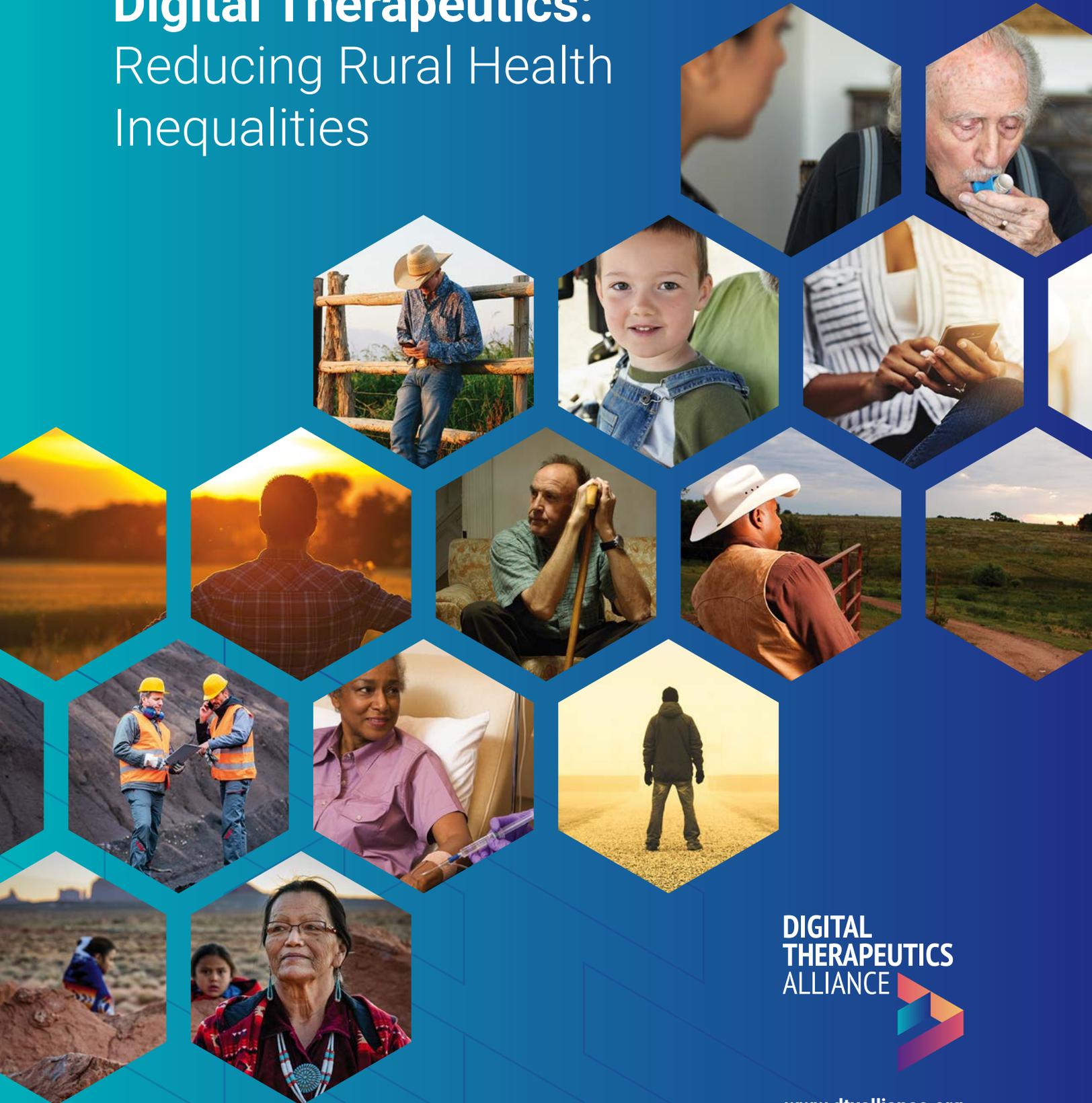


Digital Therapeutics: Reducing Rural Health Inequalities



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Inequalities Abound in Rural Healthcare

Rural America's lack of healthcare access represents a significant disparity within the country. One in five Americans lives in a rural area and the challenges facing these 60 million individuals¹ are well-documented.

