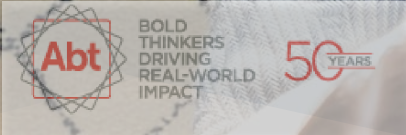


Welcome!

September 6th

Webinar: SAMHSA Advisory

DIGITAL THERAPEUTICS FOR MANAGEMENT AND TREATMENT IN BEHAVIORAL HEALTH



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- If you need tech help, please enter “tech help” into the chat.
- There will be a Q&A segment during today’s presentation
 - If you have a question for the presenters, please enter into Q&A
- At the end of today’s webinar, please complete a **brief** survey.
- Following the session, you will receive an email on how to access a certificate of attendance; must attend at least 30 minutes.
- This event is closed captioned!
- Follow us on social media:



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Acknowledgment

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At the time of this presentation, Dr. Miriam E. Delphin-Rittmon served as Assistant Secretary for Mental Health and Substance Use in the U.S. Department of Health and Human Services (DHHS) and the Administrator of SAMHSA. The opinions expressed herein are the views of the speakers, and do not reflect the official position of DHHS or SAMHSA. No official support or endorsement of DHHS, SAMHSA, for the opinions described in this presentation is intended or should be inferred.

The use of affirming language inspires hope and advances recovery.

LANGUAGE MATTERS.

Words have power.

PEOPLE FIRST.

The ATTC Network uses affirming language to promote the promises of recovery by advancing evidence-based and culturally informed practices.



