

Edition 75 -Digital Therapeutics and Their Integration into Healthcare Systems: A Public Health Perspective - HPHR Journal

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Citation

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Abstract

Digital therapeutics (DTx) are emerging as an innovative means of delivering evidence-based medical interventions via software to prevent, manage, and treat a variety of health conditions. This paper examines the potential of DTx to address major public health priorities and their integration into healthcare systems. DTx can increase access to care, lower treatment costs, provide personalized interventions, and facilitate remote monitoring. Studies demonstrate DTx efficacy for conditions like diabetes, mental health disorders, and smoking cessation. However, barriers to adoption exist including the digital divide, privacy concerns, limited evidence, and regulatory uncertainties. Thoughtful implementation of DTx into clinical workflows, leveraging capabilities for public health surveillance, and partnerships among stakeholders can maximize population health benefits. While not panaceas, DTx holds promise to complement traditional interventions by improving outcomes, promoting wellness behaviors, and supporting self-management of chronic diseases if vigilance is maintained regarding ethical risks and equitable access globally. Overall, DTx offers new avenues to reshape healthcare and public health, but require continued research, policy evolution, and collaborative efforts among technology developers, providers, regulators, and communities.

Introduction to Digital Therapeutics

DTx are evidence-based software interventions used to prevent, manage, or treat medical disorders. They differ from general health and wellness apps in that they make specific therapeutic claims and require regulatory approval ¹. While wellness apps promote overall wellbeing, DTx are focused on treating one specific condition such as diabetes or substance abuse. They must demonstrate safety and efficacy through rigorous clinical trials before being cleared by regulatory bodies like the FDA ². As software-based therapies, they have the potential to help achieve United Nations Sustainable Development Goals related to health and technology. This paper examines the potential of DTx to address major public health priorities and their integration into healthcare systems. DTx can increase access to care, lower treatment costs, provide personalized interventions, and facilitate remote monitoring.

Current State of Digital Therapeutics

The FDA has approved several prescription DTx products in recent years. In 2017, Pear Therapeutics' reSET became the first mobile medical app cleared to treat substance abuse disorders ³. It delivers cognitive behavioral therapy digitally as an adjunct to standard outpatient treatment. In 2020, Akili Interactive received FDA clearance for EndeavorRx to improve attention function in children with ADHD ⁴. Other examples include Welldoc's BlueStar for diabetes management and Pear's reSET-O for treating opioid use disorder. These represent some of the first software-only digital drugs sanctioned by the FDA. As evidence continues to grow, DTx are emerging as valid therapeutic modalities for diabetes, mental health, addiction, and other chronic conditions.

Digital Therapeutics from a Public Health Perspective

DTx hold promise as innovative tools to address major public health priorities in the United States including managing chronic diseases, reducing health disparities, and promoting preventive care across populations. DTx are evidence-based interventions that use digital technologies to deliver medical treatments, frequently via software apps, with the purpose of improving health outcomes and encouraging behavior change. The article critically examines the potential of digital medicines to solve important public health concerns, with a focus on their ability to improve access to care, reduce health disparities, manage chronic diseases, and encourage beneficial health habits on a population-wide scale.

DTx have the ability to break down geographic boundaries and increase access to healthcare services, particularly in underserved and distant geographies. One use case is remote consultations, which can be facilitated by telemedicine platforms and mobile health applications, which provide users with expert medical assistance and support. Notably, studies have shown that DTx can lower barriers to care, increase patient participation, and promote self-management, all of which contribute to better health outcomes ^{5,6}.

Addressing health disparities is an important public health challenge. DTx can help to close these gaps by providing personalized interventions that take cultural, socioeconomic, and language aspects into account. Personalized digital interventions have been found to be successful among diverse populations, bridging gaps in healthcare access and outcomes ⁷. It also provides a platform for continuous monitoring, drug adherence, and lifestyle modification. Diabetes management apps and hypertension tracking tools, for example, enable patients to actively manage their diseases, resulting in better disease control and fewer hospitalizations ⁸.