Factors such as hospital closures, clinician shortages, and barriers to care increase clinician and caregiver burden and intensify the social and financial impacts of under-addressed and uncontrolled diseases on the healthcare system.

Government initiatives such as Healthy People 2020 provide national frameworks for setting and tracking public health priorities. Through this program, seven major causes of death were identified – coronary heart disease, cancer, diabetes, stroke, chronic obstructive pulmonary disease (COPD), unintentional injury, and suicide – and differences in target outcomes between rural and urban areas were tracked by researchers over a ten-year period.

As of 2017, age-adjusted death rates in rural populations were higher for all seven major causes of death, and disparities compared to non-rural populations had widened for five of these diseases (COPD, diabetes, coronary heart disease, cancer, and suicide).²

Current treatments and resources have been unable to sufficiently address these unmet medical needs. A quickly evolving category of medicine has emerged that could help mitigate many of these substantial gaps in care.

Death rates were higher in rural areas than urban settings for all seven of Healthy People 2020's targeted health conditions.³



Digital Therapeutics (DTx): An Important Treatment Option

Digital therapeutics (DTx), a new category of medicine, deliver therapeutic interventions directly to patients using scientifically developed, evidence-based, and clinically evaluated software to treat, manage, and prevent diseases and disorders. DTx products are subject to rigorous patient-centered core principles,⁴ an industry code of ethics,⁵ and product development best practices.⁶

DTx products are used independently, alongside medications, or in tandem with clinician-delivered therapy. They differ from pure lifestyle, wellness, adherence, diagnostic, and telehealth products, and are distinct from the over 350,000 digital health apps available online.

The term “digital therapeutic” only applies to products that deliver therapeutic interventions to prevent, manage, or treat a medical disorder or disease; incorporate best practices relating to product design, clinical evaluation, usability, and data security; and are reviewed by regulatory bodies as required to support product claims regarding risk, efficacy, and intended use.

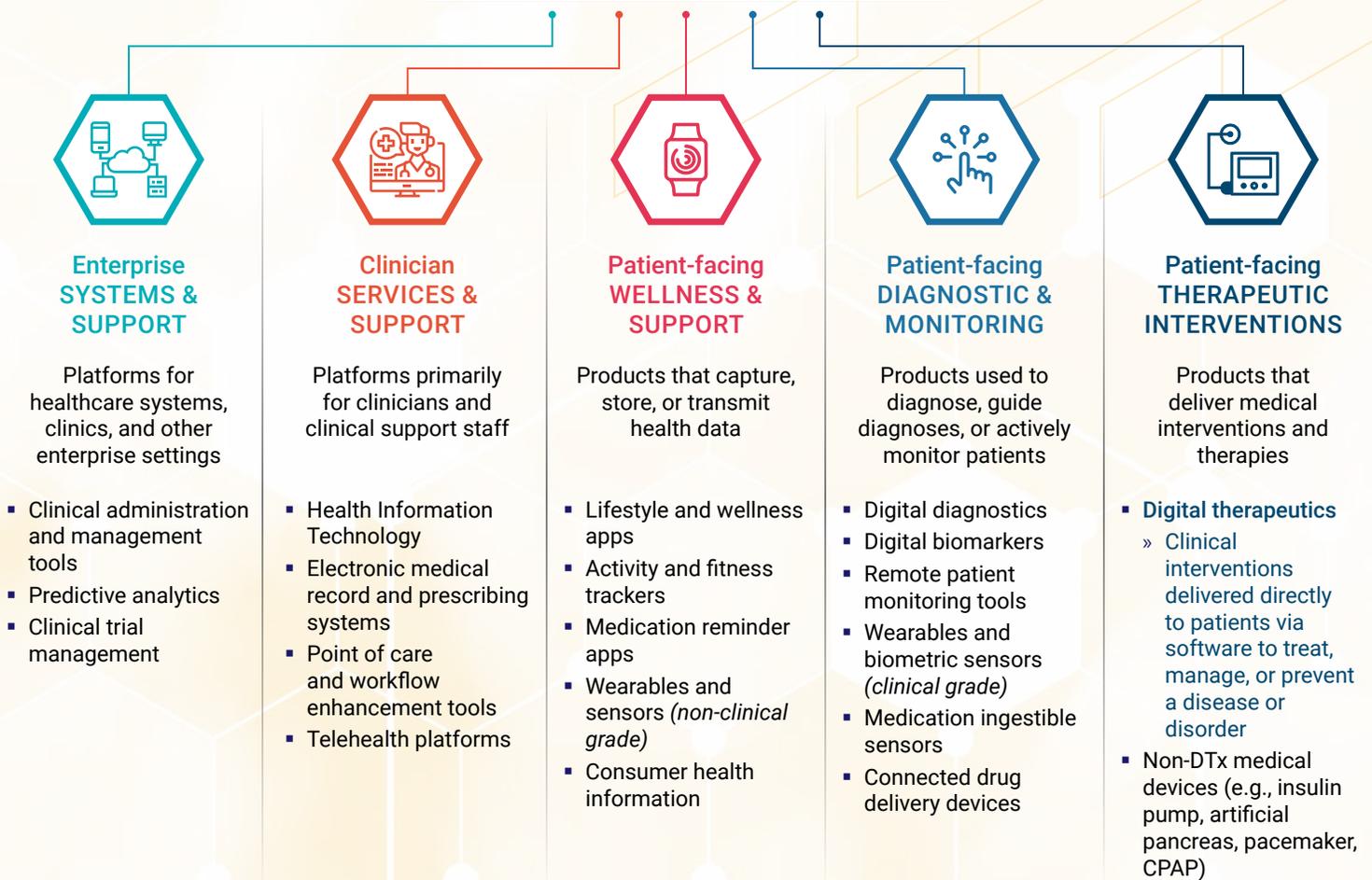
Patient access to DTx products is generally granted through a prescription, referral from a clinician, or delivery of an activation code via an electronic health record, employer, or third-party payor.

