PERSPECTIVE

A Public Health Policy Perspective on the Effective Implementation of Digital Therapeutics in India

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DOI: 10.55489/njcm.161120255796

ABSTRACT

Digital Therapeutics (DTx) represent a novel category of medical interventions that utilize software applications to prevent, manage, or treat various health conditions. Global evidence from nations like Germany, the United States, and Japan have demonstrated the effectiveness of digital therapeutics (DTx) in the healthcare systems. India needs to implement a comprehensive policy strategy to integrate the (DTx) in the public health ecosystem. Initially, the Central Drugs Standard Control Organisation (CDSCO) ought to officially acknowledge Digital Therapeutics (DTx) as a separate category within Software as a Medical Device (SaMD). Next, the National Health Authority (NHA) should test reimbursement models under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY). Additionally, it is essential for DTx platforms to comply with the interoperability standards established by the Ayushman Bharat Digital Mission (ABDM). Furthermore, the challenge of human resources needs to be considered within the policy structure. Lastly, attention should be given to the pace and evolution of development to incorporate Public Private Partnerships (PPPs). Thus, it can be concluded that the process of integrating digital therapeutics (DTx) into the public health systems has the potential to improve operational efficiency, stimulate better engagement on the side of patients, and lower the long-term cost of healthcare delivery.

Keywords: Digital Therapeutics (DTx), Public Health, Health Policy, Software as a Medical Device (SaMD), Ayushman Bharat Digital Mission (ABDM), Non-Communicable Diseases (NCDs)

ARTICLE INFO

Financial Support: None declared
Conflict of Interest: The authors have declared that no conflict of interests exists.
Received: 14-07-2025, **Accepted**: 25-09-2025, **Published**: 01-11-2025
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How to cite this article: Banerjee SK, Choudhary N. A Public Health Policy Perspective on the Effective Implementation of Digital Therapeutics in India. Natl J Community Med 2025;16(11):1172-1178. DOI: 10.55489/njcm.161120255796

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www.njcmindia.com | pISSN: 0976-3325 | eISSN: 2229-6816 | Published by Medsci Publications

INTRODUCTION

Digital Therapeutics (DTx) is a category of the medical intervention that utilizes software applications to help prevent, manage, or treat different health concerns. As opposed to the regular wellness apps, they are thoroughly clinically tested, as a rule, prescribed by a doctor, and targeted to solving health problems such as diabetes, depression, and hypertension, as well as insomnia.[1] Germany, the United States, and Japan have made significant progress in integrating digital therapeutics (DTx) into their healthcare systems, including coverage by public health insurance and recognition by regulatory authorities.[2,3,4]

Germany's Digital Health Applications (DiGA) initiative has created new prospects for addressing mental health issues such as depression through clinically validated digital therapeutics (DTx). Numerous DiGA-approved applications focus on depressive disorders by offering modules for cognitive behavioural therapy (CBT), mood tracking features, and guided self-help strategies. After these applications prove adherence to safety, data protection, and clinical effectiveness criteria, they are included in the official DiGA directory, allowing healthcare providers to prescribe them with expenses covered by statutory health insurance. This expedited process facilitates broader patient access to innovative and effective digital solutions for managing depression, alongside conventional treatment methods.[5]

This perspective outlines key challenges, opportunities, and policy recommendations for integrating DTx into India's public health system

KEY DIFFERENCES BETWEEN WELLNESS APPS AND DIGITAL THERAPEUTICS

Wellness apps and digital therapeutics (DTx) widely vary in their objectives, regulation status, and outcome. Normally, wellness applications are meant to foster healthy lifestyles and may not require clinical support and regulatory clearance by any health agency; examples of features displayed by them may include fitness applications, meditation applications, or meal planning applications. Given below are the examples of some commercially available calmness mobile applications in India. Kindly refer table 1.

