2 infection. With immediate access to data from existing, diverse study populations, it is anticipated researchers will be able to accelerate the timeline for this important research.

"This scientifically rigorous approach puts into place a collaborative and multidisciplinary research community inclusive of diverse research participants that are critical to informing the treatment and prevention of the long-term effects of Covid-19," said Gary H. Gibbons, M.D., director of NIH's National Heart, Lung, and Blood Institute and one of the co-chairs of the RECOVER Initiative.

Studies will include adult, pregnant, and paediatric populations; enrol patients during the acute as well as post-acute phases of the SARS-CoV-2 infection; evaluate tissue pathology; analyse data from millions of electronic health records; and use mobile health technologies, such as smartphone apps and wearable devices, which will gather real-world data in real time. Together, these studies are expected to provide insights over the coming months into many important questions including the incidence and prevalence of long-term effects from SARS-CoV-2 infection, the range of symptoms, underlying causes, risk factors, outcomes, and potential strategies for treatment and prevention.

Reducing the impact of vascular dementia

Vascular dementia is the second most common form of dementia after Alzheimer's disease. Between 5 and 10 per cent of people with dementia have vascular dementia alone. In the Middle East the condition affects up to 18 per cent of people 80 years and above, and is set to rise by 5% in the next 30 years as the ageing population grows.

Stroke-related dementia

Sometimes vascular dementia follows a stroke due to the blood vessels in the brain becoming narrowed or blocked by a clot. This can cause cognitive impairments which can lead to a diagnosis of 'post-stroke dementia' or 'single infarct dementia'.

Sometimes, vascular dementia may be caused by transient ischaemic attacks (TIAs) which can be so small that the symptoms last less than 24 hours or there are no symptoms whatsoever – as the blockage clears itself. However, the brain can be left with small but widespread damage leading to 'multi-infarct dementia'.

Subcortical dementia

It is thought subcortical dementia is the most common type of vascular dementia. It happens when very small blood vessels deep within the brain develop thick walls and become stiff and narrowed, causing a reduction in blood flowing through them. This causes damage to the bundles of nerve fibres that carry signals around the brain, leading to symptoms of dementia.

Reducing the risk of vascular dementia

Not everyone that has a stroke will develop post-stroke dementia, but about 1 in 5 people who have a stroke will develop vascular dementia within 6 months. Vascular dementia is an age-related condition that rarely affects people under 65. However, stroke-related vascular dementia shares the same risk factors of stroke.

Royal Brompton Hospital's consultant cardiologist, Dr Resham Baruah, explains: "The risk of vascular dementia can be reduced by leading an active, healthy lifestyle and avoiding smoking. It is important to identify heart rhythm issues, as well as controlling high blood pressure and cholesterol with medication and regular check-ups."

A healthy heart ensures that enough blood is pumped to the brain, while healthy blood vessels enable the oxygen- and nutrient-rich blood to reach the brain so it can function normally.

- To find out more visit: *rbhh-specialistcare.co.uk*

Obesity: It's what we eat, not how much we eat

A perspective in *The American Journal of Clinical Nutrition* challenges the 'energy balance model', which says weight gain occurs because individuals consume more energy than they expend. According to the authors, "conceptualizing obesity as a disorder of energy balance restates a principle of physics without considering the biological mechanisms underlying weight gain". The authors argue for the "carbohydrate-insulin model", which explains obesity as a metabolic disorder driven by what we eat, rather than how much.

Obesity has reached epidemic proportions globally, with at least 2.8 million people dying each year as a result of being overweight or obese, according to figures from the World Health Organisation. Countries in the Middle East have some of the highest obesity rates in the world. Around 35% of the populations of Jordan, Saudi Arabia and Qatar are classified as obese. In the United Arab Emirates it is 31% according to the World Population Review[1] which cites figures from the WHO.

In general, dietary guideless such as the Dietary Guidelines for Americans 2020 – 2025[2] state that losing weight "requires adults to reduce the number of calories they get from foods and beverages and increase the amount expended through physical activity".

This approach to weight management is based on the century-old energy balance model which states that weight gain is caused by consuming more energy than we expend. In today's world, surrounded by highly palatable, heavily marketed, cheap processed foods, it's easy for people to eat more calories than they need, an imbalance that is further exacerbated by today's sedentary lifestyles. By this thinking, overeating, coupled with insufficient physical activity, is driving the obesity epidemic. On the other hand, despite decades of public health messaging exhorting people to eat less and exercise more, rates of obesity and obesity-related diseases have steadily risen.

Flaws in the energy balance model

The authors of "The Carbohydrate-Insulin Model: A Physiological Perspective on the Obesity Pandemic," a perspective published in *The American Journal of Clinical Nutrition*[3], point to fundamental flaws in the energy balance model, arguing that an alternate model, the carbohydrate-insulin model, better explains obesity and weight gain. Moreover, the carbohydrate-insulin model points the way to more effective, long-lasting weight management strategies.

According to lead author Dr. David Ludwig, Endocrinologist at Boston Children's Hospital and Professor at Harvard Medical School, the energy balance model doesn't help us understand the biological causes of weight gain: "During a growth spurt, for instance, adolescents may increase food intake by 1,000 calories a day. But does their overeating cause the growth spurt or does the growth spurt cause the adolescent to get hungry and overeat?"

Modern dietary patterns

In contrast to the energy balance model, the carbohydrate-insulin model makes a bold claim: overeating isn't the main cause of obesity. Instead, the carbohydrate-insulin model lays much of the blame for

the current obesity epidemic on modern dietary patterns characterized by excessive consumption of foods with a high glycaemic load: in particular, processed, rapidly digestible carbohydrates. These foods cause hormonal responses that fundamentally change our metabolism, driving fat storage, weight gain, and obesity.

When we eat highly processed carbohydrates, the body increases insulin secretion and suppresses glucagon secretion. This, in turn, signals fat cells to store more calories, leaving fewer calories available to fuel muscles and other metabolically active tissues. The brain perceives that the body isn't getting enough energy, which, in turn, leads to feelings of hunger. In addition, metabolism may slow down in the body's attempt to conserve fuel. Thus, we tend to remain hungry, even as we continue to gain excess fat.

To understand the obesity epidemic, we need to consider not only how much we're eating, but also how the foods we eat affect our hormones and metabolism. With its assertion that all calories are alike to the body, the energy balance model misses this critical piece of the puzzle.

The carbohydrate-insulin model

While the carbohydrate-insulin model is not new – its origins date to the early 1900s – *The American Journal of Clinical Nutrition* perspective is the most comprehensive formulation of this model to date, authored by a team of 17 internationally recognized scientists, clinical researchers, and public health experts. Collectively, they have summarized the growing body of evidence in support of the carbohydrate-insulin model. Moreover, the authors have identified a series of testable hypotheses that distinguish the two models to guide future research.

Radical implications for weight management

Adoption of the carbohydrate-insulin model over the energy-balance model has radical implications for weight management and obesity treatment. Rather than urge people to eat less, a strategy which usually doesn't work in the long run, the carbohydrate-insulin model suggests another path that focuses more on what we eat. According to Dr. Ludwig, "reducing consumption of the rapidly digestible carbohydrates that flooded the food supply during the low-fat diet era lessens the underlying drive to store body fat. As a result, people may lose weight with less hunger and struggle."

The authors acknowledge that further research is needed to conclusively test both models and, perhaps, to generate new models that better fit the evidence. Toward this end, they call for constructive discourse and "collaborations among scientists with diverse viewpoints to test predictions in rigorous and unbiased research". MEH

References:

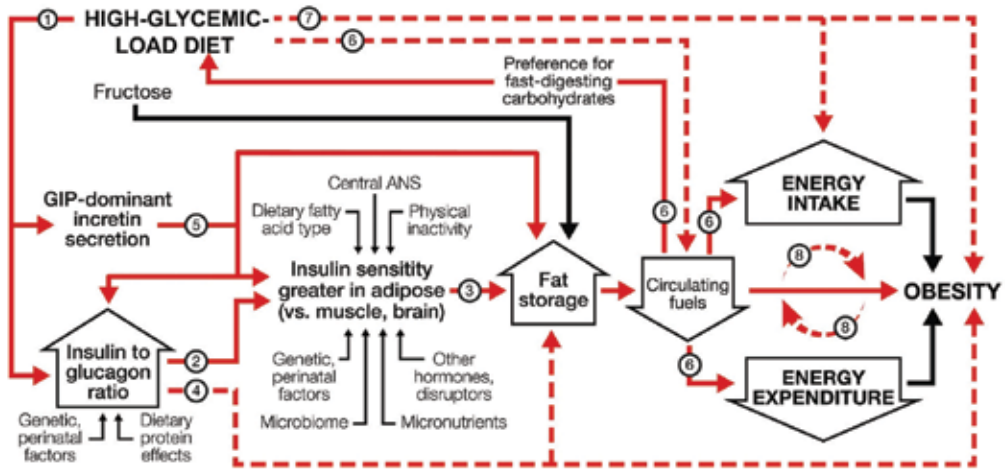
[1] *https://worldpopulationreview.com/country-rankings/obesity-rates-by-country*

[2] *https://www.dietaryguidelines.gov/*

[3] Ludwig D.S., et al. The carbohydrate-insulin model: a physiological perspective on the obesity pandemic. *The American Journal of Clinical Nutrition*.

doi: *https://doi.org/10.1093/ajcn/nqab270.*

FIGURE 1 Dynamic phase of obesity development in the carbohydrate-insulin model. The relation of energy intake and ...



Ludwig et. al. / Oxford University Press

Dynamic phase of obesity development in the carbohydrate-insulin model. The relation of energy intake and expenditure to obesity is congruent with the conventional model. However, these components of energy balance are proximate, not root, causes of weight gain. In the compensatory phase (not depicted), insulin resistance increases, and weight gain slows, as circulating fuel concentration rises. (Circulating fuels, as measured in blood, are a proxy for fuel sensing and substrate oxidation in key organs.) Other hormones with effects on adipocytes include sex steroids and cortisol. Fructose may promote hepatic de novo lipogenesis and affect intestinal function, among other actions, through mechanisms independent of, and synergistic with, glucose. Solid red arrows indicate sequential steps in the central causal pathway; associated numbers indicate testable hypotheses as considered in the text. Interrupted red arrows and associated numbers indicate testable hypotheses comprising multiple causal steps. Black arrows indicate other relations. ANS, autonomic nervous system; GIP, glucose-dependent insulinotropic peptide.

Exercise is medicine

New studies and technologies on exercises for older adults

There is emerging evidence that older adults who participate in regular exercise will see significant psychological and cognitive benefits. With more people living longer and healthier, the WHO predicts that the population aged 60+ years will nearly double by 2050 from 12% to 22%.

According to the American College of Sport Medicine, exercise prescription for older adults should include aerobic exercise, muscle strengthening exercises, and flexibility exercises.

The U.S. Centers for Disease Control and Prevention, says that strength training helps reduce the symptoms of many chronic diseases and conditions that commonly afflict older adults, including arthritis, diabetes, osteoporosis, heart disease, obesity and back pain.

Technogym – brand leader in the field of fitness, wellness and health solutions and services, thanks to its over 35 years of experience and collaborations with prestigious universities around the world – has taken this concept to the extreme and is currently working with Professor Robert Newton from Edith Cowen University of Perth on the effect of exercise with cancer patients that were originally believed to not benefit from strength training.

The four core elements to exercise. Exercise must be *SIMPLE, EFFICIENT, ASSISTED and QUICK*. Technogym's Biocircuit embodies these core elements and is the perfect solution.

Biocircuit is a fully automated circuit that guides members throughout the whole workout, not only where to go and how long to work for, but on specific loads related to their calculated 1 repetition max, repetition number, tempo and range of motion. It also pre-sets the equipment into position based on the individual's anthropometrics.

Moreover, thanks to the Biodrive patented technology, Biocircuit is the first training line offering a personalized workout in a safe, guided, and effective way. Biodrive's balances all phases of movement, both concentric and eccentric. This means that resistance and pace are optimized for maximum effectiveness and safety, based on individual needs and objectives.

Biocircuit's range of resistance offering suits different body types, special requirements and various injuries all in one machine through it's isotonic, elastic viscous or isokinetic resistances.

The circuit comes in two forms, Biocircuit and Biocircuit Free. Biocircuit consists of six strengths and six cardio stations with a fixed work/rest time ratio, allowing up to 12 users to work simultaneously at all times with no unexpected waiting times. All of this is connected to the Technogym Mywellness Ecosystem to track and monitor all things wellness in a single touch point. MEH

On the pulse

Qualisys Motion Capture Gait Analysis Module

For more than 30 years, Qualisys has been providing motion capture solutions for Gait Analysis. We understand that there is no one-size-fits-all solution for gait labs – that's why our solutions can be as streamlined or flexible as they need to be.

The Qualisys Gait Module is optimized for day-to-day use, where data needs to be analysed efficiently and consistently. It takes advantage of our Project Automation Framework (PAF), which provides data management, data collection, analysis, and reporting – all from one interface within our Software Qualisys Track Manager (QTM).

Cameras

Qualisys offers a range of cameras for different needs, whether your room is small or big. A typical gait lab setups consist of 8-12 cameras to cover a capture volume of at least 4 × 1.5 × 2 m (length × width × height).

All your reports safe in the cloud.

A Word or online web report is populated with the gait analysis results.

The reporting platform lets you interact with your motion capture data like you never could before. The platform consists of the Report Center and Web Reports for several activities, each including data, video and a 3D viewer in a single document.

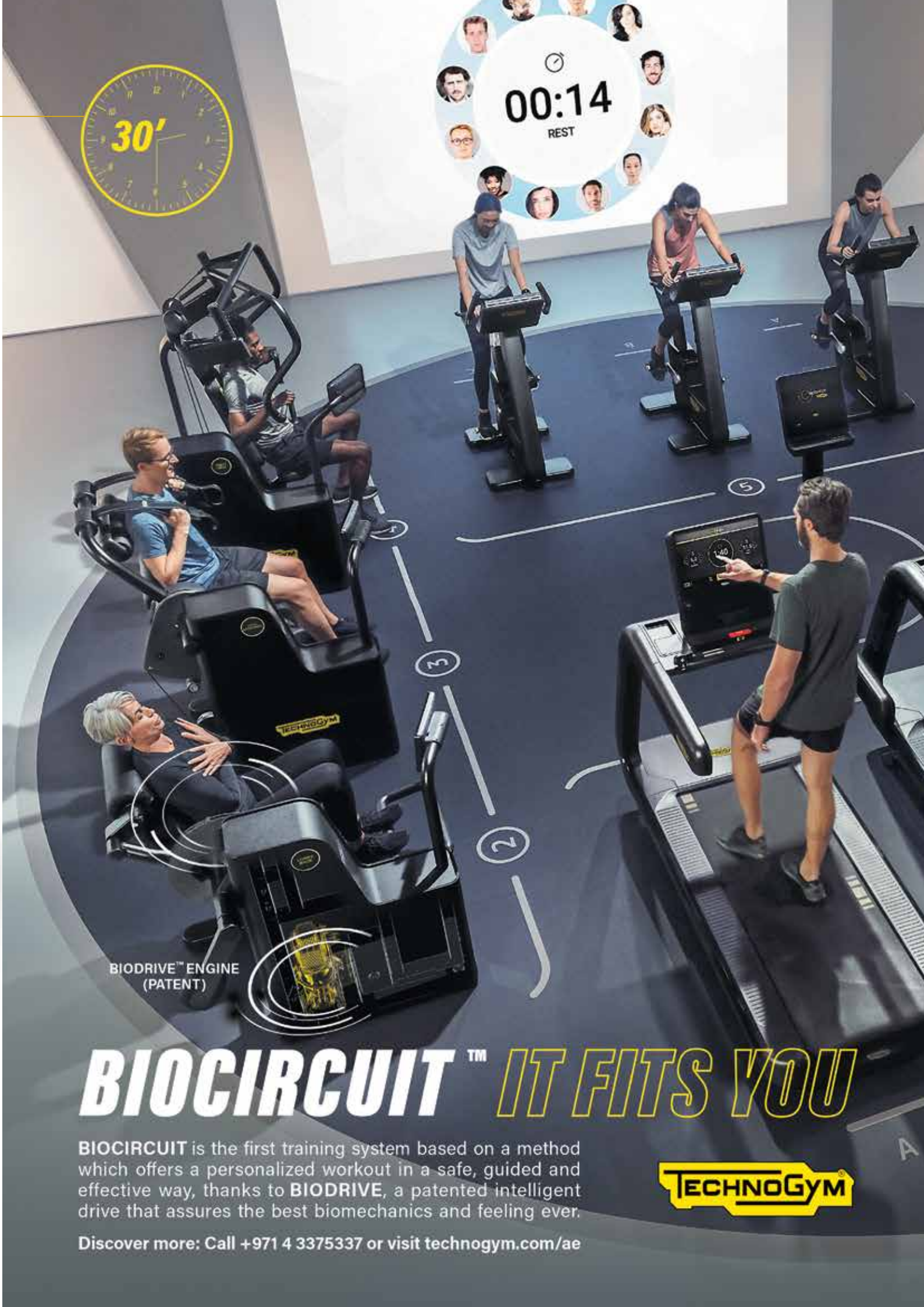
A flexible system for your research project

Qualisys camera systems integrate seamlessly with many other systems, including force plates, EMG, and eye-trackers, offering endless possibilities for your projects. Use our automatic labeling mechanism, AIM, to process the data that you need quickly and efficiently. You can export via c3d, text or MATLAB files for further analysis.