As clinicians, healthcare systems, employers, and payors continue integrating these products into patient care, digital therapeutics will increasingly influence the delivery and consumption of healthcare around the nation and world.

Digital therapeutics are distinct from digital health and wellness apps. DTx products must publish clinical trial results in peer-reviewed journals and meet industry requirements.

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*



*Categorizations of the digital health technology ecosystem will continue to evolve. This is a select representation of a broad, diverse ecosystem.

ALL PRODUCTS CLAIMING TO BE A DIGITAL THERAPEUTIC MUST ADHERE TO THESE FOUNDATIONAL PRINCIPLES:

- Prevent, manage, or treat a medical disorder or disease
- Produce a medical intervention that is driven by software
- Incorporate design, manufacture, and quality best practices
- Engage end users in product development and usability processes
- Incorporate patient privacy and security protections
- Apply product deployment, management, and maintenance best practices
- 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/or product performance data



Expanding Rural Access to Evidence-Based Treatments for Critical Diseases

The portability and scalability of DTx products uniquely position them as equalizers in the rural versus non-rural health divide. Pew Research indicates that over 70% of rural residents own a smartphone⁷ and this number is likely to increase. Since most DTx interventions are delivered at least in part through Android and iOS smartphones or tablets, few technical barriers exist to the implementation and scalability of DTx products in rural settings. As such, digital therapeutics have the ability to provide patients with asynchronous support and therapy when they are actively experiencing symptoms or are unable to immediately access their healthcare providers.

Six of the seven causes of death identified by Healthy People 2020 have DTx products available or under development to directly address the disease area or impact underlying conditions that may drive the cause of death.

- COPD**: An elderly man with white hair is shown in profile, blowing into a blue inhaler.
- CANCER**: A woman with short grey hair is sitting in a hospital bed, looking towards the camera.
- DIABETES**: A woman with glasses and a red patterned shirt is looking off to the side.
- STROKE**: A man is sitting in a chair, leaning on a wooden cane.
- CORONARY ARTERY DISEASE**: A man wearing a cowboy hat is looking out over a rural landscape.
- SUICIDE**: A person is standing alone on a dirt road in a vast, open field.



DIABETES

More than 100 million Americans have diabetes or pre-diabetes.⁸ Given that the incidence of diabetes increases with age, roughly 20% of Medicare beneficiaries are facing this condition.⁹ These individuals are also at higher risk of developing other serious conditions including stroke, kidney disease, neuropathy, high blood pressure, and foot and eye complications.

