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# Digital Health Roundup: Brain Talk On Seizures, Alzheimer's, Stress, Anxiety; Medtronic's OR Report; Health Care AI; UK Guidances

by Marion Webb

In this month's Digital Health Roundup, *Medtech Insight*'s Marion Webb highlights AI discussions at the HLTH Europe conference and an interview with Motif Neurotech's CEO Jacob Robinson. Elizabeth Orr discusses DeepWell DTx's newly launched VR game for treating stress-related hypertension and anxiety. Natasha Barrow provides an overview of Digital Mental Health Technologies regulation in the UK and Brian Bossetta reports 'the good and bad' from Medtronic's report on digital technologies' use in the operating room.

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## Medtronic Report Finds Latest Tech Absent From Most ORs

A recent report from device maker *Medtronic plc* offers good news and bad news for surgeons and patients. The good: current digital technologies, such as artificial intelligence and machine

learning, could dramatically increase operating room efficiency. But the bad: too many ORs don't have access to this technology and that is negatively impacting surgeons and their ability to deliver the best care.

Further, outdated technology, according to Medtronic's "*State of Surgery Report*" is costing US surgeons an entire month of work per year.

For the report, Medtronic surveyed a thousand surgeons across four regions and 21 cities in the US in both the private and public sectors. (Also see "*Outdated Technology Keeping Surgeons From Operating At Their Best: Medtronic Report*" - Medtech Insight, 20 Jun, 2024.)

One of the most concerning findings from the report is that 62% of surgeons surveyed reported feeling so burned out, they are considering leaving the field.

Vipul Patel, executive director of the Society of Robotic Surgery, commented on the report, referencing the burden antiquated technology places on surgeons.

"As surgeons, we want to spend our time saving lives, not completing administrative tasks," Patel said. "Digital technologies aren't just gadgets, but the key to our future health care system."

## Digital Therapeutics Reposition As Complementary Medicine

Digital therapeutics (DTX) are finding unique revenue streams as complements to traditional medicine. At the Digital Therapeutics Alliance's Annual Summit, regulators, DTX developers and investors presented their strategies for successful funding and reimbursement in a tough macroeconomic environment.

While the bankruptcy of *Pear Therapeutics, Inc.* was disheartening to the industry, creating subscription services for products, setting up brick and mortar patient centers and working with the FDA and its resources are ways that companies are gaining revenue outside of traditional reimbursement pathways. (Also see "*Industry Finds Innovative Revenue Streams For Digital Therapeutics*" - Medtech Insight, 14 Jun, 2024.)

There was also the discussion around how DTX are marketed, which previously relied on the prescription digital therapeutic (PDT) designation to gain legitimacy and reimbursement (through the proposed *Access to Prescription Digital Therapeutics Act)*. Developers are now leaning into the idea of DTX as a complement to traditional care and a way to bring underserved populations into the health care system, instead of a replacement for it. (Also see "*DTX Companies Find New Niche As Complement To Standard Of Care*" - Medtech Insight, 13 Jun, 2024.)

The DTA Annual Summit took place from 5-7 June in Washington, DC.

Also, on the digital therapeutics front, DeepWell DTx has launched the first game in Meta's VR game store intended to reduce stress and anxiety. Zengence players progress though the game by using deep, controlled breathing to aim and fire a weapon. The breathing techniques required by the game stimulate the vagus nerve, reducing sympathetic nervous system activation and lessening a player's feelings of stress. (Also see "*DeepWell DTx Brings Mental Health To Meta Store*" - Medtech Insight, 17 Jul, 2024.)

Zengence founder Ryan Douglas formed the company after learning that many people turn to video games for stress relief and finding that research backed the beneficial effects of some types of gaming. Interestingly, he said, "For mental health, the gamification stuff wasn't working at all. The most wildly successful things that were treating mental health were accidentally doing it."

The company is now pursuing FDA clearance for the game with an indication of treating stress-related hypertension and plans to research its use to treat mild to moderate anxiety and depression. Douglas explained that the company sees its main product as the technology platform underlying the game, which he hopes will allow developers to design many different games that have similar effects.

## Novel Brain Device Closes Major Gap For Patients With Brain Injury

Last month, the FDA granted 510(k) clearance to Santa Clara, CA-based medical technology company *Zeto, Inc.* for its brain monitoring device, the ONE, which is designed to detect seizures in patients with brain injury or trauma.

Zeto says the ONE addresses a "significantly unmet" need in health care due to an ongoing shortage of technologists trained in electroencephalography (EEG). Furthermore, Zeto says operating the ONE requires "only minimal training."

The innovative AI-powered device is indicated to detect seizures in brain-injured patients in ERs and ICUs, a group of patients the company says are particularly susceptible to seizures that often go undetected without EEG technology, and is approved for use in hospitals, homes, ambulances, and air transport.

What's groundbreaking about the ONE, according to Zeto, is that it is easy to use for clinicians, comfortable for the patient, and provides excellent signal quality — features which are necessary for EEG products. (Also see "*Zeto Wins FDA Clearance For Novel Seizure Detection Device*" - Medtech Insight, 4 Jun, 2024.)