Choosing the right motion capture system for your gait lab

Qualisys offers gait solutions for both research and clinical users.

- Learn more at: *www.qualisys.com* MEH



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University of Cambridge

Artificial pancreas trialled for outpatients with type 2 diabetes

An artificial pancreas could soon help people living with type 2 diabetes and who also require kidney dialysis. Tests show that the device can help patients safely and effectively manage their blood sugar levels and reduce the risk of low blood sugar levels.

An artificial pancreas could soon help people living with type 2 diabetes and who also require kidney dialysis. Tests led by the University of Cambridge and Inselspital, University Hospital of Bern, Switzerland, show that the device can help patients safely and effectively manage their blood sugar levels and reduce the risk of low blood sugar levels.

Diabetes is the most common cause of kidney failure, accounting for just under a third (30%) of cases. As the number of people living with type 2 diabetes increases, so too does the number of people requiring dialysis or a kidney transplant. Kidney failure increases the risk of hypoglycaemia and hyperglycaemia – abnormally low or high levels of blood sugar respectively – which in turn can cause complications from dizziness to falls and even to coma.

Managing diabetes in patients with kidney failure is challenging for both patients and healthcare professionals. Many aspects of their care are poorly understood, including targets for blood sugar levels and treatments. Most oral diabetes medications are not recommended for these patients, so insulin injections are the most commonly used diabetes therapy – though optimal insulin dosing regimens are difficult to establish.

A team at the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust has previously developed an artificial pancreas with the aim of replacing insulin injections for patients living with type 1 diabetes. In research

published in *Nature Medicine*[1], the team – working with researchers at Bern University Hospital and University of Bern, Switzerland – has shown that the device can be used to support patients living with both type 2 diabetes and kidney failure.

The artificial pancreas device

The artificial pancreas is powered by software in the user's smartphone that sends a signal to an insulin pump to adjust the level of insulin the patient receives. A glucose monitor measures the patient's blood sugar levels and sends these back to the smartphone to enable it to make further adjustments.

Unlike the artificial pancreas being used for type 1 diabetes, this version is a fully closed loop system – whereas patients with type 1 diabetes need to tell their artificial pancreas that they are about to eat to allow adjustment of insulin, for example, with this new version they can leave the device to function entirely automatically.

Unmet need

Dr Charlotte Boughton from the Wellcome Trust-MRC Institute of Metabolic Science at the University of Cambridge, who led the study, said: "Patients living with type 2 diabetes and kidney failure are a particularly vulnerable group and managing their condition – trying to prevent potentially dangerous highs or lows of blood sugar levels – can be a challenge. There's a real unmet need for new approaches to help them manage their condition safely and effectively."

The artificial pancreas is a small, portable medical device designed to carry out the function of a healthy pancreas in controlling blood glucose levels, using digital technology to automate insulin delivery. The system is worn externally on the body, and is made up of three functional components: a glucose sensor, a computer algorithm to calculate the insulin dose, and an insulin pump.

The team recruited 26 patients requiring dialysis between October 2019 and November 2020. Thirteen participants were randomised to receive the artificial pancreas first and 13 to receive standard insulin therapy first. The researchers compared how long patients spent in the target blood sugar range (5.6 to 10.0 mmol/L) over a 20 day period as outpatients.

Results of trial

Patients using the artificial pancreas spent on average 53% of their time in the target range, compared to 38% when they used the control treatment. This equated to around 3.5 additional hours every day spent in the target range compared with the control therapy.

Mean blood sugar levels were lower with the artificial pancreas (10.1 vs. 11.6 mmol/L). The artificial pancreas reduced the amount of time patients spent with potentially dangerously low blood sugar levels, or 'hypos'.

The efficacy of the artificial pancreas improved considerably over the study period as the algorithm adapted, and the time spent in the target blood sugar range increased from 36% on day one to over 60% by the twentieth day. This finding highlights the importance of using an adaptive algorithm, which can adjust in response to an individual's changing insulin requirements over time.

Patient experience

When asked about their experiences of using the artificial pancreas, everyone who responded said they would recommend it to others. Nine out of ten (92%) reported that they spent less time managing their diabetes with the artificial pancreas than during the control period, and similar numbers (87%) were less worried about their blood sugar levels when using it.

Other benefits of the artificial pancreas reported by study participants included less need for finger-prick blood sugar checks, less time required to manage their diabetes resulting in more personal time and freedom, and improved peace of mind and reassurance. Downsides included discomfort wearing the insulin pump and carrying the smartphone.

Senior author Professor Roman Hovorka, also from the Wellcome Trust-MRC Institute of Metabolic Science, said: "Not only did the artificial pancreas increase the amount of time patients spent within the target range for the blood sugar levels, but it also gave the users peace of mind. They were able to spend less time having to focus on managing their condition and worrying about the blood sugar levels, and more time getting on with their lives."

Dr Boughton added: "Now that we've shown the artificial pancreas works in one of the more difficult-to-treat groups of patients, we believe it could prove useful in the wider population of people living with type 2 diabetes."

What's next?

The team is currently trialling the artificial pancreas for outpatient use in people living with type 2 diabetes who do not need dialysis and exploring the system in complex medical situations such as perioperative care.

Dr Lia Bally, who co-led the study in Bern, said: "The artificial pancreas has the potential to become a key feature of integrated personalised care for people with complex medical needs."

The research was supported by the NIHR Cambridge Biomedical Research Centre, The Novo Nordisk UK Research Foundation, Swiss Society for Endocrinology and Diabetes, and Swiss Diabetes Foundation and Swiss Kidney Foundation.

Reference:

[1] Charlotte K. Boughton, et. al. Fully automated closed-loop glucose control compared with standard insulin therapy in adults with type 2 diabetes requiring dialysis: an open-label, randomized crossover trial. Nature Medicine, 2021; **doi:** *https://doi.org/10.1038/s41591-021-01453-z*

Major diabetes organisations EASD and ADA launch new Consensus Report to manage type 1 diabetes

A new comprehensive Consensus Report to manage type 1 diabetes (T1D) has been launched by two leading diabetes societies – the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA). The final report, launched at the online annual meeting of EASD late September, is also published in *Diabetologia* (the official journal of EASD) and *Diabetes Care* (the official journal of ADA).

EASD and ADA decided together that a wide-ranging document to capture best practice for T1D was needed after their successful collaboration to provide similar guidance for people with type 2 diabetes (T2D) back in 2019. Although people with T1D represent 5-10% of all people with diabetes, this still amounts to over 25 million people worldwide.

"This new consensus statement not only brings in the advances that have been made in treating type 1 diabetes in recent years, but also covers other vital areas from a patient perspective – such as the psychosocial consequences of living with the condition, that can sometimes be neglected," explains co-author Dr Anne L. Peters, Professor of Clinical Medicine at Keck School of Medicine, University of Southern California, Los Angeles, CA, USA.

While various other guidance has been published in the past relating to people living with T1D, a clear consensus document has been lacking, and recommendations for people with T1D are often confused with or 'bundled in' with those for people who have T2D.

To get a broad range of perspectives, the writing team for these new guidelines included 14 experts, with half based in the USA and half in Europe, across a range of healthcare disciplines.

Guideline content

The areas covered in the report are: diagnosis, goals of therapy and blood sugar targets, schedule of care, diabetes self-management education and additional behavioural considerations, glucose monitoring, insulin therapy, managing hypoglycaemia, psychosocial care, diabetic ketoacidosis, pancreas and islet cell transplantation, additional therapies, special populations (including pregnant women, older adults, and inpatient management), and developing/future technologies including beta-cell replacement and immunotherapy. Front and centre of the report is the need to address all these factors from the patient's perspective.

While not all the details of the guidance in this new report can be included in this article, some important highlights include an algorithm to accurately diagnose T1D, since no single factor in isolation can accurately confirm the condition. Furthermore, some 40% of individuals diagnosed with T1D as adults are initially misdiagnosed as having T2D, partly because T2D is becoming more common in younger adults due to the rising rates of obesity and physical inactivity.

Psychosocial health

Psychosocial health and living with T1D is also specifically addressed, since between 20% and 40% of people with type 1 diabetes experience diabetes-related emotional distress (including 15% with depression). These psychosocial health issues emerge particularly at the time of diagnosis and when complications develop. Thus the report recommends that self-management difficulties, psychological, and social problems be screened periodically and monitored using validated screening tools, and the healthcare team should be consistently assessing the mental health needs of those living with T1D.

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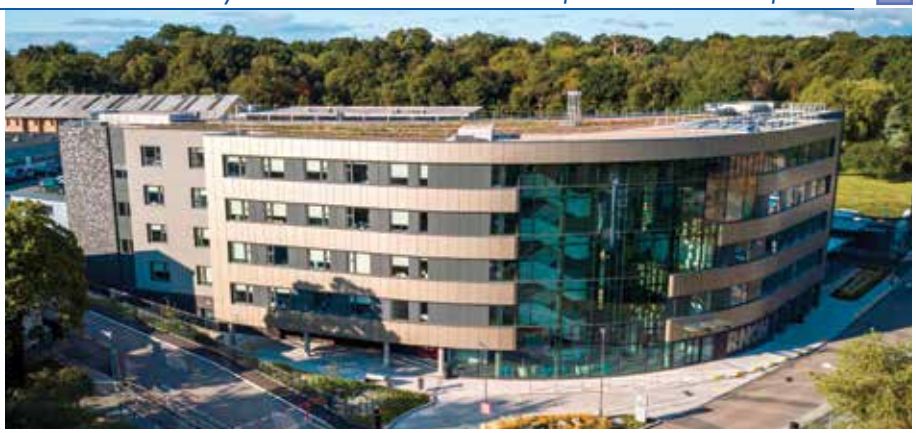
The authors together conclude: "There are still huge gaps in our knowledge about how to prevent, diagnose and treat type 1 diabetes. We are also aware that many people with type 1 diabetes experience inequalities in treatment. We hope that this report will promote better higher quality research to determine optimal care, while helping to share best clinical practice so that all individuals with type 1 diabetes have access to the care they need."

- Download the full Consensus Report here: The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetologia*. *https://doi.org/10.1007/s00125-021-05568-3*

Should I have a robot do my knee replacement?



The RNOH's Stanmore Building

By **William Aston**,
Divisional Clinical Director for Joint Replacement and Orthopaedic Oncology, Royal National Orthopaedic Hospital

Fortunately for myself and thousands of other orthopaedic surgeons the answer is no. Currently, robots cannot autonomously perform a knee or hip replacement and are unlikely to be able to in the medium term. Robots such as the MAKO from Stryker are utilised as a new technology to help the orthopaedic surgeon to improve the accuracy of implant positioning. The MAKO is a haptic robot, meaning that it will guide the surgeon's hand holding the saw within certain parameters to make the bony cuts, onto which sit the implants. It does not allow the saw blade to leave the boundaries set during the preoperative planning, therefore also minimising the risk to the surrounding soft tissue structures such as vessels, ligaments and nerves.

The aim is to improve the accuracy of the cuts and, importantly, to eliminate cuts made that are significantly out of line or angle. This leads to a more accurately placed implant, better soft tissue balancing and potentially improved longevity of the implant and long-term functional outcomes. To prove the benefit of this new technology, data out to 10 - 15 years will be needed to directly compare against outcomes with the current gold standards, however the early results are promising.

Currently there are relatively few of these haptic robots available for use in the National Health Service due to the additional costs, although there are more available in the private sector. The RNOH was the first NHS hospital to engage with this technology for use in the public sector, enabling us to treat patients and enter patients into trials and it is also available for use within the Private Patients Unit here at the Royal National Orthopaedic Hospital.

Royal National Orthopaedic Hospital

The Royal National Orthopaedic Hospital (RNOH) is one of five Specialist Orthopaedic Hospitals in the UK. It has a hand in training 20% of the country's orthopaedic surgeons and is listed as being in the top 10 orthopaedic hospitals in the world.

We provide specialist orthopaedic care across the musculoskeletal spectrum including bone and soft tissue tumours, specialist joint replacement and all areas of the arms, legs and spine. We also have the dedicated specialist complimentary services on hand that are so important to maximise patients' outcomes, including pain management, rehabilitation, orthotics and physiotherapy. Providing regional, national and international patients with specialist high quality care.

- Enquiries regarding advice and treatment can be directed to:

Royal National Orthopaedic Hospital - Private Patients Unit:
Tel: +44 208 909 5114
Web: *www.rnohprivatecare.com*
Email: *rnoh.internationalbusiness.privatecare@nhs.net*

#1 specialist orthopaedic hospital in the UK

The Royal National Orthopaedic Hospital has just been confirmed as the #1 specialist orthopaedic hospital in the UK (again!).

RNOH Private Care offer private healthcare within the NHS. This is delivered via a dedicated private ward with en suite, individual rooms. Delivering the highest standards of service alongside the clinical excellence for which the Royal National Orthopaedic Hospital is renowned. We treat adults and children (from age 0). All profits raised from private work are given straight back to the Trust.

Mr William Aston

Mr William Aston is an internationally fellowship trained orthopaedic surgeon who has worked at the RNOH as a consultant for 12 years. He was honoured to be awarded the ABC Travelling fellowship in 2014 from the British Orthopaedic Association. He specialises in primary and revision knee and hip replacement, through to end stage limb salvage and the management of benign and malignant bone and soft tissue tumours. He is currently the Divisional Clinical Director for Joint replacement and Orthopaedic Oncology and has interests in research and the training of future orthopaedic surgeons.

World leaders in fertility care

Guy's and St Thomas'
Private Healthcare

Guy's and St Thomas' Private Healthcare draws on the expertise of internationally renowned consultants, cutting-edge research and innovation to deliver best-in-class healthcare to patients from the Middle East and around the world.

Our private patient services are part of Guy's and St Thomas' NHS Foundation Trust, which offers clinical excellence combined with the highest standards of care at one of the UK's best-known, safest and most prestigious teaching hospitals.

Fertility is just one of many fields in which our pioneering research has made a significant difference in enhancing health provision. Indeed, two of our fertility services are at the forefront of innovation – our ovarian tissue cryopreservation (OTC) service and our well-established centre for pre-implantation genetic diagnosis (PGD).