Diabetes is 17% more prevalent in rural areas¹⁰ and rural residents are 30% more likely to die as a result of diabetes-related conditions than their non-rural counterparts.¹¹ Native American communities are especially impacted as they have the highest prevalence rates of diabetes of all racial and ethnic groups in the United States. In some Native American communities, diabetes prevalence among adults is as high as 60%.¹²

Unsurprisingly, there are fewer clinical resources available for individuals with diabetes who live in rural areas. According to the CDC, about 62% of non-metropolitan counties have no Diabetes Self-Management Education and Support (DSMES) program available.¹³ Unfortunately, Medicare currently does not cover DTx products, even though many have demonstrated strong records of health improvement and cost savings.

Rural Americans are 30% more likely to die from diabetes.

Several diabetes-focused DTx examples include BlueStar, Dario, and Insulia:

BlueStar, developed by Welldoc, is a DTx product for people aged 18 years and older who have Type 1 or Type 2 diabetes. It provides tailored guidance driven by artificial intelligence, and collects and analyzes health data to provide precision, real-time feedback and intelligent coaching that is driven by more than blood glucose. In numerous peer-reviewed RCTs, clinical publications, studies, and posters, Welldoc has demonstrated the ability to significantly reduce A1c.¹⁴ In prospective studies, average A1c improvements of 1.7–2.0 have been measured,¹⁵ which when independently correlated with total adjudicated claims cost, can yield estimated annual Medicare savings of:¹⁶

- \$3,672 for beneficiaries with an initial A1c greater than or equal to 9
- \$3,048 for those with initial A1c greater than or equal to 8
- \$1,392 for beneficiaries with initial A1c greater than or equal to 7

DarioHealth offers an all-in-one blood glucose monitoring system that provides patients with a comprehensive overview of their disease along with self-management guidance. It also alerts up to four different people when a patient experiences problematic low blood sugar levels. Research has demonstrated that use of Dario reduces the average ratio of high blood glucose levels by nearly 20%.¹⁷

DTx products may significantly reduce A1c and total cost of care in Medicare.

Insulia from Voluntas provides automated basal insulin dose recommendations and coaching messages for people with Type 2 diabetes while enabling the healthcare team to remotely monitor progress. The product uses patient blood glucose readings and hypoglycemic symptoms to recommend insulin doses in real-time. Data are automatically shared with the healthcare team, who can remotely monitor the patient's progress toward their goal with tailored notifications.¹⁸

Given that many individuals with diabetes who live in rural areas lack access to local clinician support and may need to drive long distances to obtain the educational support necessary to manage their condition, providing access to DTx products may empower rural residents and reduce the current outcome disparities.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE



More than 15 million Americans are estimated to have COPD.¹⁹ It is a leading cause of adult hospitalizations, with over 1 million yearly COPD admissions²⁰ at an average cost of \$11,195 per admission.²¹ Rural COPD death rates are 45% higher than non-rural ones.²² Propeller Health's DTx product is designed to help COPD patients manage their condition in partnership with their clinician. Propeller works by attaching a small sensor to a patient's existing inhaler, which communicates data on medication use to the Propeller app via Bluetooth. Propeller helps patients follow their treatment plan,

discover what triggers their symptoms, and work proactively with their healthcare provider, meaningfully reducing the risk of hospitalization in this population.

Cleveland Clinic research demonstrates the following outcomes in patients using Propeller:²³

- 35% decrease in COPD-related healthcare utilization, with 3.4 trips to the hospital decreasing to 2.2. trips over a one-year period
- Reduction in all-cause healthcare utilization

DTx products for COPD directly reduce patients' risk of hospitalization.

Due to the challenges rural residents face in obtaining hospital care, access to digitally delivered interventions that demonstrate reduced hospitalizations and readmissions is particularly beneficial.



CORONARY ARTERY DISEASE

Coronary artery disease (CAD) afflicts over 18 million adults, killing over 365,000 each year and disproportionately impacting rural residents.²⁴ African American

individuals are especially impacted: nearly 45% of African American men and 47% of African American women suffer from heart disease.²⁵

Coronary artery disease is driven by factors such as smoking, high cholesterol, hypertension, and diabetes. As mentioned earlier, research clearly shows that DTx products are able to successfully address one of CAD's key drivers – diabetes. Research also demonstrates the potential for DTx products to impact a second CAD driver – hypertension.