Positive health behaviors are frequently encouraged through public health efforts. Digital treatments provide novel approaches to delivering behavior modification interventions, utilizing gamification, social support, and real-time feedback to drive individuals. These interventions have been shown to be effective in smoking cessation, physical activity promotion, and weight control in studies ⁹.

As software-based interventions, digital therapeutics can increase access to care delivery for rural residents, uninsured patients, and other underserved groups. Digital modalities also provide more affordable treatment options that could alleviate disparities for disadvantaged populations ¹⁰. Additionally, the scalability of DTx enables large-scale implementation of programs tailored to changing health behaviors and preventing diseases which are key goals in public health.

DTx offer several advantages that can benefit public health efforts to prevent disease and promote wellness at the population level. A key benefit of DTx is scalability – as software-based interventions, they can be rapidly disseminated to large numbers of users ¹¹. For example, DTx mobile apps for smoking cessation or weight loss can be scaled up to reach many patients in a short timeframe. The digital format also enables personalization of interventions based on individual risk factors and needs, supporting behavior change ¹². Additionally, DTx can improve health outcomes for chronic conditions like diabetes and hypertension by facilitating remote patient monitoring and increasing medication adherence ¹³.

Studies have shown DTx can reduce HbA1c levels in diabetics and support weight loss for obesity ^{14, 15}. If applied at a population scale, such outcomes could reduce the public health burden of chronic illness. Furthermore, the continuous data collection capacities of DTx give them potential in preventive health. Patient data can inform public health surveillance and the development of tailored health promotion strategies targeting behavioral risks within communities ¹⁶. Overall, the scalability, personalization, and potential for leveraging big data offer means for DTx to prevent disease, reduce health disparities, and promote healthy lifestyles across diverse populations.

DTx have a significant potential to address public health challenges. While more evidence and adoption is still needed, DTx are poised to transform healthcare delivery by improving access to care, lowering health inequities, managing chronic diseases, and promoting healthy behaviors by augmenting traditional interventions ¹⁷.

Challenges and Barriers to Adoption in Public Health Contexts

A major challenge to the adoption of digital therapeutics in public health is the digital divide, which refers to unequal access to technology and the internet based on factors like socioeconomic status, age, education level, and geographic location. Those who lack access to smartphones, computers, or reliable internet may not be able to use digital mental health interventions, apps, or online therapy. Even those with access may lack digital literacy skills needed to fully utilize digital health tools ¹⁸. Bridging the digital divide requires multipronged strategies to increase access, improve digital literacy, and design interventions that are user-friendly for diverse populations ¹⁹.

Data privacy and security concerns present another key barrier, especially for digital tools that collect sensitive health data. Patients may be reluctant to share personal information digitally due to fears of data breaches or misuse ²⁰. Building trust requires transparency about how data will be protected and used, robust cybersecurity measures, compliance with privacy laws like HIPAA, and access

controls allowing patients to manage data sharing can help reassure users ²¹. However, work is still needed to develop privacypreserving data sharing models that protect confidentiality while enabling insights from health data analytics.

Limited evidence of efficacy and lack of regulatory oversight also hinder adoption of digital therapeutics. While some apps show promise in clinical trials, many lack rigorous evidence demonstrating meaningful outcomes ¹⁸. Regulatory pathways for evaluating and

approving digital health products as effective medical treatments are still evolving ¹⁹. Stricter FDA oversight could incentivize

companies to conduct more high-quality studies, but may also stifle innovation ²¹. Policymakers face the challenge of finding the right balance between regulating safety and promoting further research and development in this nascent field. Continued research, funding, and collaboration among healthcare practitioners, researchers, politicians, and technology developers will be critical in realizing their full potential to improve public health outcomes. Overall, generating more evidence through robust research and establishing appropriate regulatory guardrails will be key to wider acceptance of digital therapeutics.

Integration into Public Health Interventions and Healthcare Systems

The incorporation of DTx into traditional healthcare systems and public health interventions is an exciting opportunity for improving patient outcomes, expediting care delivery, and supporting public health efforts. The purpose of this study is to investigate how DTx can be efficiently integrated into existing frameworks, taking into account factors such as prescribing, payment, care pathways, and their role in public health surveillance.