Fertility preservation

Ovarian tissue cryopreservation offers female cancer patients the opportunity to preserve their fertility before undergoing treatment such as chemotherapy or stem cell transplants that could make them infertile.

A gynaecologist will collect the ovarian tissue through keyhole surgery before or during chemotherapy. Then, after a safe interval, and when the patient is ready to start a family, they re-implant the ovarian tissue in the pelvis.

Using ovarian tissue is faster than other fertility preservation methods, such as the standard collection of oocytes or embryos, which can take up to three weeks and delay cancer treatment. In contrast, we can arrange for ovarian tissue cryopreservation within two to five days, reducing the delay.

OTC's other advantage is that it gives women the chance to restore their menstrual cycle and conceive naturally, although many will still need in vitro fertilisation (IVF).

Dr Julia Kopeika, clinical lead for the fertility service at Guy's and St Thomas', said: "We are delighted that we are able to offer life-changing treatment for young girls and women and the opportunity to preserve their fertility after gonadotoxic treatment."

Guy's and St Thomas' recently expanded its OTC service to offer females aged 14 and over who are having chemotherapy the opportunity to freeze their ovaries at the world-renowned Evelina London Children's Hospital.

Pre-implantation genetic diagnosis

Another innovative treatment that has changed the face of fertility is our pre-implantation genetic diagnosis service, which is part of the globally respected Assisted Conception Unit (ACU) at Guy's Hospital.

Guy's and St Thomas' has offered PGD since 1997 and is the largest and most successful PGD centre in the UK. The Human Fertilisation and Embryology Authority has licenced the service to research further improvements in treatment outcomes for our patients.

PGD is a type of IVF offered to couples at an increased risk of having a child with a specific genetic disorder. We test for 300 genetic conditions, including many widespread in the Middle East, such as sickle cell disease, cystic fibrosis and alpha thalassemia.

Embryologists perform the embryo biopsy step in PGD, removing a sample of cells from an embryo to test if they are affected by a genetic condition. Then, only the unaffected embryos are returned to the womb to avoid passing on the disorder to a child as pregnancy hopefully develops.

The ACU is dedicated to improving patient treatment outcomes and runs an extensive research portfolio of academic and commercial clinical trials. In addition, our leading consultants contribute to research and scientific evidence that continually drives forward innovations in the world of fertility.

- Learn more about OTC and PGD from our expert consultants, Dr Julia Kopeika and Professor Yacoub Khalaf, at Arab Health in January 2022.
- Contact us to find out more about our fertility services:

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New building simulation framework shows full environmental impact pre-design

A team from Cornell University's Environmental Systems Lab, led by recent graduate Allison Bernett, has put forth a new framework for injecting as much information as possible into the pre-design and early design phases of a project, potentially saving architects and design teams time and money down the road.

"(Our framework) allows designers to understand the full environmental impact of their building," said Bernett, corresponding author of "Sustainability Evaluation for Early Design (SEED) Framework for Energy Use, Embodied Carbon, Cost, and Daylighting Assessment" which published January 10, 2021 in the *Journal of Building Performance Simulation*.

Principle investigators are Timur Dogan, assistant professor of architecture in the College of Architecture, Art and Planning; and Katharina Kral, a licensed architect and lecturer in the Department of Architecture.

Opportunity of impact

"How we look at this is, there's the cost of change in the design process, and then the opportunity of impact," Dogan said. "In the very beginning, changing something doesn't cost anything, but if you're a month into the project, changing something is really expensive, because now you have to rehire consultants and redesign things.

"And then the other thing is the potential of impact," he said. "In the very beginning, just with a simple nudge in the right direction, you can change a project from being an energy hog to something that's very sustainable, and integrates well into the environment."

In 2018, according to the International Energy Agency, the construction sector accounted for 39% of energy and process-related greenhouse gas emissions. That included 11% originating from the manufacturing of building materials and products.

Dynamic simulation

The SEED Framework is a decision-making tool that can dynamically and concurrently simulate several variables: building energy performance; embodied carbon (carbon emissions generated by construction and materials); construction cost; and daylighting (the use of natural light to illuminate indoor spaces).

The framework will allow architects and design teams to rapidly trial and rank tens of thousands of design iterations, using as few as four inputs.

Using publicly available data and a suite of available design simulation programs – including Rhino/Grasshopper (a CAD program); ClimateStudio, developed by Dogan, for daylight simulation and building energy modelling; and engineering software Karamba3D – Bernett and the team tested SEED in a case study of a hypothetical mid-sized office building modelled in Boston, Washington, D.C., and Phoenix.

The SEED Framework generated thousands of design options based on variables specific to the three cities in the case study, offering designers the flexibility of many options early in the process, before changing course would get too expensive.

"The idea is, you run this analysis," Dogan said, "and you get a few options that already make a lot of sense, and some options that you can completely forget about. – [It] always comes down to this lack of information in the decision-making process.

Informed decision-making

"In that sense, the construction industry is super inefficient," he said. "There's too many players who don't know the full picture and then make decisions that are not always rational. This framework that Allison worked on is geared to help bring the information to the table. Every stakeholder in the design process can then form their own opinion about design goal priorities."

SEED's greatest asset, Bernett said, is amassing a tranche of data on multiple factors in one place, and involving architects early in the design and pre-design phases.

"It takes a lot of time to gather all that data, and we have that pre-packaged. So there's definitely a hunger for that," said Bernett, who presented the SEED Framework in September 2019 at the International Building Performance Simulation Conference, in Rome.

"Right now, we rely heavily on energy modelers and consultants to do this work," she said. "And if we can involve architects more readily and more early on, I think that we're going to see a lot of improvement and cost-effectiveness to these early design decisions."

In addition to the publicly available design simulations, the team used AutoFrame, a new procedure developed by Kral for automatically computing structural systems. AutoFrame helps improve the precision of embodied carbon assessments and daylight simulations.

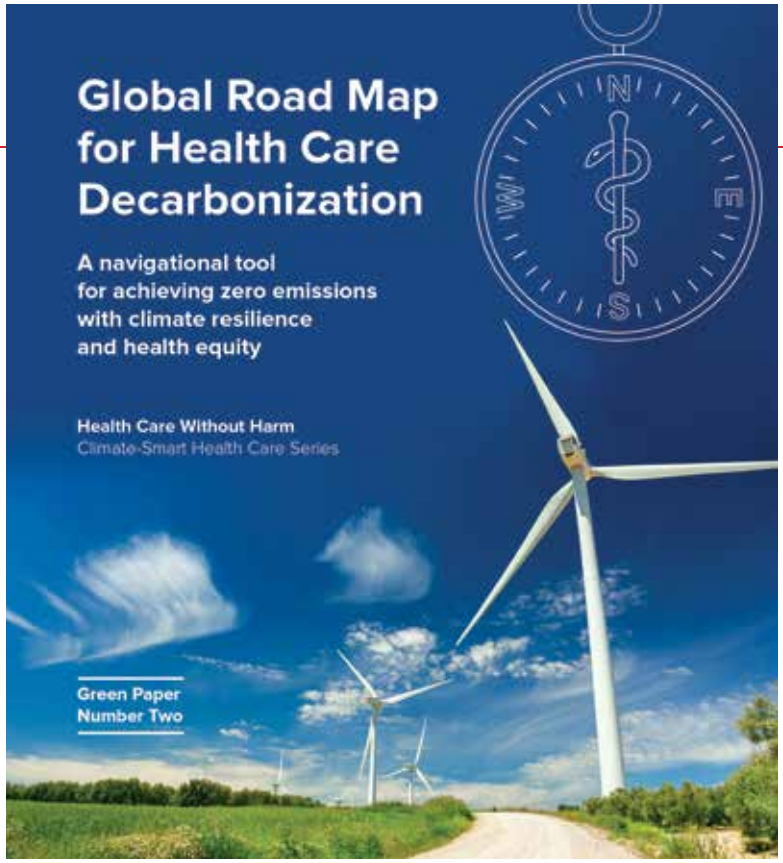
The Cornell Atkinson Center for Sustainability's Small Grants Program provided pivotal support for this work, Bernett said.

"That funding really gave it the push it needed," she said. "It allowed me to present a first iteration [of SEED] at the conference in Rome, and then to really flesh out the research more after that."

Reference:

A. Bernett, at al. Sustainability evaluation for early design (SEED) framework for energy use, embodied carbon, cost, and daylighting assessment. *Journal of Building Performance Simulation* (2021). **doi:** 10.1080/19401493.2020.1865459

New global road map provides guide for zero emissions healthcare



Health Care Without Harm, in collaboration with Arup, has developed *The Global Road Map for Health Care Decarbonization: a navigational tool for achieving zero emissions with climate resilience and health equity*. The Road Map is the first of its kind to chart a global healthcare course to zero emissions by 2050. Health care's climate footprint is already substantial, equalling 4.4% of net global emissions. Without climate action inside and outside the sector, healthcare's climate emissions would more than triple to over six gigatons a year by 2050, equal to annual emissions from 770 coal-fired power plants.

"We're experiencing the climate and health emergencies as one and the same, including increases in respiratory illness from fossil fuel pollution and those caused by dire climate impacts such as wildfires. Health care bears the brunt of these two crises while also, ironically contributing to them through its own emissions. It's imperative for health leaders to lead by example and act now to reach zero emissions by 2050. The Road Map charts a course in that direction," says Josh Karliner, international director of program and strategy, Health Care Without Harm, and the Road Map co-author.

Paris Agreement commitments

If countries can meet their Paris Agreement commitments, this could cut projected healthcare emissions growth by 70%, still leaving a large gap to zero emissions. The Road Map demonstrates how healthcare can implement seven high-impact actions to further reduce sector emissions by 44 gigatons over 36 years, equivalent to keeping more than 2.7 billion barrels of oil in the ground each year.

"In the race to zero emissions, climate action must go hand in hand with establishing healthcare climate resilience as a disaster preparedness strategy, while ending disparities in health development and access between and within countries," says Dr. K. Srinath Reddy, President of the Public Health Foundation of India, one of the featured speakers during the launch.

The Road Map also identifies distinct trajectories for healthcare decarbonization for different nations. Countries with large health sector GHG footprints need to reduce emissions the most rapidly and steepest. Simultaneously, those less responsible, low- and middle-income countries can implement climate-smart solutions to develop their health infrastructure while following a less steep trajectory to zero emissions.

"All countries' health systems will need to reach zero emissions by 2050 while at the same time achieving global health goals. Many health systems in low- and middle-income countries will require support from developed economies to facilitate access to the necessary solutions during this transition," says Sonia Roschnik, international climate policy director, Health Care Without Harm, and Road Map co-author.

The new Global Road Map finds that 84% of the sector's climate emissions are from fossil fuels used across facility operations, supply chain, and the broader economy. This use includes coal, oil, and gas to power hospitals, healthcare-related travel, and the manufacture and transport of healthcare products.

The Road Map, Green Paper Two

The Road Map, Green Paper Two, is the second in a series of research and policy papers that Health Care Without Harm and Arup have produced together to identify a set of actions the health sector can take to align itself with the ambition of the Paris Agreement while simultaneously achieving global health goals.

The Health Care Climate Footprint Report, Green Paper One, defined healthcare's climate footprint and opportunities for action. This paper sets out a broad, overarching guide for the sector to move toward decarbonization. Future papers will continue to build out this vision. MEH

on the WEB **The Road Map**
https://healthcareclimateaction.org/roadmap

The Health Care Climate Footprint Report
https://noharm-global.org/climatefootprintreport

Stiegelmeyer's modern hospital beds are easy to clean, safe and comfortable

Beds play an important role in ensuring patient comfort in hospitals. However, in addition to comfort it is of utmost importance that they are kept optimally hygienic. They must be easy to clean, thoroughly. However, this should not result in any compromises in terms of comfort, safety and durability. This is a challenge for manufacturers and German market leader Stiegelmeyer has mastered it excellently thanks to over 40 years of experience with washable beds.

Evario series of hospital beds

Stiegelmeyer's Evario series of beds impress with ideal hygiene properties while fulfilling very different requirements on the wards. The beds are characterised by a planar design with as few niches as possible. Dust and dirt cannot settle unnoticed. Cleaning by hand is effortless as all surfaces of the bed can be reached easily. The machine-washable variant beds make it even easier to maintain optimum hygiene and saves time for staff. A special cavity sealing of the frame construction as well as an exclusive casing seal of the drive components ensure that these beds easily withstand automatic decontamination.

With the Evario hospital bed, Stiegelmeyer has created an especially intelligent modular system for all wards. The optional Protega safety side is particularly innovative. This split wing-shaped safety side is made of plastic and can be operated quietly and without force even in difficult situations. On request, control panels can be integrated on both sides. They offer simple operating controls that face the patient and many practical functions for nursing staff and technical personnel. The Evario beds can be adapted to specific requirements and make a patient's hospital stay easier, safer and more comfortable.

Beds from Stiegelmeyer are a safe investment for any healthcare facility. The family-run company from Germany is well known for its high quality, continuity and reliability. With a spare parts supply for their beds going back at least 15 years, Stiegelmeyer enables its partners to work economically with a high degree of planning security.

- To learn more, visit: *www.stiegelmeyer.com*

Realigning healthcare design in a post pandemic world

By **Dr. Altaf Faiyaz**
Manager, Healthcare Advisory
at HOSMAC Middle East

Various forums are abuzz with discussions on the dramatic adaptations in healthcare design and delivery that have accompanied the post-Pandemic scenario. In a sense, the contagion has been a driver for creative and innovative solutions.

It can be widely agreed that the Covid-19 pandemic has resulted in a marked change in the way healthcare services are delivered and utilized. Key tectonic shifts include virtual healthcare being delivered at an unprecedented scale, surge in non-hospital-based care, upgradation of Emergency and Critical Care facilities and the need for more and larger testing laboratories. There are also several ancillary, non-explicit consequences such as the rise in Behavioural and Mental Health conditions and consequent impact on long-term Health. Considering that some of these shifts are transient while others may be permanent, it's more important than ever to have a prospective approach and collaborate closely with clinicians when designing healthcare facilities to ensure that they are fit for purpose.

However, it is also important to maintain perspective and practically evaluate each consideration in the context of individual health facilities and the surrounding healthcare delivery ecosystem. Broadly speaking, the impact of pandemic-related considerations on health facility design can be considered at two levels.

The first is that of strategic and operational planning, wherein considerations for surge capacity, novel service requirements (preventive medicine, personalized medicine, etc.) and renewed care delivery models need to be built in by healthcare planners and operators. These would typically be reflected in strategic documents such as the Business Plan, Capacity Plan, Functional Program, Operational and Clinical Service Delivery Plan. At this level, it is also important to separately account for:

i) strategies related to future-preparedness for similar pandemics (or natural/ manmade disasters) including potential space planning and programming implications and

ii) ii) strategies related to changes in the healthcare delivery models and positive learnings/ practices driven by the pandemic.

Once a clear strategic and capacity plan has been established, it is important to translate these to the next level of planning and design. This includes pandemic-driven short-term and long-term considerations in space programming, workflows, departmental configuration, circulation, layouts, interior, and electromechanical design. In parallel, medical technology and IT services should be planned to support the strategic objectives.

In this piece, we summarize, categorize, and reflect on some major trends and themes in healthcare planning and design that have emerged in the last 16 months based on client experiences and empirical research.

Infrastructure – building upon flexibility and adaptability as key guiding principles

In the post-pandemic scenario, designing flexibility in spaces as well as the technology to deliver the requisite services when needed will form a crucial planning criterion from the outset. The goal must be to increase and maintain resilient healthcare systems through a holistic approach to disaster preparedness and response

With rise in critical cases, the most significant need for most hospitals has been that of more inpatient beds in high acute areas (i.e. ICUs, HDUs), step-down and subacute areas for infectious diseases. In this scenario, the ability to quickly turn inpatient wards into ICUs as well as repurposing other areas will be a key design consideration.

