



Digital Therapeutics for Mental Health and Substance Use Disorders: Potential Applications for Chronic Pain

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Disclosure

- Nothing to disclose

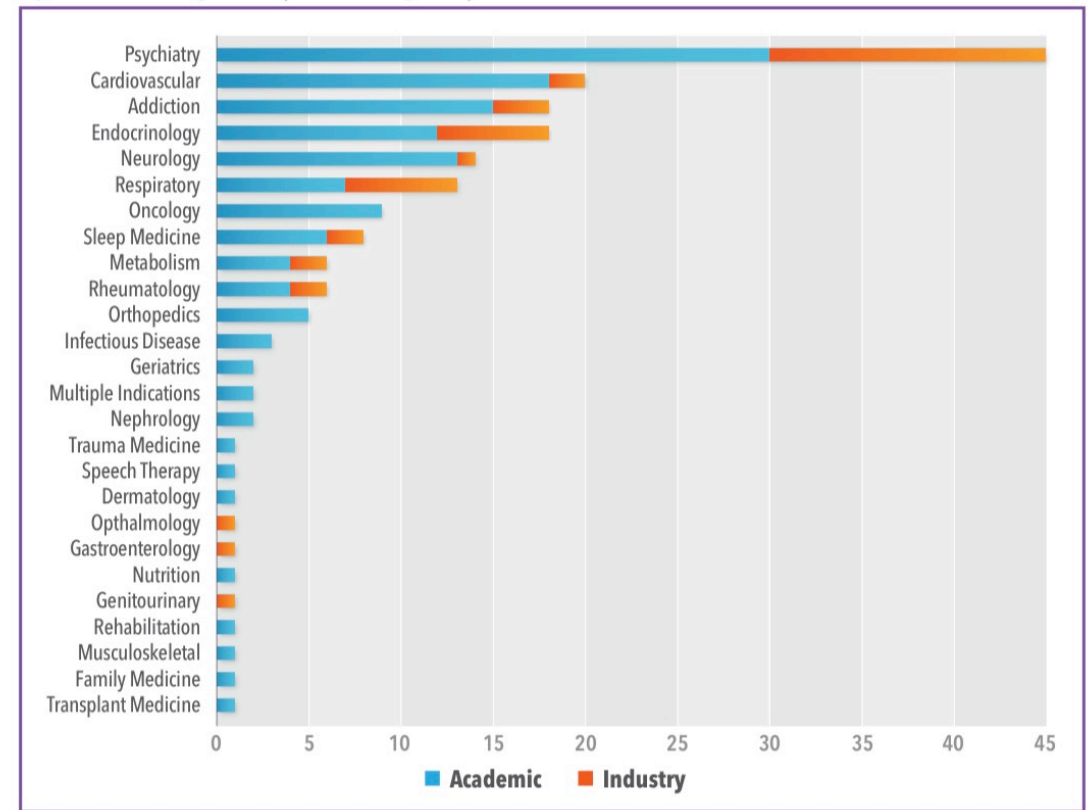
Learning Objectives

- Review the evolving field of medical technology
- Discuss digital therapeutics (DTx) use in the mental health and substance abuse populations
- Identify mental health and substance abuse needs pre and post Covid
- Cite the benefits for DTx use in the mental health and substance abuse populations
- Explore the potential intersection of DTx for mental health and chronic pain

The New World Order

- Medical Technology:
World Health Organization: 'Mobile health or mHealth is medical and public health practice supported by mobile devices'^{1,2}
 - Smart phones, portable computers, wearable devices, tablet
- Digital Therapeutics:
 - Goal of DTx is treatment, prevention and management of health conditions
 - Over 327,000 DTx apps available for download to treat over 240 health conditions³
 - Small percentage of these actually meet the goals of a DTx

Figure 2. Trends in Digital Therapeutics Trials by Therapeutic Area Over the Past Ten Years



Social Media and Machine Learning

- Machine learning has shown to identify depression markers in Instagram account analysis better than human assessments⁵
- Color analysis, metadata components, and algorithmic face detection: colors, indoors v outdoors, comments, likes, posting frequency
- Dartmouth study funded by NIDA proved machine learning analysis of Instagram accounts can identify those at risk for substance abuse⁶



DTx: Core Principles

- Prevent, manage, or treat a medical disorder or disease
- Produce a medical intervention that is driven by software and delivered via software or complementary hardware, medical device, service, or medication
- Incorporate design, manufacture, and quality best practices
- Engage end users in product development and usability
- Incorporate patient privacy and security protections⁴

DTx Core Principles

- Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals
- Be reviewed and cleared or approved by regulatory bodies as required to support product claims of risk, efficacy, and intended use
- Make claims appropriate to clinical validation and regulatory status
- Collect, analyze, and apply real-world evidence and product performance data

There's an App for that!