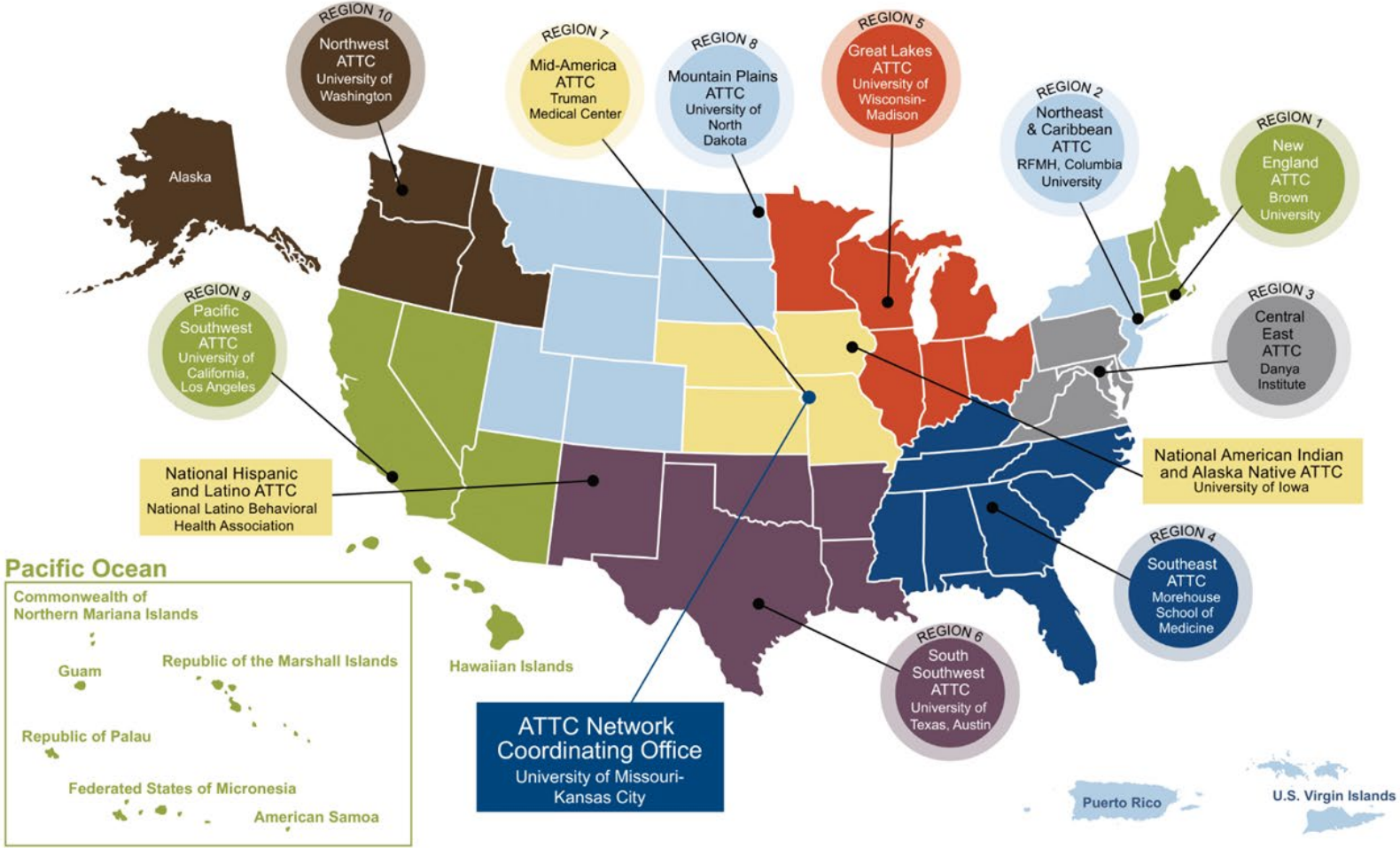
ATTC

Addiction Technology Transfer Center Network
Funded by Substance Abuse and Mental Health Services Administration

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ATTC Network



National Mental Health and Substance Use Policy Laboratory

Digital Therapeutics for Management and Treatment in Behavioral Health

September 6, 2023



SAMHSA
Substance Abuse and Mental Health
Services Administration

Welcome



Jennifer Frazier

Public Health (Policy) Advisor

Substance Abuse and Mental Health
Services Administration

SAMHSAADVISORY

Substance Abuse and Mental Health
Services Administration

JULY 2023

DIGITAL THERAPEUTICS FOR MANAGEMENT AND TREATMENT IN BEHAVIORAL HEALTH

The last decade has seen immense changes in digital health, with the expanded use of computing platforms, electronic medical records, mobile applications, and wearable devices in health care. During the COVID-19 pandemic in particular, telehealth expanded access to care for millions of people and was a critical resource to meet the behavioral healthcare needs of individuals with mental health conditions and substance use disorders. Another example of the use of technology to facilitate care is **digital therapeutics** (DTx). DTx are health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.¹ DTx may be used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.² DTx may or may not require a prescription and are generally considered medical devices subject to regulatory oversight by the Food and Drug Administration (FDA).³

Many digital platforms and applications are marketed as behavioral health and wellness interventions. However, other than DTx, few have evidence demonstrating improved behavioral health outcomes. In addition, access to high-quality digital health products can be limited for those who are uninsured or underinsured and who have inadequate broadband access and data plans for smartphone and computer use. All of these factors can result in disparities in the uptake of digital health tools.^{4,5} It is therefore important to identify the digital health interventions such as DTx that have an evidence base for both treating and managing mental health conditions and substance use disorders^{6,7} and also recognize and address barriers to access.

Key Messages

- DTx can be effective independent or complementary services in the *management and treatment* of mental health conditions and substance use disorders.
- Users should be aware that not all healthcare applications for mental health conditions and substance use disorders have an evidence base for therapeutic use.
- At least five federal agencies have initiatives to develop, research, review, regulate, distribute, and address payment for DTx.
- At this time, few health plans cover prescription digital therapeutics (PDTs), but payers continue to explore and expand this area.
- For DTx to increase behavioral health equity, they must be designed and implemented to account for differences in health and digital literacy and to be culturally and linguistically appropriate, adaptable to variable service settings, and affordable and accessible for all users.
- Continued research is needed on the efficacy of DTx, balanced with ongoing consideration of costs, patient/client privacy, and protection of health data.

Welcome



Cecelia Spitznas, PhD

Senior Science Policy Advisor

White House Office of National Drug
Control Policy

- Provides policy analysis and scientific advice on special matters of concern including incentives, naloxone, marijuana, psychedelics and neonatal abstinence syndrome
- 12 years at the National Institutes of Health's National Institute on Drug Abuse (one on detail to ONDCP) and at ONDCP for 10 additional years as an employee
- Previously an Assistant Professor in the UAB School of Medicine conducting NIH funded research with people who used crack cocaine and were homeless

Panelists



Jennifer Frazier

Public Health (Policy) Advisor
Substance Abuse and Mental
Health Services Administration



Teresa Stephenson

*Senior Director of Adult and
Family-Centered Substance use
Treatment and Recovery
Services & State Opioid
Treatment Authority*
OK Department of Mental Health
and Substance Abuse Services



