Issue Synopsis: Digital Health and Technologies

Digital health is a broad, multi-faceted term used to describe a broad category of practices, products, and processes (Figure 1). The FDA describes digital health as "the broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine. The World Health Organization, in its guidelines on the topic, describes digital health as "a broad umbrella term encompassing eHealth (which includes mHealth), as well as emerging areas, such as the use of advanced computing sciences in 'big data,' genomics, and artificial intelligence." The American Medical Association, in reporting on a 2019 survey, stated that "digital health encompasses a broad scope of tools that can improve health care, enable lifestyle change and create operational efficiencies. This includes digital solutions involving telemedicine and telehealth, mHealth, wearables, remote monitoring, apps, and others."

Figure 1. Examples of Types of Digital Health Tools. Source: IQVIA Institute, Digital Health Trends 2021, June 2021.

Generally, digital therapeutic products are used to monitor indicators of a patient's condition (e.g., blood pressure, hemoglobin A1c) or encourage behaviors (e.g., adherence to medication or behavioral therapies) and may share several similar features that may include some or all of the following:

1. A digital interface used by patients, clinicians, and medical devices
2. Wearable or mobile devices that provide information about a patient's conditions to themselves, clinicians, or other medical devices
3. Integration of disparate sources of data
4. Enhanced patient engagement with their data and treatment
5. Automated or live digital coaching features to improve patient adherence with medication and/or behavioral therapies

Digital therapeutics is still in its infancy, but in 2020 the [ASHP Commission on Goals](#) discussed several successful examples (see Figure 2):

- Livongo Health provides digital care programs for diabetes prevention and care, weight management, hypertension, and behavioral health that rely on connected devices (e.g., glucose meters, blood pressure monitors, scales, and activity tracking devices) to share data with patients and providers and provide personalized expert coaching.
- AsthmaMD, Asthma Storylines, Hailie, KagenAir, Propeller Health, and others offer mobile apps to aid asthma care. Some of these apps interface with electronic sensing devices attached to medication inhalers that comunicate in real time to patients and caregivers, enabling clinicians to monitor individual patients and an entire clinic population simultaneously. Some of these apps consolidate additional patient-entered data with outside data (e.g., weather, pollen counts) to identify potential asthma attack triggers.
- Omada for Prevention has demonstrated a significant reduction in risk for three chronic diseases: type 2 diabetes, stroke, and heart disease. Omada digital care programs provide human support to help people achieve their specific health goals through sustainable lifestyle changes, and their diabetes module connects with the Abbott FreeStyle Libre continuous glucose monitoring system.
- Several companies have obtained FDA approval of digital ingestion tracking systems (e.g., Abilify MyCite, Proteus Discover, and etectRx ID Cap), in which a wearable device detects ingestion, signaling a patient's cellphone through an app and transferring data to the care team.
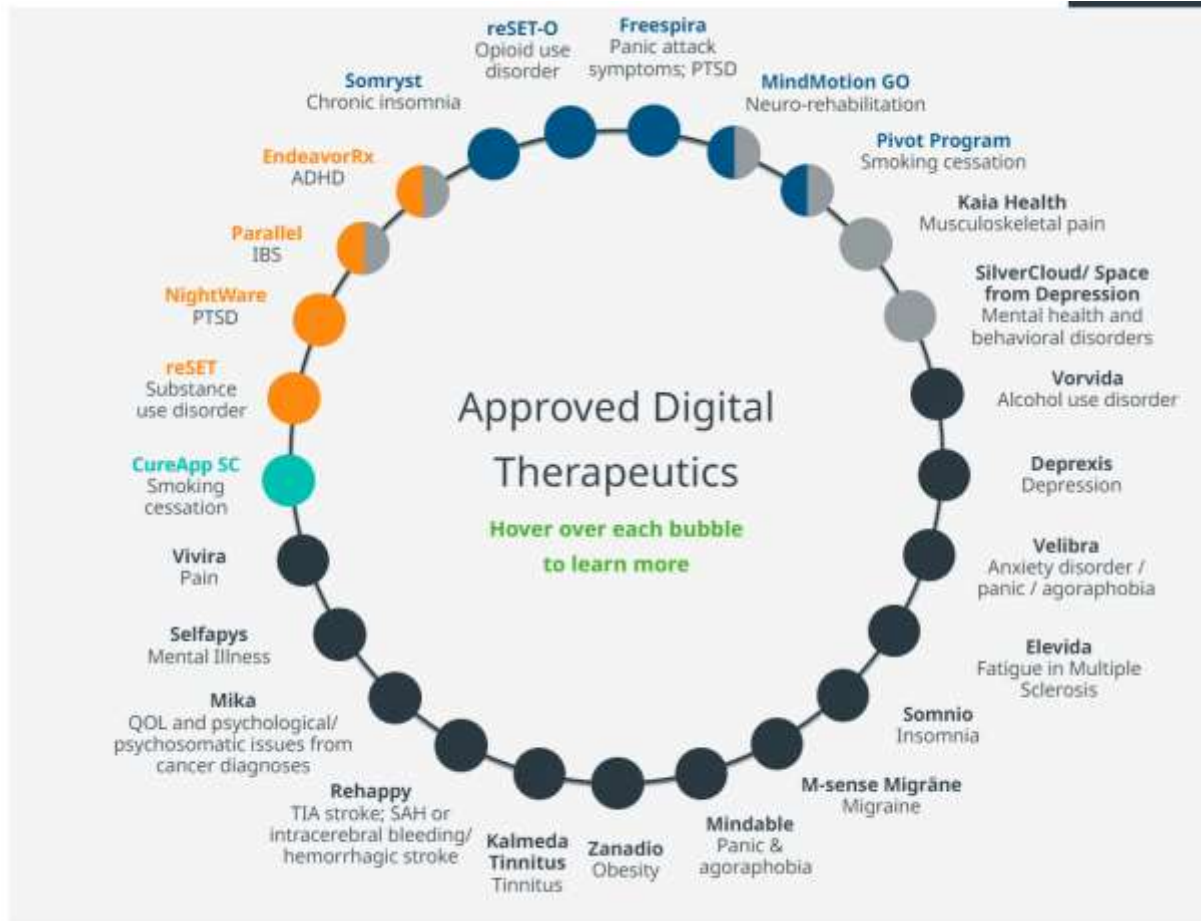
Figure 2. Examples of Approved Digital Therapeutics. Source: IQVIA Institute, Digital Health Trends 2021, June 2021.