In order to achieve this, building system designs must also be resilient; for example, designing the mechanical system to allow the floor of a healthcare facility to be converted into pandemic or emergency mode and seamless transition from normal to negative-pressure rooms as required. This configuration grants the hospital more flexibility to compartmentalize/isolate the floor space as needed. The separation of acuity by floor can make the zoning of air balance and filtration much more efficient and easier to implement quickly.

Another key department where design responses to the pandemic are likely to coalesce into trends is the Clinical Laboratory. Relevant trends include modular planning and the provision of future growth space that will drive the ability to pivot labs to new demands as current priorities fade.

Overall, the need for surge capacity and flexibility in the event of future infections will cut across almost all departments.

Other than departmental considerations, as part of long-term surge capacity planning, healthcare systems will also need to think creatively about their real estate outside of the hospital itself; including ancillary buildings, nearby hotels, clinic spaces, parking structures, etc.

Equipment and supplies – ensuring seamless supply and sufficient storage capacity

A seamless local supply chain is essential to ramp up rapidly to meet rising service demand. In addition, hospital storage facilities must be geared up to stock additional essential medical equipment and an extraordinary amount of emergency supplies (PPE kits, etc.). All this would require reorienting current materials management and support services strategy that may have an impact on hospital planning and design

Supporting staff through technology, automation, and a healthy work environment

Healthcare delivery is typically labour intensive. Consider the ICU, where the staff-patient ratio is 1:1. The staffing challenge is aggravated in a medical crisis when the number of patients dramatically increases, and this ratio is stretched. This unanticipated surge in healthcare demand has a knock-on effect across various clinical, ancillary and support service departments, often leading to stress, exhaustion and burnout.

From a planning perspective, one of the ways that healthcare providers can prepare to address these situations is by building in redundancy through AI and automation. This can be done by integrating sufficient technological infrastructure to deploy requisite medical staff-patient ratio without the use of human beings in every situation. In the case of intensive care services, this includes the deployment of technology, perhaps robotic solutions that go beyond simple physiological monitoring, to deliver intensive care services for lower-level care, leaving high level care to humans who need to make crucial decisions.

AI and automation can similarly be extended to several clinical and support functions such as the use of robots to dispense medicines (robotic pharmacies) and for the transport of food, linen and waste.

These technologies also reduce unnecessary staff exposure thereby controlling infection spread across the health workforce

With the growing relevance of AI and automation, its integration across various hospital process and functions (either in initial or subsequent operational phases) must be mapped right from project inception. This should form a key planning criterion with all design disciplines supporting its implementation.

While robotics and automation can help address resource shortage issues, a traditionally underrated concern that has been brought to the fore by the pandemic is the lack of sufficient staff spaces within most hospitals. While healthcare staff have been deemed COVID warriors and suffer from unduly long working hours, stress and exhaustion, there has been little focus on the provision of a better work environment in hospitals. It is expected that experiences of the last 18 months will provoke discussions on the provision of adequate staff spaces, both functional (such as donning and doffing spaces) and recreational (relaxation lounges, etc.) to inspire and motivate our frontline workers.

Remote healthcare delivery and integration

Perhaps one of the most evident impacts of the pandemic has been wider acceptance of remote healthcare delivery among both patients and providers. Within just a few months of the contagion reaching GCC shores, most healthcare facilities in the region upgraded existing infrastructure and adopted remote patient management technologies (including telehealth, teleradiology and online pharmacy retail) in a big way. Major integrated healthcare providers have also used remote patient monitoring systems to manage large numbers of Covid patients.

Some of the key drivers for accelerated adoption of telehealth services by patients include higher safety, acceptance by health insurance providers, convenience, and the positive predisposition of the millennial population. From a provider perspective, it has enabled the management of larger numbers of cases, reduced exposure of medical staff, reduced the crowd at medical centres, and the ability to provide service to distant areas.

Although telehealth has its own set of limitations, patients now have first-hand experience of the convenience it offers and it seems that it will be an important medium for delivering care if supported by adequate regulations going forward.

In addition to remote healthcare delivery, another key trend that was amplified during the pandemic and is likely to continue is that of integrated healthcare delivery. The pandemic provided a major boost to the concept of integrated health system and a strong link was established between a cross section of public and private healthcare facilities and medical staff and synchronized care was delivered.

The rising adoption of remote and integrated health service delivery will have a lasting impact on design and configuration of healthcare facilities and the way in which health professionals work. A key planning parameter will also be to ensure that the necessary physical IT infrastructure and connectivity is in place for appropriate technology to be accessible to both providers and patients.

Realigning healthcare design – a measured approach

It is also important to note that these planning principles are not absolute, and their implementation will depend on specific circumstances of each health facility namely the acuity level, location, catchment size, cultural factors, capacity of other facilities in the vicinity, etc. Based on these factors, providers should conduct scenario modelling exercises and critically evaluate each consideration and its design impact in terms of suitability and sustainability. What is essential is to have a well-calibrated strategy to address unplanned capacity surges – including a plan for each department and each function. Not all these plans may require immediate investments or cause design disruptions but they must be in place to immediately transform infrastructure/ obtain resources when required. MEH

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Korea makes its mark in regional healthcare

The Korea Health Industry Development Institute (KHIDI) has established a number of collaborative projects with partners in the Middle East. To learn more about this, *Middle East Health* spoke to Jee Young Yoon, General Manager of KHIDI Abu Dhabi, about their activities in the region.

The Korea Health Industry Development Institute (KHIDI) is playing an increasingly important role in healthcare in the UAE and the wider region with sharing of expertise and the provision professional medical services, as well as being the facilitator for a growing medical tourism business between Korea and the Middle East.

KHIDI is a government-affiliated institute under the umbrella of the Ministry of Health and Welfare of Korea. Since its establishment in 1999, "KHIDI has contributed to enhancing the global competitiveness of the health industry and improving public health", Jee Young said.

In 2012 KHIDI established a branch office in Abu Dhabi to oversee the whole MENA region. It is one of several overseas branches.

"Our missions include supporting export and expansion of Korean healthcare services – that is medical device and pharmaceutical companies, hospitals, etc. – and assisting foreign patients for medical tourism. These missions stem from our motivation to contribute to development of healthcare in the counterpart region. We have signed MoUs with various governmental entities in the UAE, Saudi Arabia, and Qatar for cooperation.

"In our collaborations with Saudi Arabia, Kuwait, Bahrain, and Oman, KHIDI has been providing fellowship programs that include hands-on practice in specialties such as cardiology, gastroenterology, general surgery, neurology, orthopaedic surgery, and so on."

Speaking specifically about KHIDI's collaborations in the UAE, Jee Young said KHIDI has been working closely with SEHA, the Abu Dhabi health services company and the UAE's largest healthcare network, since 2012.

"In October 2020, KHIDI and SEHA signed a MoU with extensive coverage of cooperation. The main areas of cooperation included in the MoU are medical training, clinical research, medical tourism, provision of medical services, supply chain management, and technical support in areas of AI, IoT, and the cloud.

"Periodically, SEHA and KHIDI hold joint conferences and seminars with diverse topics for exchange of knowledge, skills, and insight."

Jee Young also noted that KHIDI has been cooperating with Department of Health since 2011 and UAE Armed Forces since 2013.

"Through these cooperations, until the end of 2019, a total of 5,451 government-funded patients were referred to Korea."

He explained this put Korea second only to the United States with regards to receiving UAE-government-funded patients. About 1,000 government-funded patients from the UAE visit Korean medical facilities annually.

"There are more of these extensive cooperation plans under way," he added. "KHIDI Abu Dhabi is receiving more inquiries regarding Korean medical professionals and technology transfers. Lately, there has been a growing interest from sovereign and private funds in the UAE for innovative healthcare technology from companies in Korea, such as AI-supported software developed by Korean ventures that can detect and diagnose certain cancers and diseases with higher accuracy than doctors.

Jee Young Yoon, General Manager of KHIDI Abu Dhabi

"We will continue to expand our cooperation with the UAE to answer the growing demand [for our professional services and technology] and look forward to witnessing the achievements these partnerships will generate."

Looking specifically at the medical device sector in which Korea is an important stakeholder with numerous innovative companies, Jee Young explained that in a competitive environment many small to medium medical device companies are managing very well to maintain their global competitiveness.

"Several Korean medical device companies have branch offices and warehouses in the UAE. These Korean medical device

KHIDI and Abu Dhabi's SEHA sign MoU for cooperation in healthcare.

companies specialize in dental imaging equipment, dental implant fixture, ultrasonic diagnosis, and in vitro diagnostics (IVD) products."

He cited as examples: The Korean company Seegene, with a regional base in Sharjah specialises in IVD products including COVID-19 diagnostic test-kits; Osstem Implant, based in Dubai, is one of the world's largest dental implant material producers. And Vatech, also in Dubai, is one of the most promising dental imaging device developers in Korea.

Looking at the sharing of knowledge and cooperation with the UAE with regard to medical services, Jee Young pointed out that the number of Korean medical professionals in the UAE along with recent expansion of Korean hospitals in the region is "astonishing".

"[Through this] medical service cooperation between the UAE and Korea has been boosted both in quality and quantity."

He said that since Korea's highly qualified medical professionals and its hospital

services were first introduced to the UAE following the designation of Seoul National Hospital to manage the running of Sheikh Khalifa Specialty Hospital in Ras Al Khaimah, there has been a series of important advances.

Woorideul Spine Center in Healthpoint, Abu Dhabi; Himchan Hospital in University of Sharjah Hospital (2018); Nanuri Spine and Joint Hospital in Saudi-German Hospital (2020), and the most recent Joint and Spine Center at Burjeel Royal Hospital in Al Ain.

"It is not a coincidence that most of their specialties are orthopaedic. Many orthopaedic professionals in Korea undertake endoscopic surgery and this is still a new treatment method in UAE. Therefore, there is a high demand for skilled Korean doctors in orthopaedics," Jee Young explained. MEH

Vatech makes inroads in the MENA

Headquartered in Korea, Vatech is a global healthcare corporation with a focus on the research and manufacturing of dental imaging equipment. With a direct presence in more than 20 countries, including an office in Dubai, UAE (Vatech MENA), Vatech's devices are being used in more than 100 countries all over the world. Vatech first started exporting to the Middle East in 2005 and set up Vatech MENA in 2019. With a logistics centre in Jebel Ali, Vatech MENA expanded its reach to GCC countries and North Africa, all the while

S. J. Kim, Managing Director, Vatech MENA

cementing itself as the most preferred brand in dentistry.

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Radiation from medical imaging is a concern internationally. The EU, US and England have set up regulatory measures to protect the patients from medical radiation, including dosage recommendations for radiographic imaging. Vatech's Green products adhere strictly to these guidelines and provide even lower levels of dosage than the guidelines.

Vatech's Green CT is recognized as a premium product in its main markets, dental clinics, and radiology centres in the US and Europe, a testament to its quality and technology.

Vatech's "Green" product line boasts more than a 75% reduction in patient dose compared to previous models, while preserving image quality for diagnosis. "Green X", the latest model in this line-up, captures CT images in 2.9 seconds and cephalometric images in 1.9 seconds, but provides full-arch, sinus and TMJ images required for oral-maxillofacial and implant surgeries.

Vatech's world-leading portfolio of dental-imaging-related patents is what makes this "low-dose" technology possible. Vatech possesses technologies that enable faster scans at low radiation dose with software algorithms that can reconstruct clear images.

Furthermore, Vatech was the first company in the world to commercialize carbon nano tubes for dental imaging, enabling the acquisition of clear radiographic images without exposing patients to unnecessary radiation. MEH

Highly experienced Korean doctors practise in the UAE

Over recent years, the demand for new medical techniques and diversely experienced healthcare professionals have been continuously increasing. As a result, it is getting easier to find Korean doctors and nurses at hospitals in the UAE.

The Korean Spine and Joint Center at the Royal Burjeel Hospital in Al-Ain is an example of several recent Korean medical service establishments in the UAE. The centre opened in May 2021, through collaboration with Burjeel Hospital, one of the most popular healthcare providers in the UAE. A neurosurgeon consultant doctor, an orthopaedic consultant doctor, a nurse and a staff member, all Korean nationals, are currently present at the centre. They previously worked together at a hospital in Korea and are continuing to provide excellent service in the UAE through the solid teamwork they have built over the years.

Their smooth transition from Korea to the UAE had been assisted by MMK, a Korean healthcare company focused on the UAE.

After completing his neurosurgery training in Korea, Dr. Jin Hwa Eum honed his clinical experience at the Albert Einstein College of Medicine. He is a global pioneer in the treatment of spinal diseases using endoscopy, specifically biportal endoscopic spinal surgery. With his experience, he has trained many junior doctors in Korea using this method.

Another orthopaedic surgeon, Dr. Young Woong Back refined his clinical experience at Mayo Clinic as well as in Korea, where he practiced at a hospital specializing in shoulder surgery, performing a variety of surgeries from arthroscopic repair to shoulder arthroplasty. He is adept at using the latest surgical techniques, including multiple tendon transfer. Dr. Back also worked at a hospital in Seoul that specializes in articular cartilage regeneration surgery in the knees using stem cells. Dr. Back is also adept at using the latest technologies for shoulder and knee surgeries, making him one of only a few doctors who has experience in both upper and lower extremities.

The presence of these highly experienced doctors provides advanced surgical options for patients in the UAE. MEH

Patient testimonials

Around 1000 patients from the UAE travel to Korea each year for medical treatment. The following three testimonials give an indication of the patients' happiness with the successful treatment they received.

Hospital: Samsung Medical Center
Patient: Hamdan (male, 9 years old, UAE national)
Referral: Patient was referred by UAE Department of Health
Diagnosis: Twisted pelvis

Hamdan at the Samsung Medical Center

Hamdan's mother talks about her son's experience at Samsung Medical Centre in Seoul, Korea.

"I had no idea that the medical standard in Korea would be this high. My son had to undergo three surgeries for his twisted pelvis. However, I am very happy to have achieved good results thanks to Professor Shim Jong-sup's excellent surgical skills, professional care by medical staff, and intensive rehabilitation treatment. Although Hamdan was in severe pain due to the surgery, he was able to endure the pain and stay strong all thanks to the supporting medical staff treating him kindly. Now, Hamdan has recovered to the extent that he cannot even tell that there was a problem in the past. His condition noticeably improved as he underwent the well-organized rehabilitation. Hamdan is very satisfied with the result now that he can walk well after the surgery and rehabilitation." MEH

Hospital: Severance Hospital
Patient: Khalifah Abdulla Alremeithi (male, 15 years old, UAE national)
Referral: Patient was referred by the Military Attache's Office, Embassy of UAE
Diagnosis: Hodgkin's lymphoma

Khalifah Abdulla Alremeithi

Severance Hospital in Seoul, Korea, is one of just a few hospitals that provides a Medical Fast Track service during the Covid-19 pandemic, which allows patients in a critical state to be treated while being quarantined in the hospital.

Khalifah Abdulla Alremeithi, a 15-year-old Emirati boy was diagnosed with Hodgkin's lymphoma, nodular sclerosis, Stage IVB.

He had been treated previously in Korea and the UAE, and was then referred to Severance Hospital in November 2020, due to development of complications. He was directly admitted to the ward via the Medical Fast Track scheme.

After periodic admission for persistent chemotherapy and other treatments his complications have diminished. Dr Lyu, the paediatric hemato-oncologist is planning stem cell transplantation for Khalifah and he is currently under related pre-evaluation.

The patient is aiming for complete remission which was virtually impossible at the initiation of the treatment with his disease progression. When he first visited our hospital, his general medical condition was very poor with high fever and severe weight loss. Due to the anterior mediastinal mass and pleural effusion, he could barely take in food.

