

# The Journal of mHealth

The Global Voice of Digital Health

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## Is it Effective?

### Understanding Evidence in HealthTech

#### EXPERT OPINION

Understanding Outcomes: Measuring the Value of HealthTech



#### FEATURE

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# In This Issue

- 2 Editor's Comment
- 4 Real-world Data and Health Tech are Tightly Interlinked with the Future of Medicine
- 6 Standards of Evidence in Digital Health
- 8 Understanding Outcomes: Measuring the Value of HealthTech

In this article Natalie Nelissen, evidence and evaluation lead for mHabitat, considers the current situation when it comes to evidence in health technology and how the need to demonstrate effectiveness and benefit is evolving.



- 22 Upcoming Events

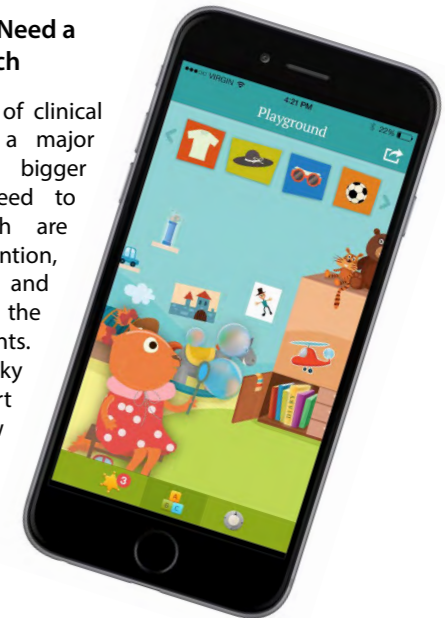


- 24 Embracing Digital Health: How Insights are Transforming Tomorrow's Trials

This article, discusses how insights generated from big data and mHealth are transforming tomorrow's clinical trials, improving the efficacy of therapies in the real world and increasing pharma R&D productivity.

- 26 Clinical Trials Need a Gamified Touch

While the cost of clinical trials remains a major challenge, the bigger issues that need to be dealt with are patient retention, engagement and adherence to the trial requirements. Peter Rakowsky of DataArt discusses how gamification can be applied to clinical trials to improve outcomes.



- 29 A Strong Value Proposition: The Key to Engaging the NHS for SMEs
- 30 Harnessing Technology to Combat Mental Health
- 32 Meet the Company Pushing the Path to Patient Safety
- 33 What Will a Future Cardiology Appointment Look Like?
- 34 Telecare-as-a-Service: Could a Microsoft-style Subscription Model Work?
- 36 Fit for Purpose: Introducing Data Mapping for a Healthier NHS

## Industry News

- 12 London's Health Hub Officially Opens its Doors
- 13 EarlySense Selected for an Evaluation of Neonatal Health Monitoring Technologies in Africa
- 14 Gaming 'Controller' boosts Stroke Survivors' Chances of Regaining Full Arm and Hand Use
- 15 Kaia Health Unveils a Feasibility Study to Explore a Digital COPD Treatment
- 16 Partnership Aims to Attain 'One Billion Special Steps'
- 17 Research Evaluates Using Data Science and Clinical AI for the Management and Treatment of Chronic Disease
- 18 Research Reveals Healthcare Email Fraud Attack Attempts Jump 473% Over Two Years
- 19 Neurologic Music Therapy Provides Significant Fall Prevention Technique in Over 65's
- 20 CardioSecur® Shines a Light on the Dark Side of the Moon
- 21 Partnership to Deliver the First Health Information Exchange in the Middle East





# Real-world Data and Health Tech are Tightly Interlinked with the Future of Medicine

By Ian Chuang, MD, MS, CCFP, Chief Medical Officer, EMEA-LAAP Health at Elsevier

## The status quo

Controlled Clinical Trial. Just by the name, we can see its juxtaposition from medical treatment in the real-world. Patients in controlled trials are carefully selected based on matching a set of criteria. Not knowing whether the treatment is likely to work, we are comfortable blinding the patient and potentially withholding treatment or using a placebo. At the end of the clinical trial, we are able to conclude that for a population of patients within a set of criteria, the treatment did or didn't work more effectively or more often than the alternative.

When it comes to patient care, from both the physician's and

patient's perspectives, the question is more specifically whether the recommended treatment is going to work for this specific individual. Using our existing methods, we are taking insights at a population level and having to make decisions for the individual. This model and approach is far from precise.

When physicians take population level research and apply it to the individual patient, that patient will match some high-level clinical criteria centred on the diagnosis, severity, and a few patient attributes. Beyond that, the treatment is really a therapeutic trial.

Traditionally, we thought of that as building experience of the treatment. The more we treat, the more experience we have with all the different patients that exist to uncover who it works best for, and how. Population-wide, we are now able to lever-

age the large real-world treatment data along with better computing power and approaches to uncover the nuanced patient attributes and treatment efficacy. The premise is not new, for decades we have looked to mine pools of data to understand how to more effectively treat our patients. The pharmaceutical industry has been a great proponent of this through Phase IV studies. However, all too often the data lived in silos and the process takes years of data mining to generate.

## Being equipped to face the challenges of medicine

Remaining at the status quo will not address the significant challenges facing healthcare practitioners, hospital managers, and health systems globally today. We must find a way to interlink real-world data and practice faster than previously. Health tech is what sits at the frontier between evidence-based data and real-world data. Health tech combines the evidence from clinical research data and real-world data obtained from practical care, to identify optimum treatment in every variation that can be present in a patient across situations and scenarios the physician will never have had personal experience with.

Let's look at oncology as an example. Life-threatening cancer often has the least luxury of time for trial and error with treatment. We suspected for a long time that cancers of a particular type are not all the same, however we didn't know where and how they were different, and more importantly, we didn't know how to treat them differently. Now, gene sequencing is revealing that certain genetic findings actually determine the body's or tumour's response to treatment. In this example, practice-based knowledge is about the real-world data from patients who responded favourably as well as those who didn't. Precision medicine is then about physicians learning from and leveraging this knowledge to save cost by reducing the trial and error routine, provide a more precise care plan for their specific patient, and quite possibly save the life of that patient with a more timely and effective action.

This type of practice-based learning is leveraging the data from patients who responded favourably as well as those who didn't across larger populations than a single physician, hospital, or system can possibly encounter. Unlike Controlled Clinical Trials, the more variables available to analyse and the larger the pool of patients to analyse, the better. Only through technology is it practical to churn through the big data. As such, technology is the enabler. It allows physician to make use of all the data available to them, evidence-based or real-world. With it, we can leverage the large real-world approaches to uncover the nuanced

patient attributes. Insight about a broad group based on diagnosis can be refined to smaller cohorts based on other factors that can impact response.

## Generating value through real-world data and technology

From a healthcare financing and cost perspective, technology has strong cost implications as well. The waste of both treatments and the associated cost from therapeutic trial and error with treatments is neither cost effective nor efficient. Unused medications are wasted, and the net cost is the sum of the failed treatment plus the cost of the eventual treatment that actually works. Precision in diagnostic and treatment now reduces the rate of non-response and can improve the cost benefit analysis of new treatments.