- Smart phones are the most accessible DTx device
- 2019 survey shows 81% of Americans have a smart phone
- 2017 survey shows 67% of Americans over age 65 have a smart phone
- App store and Google Play has approximately 10,000 mental health apps

Smart Phone Apps:

- Apps can potentially save US healthcare industry 7 billion a year
- Apps available for:
 - Diabetes education, risk reduction
 - Cardiac rehabilitation
 - Mental health: PTSD Coach, suicide risk and reduction
 - Substance abuse
 - Attention-deficit/hyperactivity disorder
 - Insomnia
 - Panic attacks, anxiety, OCD
 - Depression
 - Medication reminders
 - Chronic pain

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**"You have a rare condition called 'good health'.
Frankly, I'm not sure how to treat it."**

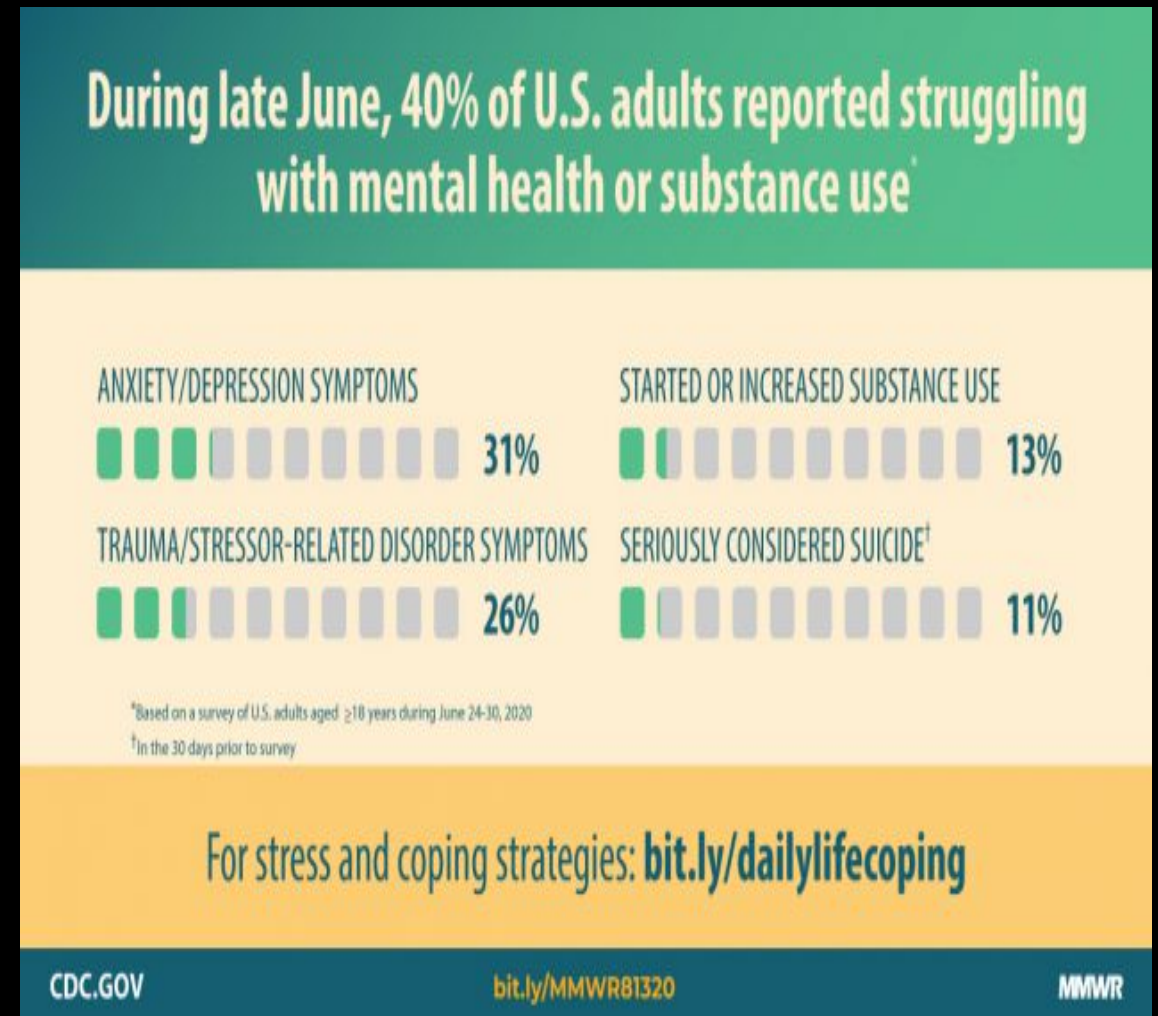
Mental Health & Substance Use Disorders: Pre Covid

