Economic Evaluation of Digital Therapeutics in Public Health: A Systematic Review of Cost-Effectiveness and Implementation Barriers

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Abstract

DTx, in public health, provide the potential for new, scalable evidence-based interventions that may prevent or manage a given medical condition. This makes software a medical device; it provides engagement for patients while staying committed to their treatments and answers access and cost concerns. This summarizes evidence of the economic value in DTx across different domains of public health such as chronic disease, cardiovascular, or mental health services as having significant savings on cost while achieving better clinical outcomes and the gaining of life years, quantified using QALYs where such interventions compare with traditional treatments. Despite the promise that DTx holds, it has been held back by numerous barriers from being generally accepted. Such barriers include a digital divide and complexity of the regulatory environment, absence of reimbursement frameworks, and cultural resistance by healthcare providers. The challenge would require good regulatory policies, standardized evaluation frameworks, and access to technology with fairness. In

addition, long-term economic evaluations and real-world evidence will be important for the comprehensive understanding of DTx on the health system and society. This review enacts the transformative potential of DTx for public health strategies while pushing for structured integration into healthcare. As the momentum builds for digital therapeutics, policymakers and other stakeholders must better align their efforts to overcome these implementation barriers in a manner equitable and effective adoption of the same.

Keywords

Digital Therapeutics, Economic Evaluation, Public Health, Cost-Effectiveness, Implementation Barriers, Chronic Disease Management, Healthcare Innovation, Digital Divide,

1. Introduction

Digital therapeutics is the novel approach in healthcare that offers evidence-based therapeutic interventions through excellent software programs. This kind of intervention is developed to help in preventing, managing, or even treating any medical disorder or disease. The Digital Therapeutics Alliance defined DTx by stating that they rely on software as a medical device and improve patient outcomes through digital means (Huh et al., 2022). It has increasingly become easier to incorporate DTx in clinical practice by using smartphone applications and wearable devices for personalized and accessible therapeutic solutions. According to Huh et al. (2022) and Kwon et al. (2023), the effectiveness of digital therapeutics is highly recognized, especially for mental health concerns where traditional face-to-face methods are less available. A significant study indicates that mental health digital applications, often the digital format for delivering CBT, fail to yield their expected results, and there could be a higher understanding of therapeutic alliance—a relation between a patient and therapist characterized by mutual co-operation-considered the panacea for those digital interventions as well (Henson et al., 2019; Tremain et al., 2020). This digital therapeutic alliance plays a very vital role in users' engagement with and adherence to treatment protocols that determine clinical outcomes (Tremain et al., 2020).

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Digital therapeutics are fast becoming important pieces of digital public health strategies that cut across broad public health frameworks. Digital public health is the involvement of digital technologies in public health, which serves to improve the health outcomes as well as optimize the delivery of health services (Iyamu et al., 2021; Wienert et al., 2022). There are many definitions of digital public health with some highlighting transformational roles that digital technologies can play in improving public health outcomes, while other definitions consider these technologies as facilitators of goals that have existed in public health (Iyamu et al., 2021). No matter the view, the general consensus would be that DTx significantly contributes to public health by offering scalable and accessible interventions in the treatment of wide-ranging health problems from chronic diseases to mental health disorders (Iyamu et al., 2021).

The adoption of digital therapeutics in health systems is a function of several factors, one of them being the acceptability of these interventions by patients and healthcare professionals. A scoping review pointed out the need to understand the barriers and facilitators to the integration of DTx into healthcare systems, which is necessary for maximizing their potential benefits (Kessel, 2023). User experience, clinical validation, and perceived value of digital therapeutics are factors that play a critical role in their adoption and sustained use (Kessel, 2023). The COVID-19 pandemic has hastened the integration of digital health solutions as patients and providers looked for alternatives to in-person visits, emphasizing the need for effective digital therapeutic options (Kwon et al., 2023). Digital therapeutics also hold promise in addressing specific health conditions, such as attention-deficit hyperactivity disorder (ADHD). According to meta-analyses conducted recently, digital therapies appear to be efficacious in the treatment of ADHD symptomatology, so these interventions are viable alternatives to or complements of traditional pharmacological treatments. Prescription digital therapies is an emerging trend whereby software-based interventions are prescribed by healthcare providers in a holistic treatment plan (Fan et al., 2023).
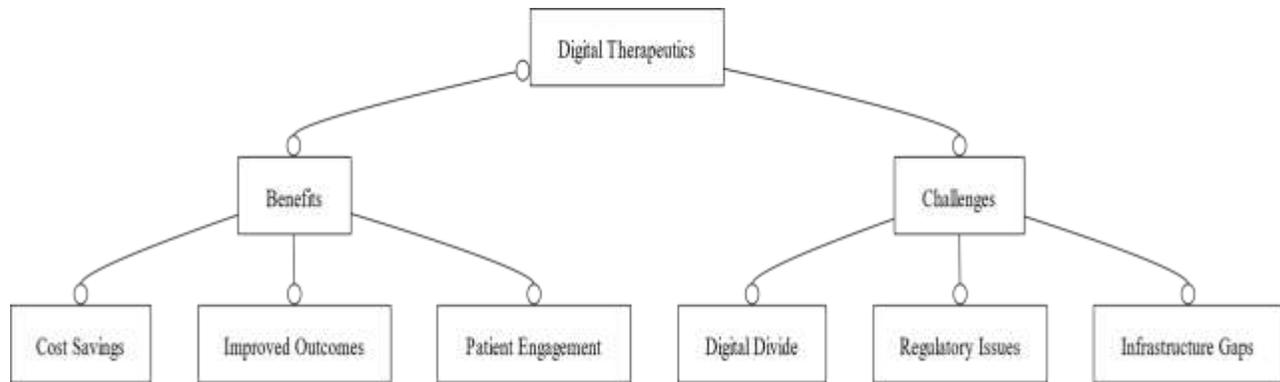
Figure 1. This flowchart presents a straightforward view of the potential and hurdles associated with adopting digital therapeutics in public health.