The breadth of treatment options only expands with each new discovery. The financial cost to achieve the desired treatment outcomes cannot follow the prices of new therapies. Without precision knowledge, the clinical risk, the associated cost, and the emotional toll on patients with such broad based therapeutic treatment trial in real world practice is not sustainable. The opportunity is to better slot treatment options to align to what known genotypic and phenotypic traits are better predictors of treatment response and achieve the desired outcomes.

Precision medicine insights and capabilities shouldn't deter or discourage pharma from continuing to research and seek novel treatment options. However, these expensive treatments should be judiciously used where we know they will more likely work. The healthcare systems cannot sustain sub-optimal or ineffective uses of high-cost therapies. As such, pharma's financial success in the future will be more dependent on their efforts towards uncovering the precision use of treatment of highest known efficacy.

Health technology and real-world data are intricately interlinked with the future of medicine, and it is a future to be welcomed. An ongoing challenge will be to ensure that we combine data so that sufficient pools of information can be created and high-quality evidence can be generated. Through this collaboration we will begin the process of democratising data, meaning that we will ensure that knowledge based on evidence from the real world is available to each and every physician, enabling physicians to make equally informed care decisions. That will require more than simply pooling; it will require vastly complex data management that only technology can provide, and due to the importance of what is at stake, trust in the provider who is holding and managing the technology will be crucial for success. ■

## DON'T MISS

our Upcoming Events section on page 20  
to find out what's on across the mHealth industry



# Standards of Evidence in Digital Health

As with all medical innovations, there is a requirement for health tech products to demonstrate evidence of clinical effectiveness and value. This is essential for patients, who deserve to receive only those technologies that have proven safety and clinical benefits. It is also important for healthcare systems, which need to know that their limited resources are being spent on new medical technologies that will deliver economic value.

The growth of this sector has been phenomenally quick, particularly in the area of digital and mobile health. The decision-making frameworks for the evalu-

ation of the digital health technologies now need to catch up rapidly to ensure that an evidence-led approach is taken. Digital solutions in other sectors have followed a 'fail fast' approach where new innovations flooding the market, are tested in an uncontrolled manner by users, and then fail or are taken up. However, this approach should not apply to the digital health tech industry, where the consequences of failure are so much greater.

In the UK, the National Institute for Health and Care Excellence (NICE) has recently published a *new evidence stan-*

*dards framework for digital health technologies.* The framework was developed in partnership with other healthcare bodies, including NHS England, with input from commissioners, industry and academia. These evidence standards are leading the way in providing both developers and commissioners with an understanding of what good levels of evidence look like for digital health technologies according to the level of risk to patients. The evidence framework also includes many aspects of user experience, ensuring that the digital technologies deliver the best value to the users, be they healthcare professionals or patients.

The NICE evidence standards framework uses a functional risk-based classification to divide the different types of digital health technologies into evidence tiers; the higher the tier, the more evidence is required on the effectiveness and economic benefits of the technology. In this way, the framework

recognises that there is a variety of different digital technologies out there that may not require the same levels of evidence. The standards also recognise that in cases where the impact of the technologies are similar to new pharmaceuticals in terms of health benefit/risk and resource impact, then the evidence requirements will also be similar.

There is much work still to be done. There is currently inconsistent evaluation and take-up of digital healthcare products across the UK. The NICE evidence standards for digital health technologies provide an optional framework for manufacturers, research funders, investors and commissioners to use in assessing new technologies. Innovators and decision makers would benefit from learning how to use these evidence standards and the value of the framework needs to be communicated to other countries that are interested in developing similar processes.

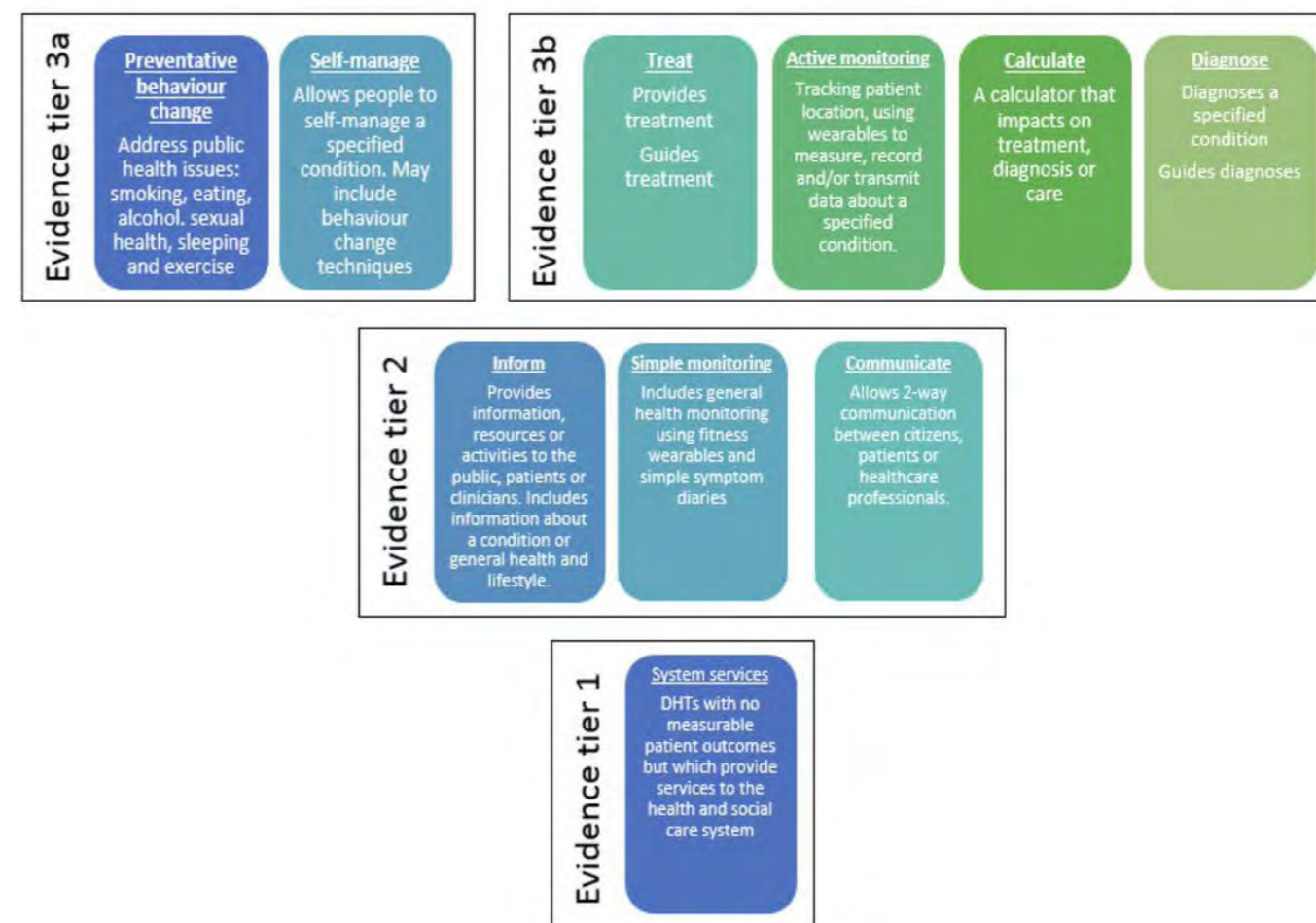
The role of real world evidence in the post-launch evaluation of digital health

technologies is potentially significant. There are huge opportunities for data collection given the digital nature of the technologies. However, they also face the same challenges in the collection and interpretation of real world data as other medical innovations, namely bias and confounding due to the non-randomised nature of the data, risk of inappropriate statistical techniques being employed, problems with missing data, and access to and anonymisation of the data. Rigorous requirements for real world evidence for digital health technologies are necessary in order to help developers maximise their data-generating potential and to ensure that the data collected ultimately benefits patients.