DTx constitute a unique approach to healthcare delivery, they frequently necessitate the reconfiguration of established systems. Integrating these interventions into healthcare systems requires careful consideration of regulatory approvals, norms of practice, and physician training. Successful integration, on the other hand, can lead to enhanced patient participation, adherence to treatment programs, and improved overall health outcomes ²². To supplement and personalize patient treatment plans, DTx can be carefully integrated into care pathways. By incorporating these interventions into care protocols, healthcare providers can improve patient monitoring, offer remote consultations, and make real-time changes to treatment regimens. This collaboration has the potential to improve care coordination and result in more effective DTx²³.

The use of DTx in public health surveillance and monitoring represents a transformative opportunity. These initiatives can collect realtime health data from a wide range of populations, allowing for early diagnosis of epidemics, tracking illness patterns, and assessing the effectiveness of digital therapeutics. Wearable devices and mobile apps, for example, can collect data on physical activity, sleep habits, and physiological measurements, allowing for a more comprehensive picture of population health ²⁴.

Integrating DTx into existing public health initiatives and healthcare systems has the potential to significantly improve patient care, optimize resource use, and strengthen public health activities. As DTx evolve, stakeholders must work together to address issues such as prescription, payment, regulatory frameworks, and data protection. The development of clear criteria, good training for healthcare personnel, and robust evaluation methods are essential for successful integration. Healthcare institutions may leverage the power of technology to enhance patient care and benefit public health by embracing DTx.

Regulatory Landscape and Public Health Policy

FDA's Regulatory Authority and The Digital Health Innovation Action Plan

By regulating medical products, including DTx, the FDA, as the cornerstone of medical product supervision, plays a crucial part in preserving public health ²⁵. Software-based interventions intended to prevent, manage, or treat medical diseases are included in the category of DTx ²⁶. In order to modernize its regulatory approach and take into account technological changes, the FDA introduced the Digital Health Innovation Action Plan in 2017 ²⁷. This was done in recognition of the dynamic nature of digital health technology. With the help of this strategic plan, innovation can be encouraged while also upholding patient safety.

Essential guidelines for the regulation of digital health technology are outlined in the Action Plan. The risk-based approach, which divides digital health technologies into groups according to their potential influence on patient health, is a key principle. According to the U.S. Food and Drug Administration (2017), this classification recognizes that some technologies, such as wellness applications, pose fewer hazards than software used for diagnosing or treating medical disorders. Furthermore, the Action Plan marks a paradigm shift in regulatory thought by introducing the idea of a "Pre-Certification" program. Instead of assessing individual products in isolation, this program evaluates the overall organizational excellence and quality of digital health enterprises. Successful pre-certified businesses may have access to accelerated evaluations of their digital therapies, expediting the market entrance procedures.

Role of Public Health Policies in Adoption

Public health regulations have a significant impact on how DTx are adopted. By creating clear reimbursement paths and providing incentives for healthcare professionals to implement these cutting-edge interventions in clinical practice, supportive policies have the

potential to accelerate adoption ²⁶. The ability of DTx to improve patient outcomes and maximize healthcare efficiency must be recognized by policymakers.

On the other hand, regulatory inconsistencies and disparities in reimbursement practices could be barriers to adoption. Healthcare practitioners may be deterred from incorporating digital therapeutic interventions into patient care by inadequate reimbursement systems. To build confidence among patients, healthcare providers, and technology developers, public health regulations must also address issues with data privacy, security, and liability ²⁸.

Community Engagement and Stakeholder Involvement

A promising new path toward improving patient outcomes and healthcare delivery has been opened up by the development of DTx. However, community members, public health professionals, and other stakeholders must work together for the creation and implementation of these interventions to be successful. In order to ensure that DTx effectively address the requirements of the communities they aim to serve, this response explores the significance of involving these various groups at every stage of the process.

Community Centered Approach

Engaging community people is essential to creating digital treatments that are impactful, relevant, and culturally sensitive. It is ensured that the treatments are customized to the individual tastes, languages, and cultural contexts of the intended users by involving people from a variety of backgrounds. This strategy maximizes engagement and adherence rates while also improving user approval. For instance, a study found that including user input in the design of a mental health app resulted in increased user satisfaction and better clinical outcomes ²⁹.