- Mental Health conditions and substance use disorders are often misunderstood by the general public
- These attitudes lead to stigma, reduced access to care
- Only 43% of adults in the US with a mental health condition receive treatment
- FLORIDA: close to 3 million have a mental health disorder (6x's the population of Miami)
- One person dies by suicide every 11 minutes in the US

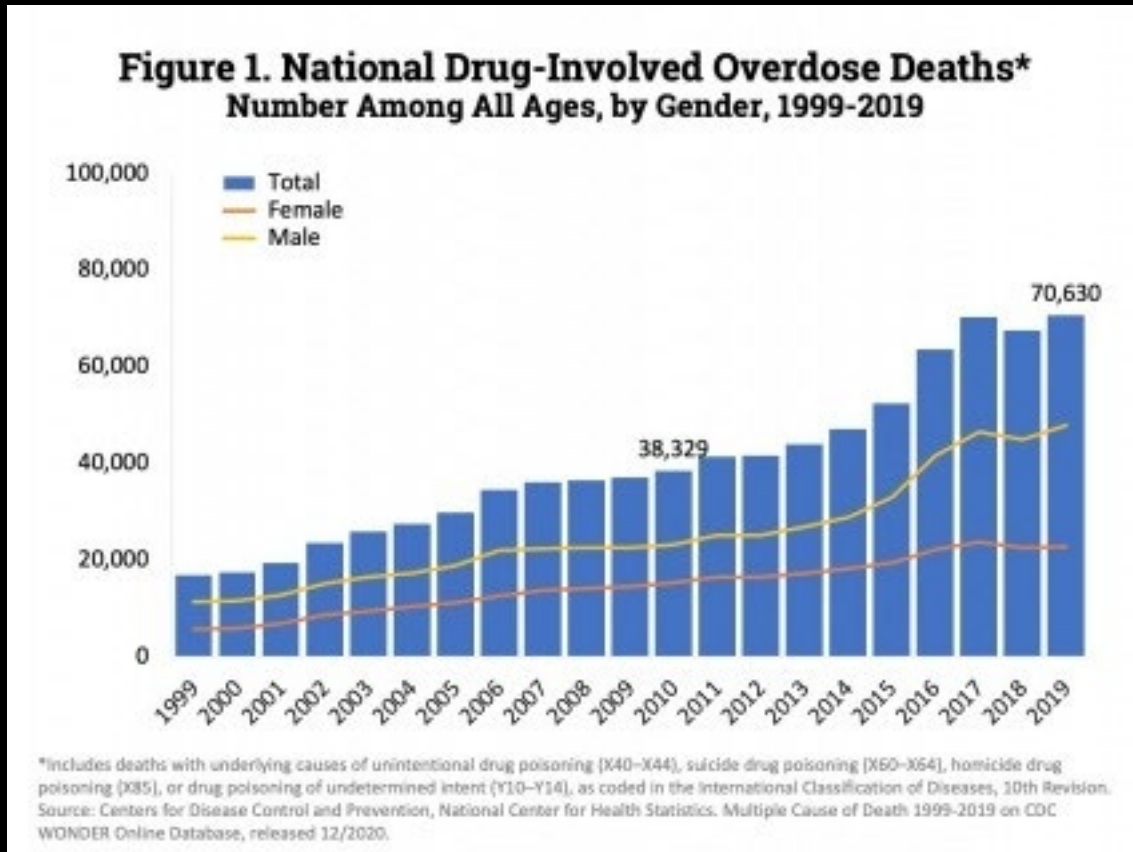


Mental Health Disorders: Post COVID

- June 2020, U.S. adults reported elevated adverse mental health associated with COVID-19.
- 42% Americans reported clinically significant anxiety and 38% clinically significant depression during Covid.
- More than half of public health workers are reporting mental health symptoms and 8% have reported suicidal ideations.
- Vulnerable populations: Younger adults, racial/ethnic minorities, essential workers, and unpaid adult caregivers