There is a global lack of clarity on the evaluation of digital health technologies by healthcare decision makers, which accentuates the need for better dialogues between the developers of the technologies and the decision makers. At NICE the Scientific Advice team, along with the developers of the evidence standards for digital health technologies, are providing

advice to commissioners and innovators who are interested in accessing the UK market. Manufacturers of any type of medical technology will also soon be able to upload the details of their technologies, together with a summary of the supporting evidence, to the HealthTech Connect web portal (due to launch soon) to allow a range of stakeholders to access this information.

These important topics on the future of evidence collection and value demonstration will be explored at the NICE Annual Conference on 9 May in Manchester. NICE 2019: Transforming Care will celebrate 20 years of NICE's commitment to innovation, excellence and evidence-based health and care. There will be sessions focussing specifically on the challenges affecting medical devices and digital technologies, including what evidence developers should provide to get their app approved within the NHS apps library and the future of HealthTech assessments at NICE. To find out more and to book your place, please visit [www.niceconference.org.uk](http://www.niceconference.org.uk). ■



# UNDERSTANDING OUTCOMES

## MEASURING THE VALUE OF HEALTHTECH



Natalie Nelissen is the evidence and evaluation lead for mHabitat. In addition to its ongoing commitment in supporting people-centred digital innovation in health and social care, mHabitat is partnering with the Yorkshire & Humber Academic Health Science Network (AHSN) to deliver Propel@YH – the region's first digital health accelerator programme which will help SMEs innovating in digital health to navigate the complex healthcare landscape and build an NHS-relevant business case.

While the number of tools for digital health and care – such as apps, websites, software and wearables – is growing rapidly, the evidence to show these tools are actually beneficial is lagging behind.

For example, there are over 318,000 apps available, yet only 22 stand-alone health apps have reported randomised controlled trials (RCT, the golden standard for evidence-based medicine). Out of these, 11 were able to demonstrate some meaningful impact on health and overall, the evidence was considered of very low quality<sup>1</sup>.

Broadly speaking, there seems to be a distinction between commercially-produced digital tools and those developed within academic or government institutions. The latter have more potential health benefits but are slower to develop, often not very good at engaging users and don't always make it to market<sup>2</sup>.

In addition, high-quality digital tools may not be presented to potential users first. For example, the highest-ranked smoking cessation apps in the app stores were of poor quality, while high-quality ones ranked lowest<sup>3</sup>.

There is debate as to whether digital health can, and should be, held to evidence-based medicine standards – similar to drugs or therapies. In a publicly funded healthcare system, digital interventions will be directly competing with non-digital ones for the scarce resources available, and therefore should be evaluated by the same standards<sup>4</sup>.

Traditional evidence collection methods, such as RCTs, usually require a stable intervention and controlled environment for several years. Digital trials, however, can recruit people more quickly, collect real-time and continuous data, and omit the

need for test locations and trained staff. Having a less controlled, more noisy trial can be offset by richer, more naturalistic data. New, more flexible and iterative evaluation designs are currently being tested (e.g. MOST and SMART), as well as other means for digital deployment of evaluation (e.g. ResearchKit)<sup>5</sup>.

Sleepio, a digital platform to treat insomnia, proves it is possible to run an RCT and even has a placebo control in place<sup>6</sup>. Placebo-controlled trials are almost non-existent in digital health, meaning that some observed benefits may be due to a placebo effect rather than a real impact of the specific tool, especially considering the strong relationship people have with their smartphone<sup>1</sup>.

Another important bias is that the people participating in digital health trials are often not representative of the general population, and may even present those who are the least in need of additional or alternative support; health app users tend to be younger, more highly educated, in better health and have a higher income<sup>7</sup>.

While digital health science is still in its infancy, consensus between experts is slowly increasing and, as a result, best practice guidelines and policies have been proposed – though these guidelines and policies are likely to change as this field rapidly evolves.

The WHO recommended the mobile health evidence reporting and assessment (mERA) checklist to improve reporting of mobile health interventions, and this will ensure they can be replicated<sup>8</sup>.

Various criteria have been proposed on how to rate the quality of digital health tools, such as the Mobile App Rating Scale (MARS)<sup>9</sup>, the Royal College of Physicians' checklist<sup>10</sup>, APEASE criteria<sup>11</sup> and the Digital Assessment Questionnaire (DAQ)<sup>12</sup>.

These criteria cover multiple domains, including effectiveness, but don't set explicit expectations for what best practice evidence looks like. Filling this information gap, NICE has recently published its first version of evidence standards for effectiveness and economic value of digital health technologies<sup>13</sup>.

The NICE framework classifies tools according to their function and associated potential risk, going from low-risk transactional tool (such as booking an appointment) to high-risk diagnostic



or therapeutic replacements (such as online therapy). More risky tools require more rigorous evidence for their benefits. This balancing of anticipated benefits versus risks reflects how healthcare professionals, and at a higher level, their organisation and commissioning group, tend to select any treatment.

The framework stays deliberately vague on the exact research designs, for example RCTs are alluded to but not seen to be the only, or best, way. All the guidelines mentioned above, including NICE, MARS and DAQ, allude to the fact that (cost) effectiveness does not exist in a bubble and should not be treated as an independent component.

The most obvious interdependent domains are clinical safety (risk assessment and mitigation) and user engagement (including user friendliness and retention). The latter is especially important to consider alongside effectiveness: if people are not using the digital tool correctly (for example, not frequent enough or not using all components), the expected benefits should be lower (for example, smaller or no effect on health). Related considerations are large scale processes such as the adoption of a tool (will people be motivated and capable to use the tool?) and its sustainability (will the tool still be relevant and available in the future?). The NASSS framework invites developers and implementers to reflect on these topics, as well as other important considerations, such as digital exclusion and organisational context<sup>14</sup>.

The current guidelines and frameworks are mainly written by experts in the field, often working in academia or government organisations. However, most digital tools are developed outside this sector, with little or no access to expert support. The guidelines also reflect an end outcome, such as an RCT-like study, without the often lengthy process to get there (including feasibility studies and process evaluation).

Moreover, software developers have a different perspective and approach, compared to researchers – for example, favouring continuous refinement and integration as opposed to static controlled testing<sup>15</sup>. The commercial sector may also question the return on this considerable investment associated with complying with these guidelines: will it make a large enough impact on their ability to sell their products? High-profile failures of previous attempts to accredit apps are not helpful, such as the lack of good practice effectiveness evidence for 12 out of 14 recommended depression apps in a previous instantiation of the NHS library<sup>16</sup>. The gap between (commercial) development and the existing knowledge base urgently needs to be bridged, with information flowing both ways.

Best practice guidance for digital health is starting to emerge but is likely to keep updating in the foreseeable future, as feedback on its implementation and new developments in research methods and technology become available. Evidence for the effectiveness and cost-effectiveness of a digital tool should not be considered in isolation, but rather as part of a larger evaluation encompassing domains such as user engagement, clinical and data safety, adoption and sustainability. A closer dialogue between those who develop the digital tools and those who create and interpret the knowledge base is needed.