Hypertension is often a comorbidity of diabetes, with an estimated two out of three people with diabetes having

a current or historic diagnosis of hypertension.²⁶ Better Therapeutics, DarioHealth, and Welldoc all have digital therapeutics under development or on the market for hypertension.

DarioHealth recently studied the impact of their DTx product on patients with combined Type 2 diabetes and hypertension. Key results included 71% of users reduced their systolic blood pressure by 8.1 mmHg and diastolic by 6.0 mmHg on average, in addition to 38% reducing their blood pressure category by one diagnostic stage.²⁷

Hypertension is highly prevalent among older Americans, with over 80% of Medicare beneficiaries dealing with the condition.²⁸ Given that rural America has a more concentrated senior population (18% over the age of 65, versus 13% in urban areas), hypertension will continue to be a challenge for aging rural Americans.²⁹



STROKE

Stroke causes nearly one in every 18 American deaths.³⁰ While the last decade has seen progress in the outcomes of rural stroke patients, rural patients are still 9% more likely to die from stroke than their non-rural counterparts.³¹ Numerous factors greatly increase the likelihood for a stroke, including high blood pressure, diabetes, obesity, smoking, and high cholesterol.³²

Stroke is also a leading cause of serious long-term disability, reducing mobility in more than half of stroke survivors aged 65 and over.³³ Appropriate rehabilitation is critical to attaining the best possible outcomes and quality of life among stroke survivors. Rehabilitation

Fewer than one-third of stroke survivors receive necessary rehabilitation services to decrease the risk of future hospitalization and mortality.

services such as occupational therapy, physical therapy, and speech-language therapy help patients regain abilities affected by stroke or develop compensatory skills that allow them to live with cognitive or physical impairments. Post-discharge care is vital to preventing long-term morbidity and improving functionality and quality of life for stroke patients. Numerous studies have recognized the cost effectiveness of rehabilitation services with respect to stroke recovery.³⁴ Despite these findings, fewer than one-third of survivors receive the necessary rehabilitation services.³⁵

Digital therapeutics are being developed or are already on the market to combat several of stroke's primary risk factors – including high blood pressure, diabetes, high cholesterol, and obesity – and also rehabilitate patients following a stroke event.

DTx innovators are focused on stroke prevention in addition to remedying the disabilities that may affect stroke survivors. Unfortunately, the national shortage of physical therapists is expected to grow to 27,000 by the year 2025.³⁶ Such a shortage is especially problematic in rural areas where there are one-third fewer therapists per capita than in non-rural areas.³⁷ The portability of

a DTx product for rehabilitation could ease access issues for rural residents and improve post-acute stroke rehabilitation care.

MedRhythms' candidate DTx platform combines sensors, software, and music to deliver Rhythmic Auditory Stimulation to improve neurologic and motor function following injury or disease. Their candidate product in stroke rehabilitation is designed to be used in a home environment and is currently undergoing a pivotal randomized controlled trial (RCT).³⁸ This follows a feasibility study, which suggests that the product could improve walking speed and walking economy for the chronic stroke population, with 80% of the participants improving their walking speed per the MCID (Minimal Clinically Important Difference).³⁹ FDA recently recognized this product's potential to impact a high unmet need by granting it Breakthrough Device designation.

Increased walking speed has been tied to positive health outcomes such as lowered fall risk, reduced hospitalization, and decreased mortality.⁴⁰ Walking speed is also directly related to determinations of community ambulation status.⁴¹

A DTx product feasibility study showed that 71% of stroke patient participants increased their walking speed.

In 2020, the American Heart Association developed a partnership with Happify Health to focus on the links between mental health, cardiovascular disease, and stroke. This collaboration is focused on incorporating AHA's science-based health content into digital mental health programs. Content delivered through this program is available via patient smartphones and is therefore accessible to most rural residents, particularly where in-person programs may be unavailable locally.