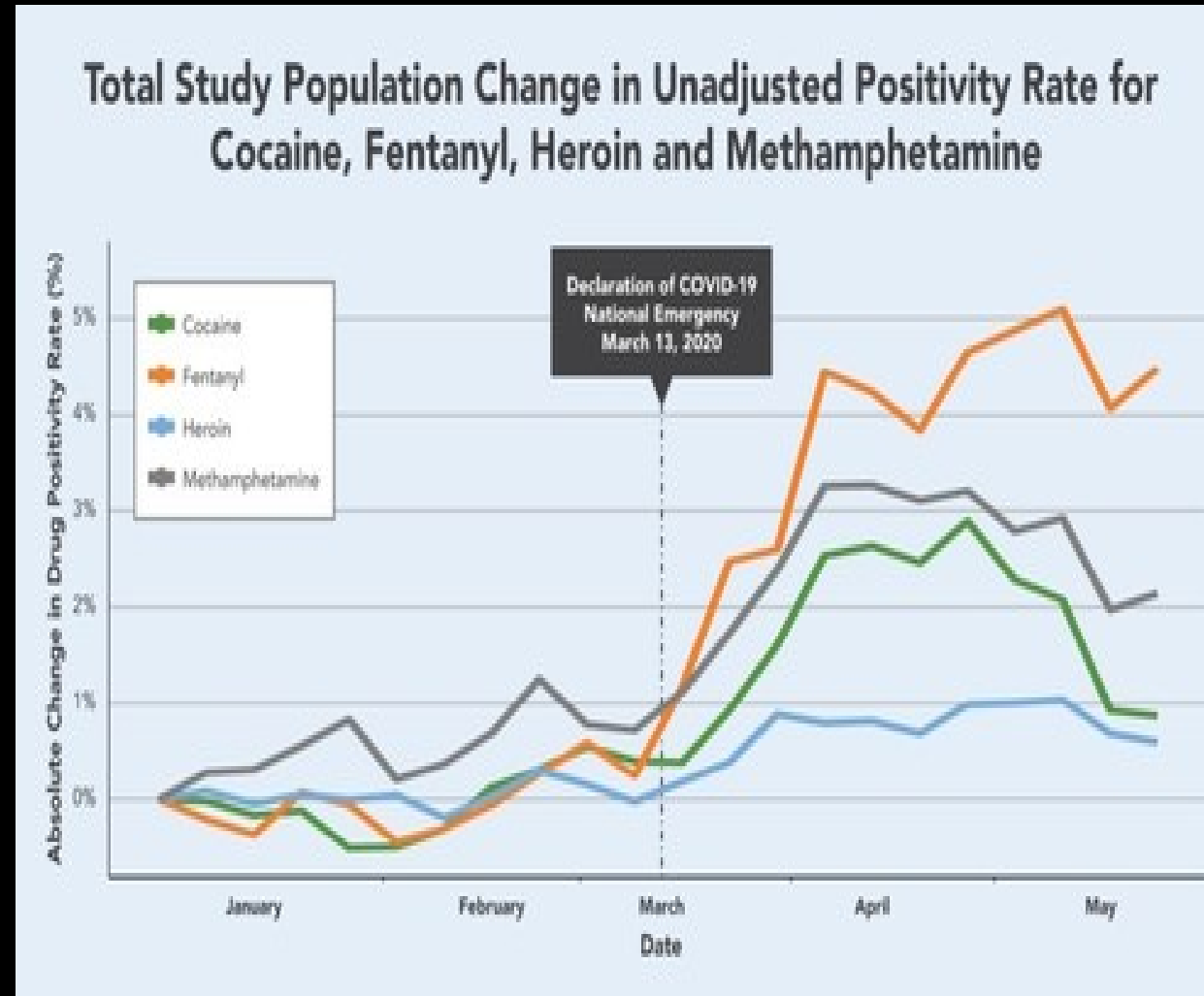
Substance Use Disorders: Pre Covid



- 1999-2018: 750,000 Americans have died of a drug overdose
- Overdose from all types of drugs measured October 2018-2019: **70,630**
- 80% of overdoses involved prescription opioids, heroin, fentanyl

Substance Use Disorders: Post COVID

- Covid disrupted drug supply chains, leading to an explosion of fentanyl availability
- Over 93,000 drug overdose deaths in 2020, highest number of overdose deaths ever recorded in a 12-month period.
- Represents 30% increase from 2019
- Social isolation related to Covid lockdowns worsened substance use disorders



DTx for Mental Health: Monitoring/Targeting Behaviors

- Circadian Rhythm for Mood App (CRM): Combo of daily log and Behavioral Correction
- Wearers of mobile devices sent warnings with irregular life behaviors detected:
 - Sleep changes
 - Light exposure
 - Activity
 - Heart rate
- Results: Showed a reduction in mood episodes in bipolar and depression
- Texas A&M: Platform based app to monitor for psychiatric distress through facial cues, voice patterns, heart rate, breathing, communicate with providers

Mental Health Apps: Treatment

- PTSD Coach: Designed as a support app for those in evidence-based therapies such as
 - Prolonged Exposure
 - Cognitive Processing Therapy
 - Designed for US combat veterans
 - Has not been well studied in community-based patients
 - Provides psychoeducation, symptom monitoring, management tools
 - Limited to small studies on veterans and military families
 - Evidence inconclusive on benefits for symptom reduction
 - One study shows clinician involvement improves self efficacy