## Motif Targets Depression With Minimally Invasive DOT

Motif Neurotech's CEO Jacob Robinson has high hopes that the firm's pea-sized Digitally programmable Over-Brain Therapeutic (DOT) will one day be used to treat depression and other mental health conditions and detect signals allowing for early intervention.

While much of the buzz surrounding brain-computer interfaces has centered on companies such as Elon Musk's *Neuralink Corp.*, *Synchron, Inc.*, *Paradromics, Inc.* and Blackrock Neurotech that are pursuing similar BCI applications to restore autonomy to severely motor-impaired individuals by enabling them to control devices using their thoughts, Motif believes BCI devices could be disruptive in psychiatry also. (Also see "*'Mental Health, Beyond Medication': Motif Targets Depression With Minimally Invasive DOT*" - Medtech Insight, 16 May, 2024.)

"As I watched the other companies form and mature, I realized there was a whole segment of the population that are suffering from mental health conditions," said Robinson. He explained that for every person with a spinal cord injury, there are 10 people suffering from major depressive disorder and not responding to drugs – "an absolutely massive market."

## Health Care AI

At the recent inaugural HLTH Europe 2024 conference in Amsterdam, AI dominated much of the conversation.

During a panel of health care leaders from *Microsoft Corporation*, *Philips Healthcare*, *insitro* and *Johnson & Johnson (Pty) Ltd* discussed how these technologies are already transforming health care and pointed to risks and challenges. (Also see "*Healthtech Leaders Discuss Impact (And Risks) Of Generative AI and AI In Health Care*" - Medtech Insight, 28 Jun, 2024.)

Jim Swanson, executive VP, chief information officer at J&J told the audience that using AI-enabled models has resulted in a two-and-a-half-fold improvement in patient enrollment in clinical trials, which translates into faster enrollment, better insights and more diversity.

David Rhew, global chief medical officer and VP of health care at Microsoft Corp. pointed out that the selection of type of AI for use cases is key, noting that capabilities of traditional AI using natural language processing has evolved.

During the HLTH conference, *Medtech Insight* sat down with Andrew Trister, chief medical and scientific officer at *Verily*, to talk about Verily's newly launched Lightpath Metabolic solution, featuring GLP-1 prescription, AI and strengthened clinical support. Trister also discussed plans for the Study Watch and offered his views on Alzheimer's research and AI development and regulation in a new era of uncertainty.

Lightpath "will be fueled by continuous data integration and AI," Verily says. He added that Lightpath will not just be a technology, but will also be paired with coaches and an affiliated advanced licensed clinical team. The system will replace Onduo, which will be phased out by the end of 2025. (Also see "*'Is This Doomsday Concern, Or Is It Reality?' Verily CMO On AI's Future, Lightpath Metabolic, More*" - Medtech Insight, 24 Jun, 2024.)

## FDA, UK Regulatory Updates

In May, FDA added 191 devices to its list of approved AI/ML medical devices. From August 2023 to March 2024, the vast majority of approved devices were radiology devices (117), and the second largest category was cardiovascular devices with 13 approved.

Only one device during that time period was approved through a de novo pathway and the rest were through the 510(k) pathways. (Also see "*Radiology Reigns Supreme: 151 New AI/ML Devices Added In Last 9 Months*" - Medtech Insight, 14 May, 2024.)

The FDA also published its guidance on remanufacturing, which some industry members felt lacking when discussing software remanufacturing.

"[Software remanufacturing] is a gaping hole," Jason Brooke, Brooke & Associates medical device attorney, told *Medtech Insight* in an interview. (Also see "*Expert: FDA Missed Opportunity For Software In Remanufacturing Guidance*" - Medtech Insight, 31 May, 2024.)

"It shows that [FDA] didn't even consider software, but they knew they had to add something related to software... and they just added it in at the last minute."

## UK Digital Mental Health Technologies Regulatory Guidance

The UK is taking significant steps to regulate Digital Mental Health Technologies (DMHTs) through a three-year initiative led by UK health care regulators, the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE), funded by the Wellcome Trust.

The project aims to provide clear guidance for developers, health care professionals, and patients regarding the regulatory and evaluation requirements for DMHTs. (Also see "*News We're Watching: UK Plans Digital Health Guidance, FDA Warns Against Getinge/Marquet Cardiac Devices*" - Medtech Insight, 10 May, 2024.)

The project's first work package, a pivotal phase that concluded in May, involved surveying potential users of Digital Mental Health Technologies. This was a crucial step in gathering insights into their perceptions and expectations, which will inform the future of DMHT regulation.

Some examples of Digital Mental Health Technologies used by participants included apps to track mood and sleep, as well as meditation and relaxation apps.

Findings revealed that while users see the potential benefits of these technologies, they should not replace traditional mental health support like therapy and medication.

Participants emphasized the need for a clear pathway for immediate care and expressed concerns about misleading information, particularly for vulnerable populations (like children).

Overall, there is strong support for regulating DMHTs, provided access is not restricted.