Digital therapeutics are grounded in scientific research, concentrating on the prevention, management, or treatment of health conditions, and are anticipated to undergo rigorous clinical trials and regulatory assessment by a relevant authority, such as the FDA, in most situations.[6] Whereas they may utilize the same technologies, DTx still must demonstrate their effectiveness and safety rates to be prominently supported by health professionals and enter the range of clinical measures to be used during treatment.[7]

Given below are examples of some commercially available digital therapeutics in the "reSET" family (& related) for substance-use disorders. These are two of the leading prescription digital therapeutics (PDTs) cleared by the U.S. FDA for SUD / OUD. Kindly refer table 2.

Key Differences between Wellness Apps and Digital Therapeutics are summarised in table 3.

SIGNIFICANCE OF DIGITAL THERAPEUTICS (DTX) IN INDIAN PUBLIC HEALTH SYSTEM

The potential applications of digital therapeutics (DTx) in India are vast. The country is facing challenges from both infectious diseases and non-communicable diseases (NCDs). While a definitive WHO report for the precise 2023-24 period is unavailable, recent data indicates that NCD deaths in India accounted for approximately 63% to 66% of all deaths by 2019-2023, with cardiovascular diseases, cancers, diabetes, and chronic respiratory diseases being major contributors. The number of NCD-related deaths is significant, with around 5.8 million deaths annually, and the trend is on the rise compared to previous decades.[8]

Digital therapeutics (DTx) hold the potential to improve public health results in India due to their scalability, capacity to evaluate outcomes, emphasis on results, affordability, and targeted interventions for chronic diseases like diabetes, hypertension, and mental health challenges. Considering the widespread use of mobile phones and the rising internet accessibility, digital health initiatives can significantly help reduce health inequalities in isolated and under-resourced regions. Additionally, digital therapeutics (DTx) in India can facilitate individualized care and ongoing tracking, which are essential for addressing the growing challenge of NCDs.[9]

Table 1: Commercially available calmness mobile applications in India

App	What it offers	Languages/Localisation
Idanim	Guided & live meditations; breathing, sleep, stress/ anxiety relief; video courses; offline meditations	Hindi & English
Heartfulness	Meditation sessions, tools for mindfulness/ inner peace.	Supports many Indian languages e.g. Gujarati, Marathi, Tamil, Telugu, Kannada, Hindi, Odia, Bengali etc.
Dhyan	Guided meditations in Hindi; high-quality tracks; relaxation, awareness, wellness etc.	Primarily Hindi (focus on people who prefer Hindi)
Saksham	Mental wellness tool; soothing music, exercises etc; various tools to help calm & well-being.	Hindi, Marathi & English

Table 2: Examples of some commercially available digital therapeutics in the "reSET" family (& related) for substance-use disorders

Product	Target / Indication	Key Features & How It Works	Evidence / Outcomes	Regulatory / Commercial Status
reSET®	Substance Use Disorder (SUD), for people whose primary substance is *not* opioids (i.e. alcohol, stimulants, cocaine, cannabis etc.)	12-week program; delivers therapy based on the Community Reinforcement Approach (CRA), along with contingency management and "fluency training" to help learning. Patients use an app (interactive modules) + clinician dashboard to track progress, cravings, triggers.	In trials, adding reSET to outpatient therapy doubled abstinence (e.g. ~40% vs ~18%) among non-opioid SUD. Improved retention in treatment (76% vs 63%) in some studies.	First FDA-cleared digital therapeutic for SUD (2017 De Novo clearance). Available by prescription in the U.S.
reSET-O®	Opioid Use Disorder (OUD), specifically as adjunct to outpatient treatment with buprenorphine + contingency management; for adults under clinician supervision.	12-week (84 day) app delivering CRA-based CBT, fluency training, plus rewards for module completion & negative urine tests. Tracks cravings, triggers, medication adherence; clinician dashboard for oversight.	In trials, reSET-O increased retention in outpatient treatment vs treatment alone. The FDA clearance was based on a randomized trial of ~170 patients with OUD using buprenorphine.	FDA cleared (510(k)) in Dec 2018 for prescription-only. Commercial deployment in the U.S.