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# INDUSTRY NEWS

News and Information for Digital Health Professionals



## London's Health Hub Officially Opens its Doors

Novartis and O2's innovation arm Wayra UK have revealed the three companies that will join its nine-month Health Hub accelerator programme following an overwhelming response to UK Minister for Health Matt Hancock's encouragement for health start-ups to apply for the new support programme.

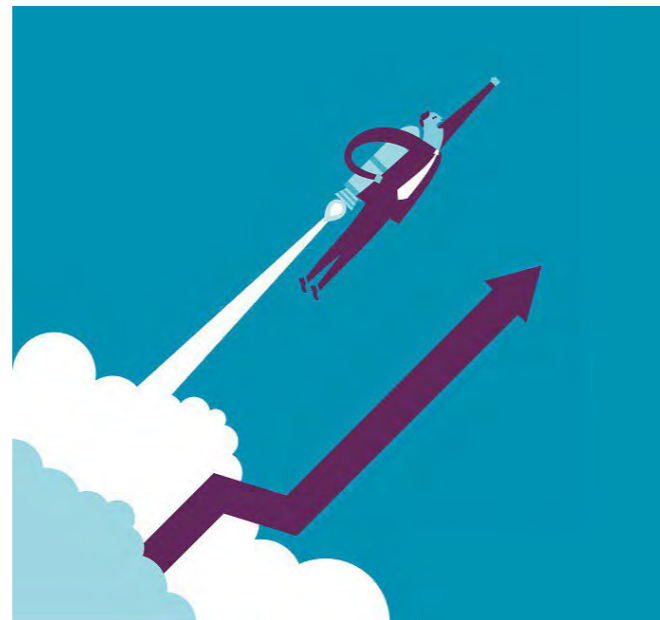
The companies selected; Virtue, Test Card and ExSeed will join the intense nine-month acceleration programme where they will gain access to our experts and extensive network to develop their cutting-edge solutions in the healthcare ecosystem. They will focus on how health tech can be used to drastically innovate long-term disease management by using practical solutions that can contribute to the quality of the healthcare in the UK.

Health Secretary Matt Hancock said: "I want the UK to be the best place in the world for health tech start-ups and, through our Long Term Plan and Tech Vision, we are transforming the NHS into an ecosystem of innovation to allow the best technologies to flourish. It is great to see Novartis and Wayra UK launching the Health Hub acceleration scheme to help innovators scale their business."

The Market Access Director at Novartis, Fiona Bride was part of the selection process she said: "The calibre of the applications received was incredible. After a rigorous judging day, I believe the innovations these three start-ups offer will make a significant difference to patients and the NHS. I look forward to supporting them over the course of the programme and wish them every success."

Wayra UK has raised over \$180 million through third party investors for its start-ups with some of the most successful being Our Path – a lifestyle change programme that raised £2.5 million, Repositve who have built the world's largest inventory of cancer models and secured £3.3 million as well as JK Rowling's favourite sleep app Pzizz.

Gary Stewart Director of Wayra UK said: "There is no bigger problem than health. We are eager to work with Novartis to support clever entrepreneurs that will find the solutions that will help our loved ones and ourselves all live longer, healthier lives."



### THE START-UPS:

**Virtue** – They create innovative products that combine science, technology, and design to treat and prevent long-term health conditions.

**TestCard** - A MedTech enterprise that has created a 'Postcard' with an embedded, pull-out urine test. Meanwhile, an accompanying mobile app provides an immediate result.

**ExSeed** – A company that tests and improve the quality of your sperm from the comfort of your home with their smartphone device and intelligent lifestyle app.

By bringing together industry expertise, mentors, coaches and investors The Health Hub is putting innovation at the core of what we do. Healthcare impacts everyone and we want to help people make better choices with better options. The Health Hub will reimagine medicine and healthcare like never before. ■

## EarlySense Selected for an Evaluation of Neonatal Health Monitoring Technologies in Africa



EarlySense, has been selected for a pilot project with Save the Children, an international nonprofit that works in 120 countries. This work is supported by a grant from the Bill & Melinda Gates Foundation. Continuous monitoring sensors will be tested first at Aga Khan University - Nairobi teaching hospital and then Pumwani Maternity Hospital, to monitor key health vitals of neonates in Nairobi, Kenya.

According to USAID, Sub-Saharan Africa has the world's highest newborn death rate (34 per 1,000 births), with its infant deaths accounting for one-third of under-five deaths globally. With EarlySense sensors, nurses and physicians will be able to continuously track key vital signs, including heart rate and respiratory rate, as well as motion. This real-time monitoring is designed to provide a broad picture of neonates' health and alert staff ahead of potential adverse events, enabling them to act quickly to improve care and prevent deaths. The contact-free sensor is placed under the bed mattress and requires no wires or hookups to the neonate.

"EarlySense's contact-free continuous monitoring technology is a novel approach in newborn care," said Rasa Izadnegahdar, deputy director on the Maternal Newborn Child Health Discovery & Tools team at the Bill & Melinda Gates Foundation. "We look forward to the evaluation by Save the Children and using the results to inform best practices in the clinical care of vulnerable newborns born in low and middle-income countries."

This will be EarlySense's first application of its contact-free continuous monitoring technology to monitor neonates. Currently, EarlySense sensors are used worldwide in hospitals, rehab and skilled nursing facilities. The sensors leverage advanced algorithms to notify nurses of potentially adverse changes in patient vital signs, sending alerts to physicians' pagers and to the central display station. The FDA-cleared and CE-approved solution has been clinically proven to help healthcare providers to prevent adverse events, including code blues resulting from cardiac or respiratory arrest, pre-

ventable ICU transfers, patient falls, pressure ulcers, and hospital readmissions for adult population.

"Part of Save the Children's core mission is to give every child a healthy start at life," said Dr. Amy Ginsburg, head of Save the Children's Technology Accelerator Unit. "We are excited to assess EarlySense's technology among newborns in African hospitals."

"We are honored to have been chosen for this important project, and to work together with Save the Children in a project supported by a grant from the Bill & Melinda Gates Foundation," said Avner Halperin, Co-Founder and CEO of EarlySense. "The infant mortality rate is a key measure of a society's overall health, and I am confident that our continuous monitoring solutions will help local health teams save lives and improve outcomes. This is another prime example of how EarlySense's continuous monitoring technology is positively impacting patients, families and health teams across the healthcare continuum and around the world." ■

# Gaming 'Controller' boosts Stroke Survivors' Chances of Regaining Full Arm and Hand Use

A first-of-a-kind gaming device that has been shown to significantly improve the outcomes of stroke survivors by helping them regain strength and movement in their stricken arms and hands has been launched today.

Created by Neurofenix, a London-based team of engineers, medical experts and designers, the NeuroBall is a one-size-fits-all 'controller' that enables stroke survivors to play video games via an app, which makes their regular rehabilitation exercises entertaining and fun.

The NeuroBall was developed over a two-year period in conjunction with stroke survivors, their families, therapists and physicians. Neurofenix wanted to create something that would encourage stroke survivors to keep doing the vital daily exercises that are crucial to regaining upper limb use.