Some health systems are already taking advantage of these technologies:

- Partners Healthcare has implemented a hypertension care program with the goal of removing hypertension care from physicians' offices, relying instead on care navigators who collect data from patients' wearable blood pressure monitors.
- Novartis, Chugai, Brigham and Women's Hospital, and Mayo Clinic use the FDA-cleared predictive Biovitals Analytics Engine from Biofourmis. The platform receives physiologic data in near real-time from FDA-cleared sensors and uses artificial/augmented intelligence (AI) and machine learning to identify correlations between multiple vital signs and the patient's daily activities, constructing an individualized biometric signature. The system can alert providers to changes in patients' measured vital signs from baseline, allowing clinicians to respond before a serious event. The system has been validated for use in monitoring cardiovascular and respiratory conditions, cancer, and acute and chronic pain.
- Highmark and ChristianaCare have launched the Center for Virtual Health, which develops, tests, and deploys virtual capabilities for primary and specialty care with the goal of improving patient access, experience, and outcomes while reducing the total cost of care.

- Ochsner Digital Medicine uses devices, advanced analytics, and communications technology to help patients with high blood pressure or diabetes manage their chronic conditions from home.

The proliferation of digital health technologies will present seismic shifts in how healthcare manages patients, establishes payment systems, ensures data accuracy and integrity, and the education and preparation of health care providers. It will also present new stressors on the challenges in resolving healthcare disparities.

One of the many issues presented by the explosion of digital health apps is their regulation. The FDA Software Precertification (Pre-Cert) Pilot Program has set a goal of approving 6-7 software-based medical devices each week, but even at that pace the number of apps in use by patients could quickly outstrip any healthcare system's ability to manage their use. This challenge has created a role for health systems in developing and managing health app formularies as well as a role for nongovernmental actors to provide guidance on development and use of health apps (e.g., the Queensland University of Technology Mobile App Rating Scale, guidelines from the Digital Therapeutic Alliance and Xcertia).

Another challenge of digital therapeutics is presented by products that collect and transmit patient data directly to a dosing device to make real-time dosing decisions, removing the provider intermediary. Artificial pancreas device systems, for example, automatically adjust basal insulin by continuously increasing, decreasing, or suspending delivery of insulin based on data from a continuous glucose monitor. Systems that directly act on patient data provided by wearable devices may become more common as consumer and provider confidence in them increase, but the legal, regulatory, and liability questions raised by such systems are substantial.

Additional Resources:
- [FDA – Digital Health Center of Excellence](#)
- [Digital Health.com](#)
- [IQVIA - Digital Health Trends 2021](#)
- [Disparities in Health Care and the Digital Divide](#)