COVID as a Catalyst: Propelling Digital Mental Health Technology into the Future

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APA Practice Leadership Conference

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Learning Objectives

- Describe what a digital therapeutic is in the context of mental and behavioral health
- Recite several potential opportunities or concerns regarding the dissemination and implementation of digital therapeutics for mental and behavioral disorders
‘Nobody Has Openings’: Mental Health Providers Struggle to Meet Demand

With anxiety and depression on the rise during the pandemic, it has been challenging for people to get the help they need.
During late June, 40% of U.S. adults reported struggling with mental health or substance use.

**ANXIETY/DEPRESSION SYMPTOMS**
- 31%

**TRAUMA/STRESSOR-RELATED DISORDER SYMPTOMS**
- 26%

**STARTED OR INCREASED SUBSTANCE USE**
- 13%

**SERIOUSLY CONSIDERED SUICIDE**
- 11%

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*Based on a survey of U.S. adults aged ≥18 years during June 24–30, 2020

†In the 30 days prior to survey

The coronavirus pandemic is pushing America into a mental health crisis

Anxiety and depression are rising. The U.S. is ill-prepared, with some clinics already on the brink of collapse.

'Some Of The Greatest Causes Of Misery': U.N. Warns Of Pandemic’s Mental Health Costs

May 14, 2020 - 11:31 AM ET

The Mental Health Crisis Generated By COVID-19: Why It’s Critical And How You Can Retain Your Sanity

Psychiatrists fear 'tsunami' of mental illness after lockdown

By Philippa Roxby
Health reporter
DIGITAL BEHAVIORAL HEALTH VENTURE FUNDING
2011-H1 2020

LEGEND
- Behavioral health¹
- [#] Deal count
- [%] Percentage of total funding

1: Behavioral health includes solutions that address a spectrum of needs from basic mental wellness through treatment of disease; it includes mental health (e.g., depression and anxiety), developmental disorders (e.g., autism spectrum disorder, ADHD), and substance use disorder.

Note: Only includes U.S. deals >$2M; data through June 30, 2020
Source: Rock Health Funding Database
Products across the digital health ecosystem serve different, but complementary purposes. Depending on each product’s intended use and risk, it is subject to increasing degrees of clinical evaluation, regulatory oversight, and real-world data requirements.

**DIGITAL HEALTH TECHNOLOGIES**

- **Enterprise SYSTEMS & SUPPORT**: Platforms for healthcare systems, clinics, and other enterprise settings
  - Clinical administration and management tools
  - Predictive analytics
  - Clinical trial management

- **Clinician SERVICES & SUPPORT**: Platforms primarily for clinicians and clinical support staff
  - Health Information Technology
  - Electronic medical record and prescribing systems
  - Point of care and workflow enhancement tools
  - Telehealth platforms

- **Patient-facing WELLNESS & SUPPORT**: Products that capture, store, or transmit health data
  - Lifestyle and wellness apps
  - Activity and fitness trackers
  - Medication reminder apps
  - Wearables and sensors (non-clinical grade)
  - Consumer health information

- **Patient-facing DIAGNOSTIC & MONITORING**: Products used to diagnose, guide diagnoses, or actively monitor patients
  - Digital diagnostics
  - Digital biomarkers
  - Remote patient monitoring tools
  - Wearables and biometric sensors (clinical grade)
  - Medication ingestible sensors
  - Connected drug delivery devices

- **Patient-facing THERAPEUTIC INTERVENTIONS**: Products that deliver medical interventions and therapies
  - Digital therapeutics
    - Clinical interventions delivered directly to patients via software to treat, manage, or prevent a disease or disorder
  - Non-DTx medical devices (e.g., insulin pump, artificial pancreas, pacemaker, CPAP)

*Categories of the digital health technology ecosystem will continue to evolve. This is a select representation of a broad, diverse ecosystem.*
The **purpose** and **function** of a digital health product determines its categorization, risk level, and requirements for clinical evidence and regulatory oversight.

End users, clinicians, and payers should understand the differences between these varied products given their important roles in the prevention, diagnosis, treatment, and management of health and disease.
What are differences between digital health products?