Additionally, by encouraging diversity and equity, community involvement makes sure that DTx address inequalities in healthcare access and results. Working with community members can help identify the particular difficulties marginalized groups encounter and direct the creation of initiatives that successfully close these gaps ³⁰.

Integration of Public Health Practitioners

The knowledge and experience that public health professionals bring to the table strengthens digital therapeutic interventions. Their knowledge in epidemiology, health behavior, and health promotion can help to direct the development of the evidence-based plans that support these treatments. Digital treatments' legitimacy and potential impact are increased through collaboration with public health practitioners, which guarantees that they are in line with recognized health goals and guidelines.

Public health professionals can also make it easier to incorporate DTx into current healthcare systems. Their understanding of healthcare procedures, legal regulations, and payment systems is crucial for negotiating implementation's difficulties ⁶.

Involvement of Stakeholders

A diverse range of stakeholders, such as lawmakers, healthcare professionals, and technology developers, are involved, which encourages a multidisciplinary approach that takes different viewpoints into account. In order to ensure that interventions adhere to legal and ethical norms, policymakers can provide guidance on regulatory frameworks and ethical issues. To create treatments that easily fit into clinical practice and are in line with patient care plans, healthcare practitioners' input is essential. Collaboration with technology developers guarantees the technical viability and usability of the interventions.

Engagement of stakeholders also advances sustainability. Long-term support and investment are more likely to be obtained by involving people and organizations having a stake in the success of digital treatments ³¹.

In conclusion, community people, public health professionals, and stakeholders must be included for the development and application of DTx to be relevant. This cooperative approach ensures that interventions are evidence-based, responsive to cultural differences, and in line with healthcare objectives, maximizing their ability to address healthcare issues and enhance patient outcomes.

DTx as a means to achieve Sustainable Development Goals

DTx have the potential to help achieve several UN Sustainable Development Goals (SDGs). Specifically, they aim to improve health outcomes and address public health priorities, aligning with SDG 3 for Good Health and Well-Being overall. DTx can also increase access to care and reduce health disparities, linking to SDG 10 for Reduced Inequalities. Additionally, partnerships among stakeholders are key to developing and implementing DTx, relating to SDG 17 for Partnerships for the Goals ³².

Challenges of DTx

DTx has opened up new possibilities for healthcare, which has prompted an investigation into any potential drawbacks. Although acknowledged for their benefits, this answer aims to shed light on several factors that can cool the zeal around DTx.

Although DTx shows promise, their efficacy varies widely. Different levels of evidence were found in a systematic review by ³³, highlighting the necessity for strong validation. Safety issues are particularly important, as situations of misinterpretation can result in inadequate care ³⁴. Comprehensive clinical validation and careful monitoring are necessary to provide the best results. It is clear that DTx has the potential to reduce healthcare costs through remote care, however there are many other aspects to cost-effectiveness. Their economic feasibility may be in doubt if development and maintenance costs exceed savings ³⁵. Additionally, there is a chance of escalating healthcare inequities since different access to DTx may keep gaps in care alive.

Despite the potential for increased healthcare access, DTx may unintentionally expand already existing socioeconomic disparities.

According to research on socioeconomic determinants and engagement, underprivileged populations may be left behind ³⁶. Concerns about data security and privacy may also prevent adoption, especially in vulnerable groups.

There is no denying that DTx has the potential to transform the way healthcare is delivered, but a nuanced perspective that takes into account potential obstacles is essential. To reach the transformative potential of DTx without worsening current problems, it is important to carefully balance the effectiveness-safety paradigm, economic factors, and fair access.