In preliminary trials, Brunel University London carried out a study with Neurofenix involving 30 stroke sufferers using the NeuroBall and app at their homes for seven weeks. Users of the NeuroBall reported improved wrist and shoulder movement and reduced impairment of the arm, as well as greater social participation.

With 1.5 million stroke survivors in the UK, this self-administered home-based rehab method could be a huge help to an increasingly overstretched health system.

London-based NeuroBall user, Shona Patterson, who had a stroke four and a half years ago, said: "Trying to motivate yourself is quite hard. I was getting bored with my daily routine of stretching and lifting weights. One day after I had finished using the NeuroBall, I checked the level I could reach with my hand and discovered I could put my hand on top of my head, which was the first time I had ever been able to do that. I could do it straightaway."

I was ranting about how excited I was



because it is amazing after four and a half years to still feel you can achieve things."

A massive 85% of stroke survivors experience arm weakness or paralysis and only 20% to 56% regain complete movement and control within three months, after which most people are discharged from inpatient rehab to continue their recovery training at home.

Once home, there is a high dropout rate from the daily exercises that are usually considered boring and repetitive and, without continued support, forgotten or ignored. This means many people never recover full motor control of their stricken arm and hand.

The Brunel University-Neurofenix study showed that despite being primarily older, with an average age of 60, and varying levels of mental and physical impairment, the test group were able to learn how to use the NeuroBall and app independently at home after just 98 minutes of training.

They played an average of 17.4 hours, or 149 minutes per week, exercising their arm 15,092 times with minimum

input of just 2.3 hours from the Brunel physiotherapists. Within an hour of play, NeuroBall users are able to complete 840 exercise repetitions, or 14 per minute.

Animal studies on neuroplasticity demonstrate that 400 to 600 repetitions per day of challenging functional tasks can lead to changes in the brain.

The National Institute for Health and Care Excellence (NICE) recommends a minimum of 45 minutes of each active therapy for stroke sufferers at least five days a week but current data shows most patients do not achieve this.

Leading UK neurologist, Professor Nick Ward, consultant at the National Hospital for Neurology and Neurosurgery, said: "Currently stroke survivors are not getting the rehabilitation that they need and this is having a significant impact on the extent of recovery each person can expect. They will need improved access to specialists who can show them what they need to do in order to achieve the best recovery."

Emerging technologies, such as the NeuroBall, can play a role in encouraging people to perform higher amounts of the

right activities, and can do it in a way that might be more entertaining than traditional exercises."

In addition, these technologies afford the possibility to measure activity and performance so that the person's progress can be monitored and the treatment can be adjusted to maximise individual benefit."

Guillem Singla Buxarrais, Co-Founder and CEO of Neurofenix, added: "Research into stroke rehabilitation shows that intensity of practice is a key factor in meaningful recovery. The more practice, in terms of both training time and increased repetitions, the better. The problem is that for most people, integrating this into their daily lives becomes a bore.

This is where the NeuroBall has proven so successful as it makes the repetitive exercises something fun and sociable. It enables stroke survivors to complete hundreds of repetitions in the comfort of their own home without even thinking about it.

"This gaming tool can help hospitals and physios increase their patients' training to get better results with a minimum time and money investment." ■

## Kaia Health Unveils a Feasibility Study to Explore a Digital COPD Treatment

Digital therapeutics pioneer Kaia Health, which uses innovative AI-powered motion tracking technology to tackle some of the world's most urgent health challenges, has unveiled a feasibility study to examine the impact of its digital therapeutic treatment of Chronic Obstructive Pulmonary Disease (COPD) in Japan's ageing population. This follows a German pilot study which successfully decreased symptoms.

COPD is an umbrella term to describe chronic lung diseases that cause limitations in lung airflow. According to the World Health Organisation, 64 million people are diagnosed with COPD and it will be the third leading cause of death worldwide by 2030<sup>1</sup>.

In Japan, COPD represents a major health problem and socio-economic burden. Patients with COPD experience a reduced quality of life (QoL) and report significant use of health care resources. The prevalence of COPD in Japan is 8.6% in patients aged ≥40 years and up to 10.3% in patients aged ≥60 years. It is hoped that the Kaia Health COPD app could be made available in Japan if the feasibility study proves successful.

In November 2018, a peer-reviewed clinical study, published in the International Journal of Chronic Obstructive Pulmonary Disease, demonstrated that Kaia Health's COPD app successfully reduced symptoms.<sup>2</sup>

Users who completed 20 therapy days with the Kaia COPD app had a clinically significant benefit in their Health-Related Quality of Life (HRQL) scores as well as other areas, including emotion, mastery, and fatigue.

The Kaia Health COPD app addresses physical and psychological factors of the disease. The content is based on clinically validated patient guidelines and allows users to better self-manage their COPD.

The app includes video-based physiotherapy which offers exercises to help patients build muscle and promote a healthy cardiovascular system, whilst a training algorithm adjusts the support based on each patient's disease profile and feedback.

Psychosocial support is provided through audio-based ↗

relaxation exercises to manage anxiety and depression and to cope with dyspnea attacks. Patients can also contact a coach via the app who will answer app-specific questions, work with users on their individual goals and offer motivation.

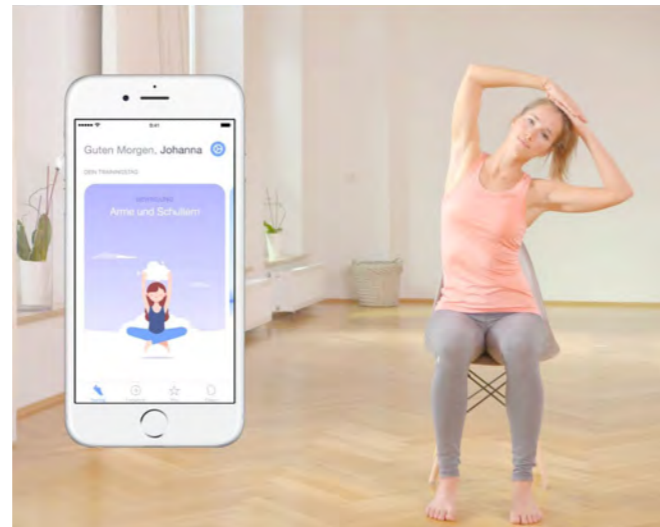
The app teaches patients about breathing and coughing techniques, nutrition and advice on the impact air pollution has on their condition. Alerts inform patients when medication is due, and video instructions help patients to perfect inhalation - a necessity as up to 60% of COPD patients do not adhere to their medication correctly<sup>3</sup>.

Konstantin Mehl, Founder & CEO of Kaia Health says: "Conventional COPD treatment is expensive and resource-intensive, particularly in developed countries such as Japan which has a huge ageing populations and rapidly increasing healthcare costs. Our AI-powered COPD treatment is effective, widely accessible and can be used at home. This empowers patients to take control and self-manage their COPD with evidenced-based, non-pharmacological, affordable alternatives which means more people globally can benefit from it. Our mission is to reduce the socio-economic burden of COPD in Japan and the impact it may have on the working-age population which, ultimately, could inform healthcare policies worldwide."