Table 3: Key Differences between Wellness Apps and Digital Therapeutics

Criteria	Wellness App	Digital Therapeutic (DTx)
Regulatory Oversight	None	Yes (FDA, CE, etc.)
Clinical Validation	Rare	Mandatory
Prescription Required	No	Yes
Targeted Conditions	General wellbeing	Specific diseases (e.g., diabetes, ADHD)
Reimbursable	No	Yes, in some countries

THE INDIAN CONTEXT: DIGITAL READINESS VS HEALTHCARE GAPS

Rural India faces critical healthcare gaps including limited infrastructure, shortage of trained health professionals, poor health literacy, and financial constraints, all of which hinder timely and quality care delivery. Many primary health centres in rural regions remain under-resourced, and the doctor-to-patient ratio is far below WHO recommendations, creating delays in diagnosis and treatment. Additionally, travel distances, high out-of-pocket costs, and low digital literacy further aggravate inequities in healthcare access. These systemic gaps highlight the urgent need for digital therapeutics (DTx), which can provide remote monitoring, evidence-based behavioural therapies, patient education, and disease management without the necessity of frequent physical visits. By leveraging mobile connectivity and digital platforms, DTx solutions hold potential to bridge rural healthcare disparities and strengthen equitable, affordable healthcare delivery in India.[10]

The Ayushman Bharat Digital Mission (ABDM) and various other programs have already laid the foundations of translating health records into digital files and providing interoperability. [11]. Several local digital therapeutics startups, such as Wysa (mental health industry), Fitterfly (diabetes sector), and Wellthy Therapeutics (cardiometabolic industry), are in a process of developing clinically validated products that would fit the specifics of the local population.

People with mild to moderate anxiety, sadness, stress, and sleep issues benefit from Wysa, an AI-based mental health software, according to studies. According to numerous users, cognitive restructuring is beneficial and less upsetting, which suggests high levels of acceptability, efficacy, and involvement. It is being tested in healthcare systems (e.g., UK IAPT) and has FDA Breakthrough Device Designation for depression/anxiety connected to chronic pain. Most findings, however, come from observational and feasibility studies rather than several randomized controlled trials, and its significance in serious mental illness is still uncertain. When everything is considered, Wysa is a potentially useful adjunct for increasing access to mental health services.[12]

Fitterfly is an Indian digital therapeutics company specializing in personalized metabolic health management for conditions like type 2 diabetes, obesity, and cardiovascular diseases. Their flagship program combines continuous glucose monitoring (CGM) with AI-driven coaching, nutrition guidance, fitness plans, and behavioural support through a mobile app. The program aims to offer scalable, real-time, and evidence-based care, particularly in underserved regions. Fitterfly's digital therapeutics program has

shown promising results in improving glycemic control, aiding weight management, and enhancing psychological well-being among individuals with type 2 diabetes. The integration of CGM technology with personalized coaching and lifestyle modifications offers a scalable and effective approach to diabetes care, with higher engagement correlating to better health outcomes.[13]

Wellthy Therapeutics is a Mumbai-based digital therapeutics company focused on chronic disease management, particularly type 2 diabetes (T2D). Its flagship platform, Wellthy CARE™, combines AI-driven decision support with behavioural science to deliver personalized, mobile-based interventions. The platform includes features like glucose tracking, lifestyle coaching, and remote support from certified educators. Wellthy Therapeutics exemplifies the potential of digital therapeutics in transforming chronic disease management. Its evidence-based, scalable platform offers a promising solution for improving health outcomes, especially in resource-constrained settings.[14]

KEY POLICY GAPS IN INDIA'S DIGITAL THERAPEUTICS LANDSCAPE

Data security vulnerabilities significantly hinder the uptake of digital therapeutics (DTx) in rural India. Because DTx solutions rely on the safe collection and transfer of sensitive health data, rural people are particularly vulnerable to threats including phishing, data breaches, and exploitation of personal health information. Issues including limited digital literacy, insufficient cybersecurity infrastructure, and social barriers make these dangers worse. These concerns not only undermine patient trust but also put compliance with data privacy laws, which are crucial for medical technology, at risk. Fair access is further limited by socioeconomic and gender disparities, and safe deployment is made even more challenging by a lack of robust standards and cybersecurity training for medical personnel.[15]

Therefore, for DTx to be successfully integrated in rural India, concurrent efforts in improving network security, increasing awareness, and strengthening digital literacy are required to guarantee that these interventions are inclusive and secure.