Future Directions and Global Implications

The potential of DTx to transform health care delivery is generating great interest, as evidenced by the rapid proliferation of apps, wearables, and virtual care models. However, significant work remains to optimize these tools and evaluate their real-world effectiveness across diverse global contexts. Global coordination and standards will be key to ensuring the quality and safety of DTx as they continue permeating health systems worldwide. If thoughtfully implemented, DTx could increase access to care and self-management resources for underserved populations, helping achieve Sustainable Development Goal of promoting health and wellbeing for all. But the digital divide poses challenges, as low-resource settings often lack the infrastructure to support widespread adoption. Thus, digital solutions must be tailored for feasibility and impact in specific countries and cultures. Partnerships between technology companies, health organizations, governments and local providers will be critical. Ultimately, DTx should complement, not replace, human-centered care. Though promising, these tools are not panaceas. Realizing their potential requires continued vigilance to ethical risks, concerted efforts to build an evidence base, and equitable policies to ensure benefits are shared globally

Disclosure Statement

We declare that none of the authors have any personal, commercial, or financial interests that could influence or bias the research findings and opinions presented in this manuscript.

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About the Author

Preet Kukreja, MBA, MHA

Preet Kukreja, MBA, MHA is the director of Population Health Initiatives at St. John's Episcopal Hospital and an expert in public health with extensive experience in project and grant-implementation, evaluation and sustainability. She serves as a co-chair of the Program Committee at Healthcare Innovation and Lean Network of New York that brings together Lean and innovation practitioners in healthcare facilities across the state. She also serves as a Judge for the SIIA CODiE Awards, American Best in Business Awards, Globee Leadership Awards and Golden Bridge Awards that honors top companies, products and people as leaders in innovation and excellence. She has also served as an abstract reviewer for the American Public Health Association (APHA) 2023 Annual Meeting & Expo. She is also a certified emergency response team member with New York City Office of Emergency Management which not only prepared her for any emergency situation but also equipped her with the ability to assist the community in times of crisis.

She has been instrumental in implementation of the public health programs and grants to address pandemic-COVID-19, public health emergencies-Mpox and health needs of the communities – Cancer, Obesity, Hypertension, Diabetes, Substance Use and HIV among others. Preet was instrumental in building partnerships with the NYC Department of Health and Mental Hygiene, churches, schools, community-based organizations, and congregations to address the health disparities prevalent in the Far Rockaway community. During the pandemic, she has secured grants through NYC DOHMH which led to expansion of access to care and improved COVID-19 vaccination rate in the community. She is passionate about serving underserved, medically marginalized and vulnerable communities through implementation of programs in addressing health disparities such as medical transportation, improving access to care, providing preventative screenings and point of care testing, health education, nutritional counseling, health-related resources, and improving vaccination rates. She has received acknowledgement and a certificate from NYC DOHMH for playing a prominent role in advancing health equity and preventing COVID-19 in NYC through Public Health Corps.

Her work has been recognized by the NYC Department of Health and Mental Hygiene through the acknowledgement of her role in advancing health equity and preventing COVID-19 in NYC through the Public Health Corps. She has been recognized as one of the Top 25 Emerging Leaders by Modern Healthcare for significant contributions to the culture of innovation and transformation in the field of healthcare. She is also a winner of the Boston Congress of Public Health – Health Innovator to Watch Award 2023 for health and healthcare innovation in the traditional public health field. She is also a winner of Stevie Award 2023 for Achievement in Management – Health Products & Services category. She has also been awarded with the International Achiever's Award for her outstanding achievements and contributions to wards nation building. She has been recognized as the Alum of the Month (May) by Hofstra University for making outstanding contributions in the field of public health. Her programs have received notable recognition such as the Food Security Program, which received membership spotlight on the Healthcare Association of NYS (HANYS) platform and the Mobile Health Outreach Program, which was nominated for a Community Health Improvement Award through HANYS.

Preet has received her MBA in India, Masters in Health Administration from Hofstra University and is currently pursuing Master's in Public Health from CUNY School of Public Health. She is a Lean green belt and six sigma white belt certified. She hold certification in DOHMH led training in HIV, HEP-C, STI, PEP, PREP & Other Biomedical Interventions, Best Practices in PEP & PrEP Education & Counseling, HIV Stigma, LGBTQIA+ Primer, HIV Rapid Testing, Linkage to Medical Care, Undetectable=Untransmittable and & Hepatitis

C Patient Navigation. She is a member of the New York Academy of Medicine, Healthcare Association of New York State, American College of Health Executives, Healthcare leader of New York, American Public Health Association, and New York State Public Health Association.