Kaia Health is rapidly expanding globally with innovative digital therapies for chronic conditions. The company recently raised \$10 million in a Series A round led by Balderton Capital to tackle some of the world's most urgent health challenges, including a range of chronic conditions.

in 2018, Kaia Health launched the world's first AI-enabled fitness app which turns a smartphone into a personal trainer, as well as a rehabilitation therapy app which significantly reduces lower back pain.

Kaia Health is a member of the Digital Therapeutics Alliance, an association of international manufacturers for digital therapeutic



products that meet excellence in high quality standards.

The Kaia COPD app is currently only available in German speaking countries on smartphones and tablets (iOS and Android) and can be downloaded via the Apple App Store or Google Play. For a limited period, individuals can download the app and participate in a free usability test for their COPD when filling out a symptoms questionnaire at the start of the therapy.

**References**

1. The World Health Organisation on Chronic Obstructive Pulmonary Disease (COPD) (2018) <http://www.who.int/respiratory/copd/en/>
2. International Journal of Chronic Obstructive Pulmonary Disease. Digitalizing multidisciplinary pulmonary rehabilitation in COPD with a smartphone application: an international observational pilot study (2018) [https://www.dovepress.com/articles.php?article\\_id=42567](https://www.dovepress.com/articles.php?article_id=42567)
3. International Journal of Chronic Obstructive Pulmonary Disorder. Medication adherence issues in patients treated for COPD (2008) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2629978/> ■

## Partnership Aims to Attain 'One Billion Special Steps'

Swiss-based global digital health engagement platform dacadoo has partnered with Daman Health Insurance in the United Arab Emirates (UAE) to offer a new location-based walking game to encourage walking for a good cause in the United Arab Emirates. The game, Daman Tamshi, aims to challenge the population of the UAE to reach a target of one billion steps as a community in four weeks. When the target is reached, Daman Health will donate 500,000 Dirhams towards the Special Olympics of United Arab Emirates.

The power of a community should not be underestimated, when people come together great things can be achieved. With Daman Tamshi, dacadoo and Daman Health are calling on the population of the United Arab Emirates (UAE) to 'dedicate their steps to magnificent people' with a challenge to collectively reach one billion steps in four weeks. When the target is achieved Daman Health will donate AED 500,000 in support of Special Olympics UAE. Special Olympics is a global organisation that serves athletes with intellectual disabili-

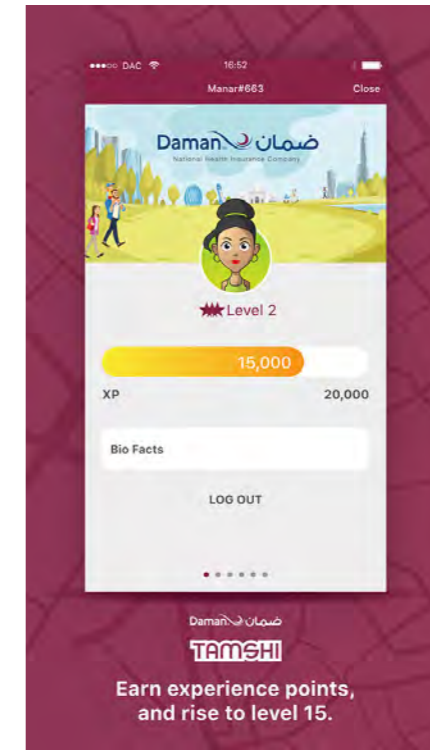
ties, working with hundreds of thousands of volunteers and coaches each year. Since the establishment of Special Olympics in 1968, the number of people with and without intellectual disabilities who are involved with the organization has been growing, but the unmet need to reach more people with intellectual disabilities is staggering.

Abu Dhabi in the United Arab Emirates will be the host of the 2019 Special Olympics World Summer Games. The Games will be held in March of 2019.

Abu Dhabi is the first place in the Middle East-North Africa Region to be host to a Special Olympics World Games, and Daman Health – head quartered in Abu Dhabi - are supporting the organisation. The Daman Tamshi app enables the population of the UAE to contribute to the cause by simply walking. Throughout the duration of the campaign, users will be able to track their own walking progress as well as the community's progress towards the target within the app. The game is available in Arabic version and it will also include fun and engaging features as players interact with the game and walk around their city.

dacadoo GO is a customisable geolocation-based walking app that transforms walking into an interactive game. It is designed to encourage players to engage and interact with the game by motivating them to simply walk more with the powers of gamification.

dacadoo develops and operates a digital, mobile health engagement platform that helps users actively manage their health in an easy and fun way. Engaging users to remain active and healthy, the company applies motivational techniques from online games, collaborative features from



social networks, and personalized feedback and the patented dacadoo Health Score to better understand and improve their health.

Peter Ohnemus, founder and CEO of dacadoo, added, "We are very happy that the leading health insurer Daman Health



chose dacadoo to partner for this fantastic project in the United Arab Emirates. As this is our first collaboration in the Middle East, we worked hard to offer a fully localised Arabic version for this purpose and look forward to how the population of the United Arab Emirates will react and use Daman Tamshi. ■

## Research Evaluates Using Data Science and Clinical AI for the Management and Treatment of Chronic Disease

Sensyne Health has announced a three-year collaboration with the University of Oxford's Big Data Institute (BDI) to establish a world-leading research alliance to develop and evaluate the use of clinical artificial intelligence (clinical AI) and digital technology to understand the complexities of chronic disease.

Initially the collaboration will focus on chronic kidney disease and cardiovascular disease, diseases with significant and growing burdens on society with the potential for the discovery and development of new medicines and improved pathways of patient care within the NHS.

The three-year research programme will draw on BDI's expertise in population health, clinical informatics and machine learning and will be facilitated by access to anonymised longitudinal datasets for those patients in the NHS Trusts which builds

on Sensyne Health's existing capabilities through its Clinical AI and Strategic Research Agreements, as well as the data generated by Sensyne's digital health applications for the management of chronic disease. It will also draw on the expertise of researchers in the Institute of Biomedical Engineering at the University of Oxford in developing technology for collecting clinical-grade healthcare data at scale.

The research will focus on two major elements to derive new datasets that capture vital information from patient-clinician consultations during long-term management of chronic disease. This work will facilitate the use of clinical AI to understand the complexities of chronic disease and hence derive insights to accelerate drug discovery and development and improve pathways of patient care.

» Automated, real-time translation of physician notes ➔

into a longitudinal, semantic structure suitable for analysis by clinical AI.

- » Remote patient monitoring using digital health tools and wearables to assess disease progression and inform clinical care.

In addition, the alliance will explore the clinical associations and consequences of diurnal changes in blood pressure, extending Sensyne's in-house project, SH-001, which identified nocturnal surges in blood pressure in a sub-set of hospital inpatients.

Alongside this, the alliance will foster the development of an effective R&D and commercialisation pathway between the two organisations and a growing network of collaborating NHS Trusts. Under Sensyne's unique business model the commercial value created from the research will be shared with the participating NHS Trusts and the University of Oxford via a shared equity ownership in Sensyne Health and a shared royalty on revenues.