<table>
<thead>
<tr>
<th>DEFINITION</th>
<th>DIGITAL HEALTH</th>
<th>DIGITAL MEDICINE</th>
<th>DIGITAL THERAPEUTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Digital health</strong> includes technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science and clinical operations.</td>
<td>Digital medicine includes evidence-based software and/or hardware products that measure and/or intervene in the service of human health.¹</td>
<td>Digital therapeutic (DTx) products deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.²</td>
<td></td>
</tr>
</tbody>
</table>

| CLINICAL EVIDENCE | Typically do not require clinical evidence. | Clinical evidence is required for all digital medicine products. | Clinical evidence and real-world outcomes are required for all DTx products. |

| REGULATORY OVERSIGHT | These products do not meet the regulatory definition of a medical device² and do not require regulatory oversight. | Requirements for regulatory oversight vary. Digital medicine products that are classified as medical devices require clearance or approval. Digital medicine products used as a tool to develop other drugs, devices, or medical products require regulatory acceptance by the appropriate review division. | DTx products must be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use. |

² [https://www.dtballiance.org/dtxproducts/](https://www.dtballiance.org/dtxproducts/)
³ It is important to check with local regulatory requirements in each jurisdiction the product is manufactured, registered, or used in.
What is a digital therapeutic?

Digital therapeutics (DTx) deliver therapeutic interventions directly to patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of behavioral, mental, and physical diseases and disorders.

Whether DTx products are used independently, in tandem with remote or in-person clinician-delivered therapy, or paired with medications, devices, and other therapies, DTA stands behind rigorous patient-centered core principles, ethical standards, and product development best practices to ensure product integrity, user-centered designs, patient privacy, and validated clinical outcomes.
Digital Therapeutic Core Principles

Product Quality Matters.

*How do I know that this product is a digital therapeutic?*

DTx products must adhere to each of these foundational principles:

1. Prevent, manage, or treat a medical disorder or disease
2. Produce a medical intervention that is driven by software
3. Incorporate design, manufacture, and quality best practices
4. Engage end users in product development and usability processes
5. Incorporate patient privacy and security protections
6. Apply product deployment, management, and maintenance best practices
7. Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals
8. Be reviewed and cleared or approved by regulatory bodies as required to support product claims of risk, efficacy, and intended use
9. Make claims appropriate to clinical validation and regulatory status
10. Collect, analyze, and apply real world evidence and/or product performance data

DTA’s industry principles, code of ethics, and best practices establish expectations for high quality DTx products.
What diseases do DTx products target?

**Blood disorders**
- Coagulation disorders, including hemophilia

**Neoplasms**
- Cancer, side effect management
- Cancer, drug therapy optimization

**Endocrine, nutritional, and metabolic diseases**
- Diabetes, type 1
- Diabetes, type 2
- Metabolic syndrome
- Obesity
- Pre-diabetes

**Mental, behavioral, and cognitive disorders**
- Alcohol use disorder
- Attention-deficit/ hyperactivity disorder (ADHD)
- Anxiety
- Autism spectrum disorder
- Depression
- Eating disorders

**Nervous system disorders**
- Epilepsy
- Insomnia, sleep disorders
- Lupus
- Migraine
- Multiple sclerosis (MS)
- Parkinson’s disease (PD)

**Circulatory system disorders**
- Hypertension
- Stroke

**Respiratory system disorders**
- Asthma
- Chronic obstructive pulmonary disease (COPD)

**Digestive system disorders**
- Irritable bowel syndrome (IBS)

**Skin and subcutaneous tissue disorders**
- Skin disorders

**Musculoskeletal system and connective tissue disorders**
- Movement disorders
- Orthopedic conditions
- Osteoarthritis

**Pregnancy and childbirth**
- Post-partum depression

**Injury, poisoning, and certain other consequences of external causes**
- Traumatic brain injury (TBI)

*As of March 2020*
## DTx Product Categories

Digital therapeutics generally align with one of these categories based on the product’s primary purpose:

<table>
<thead>
<tr>
<th>Digital Therapeutic to:</th>
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<tbody>
<tr>
<td><strong>TREAT A DISEASE</strong></td>
<td><strong>MANAGE A DISEASE</strong></td>
<td><strong>IMPROVE A HEALTH FUNCTION</strong>*</td>
</tr>
<tr>
<td><strong>Level of medical claims</strong></td>
<td><strong>Clinical endpoints</strong></td>
<td><strong>Clinical endpoints</strong></td>
</tr>
<tr>
<td>Medium to high-risk claims</td>
<td>Must use clinical endpoints to support product claims</td>
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<tr>
<td><strong>Clinical evidence</strong></td>
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<tr>
<td>Clinical trials and ongoing evidence generation required</td>
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<tr>
<td><strong>Regulatory oversight</strong></td>
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</tr>
<tr>
<td>Third-party validation of efficacy and safety claims by regulatory or equivalent national body</td>
<td>Third-party validation of efficacy and safety claims by regulatory or equivalent national body</td>
<td>Degree of regulatory oversight depends on local regulatory body frameworks</td>
</tr>
<tr>
<td><strong>Patient access</strong></td>
<td><strong>Patient access</strong></td>
<td><strong>Patient access</strong></td>
</tr>
<tr>
<td>Prescription required</td>
<td>Prescription required OR Non-prescription product</td>
<td>Non-prescription product</td>
</tr>
</tbody>
</table>

