Top 5 clinical areas where digital health is taking off

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The number of government-registered studies of digital health technology has grown at an average of 29% annually in recent years. The largest category of studies focused on cardiometabolic conditions such as heart disease, diabetes and stroke.

Those and other findings were drawn from an analysis of 1,783 studies voluntarily registered at the U.S. National Library of Medicine's ClinicalTrials.gov site up to 2017. The analysis, "Characteristics of Digital Health Studies Registered in ClinicalTrials.gov," was published in *JAMA Internal Medicine*.

The AMA has created a Digital Health Implementation Playbook that outlines key steps, best practices and resources to accelerate the adoption and scale of digital health solutions. Download the Playbook now.

Wide range of conditions

The study reported on 13 clinical categories, in terms of number of studies and percentage of the whole. These were the top 5:

- Cardiometabolic—382 (21.4%).
- Mental health—216 (12.1%).
- Wellness—183 (10.2%).
- Neurology—114 (6.4%).
- Pulmonary—113 (6.3%).

Rounding out the list were:

- Substance abuse—112 (6.3%).
- Hematology-oncology—107 (6%).
- Autoimmune—84 (4.7%).

- Infectious disease—77 (4.3%).
- Obstetrics-gynecology—63 (3.5%).
- Musculoskeletal or pain—54 (3%)
- Surgery—32 (1.8%).
- Renal—24 (1.4%)

The *JAMA Internal Medicine* research data presents a positive picture of interest in digital health solutions and suggests which conditions might be most likely represented in future product launches. But a deeper dive into the numbers may dampen some of the optimism suggested by the growth and range of the studies.

“The pipeline of digital health studies appears to be promising,” noted the researchers, but they also underscored that the small sample sizes in many studies “could limit their ability to yield a high level of evidence, demonstrate value, or motivate stakeholder adoption.”

More than 220 studies—12.4% of the total—were categorized as “other.” The 29% year-to-year average growth rate taken from those figures was from 2011–2017. The federal government or National Institutes of Health funded 369 studies and industry funded 214, with “other” used to describe the balance of 1,602.

Nearly half the studies—829, or 46.5%—had less than 100 enrollees. Only 8% had more than 1,000.

“We're not seeing a large pipeline of definitive trials of sufficient sample size that would inform adoption, reimbursement, or policy,” the study’s principal investigator, Mintu P. Turakhia, MD, said in an interview. He is an associate professor and director of the Center for Digital Health at Stanford University, and also an associate editor of *JAMA Cardiology*.

“We need more large, definitive studies and fewer pilot studies,” Dr. Turakhia said.

Digital tools test differently

An invited commentary that appeared alongside the study addressed other realities of digital health studies.

Evaluations of digital health software tools (DHSTs) are “often deeply dependent on context,” wrote Andrew D. Auerbach, MD, MPH, a hospitalist, professor of medicine and research director at the Center for Digital Health Innovation at the University of California, San Francisco.

“The technology’s effectiveness is often determined by the way in which it is provided to patients or practitioners, how it is supported (or taught), and how the DHST is added to clinical work or daily life.

As a result, randomized clinical trials of DHSTs may be more prone to limitations in terms of generalizability than traditional devices and drugs."

That extends to the future of DHST studies, Dr. Auerbach wrote.

"Most of our understanding of safety or effectiveness of DHSTs is likely to be made based on real-world evidence and performance data. The role of trials and trial registration in the future is not irrelevant but may need refocusing and repurposing," to take into account biases that result from context and how to evaluate DHSTs that have different uses, such as those that focus on risky clinical situations compared to those that help automate work.

Learn more about the AMA's digital leadership efforts.