Medical Fast Track also shortened the process and it helped with offering the proper treatment to the patient in his hour of need. According to his parents, their son's treatment experience in Severance will provide hope for other children suffering from the same disease as Khalifah.

Khalifah said: "When I arrived in Korea, I was worried about whether the treatment would work or not. However, Severance Hospital treated me with care and affection. Thanks to Severance Hospital, my health has improved a lot more than before. And my love for Korea grew. Thanks to the excellent medical staff and interpreters, I was able to receive treatment with peace of mind and my health improved very well. Thank God and thank the hospital, medical staff and interpreters." MEH

Maryam Ali Alblooshi

Hospital: Asan Medical Center
Patient: Maryam Ali Alblooshi (female, 58 years old, UAE national)
Referral: Patient was referred by UAE Department of Health
Diagnosis: Congenital mandibular retrognathia

Maryam was diagnosed with congenital mandibular retrognathia and abnormality of both temporomandibular joints (TMJ). She received surgery of the jaw in 1997 and 1999 in London. Despite the surgeries, the patient continued to suffer from apnea caused by retrognathia. Therefore, she had undergone a tracheostomy. Since then, she had been unable to speak. At Asan Medical Center, the patient had thorough preoperative evaluations, followed by several surgeries performed by the ENT and plastic surgery department. Ultimately, her surgery was successful, and the long-awaited tracheostomy tube removal took place. The patient was ecstatic to be able to find her voice again.

"First of all, I would like to express my sincere gratitude to everyone who has provided excellent medical services. In addition, I would like to thank the Crown Prince, Mohammed bin Zayed Al Nahyan for providing me an opportunity to receive treatment in Korea and for simplifying the procedure and approval process through the Abu Dhabi Department of Health. I want to express my sincere gratitude to the International Healthcare Center staff and interpreters for welcoming us warmly with open arms.

On March 30, 2021, I underwent various examinations in the plastic surgery department. Dr. Jong Woo Choi suggested two possible surgical methods. The operation was risky, but after much deliberation, I decided to go through with the first method. Without a doubt, the operation was performed successfully.

I am grateful for the efforts put forth by the Asan Medical Center staff, but especially to the professors who showed deep concern and interest in my case. I cannot express how indebted I am to the professors who performed the surgery and to the medical staff who took care of us by reaching out to help. I will never forget all of you." MEH

Andreas Heddergott / TUM

The dark field X-ray method visualizes early changes in the alveolar structure as a result of the lung disease COPD. Franz Pfeiffer, Professor for Biomedical Physics, hopes that this will significantly improve the early detection of lung diseases.

New dark-field X-ray technology improves diagnosis of pulmonary disease

For the first time, researchers at the Technical University of Munich (TUM) have successfully used a new X-ray method for respiratory diagnostics with patients. Dark-field X-rays visualize early changes in the alveolar structure caused by the lung disease COPD and require only one fiftieth of the radiation dose typically applied in X-ray computed tomography. This permits broad medical application in early detection and treatment follow-up of respiratory ailments.

There are millions of cases in which serious respiratory system illnesses place limitations on quality of life. Every year more than four million people die of serious respiratory ailments worldwide. Partially destroyed alveoli and an over-inflation of the lungs (emphysema) are typical of the life-threatening ailment Chronic Obstructive Pulmonary Disease (COPD).

However, the fine distinctions between healthy and diseased tissue are barely visible on conventional chest X-rays. Detailed diagnostic information is only available using three-dimensional computed tomography approaches, in which the computer assembles many individual images. Until now there has been no fast and cost-effective option for early detection and follow-up examinations with a low radiation exposure as used in plain chest X-rays.

A procedure developed at the Technical University of Munich could now fill this gap: dark-field chest X-rays. In the November 1, 2021 issue of *The Lancet Digital Health* a research team led by Franz Pfeiffer, Professor for Biomedical Physics and Director of the Munich Institute of Biomedical Engineering at TUM, present the results of an initial clinical patient study, which used the new X-ray technology for the diagnosis of the lung disease COPD.

The key: The wave character of X-rays

Conventional X-ray imaging is based on the attenuation of X-rays on their way through the tissue. Dark-field technology on the other hand use the wave nature of X-ray light, which is discarded in conventional X-ray imaging.

The new method thus uses the physical phenomenon of scattering in a manner similar to the long-known principle of dark-field microscopy with visible light. This allows to visualize the structure of objects that are for the most part transparent. These structures appear in the microscope as bright images on a dark background, which has given the method its name.

"The X-ray dark-field signal is particularly strong for interfaces between air and tissue," Prof. Pfeiffer points out. "This makes it possible for a dark-field X-ray image of the lung to clearly distinguish between intact alveoli, i.e. those filled with air, and regions in which less intact alveoli exist."

Lower radiation dose

In addition, an examination using dark-field chest X-ray technology involves a significantly lower radiation dose than presently used computed tomography. This is because dark-field chest X-rays require only one exposure per patient, as compared to the large number of individual images taken from different directions which are necessary in computed tomography.

"We expect the radiation exposure to be reduced by a factor of fifty," says Prof. Pfeiffer. Furthermore, the first clinical results have confirmed that the dark-field X-rays provide additional image information on the underlying microstructure of the lung.

"Given the close connection between the alveolar structure and the functional condition of the lung, this ability is of great significance for pulmonary medicine," explains Dr. Alexander Fingerle, senior physician at TUM's university hospital Klinikum rechts der Isar's Department of Diagnostic and Interventional Radiology. "In the future dark-field X-rays could help improve early detection of COPD and other respiratory ailments."

Better X-ray equipment for early detection

Prof. Pfeiffer hopes these initial clinical results with patients will accelerate the execution of further clinical studies and the development of marketable devices that use the dark-field method.

"Dark-field chest X-rays are currently giving us a chance to significantly improve the early detection of lung diseases and at the same time to implement it on a wider basis than before," Prof Pfeiffer notes.

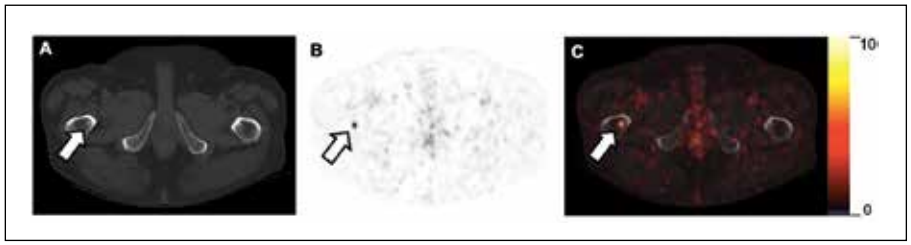
Since dark-field imaging is not limited to COPD, further translational studies with other pulmonary pathologies such as pulmonary fibrosis, pneumothorax, lung cancer and pneumonia, including COVID-19, are of great interest.

Reference:

K. Willer, et. al. X-ray dark-field chest imaging for detection and quantification of emphysema in patients with chronic obstructive pulmonary disease: a diagnostic accuracy study. *The Lancet Digital Health*. November 1, 2021. doi: *https://doi.org/10.1016/S2589-7500(21)00146-1*

PSMA PET imaging more accurate than CT in detecting hepatocellular carcinoma

PSMA (prostate-specific membrane antigen) PET/CT is more accurate than conventional CT in the detection of hepatocellular carcinoma metastases, according to research published in the September issue of *The Journal of Nuclear Medicine*. PSMA PET imaging was also found to be associated with a change of management for nearly half of the patients, allowing them to receive the most effective treatment for their disease.



(A) CT (B) PET and (C) fused PET/CT of 68Ga-Ga-PSMA-11 PET scan of a patient with distant osseous metastases in the right proximal femur, visible on PET with intermediate PSMA uptake (SUVmax = 7.8) and missed by CT, confirmed later on follow-up CT imaging.

Image created by WP Fendler, P Fragoso Costa and N Hirmas, et al., Essen University Hospital, Essen, Germany.

Hepatocellular carcinoma – a type of liver cancer – is the sixth most prevalent cancer and the third most frequent cause of cancer-related death. Despite the availability of a growing number of local and systemic therapies, patient survival remains short. Accurate staging is critical for management decisions.

"With more accurate imaging for staging of patients, we can identify early on patients who could benefit from particular treatments, like chemotherapy, which has an impact on survival and quality of life," said Nader Hirmas, MD, physician scientist at the department of nuclear medicine at Essen University Hospital in Essen, Germany.

Hepatocellular carcinoma is typically diagnosed with conventional imaging, like CT or MRI. Recent research, however, has shown that hepatocellular carcinoma has PSMA on the surface of its cancer cells. To explore this discovery, study authors assessed the impact of PSMA PET imaging on patients with hepatocellular carcinoma and compared it to CT.

The retrospective study included 40 patients who received imaging with 68Ga-Ga-PSMA-11 PET/CT. Patients received a CT as well as a PSMA PET scan. Three blinded nuclear medicine physicians determined the presence of hepatocellular carcinoma in the liver and elsewhere in the body based on the CT images and the PSMA PET images separately, and lesions were validated by follow-up imaging or biopsy. Researchers then compared the detection rates for each imaging modality, as well as changes made in staging, grouping and management plans of patients.

Results indicate that PSMA PET and CT are similar in diagnosing hepatocellular carcinoma in the liver, but that PSMA PET is more accurate for tumours that have spread beyond the liver. With a more accurate diagnosis of the locations of the hepatocellular carcinoma tumours, the original management plan changed in 19 of the 40 patients – almost half of the patient sample – leading towards a shift towards systemic therapy.

"We hope that this study encourages more research into the topic, so that multi-disciplinary oncology practices and guidelines would use PSMA PET in the diagnosis of hepatocellular carcinoma," noted Wolfgang Fendler, MD, vice chair of nuclear medicine at the Essen University Hospital in Essen, Germany. "More broadly, it shows that many of the molecular imaging techniques could supplement or even outperform conventional imaging in the diagnosis of particular tumours."

Reference:

N. Hirmas, et. al. 68Ga-PSMA-11 PET/CT Improves Tumor Detection and Impacts Management in Patients with Hepatocellular Carcinoma. Journal of Nuclear Medicine. September 2021. doi: *https://doi.org/10.2967/jnumed.120.257915*

Unsupervised AI breaks new ground by predicting the progression of Covid-19 and survival of patients directly from their chest CT images

Fast and accurate clinical assessment of the disease progression and mortality is vital for the management of Covid-19 patients. Although several predictors have been proposed, they have been limited to subjective assessment, semi-automated schemes, or supervised deep learning approaches. Such predictors are subjective or require laborious annotation of training cases.

In a multi-centre study that was published in *Medical Image Analysis*[1], a research team lead by Hiroyuki Yoshida, PhD, director of the 3D Imaging Research at Massachusetts General Hospital (MGH), showed that unsupervised deep learning based on computed tomography can provide a significantly higher prognostic performance than established laboratory tests and existing image-based visual and quantitative survival predictors. The model can predict, for each patient, the time when Covid-19 progresses and thus the time when the patient is admitted to an intensive care unit or when the patient is diseased, something that other image-based prediction models cannot do. The time information calculated by the model also enables stratification of the patients into low- and high-risk groups by a wider margin than what is possible with other predictors.

"Our results show that the prediction performance of the unsupervised AI model was significantly higher and the prediction error significantly lower than those of the previously established reference predictors," says Yoshida. "The use of unsupervised AI as an integral part of the survival prediction model makes it possible to perform prognostic predictions directly from the original CT images of patients at a higher accuracy than what was previously possible in quantitative imaging."

In a companion study that was published recently in *Scientific Reports* - Nature[2], the team had already shown that supervised AI can be used to predict the survival of Covid-19 patients from their chest CT images. However, the new unsupervised AI model breaks new ground by avoiding the technical limitations and the laborious annotation efforts of the previous predictors, because the use of a generative adversarial network makes it possible to train a complete end-to-end survival analysis model directly from the images. "It is a much more precise and highly advanced AI technology," Yoshida explains.

Although the study was limited to Covid-19 patients, the team believes that the model can be generalized to other diseases as well. "Issues such as Long Covid, the Delta variant, or generalization of the model to other diseases manifested in medical images are promising applications of this unsupervised AI model," says Yoshida.

References:

[1] T. Uemura, et. al. Weakly unsupervised conditional generative adversarial network for image-based prognostic prediction for COVID-19 patients based on chest CT. Medical Image Analysis. October 2021. doi: *https://doi.org/10.1016/j.media.2021.102159*

[2] J. äppi, et. al. U-survival for prognostic prediction of disease progression and mortality of patients with COVID-19. Scientific Reports (2021). doi: *https://doi.org/10.1038/s41598-021-88591-z*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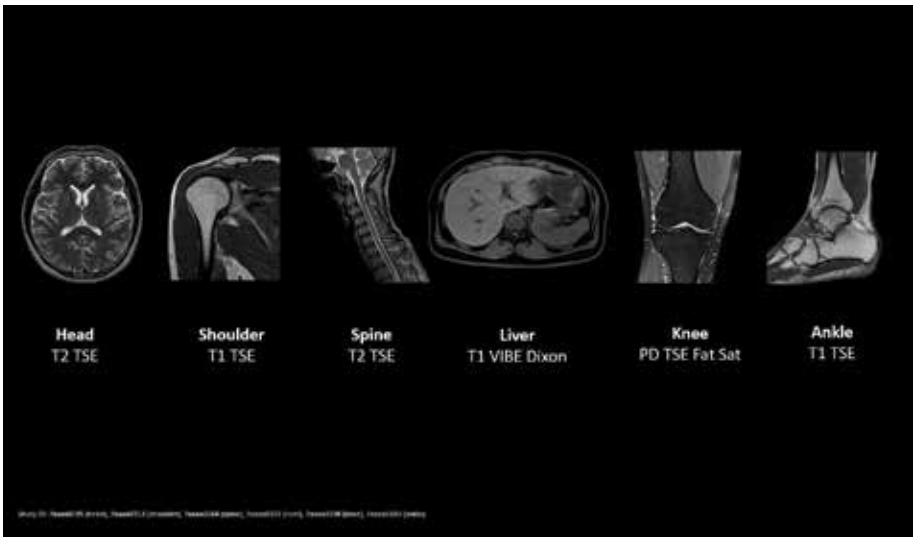
Siemens looks to increase access to MRI with Magnetom Free.Star

At the recent Siemens Healthineers Shape 22 event, the company introduced Magnetom Free.Star, a cost-effective whole-body MRI scanner, designed to significantly increase access to magnetic resonance imaging, particularly in rural areas and less-developed countries. The scanner is, however, currently under development and not commercially available.

Together with Magnetom Free.Max, Magnetom Free.Star is part of a new generation of scanners which achieve excellent image quality with a low magnetic field strength combined with advanced digital technologies. The two MRIs are based on the "High-V MRI" platform and are the smallest and most lightweight whole-body scanners that Siemens Healthineers has built.



"Right now, more than half of the world's population has no access to MRI examinations. The limiting factors include installation and operating costs as well as the lack of qualified personnel, just to name a few. I believe that every person in every country should have access to MR imaging. With Magnetom Free.Star, we are launching a scanner that is cost-effective and, thanks to artificial intelligence, so easy to use that even less experienced personnel can utilize its full potential," said Arthur Kaindl, Head of Magnetic Resonance Imaging at Siemens Healthineers.

Simple and cost-effective installation and operation

Magnetom Free.Star, like Magnetom Free.Max, belongs to a new generation of High-V- MRI scanners from Siemens Healthineers which combine a low field strength of 0.55 Tesla with the power of digital AI. Magnetom Free.Star uses Dry-Cool magnet technology, which requires less than one litre of liquid helium to cool the MRI. Previously, several hundred litres were required for cooling. Additionally, the installation of a safety related quench pipe is not necessary. The quench pipe allowed the discharge of the helium into the open air in case of an emergency. Because the compact systems can be rolled through normal hospital doors in many places, installation is much simpler than with the larger MRI scanners, which often require building reconstruction in order to house them. The significantly lower helium requirement and reduced energy consumption adds a positive effect on operating costs as well. The costs over the entire life cycle of the system are up to 30 percent lower than with conventional scanners, according to Siemens.