*Includes digital therapeutics that prevent a disease
How are DTx products’ clinical value delivered in practice?

- Treat conditions not adequately addressed through traditional therapies
- Enhance the impacts of – or optimize the use of – traditional medications
- Address specific comorbidities, side effects, or affiliated conditions to offer a more complete and well-rounded therapy
- Provide active treatment through direct activation of neural networks
- Deliver cognitive behavioral therapy (CBT) and other evidence-based treatments
- Responsive delivery of physical exercises, behavioral therapy, and education
- Provide disease management and prevention programs
COVID-19 pandemic has caused or exacerbated stress and anxiety for Americans resulting in increased demand for mental health apps in early 2020.

- First-time downloads of the top 20 mental wellness apps in the U.S. hit 4 million in April. That’s up 29 percent from 3.1 million in January. By contrast, first-time downloads of the top 20 such apps fell 30 percent during the same period last year.

- Services like Talkspace and BetterHelp, in particular, have reported a rush of new users in 2020, but teletherapy apps have been dogged by concerns around privacy and efficacy.

- [May 2020 CNBC poll](#)
Legal or regulatory considerations?

- Data Privacy
- Clinical Effectiveness
- Data Security
- Product Safety
How are health apps regulated?

- FDA?
- HHS?
- FTC?
- Relevant state laws?
- ONC?
Current federal policies impacting digital health

• 21st Century Cures Act
• CMS Interoperability and Patient Access final rule
• ONC Cures Act Final Rule
• Goal is to align policies across federal agencies to:
  • Increase patient access to health information,
  • Facilitate greater interoperability across electronic health records systems, and
  • Promote digital health
• FDA Temporary Approval Waivers for Mental Health Apps
• HHS proposed modifications to HIPAA Privacy Rule
Digital Health – Mental/Behavioral Health

- April 2020 Enforcement Discretion for Mobile Mental Health Apps during COVID-19 Public Health Emergency
- “Computerized behavioral therapy devices” & other digital health therapeutic devices for psychiatric disorders
- Low-risk general wellness & digital health products
  - Does NOT include any platforms or devices used to make a clinical diagnosis or treatment decision
  - Does NOT include videoconferencing software for telehealth (not a medical device)
- Prescription-only device
- Condition-specific therapy for temporary relief of symptoms through modalities
  - E.g., Acceptance Commitment Therapy, Cognitive Behavioral Therapy, etc.
- Adjunctive use
FDA approved prescription-only mental health DTx

• Substance Use Disorder – reSET (Pear Therapeutics)
• Opioid Use Disorder – reSET-O (Pear Therapeutics)
• Chronic Insomnia – Somryst (Pear Therapeutics)
• ADHD - EndeavorRx (Akili Interactive)*
• PTSD Nightmares - Nightmare (Nightware)*
• CBT for IBS - Parallel (Mahana)*
• Migraines/pain - Nerivio (Theranica)*
Opportunities

• Increase access and options to care (and affordability?)
• Ensure products have acceptable efficacy and safety profiles
• Extend the reach of evidence-based mental & behavioral health treatments
• Provide adjunctive support to established therapeutic relationships

Challenges

• No non-physician influence or voice at the FDA
• FDA’s prescription-only medical model excludes psychologists and most other mental health providers from assessing and using DTx
• Potential for devices to be used as a replacement for psychologists and other providers
• Traditional coverage and reimbursement models not designed to fit DTx
• Rapidly increasing pace of FDA approvals
APA’S approach to addressing digital therapeutics in mental & behavioral health care

• Reimbursement
• Regulations
• Education
• Marketplace
- Center for Workforce Studies (CWS) Data Tools: https://www.apa.org/workforce/data-tools
Questions?

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