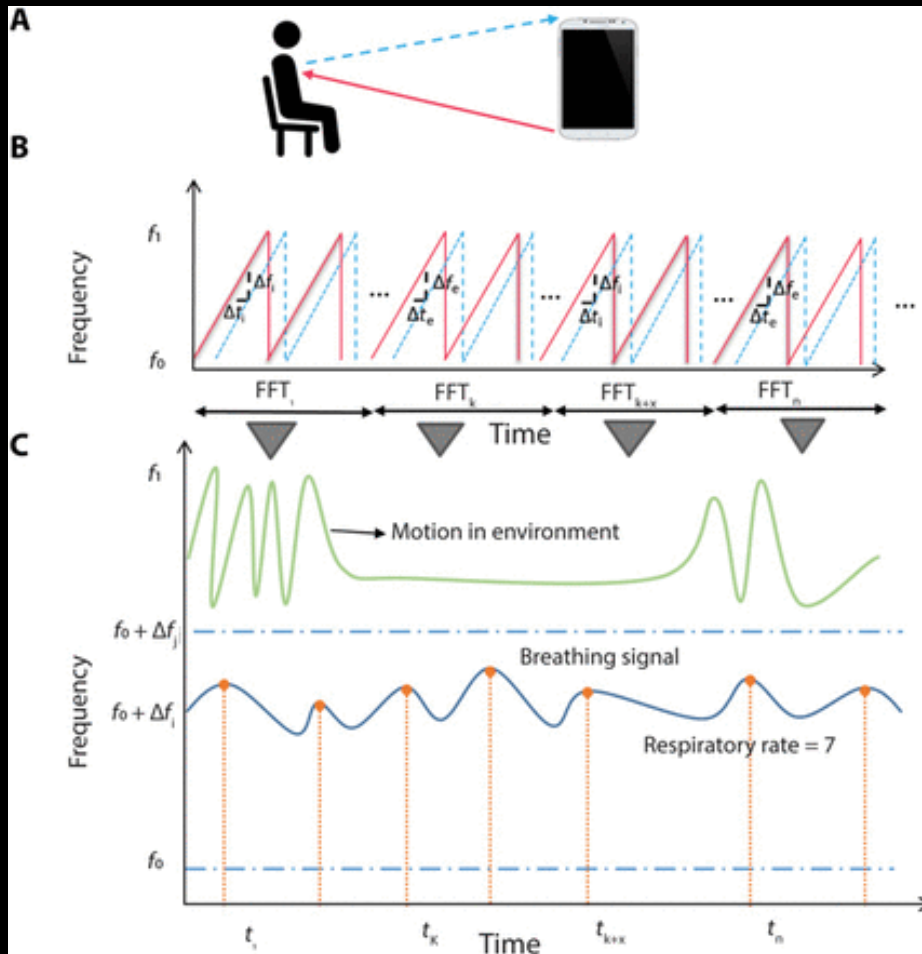
Mental Health Apps: Prevention

- Suicide Prevention Apps
- Meta-analysis of RCT of several suicide prevention apps: i-Bobbly, Virtual Hope Box, Therapeutic Evaluative Conditioning, Blueelce
- 4 studies relevant
- Authors identified:
 - Lack of standard measurements/psychometrics
 - Lack of standard language
 - Self injurious thoughts, suicidal ideations, self harm behaviors were main targets
 - Certain patients excluded due to severity of suicidality