Andy Molnar

CEO
Digital Therapeutics Alliance

Defining Digital Therapeutics (DTx)

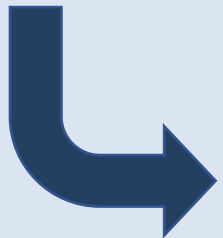
Digital Health Interventions

- Designed to achieve a specific outcome
- Encompass evidence-based DTx
- May also include interventions that do not have an evidence base to support their use



Digital Therapeutics (DTx)

- Treat or alleviate a disease, disorder, condition, or injury
- Generate and deliver a medical intervention that has a demonstrable positive therapeutic impact on a patient's health



Prescription Digital Therapeutics (PDTs)

- Cleared or approved for prescription use by the FDA
- Software-based medical devices intended to prevent, manage, or treat a medical condition
- Prescribed by a clinical provider and can support health claim payment

Barriers to Behavioral Health Care Addressed by DTx

Lack of access to
behavioral health care

Clients can use DTx remotely and
independently

Stigma

Remote access facilitates anonymity

Digital health interventions
lack an evidence base

DTx are rigorously developed
and tested

Behavioral health care costs

DTx can reduce out of pocket costs

Some populations are
hard to reach

DTx have demonstrated
effectiveness in engaging hard-to-
reach populations

Research and Development



Federal

- National Institute on Drug Abuse's Center for Technology and Behavioral Health (CTBH)
- National Institute of Mental Health
- Agency for Healthcare Research and Quality's Digital Healthcare Research Program
- Department of Veterans Affairs

Regulations and Reimbursement

- **The FDA**
 - Medical device review
 - Clearance and approval processes for DTx
 - DTx considered a Class II medical device
 - Six PDTs currently cleared
- **Medicare, Medicaid, and Private Insurance**
- **Cost benefits**
 - Enhanced efficiencies in quality care
 - Improved retention in care
 - Reduced use of pharmaceuticals

FDA Cleared Prescription Digital Therapeutics (PDTs)*

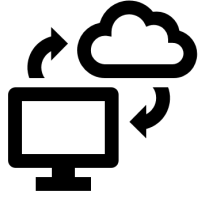
Six examples of DTx that have received FDA clearance for behavioral health treatment



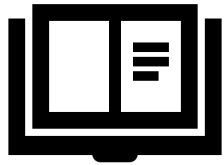
Name	Used to Treat
EndeavorRX	Attention-deficit/hyperactivity disorder
Freespira	PTSD, panic disorder, panic attacks
NightWare	PTSD
reSET	Substance use disorders
reSET-O	Opioid use disorder
Somryst	Chronic insomnia

*Although all six have received FDA clearance, some have been more extensively researched, and long-term outcomes are still being examined.

Increasing Equity in DTx



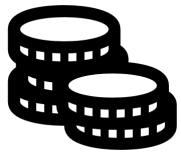
Access to technology, broadband, and sufficient data plans