The other area that seems to have come under change is the classification of digital public health interventions. This has involved research on frameworks for leading implementation and assessment (Wienert et al., 2022). Such frameworks would be very instrumental in ensuring the effective integration of digital therapeutics into public health strategies while having their impacts systematically evaluated on health outcomes (Wienert et al., 2022). It further complicates the interplay between digital therapeutics and public health, in terms of ensuring robust regulatory frameworks for the safety and efficacy of such interventions (Rafiei et al., 2021).

Economic evaluation is very important to the integration of DTx into public health policy primarily because one needs to assess whether such novel interventions are value-for-money interventions and create any value at all. At this time, the world's health systems face various constraints in resources while there is growing demand for efficacious treatment; hence, an economic appraisal of adopting DTx becomes imperative in guiding decisions of policymakers, providers, and stakeholders (Yan et al., 2021;. The economic evaluation of DTx encompasses a variety of methodologies, including cost-effectiveness analysis, cost-utility analysis, and budget impact analysis, which together inform the potential return on investment (ROI) and long-term sustainability of these digital interventions (Oliveira et al., 2023; Sverdlov et al., 2018). One of the main reasons economic evaluation is important for DTx is because it offers a structure for

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comparing costs and outcomes of digital interventions against traditional therapeutic options. Comparing is most crucial in chronic diseases where there may be an ongoing need for management, and the economic impact can be huge. For instance, some of the studies have depicted that interventions for digital health may lead to major savings in health care costs that are associated with chronic diseases, including T2DM, based on the better skills of patient self-management and their adherence to treatment regimens prescribed (Oliveira et al., 2023). In turn, economic evaluations can establish such cost savings and use it as a way to justify up-front investment into DTx in order to open up its further-scale adoption into healthcare systems.

Economic evaluations could also help in determining the best strategies through which DTx can be implemented. According to the literature, for digital therapeutics to be successfully adopted, there is a need for implementation support, with consideration of the different needs that diverse patient populations may require (Lord et al., 2021; Prodan et al., 2022). An examination of the costs and consequences related to various forms of implementation approaches should help stakeholders with resource optimization for the effective roll-out of DTx in the most beneficial form while incurring the least amount of costs, especially within a public health setup where access must be fair (Azzopardi-Muscat & Sørensen, 2019). In addition to what is described above, more and more, social analyses of the economic effect consider society-wide consequences. Thus, for example, digital therapeutics in the area of public health can improve patients' health literacy along with active patient engagement; further, there might be the possible downstream population-health and productivity advantages in economic analysis (Azzopardi-Muscat & Sørensen, 2019). Economic analyses thereby capture a great deal more benefits and create comprehensive value information over DTx with a chance at being considered through public health interventions.

In addition, it is when such digital therapeutics gain regulatory clearance and are on the market that such strong economic evaluation becomes a necessary step. Evolving HTA frameworks for incorporation of DTx unique characteristics take into account these features and use economic evaluations for the assessments; see Yan et al. 2021, Sverdlov et al. 2018. By aligning economic evaluation methodologies with HTA processes, it is possible to ensure that digital therapeutics

are consistently and transparently evaluated, paving the way for their integration into existing healthcare systems and reimbursement models (Yan et al., 2021). The fast pace at which technology has been advancing within the digital health space also brings into the fore economic evaluation. Evaluation of the continued economic impact will be required every step of the way as digital therapeutics roll out and emerge into the marketplace to keep track of innovation as well as how the healthcare market changes (Sverdlov et al., 2018).

2. Cost-Effectiveness of Digital Therapeutics

Of late, there has been an increased interest in the cost-effectiveness of digital therapeutics across different public health domains. This reflects growing recognition of the potential for better health outcomes within affordable healthcare delivery costs. Economic evaluations are fundamental to understanding financial implications for these interventions, particularly with regard to chronic disease management, mental health, and preventive care. This synthesis will examine the evidence on the cost-effectiveness of digital therapeutics across different public health domains using a collection of studies and systematic reviews.