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Kinshuk Saxena, MBA

Kinshuk Saxena, a distinguished expert in the life sciences and healthcare sector, currently holds a pivotal role as part of the Internal Strategy group at Novartis. Throughout his illustrious career, Kinshuk has demonstrated unparalleled expertise in strategy development and execution across a spectrum of pharmaceutical and medical technology organizations. Prior to his tenure at Novartis, Kinshuk led transformative initiatives, advised executive leadership teams, and drove digital transformations in his roles at Strategy& and IQVIA Consulting.

In his current position at Novartis, Kinshuk steers key strategic initiatives and transformations, working closely with the Executive Leadership Team. His leadership has been instrumental in developing business case briefs, designing and delivering operating models, spearheading oncology operating model transformation, and leading the Intellectual Property and Strategic Transactions (IPST) and Budgeting workstreams.

Before Novartis, as an Engagement Manager at Strategy&, Kinshuk led the development of a "Reimagine Primary Care" strategy as part of a digital transformation effort. His work at IQVIA Consulting involved leading international project teams on a wide range of assignments, including market analytics, due-diligence, portfolio optimization, launch strategy, market access, patient journeys, clinical development transformation, and regulatory strategy.

Kinshuk holds an MBA from Rutgers Business School, where he was a two-time winner of the Biopharmaceutical Case Competition. He also holds a Doctorate of Pharmacy from Manipal University. Earlier in his career, Kinshuk formulated regulatory strategies, managing the submission and approval of Phase 2/3 oncology products while laying the groundwork for breakthrough therapy designation. He was recognized by the CEO for his work in the development and commercialization of an orthopedic medical device.

A dynamic speaker and thought leader, Kinshuk is frequently invited to speak at multiple life science conferences. His contributions extend beyond his professional roles, as he actively engages in podcasting on life-science and healthcare topics. When he's not shaping the future of healthcare, Kinshuk enjoys spending quality time outdoors with his family.

Snigdha Santra, MPH

As the Director and Head of Business Insights and Strategy at Chugai Pharmaceuticals, **Snigdha Santra** leads with a clear purpose: to bring unique, patient centric clinical insights into early drug development and strengthen partnerships in the drug development continuum, ultimately aiming to have a transformational impact on human health.

Over the course of her diverse career spanning more than a decade, Snigdha has held several senior positions across a variety of markets and disciplines, from leading payer analytics at Wunderman Health to multiple commercial leadership roles at Novartis Pharmaceuticals. Her experience working with international teams and managing cross-functional collaborations has enriched her understanding of the global healthcare landscape, further fueling her commitment to ensure equitable access to medicines.

At Chugai Pharmaceuticals, Snigdha has led insights generation for early-stage products in rare diseases. She has fostered a culture of innovation, courage, and excellence within her team, driving them to become more science-driven and research-oriented. This focus on innovation has led to the start of multiple patient centered engagements within the organization.

One of Snigdha's most notable achievements is her work with patient advisory groups in rare diseases and diseases with high unmet need. Her dedication and relentless efforts have led to the development of resources to support patient education – an accomplishment that echoes the company's commitment to improving patient outcomes.

In addition to her role at Chugai, Snigdha also upholds her commitment to social responsibility. As a former Lead Health Columnist for Impakter, an online magazine, she contributed to global health discussions that help shape the discourse in her field.

Snigdha holds a Master's in Public Health with a focus on Health Policy and Management from Columbia University, New York and a Master of Clinical Pharmacy from Manipal University, India. In recognition of her leadership and contributions to the field, she has received several awards including Most Valuable Player at Wunderman Health and the Chugai Awards for Product Lifecycle Innovation from 2019-2022.

In her various roles, Snigdha remains a member of the global healthcare community, dedicated to improving patient outcomes and advocating for equitable access to medicines. Her leadership and commitment to innovation continue to inspire her colleagues and others in her field.