 - None demonstrated ability to reduce suicidal ideations, only reduction of depression and anxiety

Substance Abuse Apps

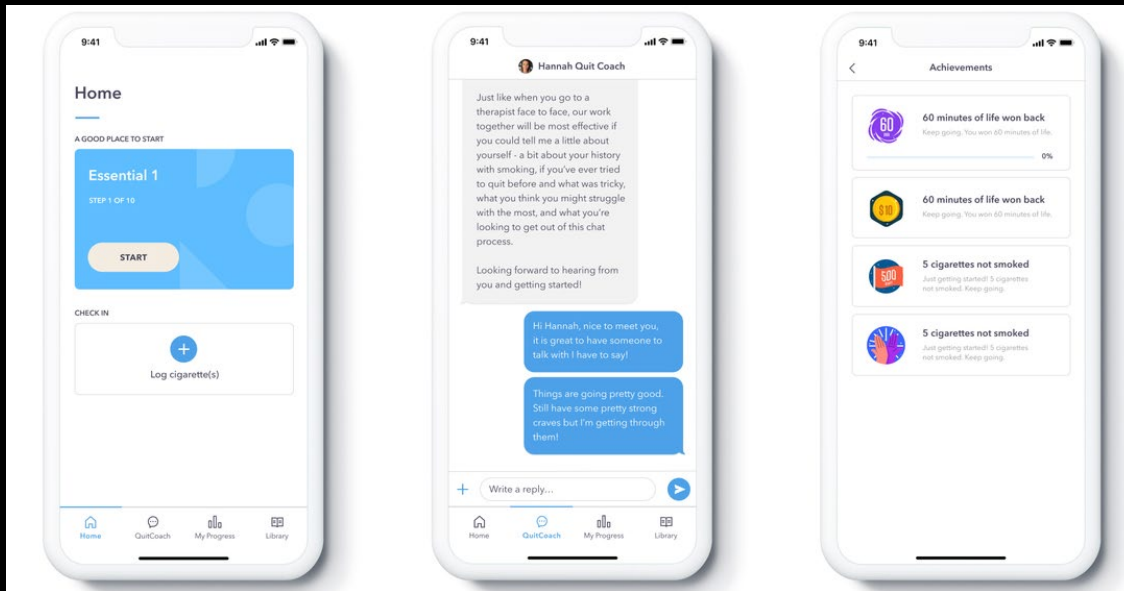
- reSET-O: approved by FDA as a prescriptive digital therapeutics prescriptive Jan 2019
- 84-day prescription to enhance MAT treatment with buprenorphine
 - Designed to target retention in treatment
 - Uses CBT with audio and video lessons
 - Contingency management
 - RCT shows 82% retention vs 68% for treatment as usual group
- reSET: Newest DTx targeting non-Opioid Use disorders using CBT and contingency management