CANCER

Significant disparities persist in cancer care for rural patients, with death rates that are 114% of their non-rural counterparts. This represents a significant widening of

the disparity gap from a decade ago, when rural death rates were 108% of non-rural residents.⁴² According to recent research in the *Journal of Cancer Research and Clinical Oncology*, “Cancer patients suffer from a variety of symptoms derived from the malignancy itself, whereas some arise as side effects of the given cancer treatments...In general, worsening of symptoms indicates cancer progression or severe side effects of the treatment and is linked to poorer cancer survival.”⁴³

New developments in cancer care include immune checkpoint inhibitor therapies that inhibit T-cell blocking, resulting in T-cell mediated cancer cell death. However, one issue with these advances in treatment are side effects that resemble autoimmune diseases. These side effects may include gastrointestinal toxicity, hepatitis, endocrine toxicity, and pneumonitis. Some of these may be life-threatening. In addition, side effects may appear after a significant time lapse from therapy – up to months and even years – after therapy has been stopped. Timely identification of problematic side effects is crucial, warranting the need for long-term follow-up with patients after therapy termination.⁴⁴

DTx products will be especially helpful for rural cancer patients who may be located long distances from their oncologist and other health services.

Cancer patients require long-term monitoring given that potentially life-threatening side effects may appear months or years after therapy is complete.

Companies such as Voluntis and Kaiku Health are developing DTx technologies for cancer patients to monitor for and treat side effects and affiliated symptoms. While these DTx products vary in their precise applications, they monitor and communicate with cancer patients throughout the care journey and provide actionable, real-time recommendations directly to patients to address side effects while or before they occur. Moreover, DTx products may also alert the provider care team if symptoms reach problematic levels.

DTx products will be especially helpful for rural cancer patients who may be located long distances from their oncologist and other health services. With the assistance of a DTx product in the convenience of their home environment, patients may be more likely to report side effects in a timely and consistent manner. With this more immediate reporting, the DTx product is able to better provide guidance on personalized therapeutic interventions such as the initiation and dosing of supportive therapies.

When paired with a DTx product, scheduled electronic patient reported outcomes (ePROs) enable early and continuous collection of symptoms. If ePROs are linked to an urgency algorithm, they also offer a chance for prompt reaction to critical medical situations.⁴⁵

SUICIDE



Death rates from suicide in rural areas are about 1.45 times those of urban communities.⁴⁶ While the causes of suicide are multi-faceted and complex, it is estimated that over 90% of people who die by suicide suffer from a mental health condition – particularly depression and/or substance abuse.⁴⁷ Research shows that over 60% of individuals who die by suicide have a documented mood disorder (e.g., depression),⁴⁸ and about one in three were under the influence of alcohol.⁴⁹

Access to reliable, effective treatment is a key differentiator in suicide rates. The American Academy of Suicidology notes that the suicide risk for patients with untreated depression is approximately 20%, but this risk drops to 0.14% for patients who have received treatment.⁵⁰

As with other healthcare services, rural residents are at a significant disadvantage regarding access to therapy. Rural areas have less than half the psychologists per capita than urban communities.⁵¹ Recent research further demonstrates the unmet behavioral health needs of rural residents. Overall, rural patients received 59%–73% fewer mental health ambulatory visits and 41%–73% fewer mental health specialist visits than their urban counterparts.⁵²

Digital therapeutics do not directly prevent suicide, but there are extensive product options that target critical behavioral and mental health conditions. However, many

rural residents unfortunately still lack access to DTx products because Medicare and most Medicaid programs lack systemic payment pathways for DTx treatment regimens.

DTx products are available for the following behavioral and mental health conditions:



Alcohol Use Disorder



Anxiety Disorders



Depression



Insomnia and Sleep Disorders



Post-Traumatic Stress Disorder



Substance and Opioid Use Disorders

Over 90% of people who die by suicide suffer from a mental health condition.