Lord (Paul) Drayson, CEO of Sensyne Health, said, "This new collaboration with the BDI is designed to apply world-class data science to the growing burden of chronic disease on society, and create an effective partnership between the NHS, industry and academia that delivers scalable improvements to patient care, accelerates the discovery and development of new medicines and shares the commercial value created with our partner NHS



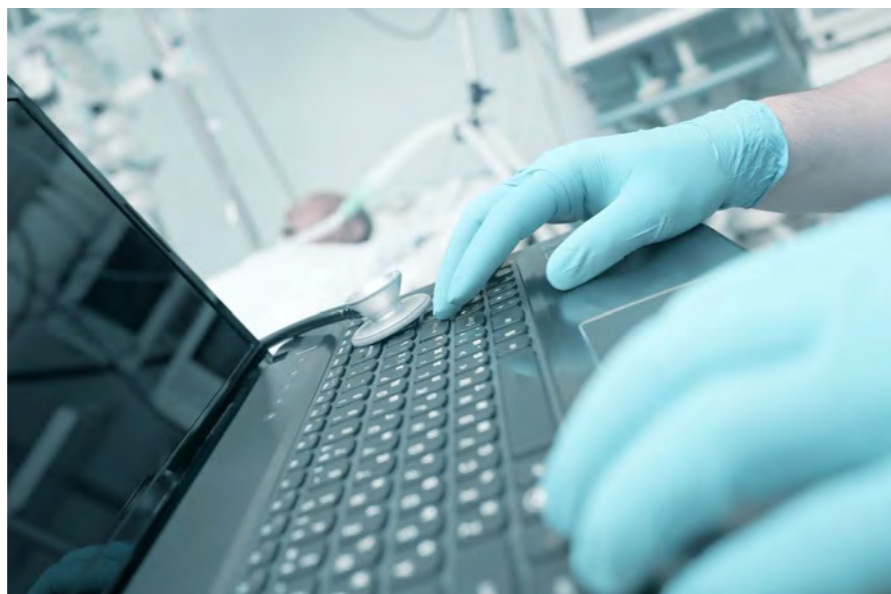
Trusts and the University of Oxford."

Professor Martin Landray, Deputy Director of the Big Data Institute and Professor of Medicine and Epidemiology, commented, "This new collaboration sets out to improve our understanding of common chronic diseases, identify opportunities for better treatment, and enhance the quality and efficiency of clinical care. This work will provide benefits for individual patients, the NHS, and population health." ■

## Research Reveals Healthcare Email Fraud Attack Attempts Jump 473% Over Two Years

Proofpoint, a leading cybersecurity and compliance company, has released its Email Fraud in Healthcare 2019 Report, which found that healthcare organisations were targeted in 96 email fraud attacks on average in Q4 2018 – a 473 per cent jump from Q1 2017. More than half of these organisations (53 per cent) were attacked more often, with incidents up between 200 and 600 per cent during the two-year period. The report analyses more than 160 billion emails sent across 150 countries in both 2017 and 2018 to identify email fraud attack trends targeting more than 450 global healthcare organisations.

Email fraud, also known as Business Email Compromise (BEC), is one of today's biggest cyber threats. According to the FBI, BEC has cost organisations across the world \$12.5 billion USD since



the end of 2013. As part of these attacks, cybercriminals often use identity deception tactics, such as domain spoofing,

to pose as trusted colleagues and business partners. In Q4 2018, 95 per cent of healthcare organisations were targeted

by an attack using their own trusted domain.

"Healthcare organisations are high-value targets for cybercriminals due to the large amounts of personal information that they store. Unfortunately, these organisations are also extremely vulnerable to email-based attacks as their often-complex supply chains offer multiple opportunities for cybercriminals to insert themselves into various business transactions and trick employees into sharing information or wiring funds," said Adenike Cosgrove, Cybersecurity Strategist, EMEA at Proofpoint. "It is critical that organisations

implement a multi-layered security approach to secure the email gateway and educate employees on cybersecurity best practices. Employees should always confirm the source of all emails that are sent to their personal and corporate email inboxes and be wary of emails that urgently request a password change, patient data, or a link be clicked."

### Additional Proofpoint Healthcare Research Findings:

- » Wire-transfer fraud is the most common form of email fraud for healthcare.
- » Sixty-five staff members on average were attacked in Q4 2018 within tar-

- » Forty-five per cent of emails sent from healthcare-owned domains in Q4 2018 appeared suspicious. Of those 65 percent were sent to employees, 42 per cent were sent to patients, and 15 per cent were sent to business partners.
- » The highest volume of email fraud attacks targeting healthcare arrived on weekdays between 7 a.m. and 1 p.m. in the targets' time zone.

The full Email Fraud in Healthcare 2019 Report can be found here: [www.proofpoint.com/us/resources/threat-reports/healthcare-email-fraud-report](http://www.proofpoint.com/us/resources/threat-reports/healthcare-email-fraud-report) ■

## Neurologic Music Therapy Provides Significant Fall Prevention Technique in Over 65's

Winter poses a significantly increased risk of falls in the elderly. Each year over three million older people are treated for fall related injuries, and approximately 60,000 of them require hospitalisation usually from hip fractures or head injuries<sup>1</sup>. The chances of falling in winter months increase after 65 and increases furthermore after 75 years old.

Daniel Thomas, Joint Managing Director & Neurologic Music Therapist at Chroma, the UK's leading national provider of arts services, suggests winter poses a serious risk of falling to the elderly for a number of reasons.

"Many older people take numerous medications that may have side effects including dizziness, which pose an increased risk of falling.

"With age, sensation in feet decline, especially if there is an underlying condition such as diabetes, poor circulation, arthritis or lingering complications following a stroke. With decreased sensation, balance is affected. Slippery surfaces, such as those covered in snow or ice, can further reduce balance increasing the likelihood of a fall.

"Many over 65's walk with an unstable gait, during any weather. Those who do not exercise have weakened muscles, increasing the likelihood of a fall."

According to Age UK, falls in the over 65's costs the NHS around 4.6 million a day. With the increased risk of falls in cold weather, underlying health conditions, medications and weakened muscles, fall prevention in the over 65's is a priority. And if current stats are correct, by 2039 there will be some places in



the UK with over 45% of their population over 65. If nothing is done about fall prevention now, the costs upon the wellbeing and quality of life of the elderly, as well as the healthcare sector will be significantly higher.

Chroma believes the solution to fall prevention in the over 65's lies within Neurologic Music Therapy (NMT) - the therapeutic application of music to cognitive, affective, sensory, language and motor dysfunctions due to disease or injury to the human nervous system.

NMT relies on engaging with patients to maintain exercise and physical activity, encouraging older people and patients to move more for therapeutic and health reasons. It recruits healthy and uninjured areas of the brain, rather than trying to fix the damaged ➔

or 'broken' part of their brain linked to the loss of function.

Rhythmic Auditory Stimulation (RAS) is an important aspect of NMT. Within RAS programs, strong and predictable rhythmic patterns are used to guide the sensori-motor movements required for walking. Predictable rhythmic structure allows the sensori-motor system to move in sync with the beat. Stroke patients have reported improved stride length and symmetry with RAS.

Daniel suggests, "Music with high beats per minute (BPM) count promote movement, good cadence and walking speed, so songs like Nancy Sinatra's These Boots are Made for Walkin, which has 85 BPM is ideal.

"Walking speed correlates with functional ability and balance confidence. It has the potential to predict future health status,

the risk of falls and a client's fear of falling. BPM strongly correlates to step cadence, and therefore walking speed. Improved walking speed equates to improved balance."