Several critical policy and structural challenges hinder the widespread adoption of DTx in India. First, there is no formal recognition or classification of DTx by the Central Drugs Standard Control Organization (CDSCO), making regulatory pathways unclear. This is unlike the United States, where the Food and Drug Administration (FDA) regulates DTx under its Software as a Medical Device (SaMD) framework. Second, there are no established reimbursement mechanisms for DTx within public or private insurance systems in India. As a result, patients bear the full cost, limiting scalability and adoption. Third, while the Digital Personal Data Protection (DPDP) Act, enacted in 2023, provides general data privacy safeguards, there are no DTx-specific compliance standards, particularly around user consent, anonymization, and third-party data usage.[16] Moreover, integration of DTx solutions with the Ayushman Bharat Digital Mission (ABDM) remains minimal, and awareness among both healthcare providers and patients is low. (Table 4)

Table 4: Key Policy Gaps in India's Digital Therapeutics Landscape

Domain	Current Status	Gap Identified
Regulatory	No DTx classification under CDSCO	Absence of approval pathways for DTx
Reimbursement	Not included in insurance schemes (public/private)	Patients bear full costs
Data Governance	DPDP Act enacted (2023)	No DTx-specific compliance guidelines
Integration with ABDM	ABDM focuses on EHRs and eKYC	Lack of interoperability mandates for DTx
Awareness & Training	Low among providers and patients	No national capacity building or CME programs

Table 5: International Best Practices in DTx Implementation

Country	Regulatory Framework	Reimbursement Mechanism	Notable DTx Example
USA	FDA SaMD Pre-Cert Program	Pilots with Medicaid & private insurers	Pear Therapeutics
Germany	DiGA Fast-Track	Full reimbursement under statutory insurance	Zanadio (Obesity DTx)
Japan	MHLW Classification	Public insurance covers DTx for smoking & HTN	CureApp SC

GLOBAL BENCHMARKS AND LEARNINGS

India can draw valuable lessons from global best practices. In Japan, DTx for smoking cessation and hypertension are reimbursed through national insurance schemes.[17] In the U.S., the FDA has established a Pre-Cert program to expedite digital health innovations and regulate them under the Software as a Medical Device (SaMD framework).[18] These models show that regulatory clarity, financial incentives, and provider engagement are key to successful DTx integration (Table 5).

Japan's national insurance payment of digital therapeutics (DTx) for smoking cessation and hypertension is an example of how integrating evidence-based digital health tools into mainstream care can improve access, adherence, and outcomes while reducing long-term healthcare costs. By creating transparent regulatory processes, incorporating DTx into public health programs like Ayushman Bharat, and stream-

lining reimbursement through national insurance programs, India can gain from this model. This is particularly crucial because of the nation's large rural population and high rate of lifestyle-related illnesses. This approach would boost the sustainability and equity of digital health in India while also enhancing patient participation and disease management.

India can learn a lot from the U.S. FDA's Pre-Certification (Pre-Cert) Program for SaMD. By adopting a structure that places more emphasis on organizational excellence, quality culture, and total product lifecycle monitoring than a limited focus on individual goods, India may speed regulatory approval, accelerate innovation, and maintain safety and efficacy. For instance, India might establish a voluntary precertification pathway for software developers who demonstrate strong quality systems and real-world performance tracking to minimize duplication in premarket evaluations, especially for lower-risk digital health technologies. Furthermore, as demonstrated in the FDA's pilot, a balance between patient safety and innovation can be achieved using transparent product performance, real-world monitoring, and unambiguous risk-based categorization.