Some of the behavioral and mental health conditions for which DTx products are available include:



Alcohol Use Disorder

Nearly 15 million Americans suffer from alcohol use disorder (AUD) and each year over 88,000 individuals die from alcohol-related causes.⁵³ The overall rate of death due to alcohol-induced causes increased from 2000 to 2016, with the highest age-standardized rate observed within the American Indian Alaskan Native population.⁵⁴

Vorvida, a digital therapeutic currently offered by Orexo, is intended to promote, track, and encourage choices that may help reduce the risk of alcohol dependence for adults with heavy drinking patterns. Vorvida is a fully automated digital therapy that uses artificial intelligence and is designed to help reduce alcohol consumption. An RCT demonstrated significant improvements in patients using Vorvida versus the control group. At study initiation, only 7.5% of participants demonstrated low-risk drinking patterns. After three months, 20.9% of participants qualified as low-risk, with 38.9% qualifying by six months. Meanwhile, only 18.5% of participants in the control group achieved low-risk categorization. In addition, Vorvida users reduced the number of days spent binge drinking per month by nearly half, whereas control group users essentially maintained their current drinking levels.⁵⁵

Hello Sunday Morning, an Australian-based company, is developing a digital therapeutic to curb misuse of alcohol. The Australian government is currently covering the cost of Daybreak for 20,000 residents to stem the negative social, clinical, and economic impacts of AUD.⁵⁶



Anxiety Disorders

Anxiety disorders are extremely common, with a yearly prevalence of 18% among Americans.⁵⁷ Approximately 58% of people with anxiety disorder are also affected by depressive disorders.⁵⁸ These disorders are associated with significant health, workplace, and quality of life impairments. Globally, anxiety disorders are ranked as the sixth largest contributor to global disability of any health condition (physical or mental).⁵⁹ Of significant importance, anxiety disorders are also independently associated with suicide attempts, with one national epidemiologic study estimating that among individuals reporting a lifetime history of suicide attempts, over 70% had an anxiety disorder.⁶⁰

Cognitive behavioral therapy (CBT) offers an effective intervention for anxiety disorders. However, numerous barriers limit access, including costs of therapy, patient wait times for in-person clinician visits, geographic distance from service delivery points, and perceived stigma.⁶¹

To reduce these barriers, Daylight, a fully automated digital therapeutic, was developed by Big Health to provide cognitive and behavioral techniques for worry and anxiety. An RCT demonstrated that Daylight significantly outperformed a waitlist control condition, with approximately 71% of participants who used Daylight moving from clinical to non-clinical levels of worry and anxiety ten weeks after accessing Daylight. These changes were maintained at six months post-Daylight use, with participants experiencing greater reductions in depressive symptoms and sleep difficulties, in addition to improvements in overall well-being and quality of life.⁶²



Depression

The National Institute of Mental Health (NIMH) estimates that over 17 million adults had a major depressive episode in 2017, with over 35% not receiving treatment.⁶³ Access to behavioral health services remains a significant challenge, with 20 states reporting mental health worker ratios of 500:1, or higher. West Virginia, Texas, and Alabama reported the highest ratios of 830:1, 960:1, and 1100:1, respectively.⁶⁴

One example of a company working to help mitigate this provider gap, SilverCloud Health, has developed a DTx product for patients with depression and anxiety disorders. An RCT conducted in a routine clinical setting demonstrated the efficacy of this DTx product. Based on an established diagnosis, 60% of patients with a depression diagnosis, 50% of patients with an anxiety diagnosis, and 46% of patients with dual depression and anxiety diagnoses achieved recovery criteria after three months of usage.⁶⁵



Insomnia and Sleep Disorders

Research indicates that sleep problems and depression are intertwined. In some cases, sleep challenges precede depression, while in others, depression triggers sleep disorders. Evidence indicates that people with insomnia have a tenfold risk of developing depression compared to those with normal sleep patterns.⁶⁶

Furthermore, chronic sleep problems plague 50–80% of patients in a typical psychiatric practice and impact a patient's response to care.⁶⁷ Research shows that patients who have depression with insomnia are less likely to respond to treatment; those who have successfully responded to antidepressants are at heightened risk for relapse. Even more troubling — patients with comorbid depression and sleep problems are increasingly prone to dying by suicide than patients with depression and normal sleep patterns.⁶⁸

Digital therapeutic companies such as Big Health, Pear Therapeutics, and SilverCloud have developed personalized and portable treatment options to address this critical health problem. In a placebo-controlled RCT, Big Health's DTx, Sleepio, resulted in 76% of users achieving healthy sleep levels.⁶⁹