Magnetom Free.Star and the High-V MRI platform

Magnetom Free.Star, with a patient bore of 60 cm, combines all the technological innovations of the new High-V MRI platform. The field strength of 0.55 Tesla offers high diagnostic value when used with AI-based reconstruction algorithms such as Deep Resolve Sharp. It raises the image quality to a level that could previously only be achieved with significantly higher field strengths. In addition, this new field strength offers advantages for clinical fields such as implant and lung imaging.

Digital innovations such as myExam Companion, which significantly simplifies the operation and adjustment of the scanner, are designed to make it more accessible to inexperienced operators.

Remote diagnostic services as a supplement

Siemens Healthineers wants to significantly lower barriers to entry for access to MR imaging with solutions such as WeScan, a remote scanning service, as well as a remote reading and reporting service. These optional remote services can support healthcare providers in remote operation of the MRI scanner and tele-diagnosis of clinical images. MEH

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Dunlee delivers on liquid metal bearing CT tube promises

DA200P40+LMB-CT liquid metal bearing tube successfully installed in USA and Europe – full registration for Canada and Middle East also now available

The DA200P40+LMB with Dunlee CoolGlide technology, designed for GE Revolution Evo and Optima CT660 CT scanners, has proven to be a reliable, easy-to-install CT tube that performs well in a clinical environment.

Ease of installation and tube performance stand out

The first DA200P40+LMB CT tube was purchased by Rob Steele from Legendary Supply Chain in the USA. The in-house engineering team installed it along with a subsequent LMB tube, with no assistance, and indicated that the tube is not only "whisper-quiet," but works great.

"We purchased the first LMB tube in December 2020 and the second one shortly after. Both have been running without interruption since then – smooth and quiet," says Steele. "We calculate the cost of ownership for our customers, and product lifetime is a key part of the calculation. With Dunlee CT tubes, we have an advantage."

The DA200P40+LMB tube was also successfully installed at sites in Europe. "We are pleased that we can offer this alternative to OEM tubes to meet our customers' needs," says Guido Stoeckmann, regional sales manager, Europe. "Our customers have always trusted Dunlee tubes, and this is no exception. The customer's feedback is very positive, and they will continue to use the LMB replacement tube to replace tubes in Revolution Evo and Optima CT 660 scanners."

Less wear brings long tube life

Alexander Eitel, head of marketing and business development, is pleased with the market entry of the DA200P40+LMB. Eitel states: "Having a CT replacement tube alternative to OEM tubes helps our customers – and the patients and hospitals they serve – in offering affordable healthcare, and allows them to choose their partner of trust. The feedback we've received is that service engineers like the easy installation, while radiologists like the smooth operation, and patients appreciate the quiet environment. The ability to run without interruptions was especially important when COVID demanded high patient throughput."

He adds: "LMB technology results in less wear, and thus a longer life, than traditional ball bearings. Today, with tubes in use for nearly one year, we are on our way to confirming our expectations for the exceptionally long life of the DA200P40+LMB tube."

Future plans include validation for additional GE CT scanners types with LMB tubes, and finalizing registration for China.

Manufactured in the USA

All DA200P40+LMB tubes are manufactured in Illinois, USA with imported parts. The Liquid Metal Bearing with CoolGlide™ is designed and manufactured in Germany, based on knowledge gained from over 30 years of LMB technology development and over 100,000 LMB units sold worldwide. It was developed by the research and development team that was the first in the world to bring LMB technology to the X-ray market in 1989.

About Dunlee

Dunlee is a leading provider of CT replacement tubes. Dunlee's full line of CT replacement tubes are specifically engineered to be compatible with select GE and Siemens CT scanners and are a cost-effective alternative to OEM CT replacement tubes. All replacement tubes are manufactured in the USA with imported parts. For prompt and efficient delivery, we have regional stocking locations. MEH

Picture this – how medical printing adds marketing value to sterile healthcare organisations

Personalised medical imaging could increase patient satisfaction in the healthcare industry, says Javier Lopez, General Manager, Vertical Solutions, OKI Europe Ltd.

Simple measures, such as a friendly, personal service make all the difference for patients and customers in doctor visits, and if those measures were reflected in the medical results and documentation supplied to patients, medical organisations could benefit from increased confidence and patient satisfaction.

Businesses and healthcare organisations offering radiology services, such as cardiologists, gynaecologists, medical centres and others with X-ray facilities, must rely on medical imaging manufacturers to produce informative, easy to digest images. These essentially enable medical staff to recognise medical complications, assert the best course of action, and help patients understand complex issues.

Building patient trust

For medical imaging manufacturers, there is a clear opportunity to help those radiology-based organisations build trust with their patients while reducing time spent describing those complex issues. Presenting patients with sharp, high quality colour images will undoubtedly increase the ease of describing issues and treatments. For patients, this creates a friendlier more personalised and satisfying experience that will provide a valued level of comfort during an otherwise daunting experience.

However, the benefits of DICOM are only recognised by medical imaging manufacturers and medical staff.

Traditionally, DICOM image files are not easy to share with patients. While other image file formats such as JPEG, PNG or TIFF files are recognised and easily read by personal computers, DICOM files are not recognised by the standard home PC or laptop running Windows or MacOS operating systems. While medical organisations could share the images via email, the patient would require additional software in the form of a DICOM viewer to access the file and would need additional information in a separate text file to explain the image's findings.

Personalising the patient experience

This is where medical imaging manufacturers can provide a simple yet effective solution in the form of personalised booklets, providing a referenceable take-home source of information for patients, including post-diagnosis radiology report, and detailed, high quality images. To maximise their marketing value, the booklets should include relevant information alongside the images, explaining the findings of the scan or X-ray, or detailing proposed surgery in booklets that present visual renderings of potential cosmetic procedures.

Through variable data printing, the booklets can be further personalised with the patient's name, surname and date of birth clearly displayed on the front cover.

A patient requiring cosmetic surgery could be presented with an A3 colour booklet during the consultation stage, prior to deciding on whether to go ahead with the surgery. Having the personalised booklet with details including before and after images, will enable the patient to make an informed decision.

For patients requiring dental care, the personalised booklet will help keep them updated with the course of treatment, and new updated booklets during treatment will increase patient satisfaction by highlighting the patient's progress on the road to recovery.

Personalised booklets will also be of great value to expecting parents, presenting high quality ultrasound scans of the foetus that will provide a lasting keepsake which can be shared with friends and family members.

For medical organisations, there is opportunity to increase marketing value through increased satisfaction in a highly personalised experience. In turn, this creates a clear opportunity for medical imaging manufacturers that can provide high quality personalised booklets in a flexible range of formats and sizes that include sharp, colourful images that will inform and placate medical patients in an age of high expectations.

- Find out about OKI's unique DICOM embedded printers: *http://www.oki.com/me/printing/products/colour/dicom/index.html*
- OKI's medical health solutions: *http://www.oki.com/me/printing/services-and-solutions/industry-solution/healthcare/index.html*

Why innovation is the lifeblood of cost-effective care

By Andrew Thelwell

A report from the World Health Organisation found that the global average life expectancy increased by more than six years between 2000 and 2019[1]. During this period the global population grew by more than one billion. This rising, ageing population, combined with increasing cases of sustained illnesses, such as diabetes and obesity, is putting healthcare systems under pressure to treat more people in need of ongoing care.

Traditionally, healthcare systems have operated under a 'maintenance approach' whereby medical professionals follow the standard of care which is designed to monitor a patient's illnesses rather than cure it. However, this method is more costly and time-consuming than curing a patient and has long been accepted as the best method of treatment because it is considered low-risk.

Increasing cases of chronic wounds

For medical conditions that are difficult to cure, or in cases where a condition can develop and worsen with age, the situation is more complex. Both instances are typical of chronic wounds, particularly venous leg ulcers (VLU).

A 2006 report by the Wound Healing Society found that chronic wounds – including pressure ulcers, diabetic ulcers, venous ulcers, and arterial insufficiency ulcers – are becoming more frequent as the global population is living longer. VLU alone are estimated to affect up to three percent of the global adult population[2].

According to the NHS[3], one in fifty people over the age of 80 has a VLU, and each case can take up to 3 to 4 months to heal, if they even heal at all. Now consider the treatment of leg ulcers: the wound will need cleaning and redressing sometimes as often as three times a week to avoid infection requiring a lot of time and resources from medical staff. Treating the wound over time, however long that is, can therefore cost a lot of money.

The cost of maintenance

Conditions associated with ageing, such as chronic wounds, continue to rise in correlation with the growing life expectancy. This will require healthcare systems to dedicate more time and resources towards wound treatment; however this will increase the costs associated with treating these patients, which is already expensive.

The current standards of care for treating chronic wounds costs global healthcare systems billions each year: treating VLU costs the US approximately $3 billion,[4] while treating leg ulcers in the UK costs the NHS £1.94 billion. These costs are largely attributable to nurse visits and the bandages and dressing needed for treatment. This means, in theory, if healthcare systems could reduce the number of nurse visits and dressing needed to treat chronic wounds, the costs would reduce.

Until recently, the 'maintenance approach' has been widely adopted for treating chronic wounds, however innovation in medical technology (MedTech) is introducing fast and cost-effective methods of treatment which are helping healthcare systems become more efficient.

Reducing costs and improving patient outcomes

Medical devices are allowing new methods of treatment to be implemented into healthcare systems around the world, particularly in the treatment for chronic illnesses such as leg ulcers and diabetes. MedTech is working alongside, and in some cases instead of, traditional methods of treatment to speed up patient recovery times, reducing the need for ongoing treatment and, crucially, decreasing costs for patients. This new breed of technology can also provide a permanent treatment to chronic medical conditions, rather than solely maintain a patient's wellbeing over time.

Clinical data has found[5] that by increasing blood flow to the wound surface, thus enhancing oxygen and nutrient delivery, ulcers can eventually be cured rather that treated and monitored over time.

MedTech devices can be used in the treatment of leg ulcers. Sky Medical Technology's wearable geko™ device, for example, can increase blood flow in stationary patients. The device sits behind a patient's knee and sends short, painless electrical pulses down the leg to promote blood flow equal to 60 percent of walking. This in turn increases circulation, reduces swelling and accelerates wound healing allowing the wounds to close in a matter of weeks as opposed to months or not at all.

This improved method of treatment requires less resources and time from healthcare professionals and therefore be more cost-effective. However, implementing MedTech devices into healthcare systems is time-consuming, expensive and requires a lot of work.

MedTech adoption and regulatory hurdles

Integrating new devices within healthcare systems is not easy. It can take decades of consistent work and requires a lot of money, clinical data, regulatory approval and backing from clinicians. For a device to be adopted into healthcare systems, companies must prove to clinicians that it improves the current standard of care that is practiced.

MedTech devices are also required to

meet regulatory approval before they can be implemented into healthcare systems; the US Food and Drug Administration (FDA) and the UK National Institute for Health and Care Excellence (NICE) are two of the world's leading regulation services and help to set standards for healthcare across the globe.

However, the rewards outweigh the challenges: currently, approved and regulated devices are being implemented by forward-thinking clinicians to treat conditions such as leg ulcers, significantly reducing the financial and staffing strains on healthcare systems all while improving patient outcomes.

Implementing devices into evolving healthcare systems

The challenges that drivers of MedTech innovation now face involve finding ways to reward innovation and risk without negatively impacting what already exists: how can healthcare systems adopt new and improved solutions into existing treatment plans without causing harm, losing money or wasting time?

The vast differences in healthcare systems around the world make this particularly complicated, especially in terms of costs. Healthcare payments vary depending on the type of treatment a patient needs, how long treatment can take, whether the patient can access public or private healthcare, and in some cases whether the patient is a native or an expatriate.

Many healthcare systems across the world, including the US and parts of the Middle East, have traditionally operated under a "fee for service" payment scheme. This means a healthcare provider will get paid for each separate service they provide. For example, if a nurse attends a patient's home to redress a wound, that is one cost; if a patient needs a specialist assessment, that would be another, separate cost.

Under this model, healthcare providers get paid regardless of whether the service leads to a positive patient outcome. If a medical professional is treating a leg ulcer over time that does not ever heal, they will still get paid, and the patient will still be charged. For the growing number of global patients suffering with chronic conditions who require long-term care management, especially wound care, this can result in expensive medical bills.

However, many healthcare systems are shifting towards a "fee for quality" or episode-based approach. Under these systems, patients will pay for the quality of care they receive irrespective of how long and how often treatment is needed. Healthcare systems can predetermine the best products and approaches for treatment based on medical evidence, enabling patients to access the best quality and most cost-effective care, making it fairer and more effective for both providers and patients.

This should – in principle – help to ease the pressure on healthcare systems which are having to treat an increasing number of individuals with chronic illnesses. The sooner patients can be treated and cured, more patient beds will be available, fewer nurse visits will be required and less resources will be needed.

Improved patient outcomes, more effective healthcare

More efficient and cost-effective treatment plans will help healthcare systems provide the best care possible. MedTech is uniquely placed to bring about positive change across global healthcare systems. Instead of trying to ensure adoption of new innovations within the confines of the previous system, healthcare systems are changing to actively foster adoption.

Embracing and adopting medical innovation with the aim of curing a patient's illness will help patients recover as quickly and effectively as possible. This important shift will enable more investment in the development of new medical technologies and help lessen the pressure on the entire healthcare operation – creating a brighter, more effective, and affordable system for all. MEH

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The author

Andrew Thelwell is Chief Commercial Officer at Sky Medical Technology. Sky Medical Technology is a highly innovative UK-based medical devices company that has developed a ground-breaking neuromuscular electrostimulation technology platform, OnPulse. The company develops a range of products tailored to the needs of different medical application areas selling both direct and through strategic partnerships or distributors in each major clinical area. Clinical areas of interest include DVT prevention, oedema treatment and prevention, and wound healing. The goal in each clinical area is to improve clinical outcomes and patient care whilst saving health system resources.

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Interview

Digitization improves patient outcomes and workflow productivity

Businesses worldwide are embracing digital transformation. In the past decade, many organizations have ramped up their digital efforts in order to overhaul their business processes and improve the customer experience. The same can be said of the healthcare sector and medical imaging specifically. Through a variety of digital initiatives, healthcare as an enterprise is changing the way it is performing its workflows and improving its patient outcomes. *Middle East Health* spoke to Ahmed Alkhatib, Sales Manager Healthcare MEA at Barco, to learn more about some of the most prominent digital imaging trends in healthcare today.

***Middle East Health*: Where does the need for digital transformation in healthcare come from?**

■ **Ahmed Alkhatib:** Digitization is permeating all aspects of the healthcare industry. This is driven by a need to deliver a better patient experience, more favorable patient outcomes, but also to improve profitability of the healthcare enterprise. Just think of what artificial intelligence can do for radiology today. AI can reduce workload, but it can also detect lesions that are sometimes hard to find for the human eye. Instead of studying a chest image for forty minutes, it can now be done in less than five. So, it's a mix: digitization improves patient outcomes, but it also increases productivity.

MEH: How is Barco contributing to the digitization of healthcare enterprises?

■ **AA:** Barco has been developing medical display solutions for more than 20 years and has always been a frontrunner in improving medical workflows for radiologists. Today, Barco's offering is much wider, stretching into the digital operating room, digital pathology, and even healthcare operations centres.

MEH: How does digitization help the operating room?

■ **AA:** More and more imaging technology is brought into the OR today. While this is a good thing, it has also made the setup and configuration before surgery complex and time-consuming. As a result, it has become increasingly difficult to prevent surgery delays, cancellations and long patient waiting lists.