Opportunities for India

Given India's digital scale and NCD burden, the following strategic opportunities stand out:

Remote Chronic Disease Management: Platforms for digital therapeutics (DTx) are showing promise as a remote management tool for chronic illnesses, especially in low-resource or distant locations with limited access to specialized treatment. By using mobile devices or simple connected tools (such as wearable sensors, glucometers, or blood pressure monitors) to enable continuous vitals monitoring, early symptom detection, personalized health education, and remote consultation, these platforms cut down on the time, travel, and costs usually associated with repeated in-person visits. For example, employing a mobile app in addition to linked devices significantly reduced hospitalizations and improved medical therapy optimization for patients with heart failure in pilot research that combined DTx and Remote Patient Monitoring.[19]

Health System Efficiency: The efficiency of India's healthcare system is hampered by a lack of specialists, high patient volumes, and resource constraints. Digital therapeutics (DTx) can fill these gaps by integrating personalized behavioural coaching with automated patient monitoring. By monitoring vital signs, medication compliance, and lifestyle decisions in real time, these interventions reduce the need for frequent in-person visits. By shifting routine follow-ups and lifestyle advice to digital platforms, physicians can focus on challenging situations while patients receive continuous, evidence-based assistance. This improves health outcomes and the overall efficacy of the system in managing chronic disorders such as diabetes, hypertension, and cardiovascular diseases, while also reducing the workload for clinicians.[20]

Diabetes Management: Digital therapeutics (DTx) can dramatically reduce the long-term financial burden of diabetes treatment by improving glucose control, lowering the risk of complications, and eliminating the need for intense in-person monitoring. According to research, adding DTx to diabetic treatment might lower medical expenses by up to 30%, making it a cost-effective addition to conventional therapy. These savings come from fewer hospital stays, improved pharmaceutical utilization, and improved patient self-management.[21]

Policy recommendations for effective implementation of digital therapeutics in India

To address these challenges and capitalize on opportunities, India must adopt a multi-pronged policy approach.

CDSCO should formally recognize DTx as a distinct category under Software as a Medical Device (SaMD), drawing upon definitions provided by WHO and the FDA.[22] Regulatory approval should be liable upon clinical trial evidence, real-world efficacy, and software safety standards such as IEC 62304.

The National Health Authority should pilot reimbursement models under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY), as well as Employee State Insurance Corporation (ESIC) schemes. These pilots could first target conditions that have a significant disease burden, including diabetes, hypertension, and depression. At the same time, the validation of DTx adoption should motivate private insurance providers to incorporate them into their policies, potentially utilizing an outcome-based reimbursement model that incentivizes clinical enhancements.[23]

DTx platforms should be required to adhere to Ayushman Bharat Digital Mission (ABDM) interoperability standards, including FHIR (Fast Healthcare Interoperability Resources) and open Application Programming Interface (APIs), to facilitate their seamless integration into the Indian digital health landscape. Furthermore, the Digital Personal Data Protection (DPDP) Act ought to be enhanced by tailored compliance frameworks for the industry that outline the best practices regarding data consent, sharing, and storage within the realm of digital health.[24]

The issue of human capital must be addressed in the policy framework. The traditional risk-averse culture might be one reason for the slow implementation of digital therapeutics programs, but if those programs are incorporated into the curriculum for medical, nursing, and pharmacy students, healthcare practitioners will be more familiar with such tools. Such in-

itiatives and awareness programs should be taken up on a sustained basis by organizations such as National Health Systems Resource Centre (NHSRC) and state resource centres.[25] Policies should be laid down to incorporate DTx modules in MBBS curricula via NMC guidelines, targeting 50% coverage by 2027.

Consideration should be given to the progression and pace of development to include Public Private Partnership (PPPs). Government institutions like the Indian Council of Medical Research (ICMR) and the All-India Institute of Medical Sciences (AIIMS) may collaborate with the government to develop DTx solutions and test them in clinical trials. The setting up of a National Digital Therapeutics Innovation Fund can provide early investment opportunities to startups working on Indian health challenges. (Fig 1)