Pear Therapeutic's FDA-cleared Somryst delivers cognitive behavioral therapy and is indicated to treat chronic insomnia. In its pivotal trial at one-year follow-up, 56.6% of participants using the digital intervention achieved remission of insomnia (compared to only 27.3% of control group) and 69.7% achieved treatment response (compared to 43% of control group).⁷⁰



Post-Traumatic Stress Disorder

Palo Alto Health Science's DTx product, Freespira, has produced significant improvements in patient health outcomes for post-traumatic stress disorder (PTSD). Fifty percent of PTSD patients were in remission at six months after the completion of this 28-day treatment. Furthermore, 82% of patients had at least a 13-point reduction in their CAPS-5 score (validated PTSD assessment) at six months post treatment, which was statistically and clinically significant.⁷¹



Substance and Opioid Use Disorders

Substance abuse costs the United States over \$600 billion annually. Treatment for this disorder can meaningfully reduce these costs. In fact, the National Institute on Drug Abuse (NIDA) estimates every dollar spent on Substance Abuse Disorder (SUD) treatment yields a \$5 to \$8 return in healthcare costs, and returns as much as \$12 in overall societal costs (e.g., reduced criminal justice costs, theft).⁷²

The FDA authorization of reSET and reSET-O by Pear Therapeutics creates new treatment opportunities. These prescription-only DTx products were developed to address SUD and opioid use disorder (OUD), respectively. For patients with SUD related to alcohol, cannabis, cocaine, or stimulants, substance abstinence rates more than doubled for patients randomized to reSET (40% to 18%) compared to patients undergoing treatment as usual. Rates of treatment retention were nearly 15% higher for patients randomized to reSET (76% vs. 63%) compared to the control group.⁷³

reSET-O is intended for patients with primary OUD receiving buprenorphine pharmacotherapy. The addition of reSET-O to treatment-as-usual resulted in increased treatment retention rates (82% vs. 68%) and a more than two-fold increase in abstinence rate (40% vs. 18%).⁷⁴ reSET and reSET-O also include a clinician dashboard that allows real-time feedback on patients' progress, which facilitates more patient-centered treatment.

A common genesis of SUD is an initial opioid prescription for chronic and/or acute pain, and clinicians are searching for alternatives to medications for pain management. Kaia Health has developed a DTx product for musculoskeletal disorders. An RCT found that Kaia was more effective at treating lower back pain than traditional physical therapy and education. Using a numeric 1–5 pain measurement scale, Kaia users reported pain levels at only 2.7, versus the higher pain level of 3.4 for the control group (a clinically relevant difference) after 12 weeks. Continued use of Kaia's DTx program lowered pain levels even further over time.⁷⁵



Public Policy Changes Are Necessary to Enable Rural Access to DTx Products

Comprehensive, multi-faceted solutions are necessary to achieve healthcare parity for rural residents. It is crucially important that a key component of these plans include the expansion of digital therapeutic coverage and patient access.

We encourage legislators to direct CMS to expand access to DTx products as follows:

- **Formally recognize DTx products:** Officially define and recognize DTx products in legislation so that Medicare and Medicaid patients have access to these critical (and quickly evolving) therapies.
- **Codify DTx product coverage:** Require CMS to assure that Medicare and Medicaid covers technologies that meet the bona fide definition of a digital therapeutic.
- **Expand payment and coding to address DTx products:**
 - Direct CMS to expand its existing payment system (including the addition of new codes) to enable

administratively efficient and adequate direct payment to DTx companies for provision of DTx software, as well as any associated hardware or DTx-provided caregiver support.

- Direct CMS to ensure an adequate payment mechanism (including new codes as necessary) exists to pay primary care providers, family physicians, and other clinicians who authorize the use of a DTx product, review a patient's DTx data, incorporate actionable DTx data into their patient care plans, or directly obtain and provide bona fide DTx products to their patients.

Digital therapeutics offer a new ability to provide interventions to patients in rural and underserved areas. In addition, these products monitor and report on patient outcomes and engagement in near real time. These opportunities — among others — can be capitalized on if Medicare creates an adequate clinical payment mechanism for DTx-related activities.

Endnotes

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