Digital and health literacy



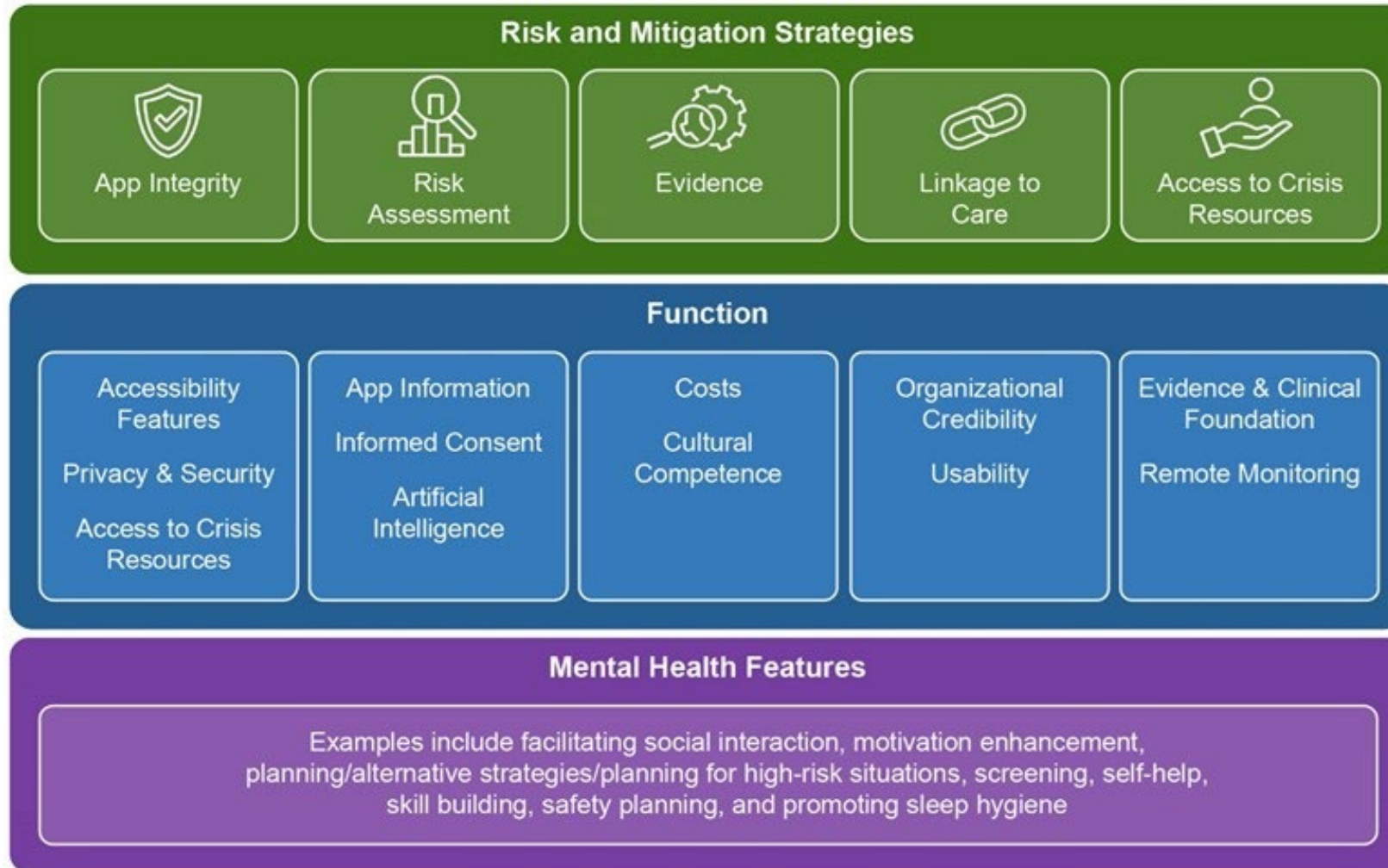
Cultural and linguistic appropriateness



Affordability

Assessing and Selecting DTx

Framework to Assist Stakeholders in Technology Evaluation for Recovery (FASTER)



Source:

Agarwal, S., Jalan, M., Wilcox, H. C., Sharma, R., Hill, R., Pantalone, E., Thurl, J., Rainey, J. C. & Robinson, K. A. (2022). Evaluation of mental health mobile applications. Technical brief 41. AHRQ Publication, No. 22-EHCO16.



OKLAHOMA
Mental Health &
Substance Abuse

Roundtable Discussion





A lot of different terms are used for technology in healthcare. What is the relationship between these technologies (e.g., apps, telemedicine, telepsychiatry)? How do they differ, and why do the distinctions matter?

As digital therapeutics become more a part of healthcare, what are implications related to privacy, confidentiality, and security of data? What are considerations for mobile health?





What is the role of funding for DTx?
How are they financed and reimbursed?
What are implications for sustainability and broad adoption?

Q & A and Discussion



Digital Therapeutics Advisory

SAMHSAADVISORY
Substance Abuse and Mental Health
Services Administration

JULY 2023

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- The advisory is available on the SAMHSA Store:
<https://www.samhsa.gov/resource/ebp/digital-therapeutics-management-treatment-behavioral-health>
- For more information, contact ebprc@samhsa.hhs.gov

Next Steps

The ATTC Network is funded through SAMHSA to provide this training. As part of receiving this funding we are required to submit data related to the quality of this event.

Please take a moment to complete a **brief** survey about today's training.

Survey: <https://ttc-gpra.org/P?s=196752>

Within a week:

- The recording of today's session will be available on attcnetwork.org.
- Attendees will receive a follow-up email with instructions for downloading a certificate of completion.



The image features a central blue square with diagonal stripes in various shades of blue. This square is set against a background of light blue geometric shapes, including a large triangle on the left and a trapezoid on the right. The overall design is clean and modern.

THANK
YOU