With a technology called OR-over-IP, you make the IP network the universal communications platform, allowing OR technicians to share uncompressed, high-resolution video in and between operating rooms. This is exactly what Barco's Nexxis OR-over-IP platform does. With Nexxis, you can add new devices or switch sources on a plug and play basis, and display images on any OR display connected through the network.

Ahmed Alkhatib, Sales Manager Healthcare MEA at Barco

Again, digitization benefits everyone. Surgeons can use the Nexxis system to

view images with near-zero latency and thus improve their hand-eye coordination. In turn, this allows the OR to treat more patients, which increases revenue.

With a solution like NexxisLive, you can even share surgical images with remote professionals, who are joining the case to provide assistance, or with students who can follow the procedure in an external auditorium.

MEH: Barco has also entered the field of digital pathology. How would you describe this niche?

■ **AA:** Digital pathology is an emerging technology in pathology, in which a scanner converts glass tissue slides into digital slides that can be viewed and analyzed on a display with the help of viewing software. In contrast to the often-time-consuming analog method of looking at slides under the microscope, digital pathology makes it possible to view slides much faster and diagnose more efficiently. Biopsy or sample collection techniques, laboratory workflow and final reporting with treatment decisions remain largely unchanged, but the slide review phase of the pathology process can now be done in a digital way, in combination with or even replacing a microscope.

MEH: What innovations in pathology can we expect from Barco?

■ **AA:** Barco has contributed to digital pathology innovation by the recent launch of the MDPC-8127, the first ever medical-grade display designed exclusively for digital pathology. With regulatory clearances for use in digital pathology, including primary diagnosis, it's the first display that you can confidently integrate into your digital pathology workflow with multiple whole slide imaging systems.

The MDPC-8127 is an 8-megapixel, display that offers high pixel density and color per-pixel-uniformity, so slide images are displayed extremely sharp and consistent. The display's color gamut is also tailored for digital pathology images, and offers up to 1.07 billion possible colors. This brings an unprecedented visual richness to digital pathology.

You can say that digitization really makes a huge difference for pathology imaging. To efficiently view slides, you need great detail and high zooming capability. And this is exactly what Barco's MDPC-8127 display offers. It provides pathologists with optimal viewing confidence and improved workflow efficiency.

We are looking forward to showcasing this display at Arab Health in January 2022.

MEH: Barco is now also helping healthcare facilities to streamline operations. How are they doing this?

■ **AA:** Barco has many years of experience with visualization and collaboration solutions for command centres. Just think of the large video wall screens and operator consoles you know from a traffic or utility centre. The value Barco offers there is to bring information and data from different sources, stakeholders and departments together in a clear and efficient overview. Today, we see an increased need to do just that, with the rise of the healthcare operations centre.

Nowadays, hospitals are complex organizations that communicate and collaborate across multiple health systems, sites and departments. If you want to guarantee high-quality patient care and coordinate these operations efficiently, you need to have a clear overview of your patient flows and capacity. This way, you can better allocate resources and reduce waiting times for patients. A healthcare operations centre acts as the nerve centre of a hospital, and brings all that information data and information together, so hospital personnel can make the right decisions to optimize their patient flow, monitor bed capacity and manage OR occupancy for example.

During the Covid pandemic, authorities

and healthcare facilities needed to have an efficient overview of their bed capacities. Thanks to these healthcare operations centres, different clusters of healthcare facilities could easily communicate and align their operations with each other. But even beyond the pandemic, decision-makers are realizing the benefit of having such a real-time operational overview to take decisions that have an impact nation-wide.

MEH: This is what is already happening today. How do you see digitization developing within five to ten years?

■ **AA:** The trends mentioned above will remain in effect for years to come, but you can also expect AI, robotic surgery and interactive patient care to become more important. At Barco, we are continuously monitoring market trends and anticipating future trends, so we can meet the increasingly high expectations of medical professionals and patients. MEH

It's time for healthcare to embrace IoT

By **Patrick Linnenbank**,
MD MBA FAWM CMAS
Partner at Arthur D. Little

The Internet of Things (IoT) has become a hot topic across many sectors worldwide. Some organizations are beginning to test the water, while others have taken the plunge, rolling out a range of IoT solutions, with benefits already shining through – reduced costs, greater efficiency, and enhanced connectivity counting amongst them. When it comes to healthcare, the story has been somewhat different with IoT uptake initially slow, but in the context of a global pandemic and advancing technologies, the situation is changing fast.

Since the arrival of Covid-19, telehealth has become a vital tool in healthcare provision, while the IoT offering has become more sophisticated, with solutions now tailored to the specific needs of individual organizations. Combined with the roll out of 5G, these factors serve as a call to action: now is the time for healthcare providers to create IoT roadmaps and chart the course for a connected future.

But there is a caveat: the greatest gains will not come from connecting equipment piecemeal; to unlock the potential of the connected world, healthcare providers must commit to fundamental transformation. The logic is simple: the more "things" they connect, the more data they generate, and the greater the rewards.

The state of IoT in healthcare

The potential is huge, but the initial resistance to IoT from the healthcare sector is understandable. When IoT was in its infancy, vendors underestimated the unique needs of healthcare organizations and early attempts to adopt IoT solutions were premature – neither the healthcare industry nor the technologies were ready. Today, however, the timing couldn't be better.

With IoT solutions ready for the taking, healthcare organizations are rethinking their ICT architecture, moving away from legacy solutions to more enterprise-based implementation. Meanwhile, Covid-19 is increasing familiarity with digital tools, fast-tracking new processes, and accelerating IoT adoption. For their part, payers and insurers are compelling healthcare organizations to rethink data management, while device manufacturers are ramping up the digitization of their products.

With technologies and circumstances aligning, attitudes towards IoT are shifting. For the first time, healthcare organizations and the people they serve are viewing technology as an enabler when it comes to delivering quality care.

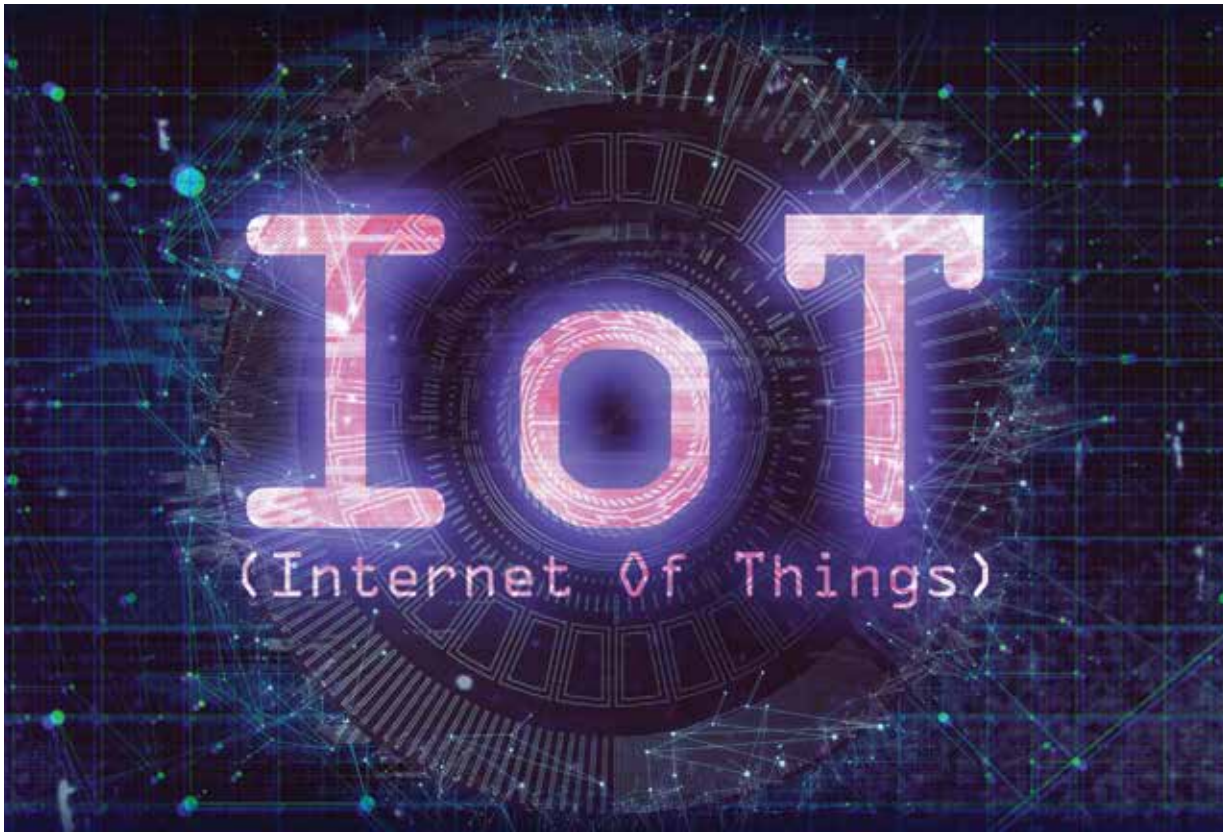
IoT in action

The world of IoT can seem complex and overwhelming, but most use cases are built around core functionalities ranging from simple track-and-trace solutions to complex automation. These functionalities can, in turn, be leveraged to enable the key pillars of a smart hospital: clinical excellence, patient-centric care, and operational efficiency.

In the UAE, use cases are aplenty. Abu Dhabi Telemedicine Centre, a joint venture between Mubadala and Medgate, offers high-quality medical consultations over the phone, while Mubadala Healthcare is working in partnership with the Abu Dhabi Center for Public Health to allow non-critical Covid-19 patients to be monitored at home through a remote healthcare platform.

Ground-breaking technologies, such as robotic-assisted surgery equipment, are also present in the UAE. In just one example, in 2020, Cleveland Clinic Abu Dhabi performed the country's first robotic "whipple" procedures to treat pancreatic and duodenal tumours.

IoT initiatives are underway in neighboring Saudi Arabia too. Prime among them are the Mawid and SEHA apps, developed by the kingdom's ministry



of health. Through Mawid, patients can book, amend, or cancel healthcare appointments, while SEHA provides in-app medical consultations with ministry-accredited doctors from all specialties. Telecom operator, Mobily, is also playing an instrumental role in building the required infrastructure.

The challenges

The progress made by the UAE, Saudi Arabia, and other countries in the region is impressive, but the achievements belie the challenges that inhibit IoT uptake. In Saudi Arabia, the greatest challenge relates to patient privacy and security, followed by poor experiences, staff shortages, and weak infrastructure. Cost, device maintenance, data storage, and change management also feature among the obstacles. Yet, none of these hurdles should deter the healthcare industry from embracing the power of IoT. With the right roadmap in place, healthcare providers can overcome the challenges and benefit from the advantages that unprecedented connectivity can bring.

Healthcare regulation also needs to play a key role in ensuring that cybersecurity and data privacy guidelines are defined and implemented across devices. The region is beginning to develop its own standards, such as Abu Dhabi Department of Health's stand-alone policy defining security standards for IoT applications and devices. However, more comprehensive guidelines are required to ensure cybersecurity across all players in the ecosystem: regulators, providers, MedTech companies, and information service providers.

The next steps

To help healthcare providers embark on their individual IoT journeys, Arthur D. Little proposes a six-step approach to building a cohesive roadmap:

1. *Assess potential of IoT use cases:* Identify the pain points that you hope to solve, and what solutions could help.

2. *Review existing technical architecture and infrastructure:* Identify the gaps in your infrastructure, the resources needed to support the use cases, and the infrastructure that would best fit into your roadmap.

3. *Review impact to organization and processes:* Consider how implementation of the use cases might disrupt existing processes and what identity ways of mitigating risks.

4. *Assess scalability:* It is important that use cases are easy to scale across settings and that they can be combined in a logical way to enable better insights.

5. *Calculate the resulting business cases and make prioritizations:* Establish which cases to prioritize and identify the available budget, ensuring that business cases cover all costs related to the implementation and management of any new solution.

6. *Build the roadmap:* Build out a roadmap of the prioritized use cases, taking into account when the required technology and budgets will be available, the rate of change the organization can manage, and the overarching goals.

Conclusion

While the expected near-term growth of IoT in healthcare has often been inflated, its potential has not. Healthcare organizations that succeed with IoT have the potential to provide expanded and better care at the same cost. To achieve this, several hurdles must be overcome, but with the right planning and implementation, these real gains are a real possibility. Like all the best planned journeys, it all starts with the right map. MEH

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Drug data unity: Realistic and idealistic futures for information exchange

Is it realistic to envision a healthcare landscape in which all players are fully interoperable, enabling consistent communication between various providers and coverage sources? Short answer: Yes. And no. Idealistically, we have, right now, the data and the capabilities to achieve this vision, informatics experts say.

If every healthcare entity in a given region committed to adopting a set of standards for data sharing, including broadening what types of patient information is shared, and to implementing and developing a consistent interoperable technology, it could enable widespread data unity and information exchange.

Realistically, however, that doesn't happen. In the United States, for example, where the government sponsored HITECH act invested millions in helping hospitals and healthcare providers acquire and implement electronic health record (EHR) technology to collect and store patient data, very little of that investment has gone toward encouraging interoperability or developing unified data sharing[1].

However, every step forward pays dividends in creating a stronger digital health infrastructure to help connect different departments, organizations, regions, and even countries, and turn data into meaningful information that can improve patient safety.

Patient safety and the data input gap

Medication errors can have a devastating impact on patients, leading not only to patient harm, but to high care costs and drains on staff resources:

- In England, more than 237 million medication errors are reported every year costing the NHS upwards of £98 million and resulting in more than 1,700 lives lost, according to a 2020 report[2]
- Ten percent of U.S. hospital patients are subject to a medication error, while U.S. community pharmacies have an estimated dispensing error in 1.5% of all prescriptions[3]
- Globally, the WHO estimates 6 to 7% of hospital admissions in some countries to be medication-related[4]

"Drug errors, it's pretty clear, cost society a lot," says Steven Hart, MD, a clinical informatics expert. "That includes the individual patients who might be harmed and maybe have a longer hospitalization or become permanently impaired or die. That's a big deal to that patient, but it's also a big deal to the insurance company that has to pay for the ramifications and to the hospital, potentially. That's where it becomes a systemic issue. If you can reduce adverse drug events, the net benefit to society would be quite large financially."

With the advent of electronic health systems and the increasing digital maturity in many developed healthcare ecosystems, professionals turn to clinical decision support (CDS) to help prevent medication errors. In a hospital setting, healthcare professionals have access to a wealth of inputs from which to draw context for clinical drug safety screenings: lab data, current patient weight, problem lists, demographics, and more. But then, that patient and their prescription leave the hospital and head out into the wide world of retail pharmacies, clinics and outpatient care.

The whole role of the pharmacist is to monitor drug therapy and make sure it's right for the patient and then bring anything to the physician's attention if it's not. But retail pharmacists and other providers only have access to a small fraction of the demographic and diagnostic data that prescribers consult.