"Increased muscle strength, gait and walking speed are all necessary factors required to reduce the risk of falls in the elderly. NMT has proven itself to be a cost-effective intervention to help improve such factors, and as a result, enhance the wellbeing and health of the elderly and the healthcare sector simultaneously".

Neurologic music therapy used alongside physiotherapy enables goals to be achieved sooner, due to patient engagement and the way music interacts with the sensori-motor systems of the body and brain.

1. <https://www.ageuk.org.uk/latest-press/archive/falls-over-65s-cost-nhs/> ■

## CardioSecur® Shines a Light on the Dark Side of the Moon

*Up to 57% STEMI cases are not visible on a 12-lead-ECG. This is why the European Society of Cardiology and the American Heart Association (AHA) recommend recording additional leads to detect posterior and inferior infarcts.*

When a myocardial infarction is suspected, but the 12-lead ECG is inconclusive, the guidelines of the European Society of Cardiology recommend the recording of additional leads (V7-V9, VR3-VR4). This recommendation is shared by the American Heart Association (AHA), which already advocated for expanded lead systems in 2009. The American Heart Association also called for ECG machines that are "programmed to suggest the recording of right-sided chest leads V3R and V4R when ST elevation is greater than 0.1 mV occurs in leads II, III, and aVF." [Moreover, they also called for "ECG manufacturers [...] to develop software capable of displaying the spatial orientation of the ST-segment in both the frontal and transverse planes" and to provide "algorithms [that] should refer to the occluded vessel and to the site of the occlusions within that vessel."

The reasons for this are due to the fact that the diagnosis of posterior myocardial infarctions is still considered to be the "dark side of the moon" of ECG interpretation. Almost half of all posterior myocardial infarction cases are



not detected by conventional 12-lead ECGs. If lateral leads (12 +V7-V9) are applied, then the accuracy of the diagnosis increases significantly. Studies have found that up to 57% of STEMI cases could be detected with the use of additional leads.

CardioSecur is the only ECG that implements the guidelines of the European Society of Cardiology and the recommendations of the AHA into practice, without the need to reattach electrodes. The solution offers physicians a 360° view of the heart with a 22-lead clinical-quality ECG (12-leads + V7-V9, VR3-VR9) that uses

only four electrodes. It gives medical professionals the opportunity to explore new diagnostic dimensions and detect anterior, lateral, inferior and posterior wall infarctions in one measurement. Which in turn allows for immediate reperfusion therapy and reduces morbidity and mortality.

The significant advantage of CardioSecur in detecting posterior myocardial infarctions compared to conventional 12-lead ECG systems has been proven again in a recent clinical trial in which it was used in ambulances. With CardioSecur physicians are finally able to explore the dark side of the moon. ■

## Partnership to Deliver the First Health Information Exchange in the Middle East



*Orion Health has announced a commercial agreement with Abu Dhabi Health Data Services, a new project company established as part of the Public Private Partnership (PPP) between the Department of Health - Abu Dhabi (DoH) and Injazat Data Systems, a subsidiary of the Abu Dhabi government-owned Mubadala Investment Company, to deliver a Health Information Exchange (HIE) platform. The HIE will be known as "Malaffi" and is the first of its kind in the Middle East.*

"Malaffi" will provide a platform that will centrally store and enable the meaningful exchange of patient health information between healthcare professionals and will ultimately connect 2,000 public and private healthcare providers in Abu Dhabi. "Malaffi" was officially launched last week on 23 January, and is initially joined by six Abu Dhabi healthcare organizations, including SEHA (Abu Dhabi Health Services Company), Cleveland Clinic Abu Dhabi, Imperial College Diabetes Centre, Healthpoint, United Eastern Medical Services (UEMedical) group and Oasis Hospital, Al Ain.

The access to the centralised patient records will provide physicians with a tool to make well informed, fast decisions, enhance patient safety, reduce the duplication of diagnostic procedures and ultimately improve the quality of care and outcomes.

The HIE platform is powered by Orion Health, a global leader in health care technology and the implementation of HIE systems, serving more than 100 million health records across the world. The highly scalable platform will also have the capability to harness the power of patient and population data, and by creating insights into the emirate's public health, will have

a significant impact on improving the overall efficiency of Abu Dhabi's health system.

"The Department of Health-Abu Dhabi has recognized the need to centrally and efficiently, store, exchange, and analyse the enormous amount of data that is being created in healthcare every day, and by using advanced technologies, such as Artificial Intelligence (AI) and machine learning, to drive the digital transformation of the healthcare system, for a happier and healthier Abu Dhabi. The partnership with Orion Health, will enable us to deliver a best-in-class HIE platform, that will guarantee the success of connecting all Abu Dhabi healthcare providers, and place Abu Dhabi on the top of the global map of successful HIE implementations," said Atif Al Braiki, Chief Executive Officer of Abu Dhabi Health Data Services.

"Orion Health is delighted to be selected as the partner of choice, to deliver UAE's first HIE platform," said Ian McCrae, Founder and Chief Executive Officer of Orion Health. "Storing and aggregating vast volumes of different clinical data, and surfacing it in data analytics, will bring Abu Dhabi a step closer to the practice of precision medicine, which is only possible when health providers have a complete picture of a person's health. Today, healthcare systems around the world, annually waste more than a trillion dollars on healthcare spend, from unnecessary administration, avoidable lab and radiology testing, and re-admissions of patients into hospitals. "Malaffi" will use the most current technology and data analytics, that will reduce the avoidable and duplicated procedures, and therefore improve the efficiency of Abu Dhabi's health systems and the overall delivery of care." ■

# Upcoming events

## April 2019

3-4

### ebme Expo

Milton Keynes, UK  
For more information visit  
<http://www.ebme-expo.com/>

8-9

### ACO & Payer Leadership Summit

Braselton, GA, USA  
For more information visit:  
[www.events.marcusevans-events.com/aco-payer2019/](http://www.events.marcusevans-events.com/aco-payer2019/)

9-11

### DMEA

Berlin, Germany  
For more information visit  
<https://www.dmea.de/en/>

15-17

### IMPACCT mHealth in Clinical Trials

London, UK  
For more information visit  
[www.impactt-mhealth-london.com](http://www.impactt-mhealth-london.com)

26-27

### International Conference on Digital Health

Houston, TX, USA  
For more information visit:  
[www.digitalhealth.conferenceseries.com](http://www.digitalhealth.conferenceseries.com)

## May 2019

9

### NICE 2019

Manchester, UK  
For more information visit  
[www.niceconference.org.uk](http://www.niceconference.org.uk)

14-16

### The MedTech Forum

Paris, France  
For more information visit:  
[www.themedtechforum.eu](http://www.themedtechforum.eu)

16-17

### Digital Transformation in Healthcare Conference

San Francisco, CA, USA  
For more information visit  
[www.events.marketsandmarkets.com/Digital-transformation-in-healthcare-conference/](http://www.events.marketsandmarkets.com/Digital-transformation-in-healthcare-conference/)

22-23

### Digital Health & Care Congress

London, UK  
For more information visit  
[www.kingsfund.org.uk/events/digital-health-and-care-congress-2019](http://www.kingsfund.org.uk/events/digital-health-and-care-congress-2019)

## The King's Fund

# Digital health and care congress 2019



22-23 May 2019, London

#KFdigital19

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- using co-design in digital health and care
- scaling digital projects.

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