Substance Abuse Apps



- Second Chance: Monitors users breathing patterns with sound waves, tracks overdose symptoms, alerts EMS
- Wearable Sensors: Mobile phone–linked breathalyzer technology: Demonstrated to improve outcomes for AUD treatment
 - Triple A, SoberDiary, and SoberLink

Tobacco Cessation: Quit Genius



- Evidence based RCT with control group showed efficacy in assisting someone to quit smoking in 4 weeks
- Built on Prochaska's stages of change
- Promotes Motivational Interviewing/Self efficacy
- App Utilizes:
 - Self monitoring
 - Goal setting
 - Medication adherence

DTx Benefits

- 24/7 Access
- Teach patients evidence-based skills
- Connects user to their healthcare provider
- Retention in treatment
- Extend treatment reach
- Gather/measure data

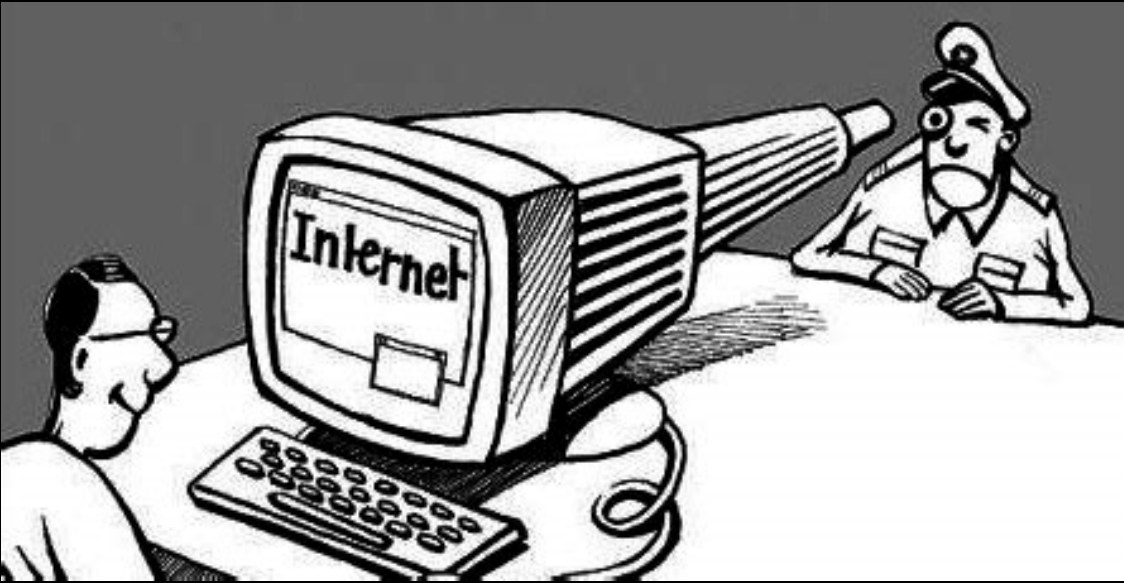


DTx is still the Wild Wild West: Where is the evidence?

- Multiple reviews show few RCT that demonstrate benefits of DTx
- Germany is leading the way by allowing for the reimbursement of DTx.
- DTx approval will require to undergo a formal process of evidence assessment



Privacy Concerns



- Privacy at risk for the general patient
- Apps require and gather personal health information
- Mental health specifically a target for privacy concerns
- Few apps address or protect information

Therapeutic Rapport and Attachment

- There is an ease of blocking others on social media
- Can this translate into terminating a therapist on a digital app more quickly?
- Loss of opportunity to work through transference, conflict
- Weak rapport
- Boundary settings are lost



Who Should Recommend or Prescribe an App?