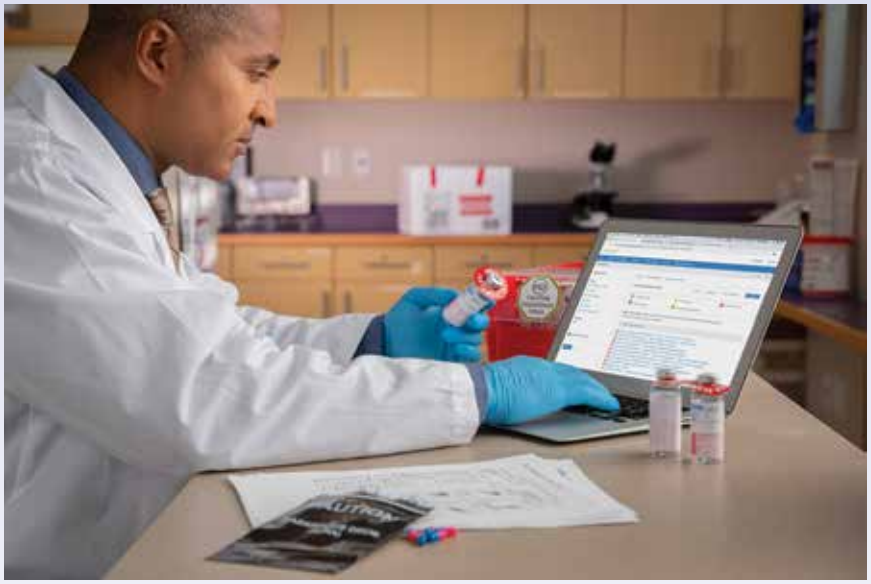
When it comes to data, location matters

Your data sharing is often affected by your location. In Germany, for example, medical information sometimes cannot be shared even across different departments of the same hospital due to data protection regulations[5].

The data gap that exists between providers is not a universal phenomenon. It is a common challenge in healthcare ecosystems in which organizations have the ability to purchase their own healthcare information system and patients have the choice of private insurers, either through their employers or out-of-pocket purchase. This economic choice creates data silos. Each system or business owns its own data, and patients and professionals must rely on government regulations or standards bodies to develop and enforce interoperability.

Some countries such as the U.S., the U.A.E and the Kingdom of Saudi Arabia have achieved a higher level of digital maturity. However, data silos exist in some countries where healthcare infrastructure is lacking. Informatics experts describe similarly siloed situations in less developed regions where healthcare professionals have compensated for lack of resources by supplementing paper charting with homegrown EHRs of their own design.

The barriers to information sharing are lower in countries with national health systems, which strive to create equal access to care for all citizens. But even when a



national identification system for patients helps enable information sharing between a country's provider organizations, there are still barriers to interoperability, including gaps in technology infrastructure and data quality in different regions and hospital locations.

Improving how and what we share

Experts agree, the key to improved data sharing and interoperability lies in two areas of investment:

1. Standardized, sophisticated technology infrastructure
2. Quality data delivered in sharable format

The worldwide push to adopt EHR technology over the last two decades represented a first step in the global digitization of healthcare. Although disparate systems cannot always share information smoothly and different regions operate at vastly different levels of technological maturity, we now have a global consensus toward electronic records and information sharing.

Newer technologies like SMART on FHIR help further streamline app development and enhance decision support with CDS Hooks. Except in cases where a platform or type of data is mandated nationwide by a ministry of health, there will always be a mix of choices. Interoperability and data sharing will depend on standards, quality, and our willingness to adhere to them. To be as prepared as possible, experts suggest investing in a data system that is "future-proof", or able to map to variety of standard concepts and identifiers so as to adapt to unexpected industry demands.

The future of data can start right now

Data unity may still, in many ways, be an ideal, but our reality is a more interoperable, interactive healthcare information technology landscape than we had even a decade ago.

"I personally see this problem as an opportunity," says Hart. Instead of looking at health information exchanges and only seeing the gaps where information isn't being shared, he advises that the healthcare industry and innovators instead ask themselves, "can we provide a product or a mechanism where we can pull that information into the system, and all of a sudden, you can provide better results".

To be as prepared as possible, experts suggest investing in a data system that is future-proof, or able to map to variety of standard concepts and identifiers so as to adapt to unexpected industry demands.

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Daedalus online database provides regulatory intelligence for the medical device market

An online database called 'Daedalus', developed by German company RegIntA, is shining a light in the darkness of internationally varying legal regulations for medical devices and pharmaceuticals. Medical technology and pharmaceuticals are one of the most heavily regulated sectors in industry. Country-specific regulations and laws that cover the entire life cycle of a product, from its development to market approval, change notifications and re-registrations, as well as market surveillance, are increasingly complicating business for manufacturers who want to sell abroad. Daedalus provides a solution for this.

Katrin Rosen, founder and managing director of RegIntA, commented: "Country specific regulations are always a challenge for international expansion. Regulations and requirements are constantly changing, becoming more stringent and opaquer. For many companies, the need to check the requirements on an ongoing basis is becoming increasingly time-consuming and costly, as well as a real business risk. With our Daedalus database, we offer a 24/7 up-to-date country- specific insight that helps companies meet the legal requirements in their respective markets, all based on a simple booking and billing model."

Continually updated data

The online platform bundles the concentrated know-how of international legal regulations and relieves companies' regulatory affairs departments from having to do time-consuming and cost-intensive research of the their own. To this end, an international team of native speakers – from Chinese to Arabic – evaluates the latest legal requirements from a wide range of sources around the clock. All sources undergo a separate impact assessment in the specially designed document management system. As a result, the customer receives bundled and clearly arranged information on all aspects of the life cycle of the medical device, such as product registration or safety notifications.

Rosen added: "With our information, the customer gets everything they need to bring their product to market without delay and in compliance with the national regulations. Daedalus saves human resources and minimizes the risk of making mistakes during the critical registration phase."

She said this was also useful if, for example, changes are made to the product down the line and it again becomes necessary to comply with the requirements of the respective authority.

Regulatory information

RegIntA generated its Quality Management System and the related processes based on ISO 9001:2015. The most stringent quality checks are performed at every stage of development of the regulatory information, before the new version is uploaded for the customer.

The regulatory information is offered in different packages. Depending on the package, this includes among others the legal framework, definitions, documents to be submitted for registration, special requirements for tests or clinical studies, language requirements or submission types, change notifications, re-registrations and labelling. In addition, the manufacturer can download original documents such as registration forms or guidance documents.

The listed countries can be selected separately and, if not yet included in Daedalus, will also be prepared at the customer's request. Changes in regulatory information are marked for the customer within the online database and documented in the history section. In addition, the customer receives an e-mail notification of any changes. In this way, the customer remains continuously up to date.

Katrin Rosen, founder and managing director of RegIntA

Individual consulting

RegIntA also offers its expertise as part of individual consulting related to country-specific regulatory affairs questions for medical devices as well as for medicinal products.

Rosen explained: "In addition to Daedalus, we make our expertise available offline and take manufacturers by the hand with customized consulting services – regardless of whether this involves support with national approval processes, analysis of individual regulatory hurdles during market entry, support for pharmacovigilance and vigilance processes, and the Quality Management System."

The extended range of services can be used either on its own or as an additional service to Daedalus.

- For more information, visit *www.reginta.de*. MEH

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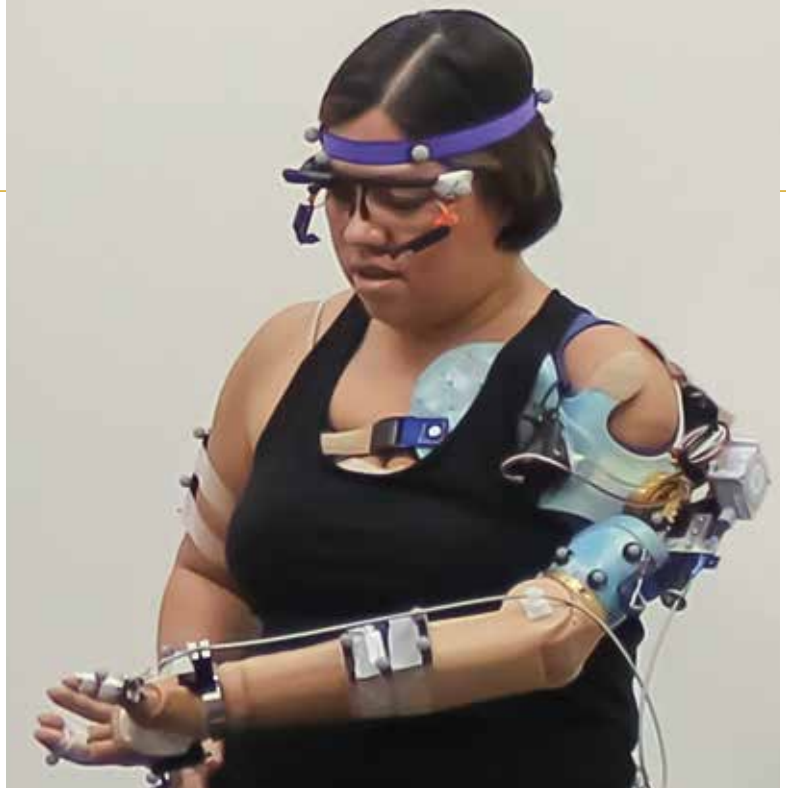


The advanced prosthetic arm feels grip movement sensation, touch on the fingertips, and is controlled intuitively by thinking. Reflective markers on users' arms and body help a computer see their movements in a 3D-environment, while glasses allow a computer to see exactly what they see.

Researchers engineer bionic arm with intuitive control as well as touch and movement sensation

A Cleveland Clinic-led international research team have engineered a first-of-its-kind bionic arm for patients with upper-limb amputations that allows the wearer to control the arm with their thoughts and feel the sensations of touch and movement.

The bionic system combines three important functions – intuitive motor control, touch and grip kinaesthesia, and the intuitive feeling of opening and closing the hand.

The system is the first to test all three sensory and motor functions in a neural-machine interface all at once in a prosthetic arm. The neural-machine interface connects with the wearer's limb nerves. It enables the patient to send nerve impulses from their brain to the prosthetic when they want to use or move it, and to receive physical information from the environment and relay it back to their brain through their nerves.

The artificial arm's bi-directional feedback and control enabled study participants to perform tasks with a similar degree of accuracy as non-disabled people.

"Perhaps what we were most excited to learn was that they made judgments, decisions and calculated and corrected for their mistakes like a person without an amputation," said lead investigator Paul Marasco, Ph.D., associate professor in Cleveland Clinic Lerner Research Institute's Department of Biomedical Engineering. "With the new bionic limb, people behaved like they had a natural hand. Normally, these brain behaviours are very different between people with and without upper limb prosthetics."

The researchers tested their new bionic limb on two study participants with upper limb amputations who had previously undergone targeted sensory and motor reinnervation -procedures that establish a neural-machine interface by redirecting amputated nerves to remaining skin and muscles.

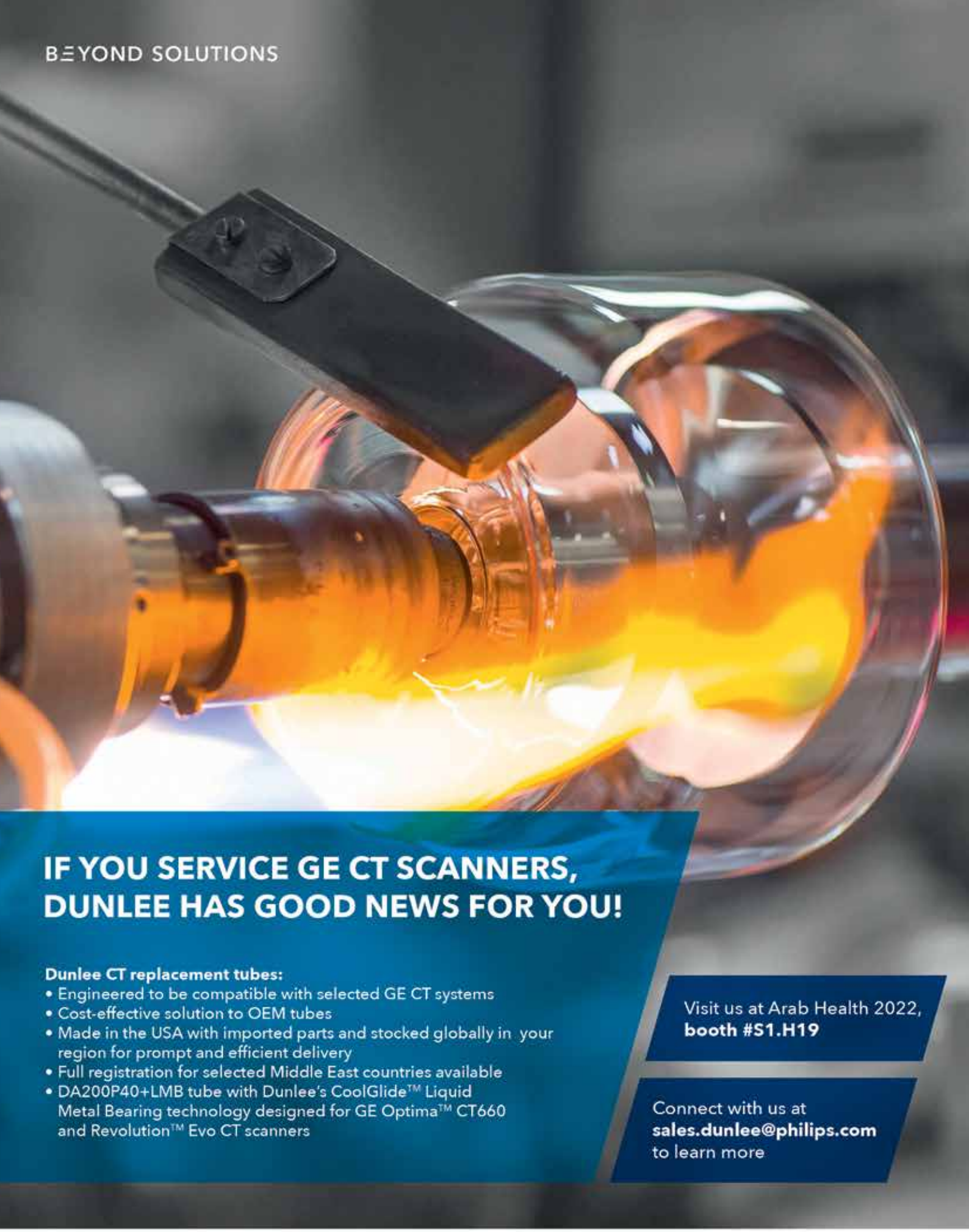
In targeted sensory reinnervation, touching the skin with small robots activates sensory receptors that enables the patient to perceive the sensation of touch. In targeted motor reinnervation, when the patient thinks about moving their limbs, the reinnervated muscles communicate with a computerized prosthesis to move in the same way. Additionally, small, powerful robots vibrate kinaesthetic sensory receptors in those same muscles which helps the wearer feel that their hand and arm are moving.

According to Dr. Marasco, because people with traditional prosthetics cannot feel with their limbs, they behave differently to people without an amputation while completing tasks during daily living. For example, traditional prosthesis wearers must constantly watch their prosthetic while using it and have trouble learning to correct for mistakes when they apply too much or little force with their hand.

With the new artificial arm and the advanced evaluation tools, the researchers could see that the study participants' brain and behavioural strategies changed to match those of a person without an amputation. They no longer needed to watch their prosthesis, they could find things without looking, and they could more effectively correct for their mistakes.

"Over the last decade or two, advancements in prosthetics have helped wearers to achieve better functionality and manage daily living on their own," said Dr. Marasco. "For the first time, people with upper limb amputations are now able to again 'think' like an able-bodied person, which stands to offer prosthesis wearers new levels of seamless reintegration back into daily life."

The study was funded in part by the Defense Advanced Research Projects Agency, a research and development arm of the U.S. Department of Defense. MEH



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MAGNETOM Free.Max[1] breaks barriers to expand the reach of MRI. Where patients have felt discomfort, the world's first 80 cm bore sets a new paradigm in patient comfort. Where infrastructure was an obstacle to MRI, MAGNETOM Free.Max slots into an existing helium-free infrastructure. Where access to MRI was not viable, MAGNETOM Free.Max makes access affordable. And where conventions have limited our thinking, MAGNETOM Free.Max breaks out of conventions to explore new clinical opportunities in MRI.

[1] The product is still under development and not yet commercially available. Its future availability cannot be guaranteed.

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