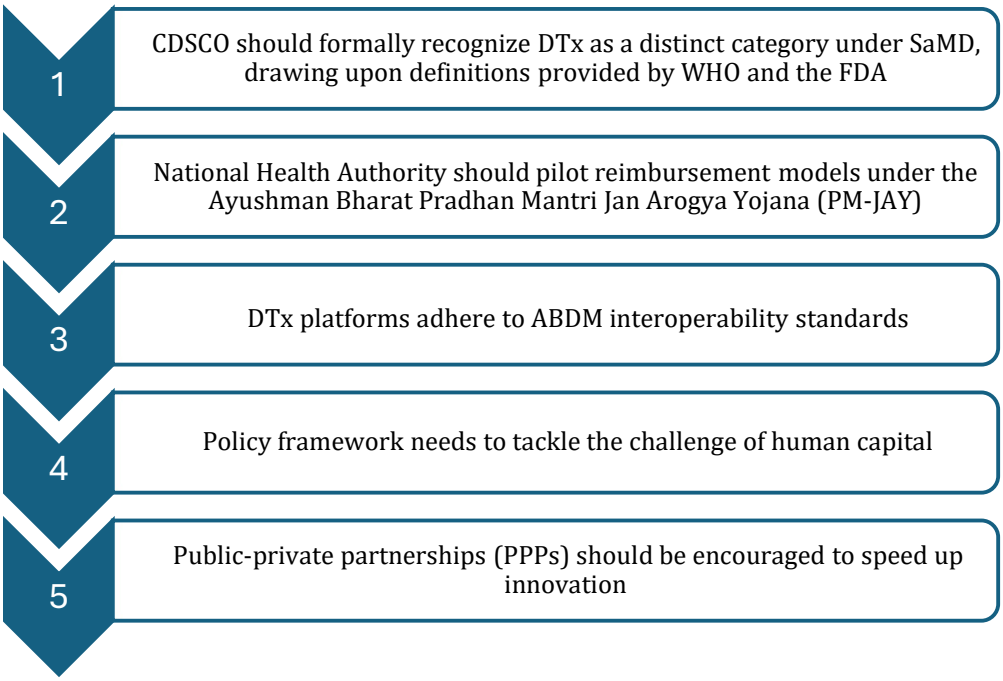

Figure 1: Policy Recommendations for effective Implementation of Digital Therapeutics in India

Table 6: Strategic Roadmap for DTx Integration in India

Timeline	Action Items
0-6 months	Form DTx policy task force; release draft regulatory guidelines
6-12 months	Launch reimbursement pilots under PM-JAY; test ABDM sandbox integrations
12-24 months	Scale DTx approvals; roll out provider training programs
2+ years	Nationwide adoption across public insurance and healthcare systems

Implementation Roadmap

For the adoption of digital therapeutics (DTx) in India, a tiered roadmap may begin with the creation of a national task group and the release of draft regulatory guidelines within the first six months. It will take six to twelve months to start reimbursement pilots under PM-JAY, test integrations with the Ayushman Bharat Digital Mission (ABDM) sandbox, and set up a monitoring framework to assess patient outcomes and system performance. The top priority for the next 12 to 24 months should include expanding DTx approvals, strengthening safety and efficacy monitoring systems, and putting provider training programs into place.

Longer term, with continued supervision to ensure sustainability, quality, and equitable access, broad adoption across public insurance programs and healthcare systems can be achieved after two years. (Table 6)

Conclusion

Urgent policy enactment by the Ministry of Health and Family Welfare (MoHFW) could accelerate India's digital therapeutics (DTx) ecosystem, positioning the country as a global leader by 2030. By establishing clear regulatory pathways, integrating DTx into the Ayushman Bharat Digital Mission (ABDM), and enabling reimbursement under national insurance schemes, India can foster innovation, ensure patient access, and drive large-scale adoption. Such timely action would not only strengthen healthcare delivery and reduce costs but also create opportunities for India to export scalable DTx models to other emerging markets.

Individual Authors' Contributions: The conceptualization of the study was carried out by **SKB**. The literature review was conducted by **NK**. **SKB** was responsible for developing the methodology and

framework. Referencing was jointly managed by **SKB** and **NK**. The final proofreading of the manuscript was completed by **SKB**.

Declaration of Non-use of Generative AI Tools: This article was prepared without the use of generative AI tools for content creation, analysis, or data generation. All findings and interpretations are based solely on the authors' independent work and expertise.

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