- For therapists and providers these are the hurdles:
 - Strong evidence still lacking for benefits
 - Uneven approach to DTx
 - Technological literacy required for both patient and provider
 - Economics and limited availability for patients
 - Providers have shown a poor awareness of available apps
- The greater the therapist input, the more effective the interventions seem to be
- Perhaps the best method is to incorporate an app into a traditional delivery

DTx Formularies May Assist Providers in Prescribing

Table 1. The First Cohort of Solutions in the Express Scripts Digital Health Formulary*

Clinical Category	Sub-Categories	Digital Health Formulary	
Diabetes	Type 1 diabetes Type 2 diabetes	PREFERRED:	Livongo® Health for Diabetes
		ALTERNATIVES:	Omada Health for Diabetes LifeScan's OneTouch Reveal® Plus, powered by Welldoc's BlueStar® platform
	Diabetes prevention	PREFERRED:	Livongo® Health for Pre-Diabetes
		ALTERNATIVES:	Omada Health for Pre-Diabetes
Cardiovascular	Hypertension	PREFERRED:	Livongo® Health for Hypertension
		ALTERNATIVES:	Omada Health for Hypertension
Pulmonary	Asthma COPD	Propeller Health	
Mental Health	Depression Anxiety Insomnia	Learn to Live Cognitive Behavioral Therapy SilverCloud Health Cognitive Behavioral Therapy	

ADDITIONAL SOLUTIONS COMING 2020

*Released in December 2019, the formulary includes 15 solutions, including remote monitoring services and digital therapeutics that aid in the management of eight of the US's most common chronic conditions.

Source: Express Scripts Website

What is the Landscape of DTx for Chronic Pain?

- The Bad News:
 - DTx for chronic pain has little evidence-based medicine content
 - Populations such as older patients require more training and digital literacy
 - Financial constraints and availability are obstacles for certain populations
 - DTx for pain commonly do not connect patients to their HCP
 - Limited self efficacy and management built into pain DTx

What is the Landscape of DTx for Chronic Pain?

- The Good News:

- Studies exploring DTx show emerging potential of benefit for people managing cancer pain
- DTx specifically for teens and young adults: ages 15-25 has shown benefits teaching on self management, monitoring sleep, mood, activity
- DTx for older adults with chronic pain show benefit if offered training in digital technology

Where can DTx for Mental Health and Chronic Pain Intersect?

Complexity of Chronic Pain often involves:

- Anxiety
- Depression
- Diminished sense of self efficacy
- Cognitive Distortions

Studies show that interventions such as meditation, mindfulness, guided imagery can aid with reducing pre and post operative acute and chronic pain.

Where Can DTx for Mental Health and Chronic Pain Intersect?

Development of DTx for chronic pain to incorporate:

- Self management techniques
- Goal setting
- Social support, being able to interact with other users in a community setting
- CBT focus/features

Case: Anna M

Anna is a 13-year-old adolescent female with a history of sexual and physical abuse. She has been hospitalized three times for depression and suicidal ideation in the last 2 years.

During Covid, she is unable to attend in-person school and is home the majority of the week with her mother and stepfather. There is ongoing conflict at home between her parents. She has limited social interactions. She reports worsening depression during her last telehealth visit and shares chronic suicidal thoughts along with self-injurious behaviors, cutting specifically.

You do not assess a need for immediate hospitalization but want her to engage in more treatment. What would your next recommendation be?

- a. In person PHP programming
- b. DBT group therapy
- c. Have her download a MH app to track her self injurious thoughts
- d. All of the above

Case: Anna M

- You decide to prescribe Virtual Hope Box for Anna targeting her self injurious thoughts and cutting.
- What is the most accurate reason to prescribe a mental health app for Anna?
 - a. Apps targeting suicidal thoughts are well studied and show good evidence for reducing suicidality
 - b. All mental health apps are cognitive behaviorally based
 - c. Digital therapeutics are only effective for substance use disorders
 - d. None of the above

Case: John B

- John sees you for his alcohol use disorder. He has been in recovery for 1 year and takes acamprosate for maintenance therapy. In the last 6 months he injured his back at the construction site and has been treated with oxycodone/acetaminophen. He quickly started abusing the oxycodone/acetaminophen. You diagnose him with an opioid use disorder and start him on buprenorphine/naloxone. You are considering prescribing him an DTx app to support his buprenorphine/naloxone treatment. What evidence would support this decision?
 - A. DTx apps are low-cost ways to keep patients in treatment
 - B. DTx apps carry no real privacy risks
 - C. DTx apps have demonstrated good retention in treatment up to 80% or more versus those who do not use an app
 - D. DTx apps are only prescribed by cool doctors

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