Most of the studies have shown that the incorporation of digital therapeutics is even highly cost-effective in chronic disease management in type 2 diabetes. One such recent study is the impact of a digital Diabetes Prevention Program: in this case, it was concluded that there would be a saving of all-cause healthcare spending about USD 1169 per participant due to lower hospital admissions and shorter lengths of stay Davison (2024). This fact proves the potential of an app to deliver a healthcare intervention, with patients developing healthy behavior, adherence, and, therefore, lower healthcare cost. Systematic reviews further strengthen the economic benefits of DTx in managing T2D, as results are continually reported with favorable cost-effectiveness ratios (Morris et al., 2022). The other critical area where digital health interventions have shown promise is cardiovascular diseases (CVD). A systematic review of 14 studies concluded that all the DHIs evaluated were cost-effective, with 43% of the studies reporting both higher QALYs and cost savings (Jiang et al., 2019). The remaining studies showed that DHIs added QALYs at an acceptable incremental cost-effectiveness ratio, which reinforced the idea that digital

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interventions could add both clinical and economic value in the management of CVD. This evidence is highly relevant, given the high prevalence and associated healthcare costs of cardiovascular conditions.

Oncology is the evidence where digital health interventions seem to have benefits in supportive care, particularly to overcome cancer-related fatigue and enhance the quality of life (QOL) (Aapro et al., 2020). Nine trials demonstrated statistically significant effects of digital interventions such that there would be a good deal of healthcare outcome but perhaps also possibly save the health system money in the future. Hence, though it may be cost-effective to improve the patient's well-being with the integration of digital therapeutics in cancer care pathways, this will still be helpful in the management of health care costs. Another area where digital therapeutics has been proven to be cost-effective is essential hypertension. A cost-effectiveness analysis of DTx in the treatment of hypertensive patients illustrated that at a cost of ¥5,000 per month, DTx dominated conventional treatment as it is not only inexpensive but also results-oriented (Nomura et al., 2022). Thus, this finding further establishes the fact that DTx can indeed be an easily accessible management technique for hypertension as it ensures prolonged health benefits coupled with lower expenditures.

Digital therapeutic care apps also have been accepted in the treatment of low back pain (LBP). An assessment of value for money suggested that a multidisciplinary therapy app that includes several exercises with accompanying educational material may serve as a cost-effective substitute for traditional rehabilitation programs in Germany (Lewkowicz et al., 2022). It can be seen that digital therapeutics could bring about important cost savings in healthcare systems for the treatment of LBP and its associated huge economic burden, which is found to be widespread. This study also delved into the economic evaluation of the more general landscape of mHealth solutions. Systematic review on the economic evaluation of mHealth solutions reveals that although a lot of the interventions might not be cost-saving, they can still be regarded as cost-effective when they deliver adequate health benefits for the costs incurred (Iribarren et al., 2017).

Additionally, the impact of digital health interventions spills over and impacts indirect economies as well. For example, digital therapeutics could help a patient adhere better or get more engaged with treatments in full. That would result in downstream effects across overall healthcare utilization and costs (Sinha et al., 2022). Good usage of digital mental health interventions has been observed to result in very high user retention and engagement, indicating effective addressing of a common issue among traditional therapeutic methods: suboptimal engagement.

Table 1: Comparison of cost-effectiveness across different public health domains

Domain	Intervention Type	Key Findings	Metrics	References
Chronic Diseases	Digital Diabetes Prevention Program	Reduced healthcare costs by $1169 per participant due to lower hospital admissions.	Cost savings, improved adherence	Davison (2024), Oliveira et al. (2023)
Cardiovascular Diseases	Digital Health Interventions (DHIs)	Achieved higher QALYs and cost savings in 43% of studies reviewed.	Incremental Cost-Effectiveness Ratio (ICER), QALYs	Jiang et al. (2019)
Mental Health	Digital CBT Applications	Improved therapeutic engagement and cost reductions by avoiding in-person visits.	Health outcomes, reduced barriers	Tremain et al. (2020)
Hypertension	Digital Therapeutics for Hypertension	Found to dominate conventional treatment with better health outcomes at lower costs.	Monthly cost ($5,000), prolonged benefits	Nomura et al. (2022)

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Oncology	Supportive Care for Cancer Patients	Enhanced quality of life and healthcare outcomes; potential for future cost savings.	QALYs, cost-effectiveness ratio	Aapro et al. (2020)
Musculoskeletal	Digital Therapeutics for Low Back Pain	Multidisciplinary apps were cost-effective substitutes for traditional rehabilitation programs.	Cost savings, convenience	Lewkowicz et al. (2022)

While there is promising evidence for the cost-effectiveness of digital therapeutics, generalizing economic evaluations to a wide range of populations and healthcare settings is difficult. A methodological systematic review indicated that solid analytical frameworks and outcome measures are crucial in the evaluation of digital health interventions for the multi-stakeholder effects that it could bring (Benedetto et al., 2022). Clearly, digital therapeutics are some of the best innovations in health care, especially when compared with traditional health interventions. Several advantages and challenges associated with evaluating the cost and health outcomes of DTx make them more adoptable in numerous public health domains. The scope of this synthesis will comparatively assess DTx with conventional interventions with an eye on cost-effectiveness, health outcomes, and patient engagement.

One of the key advantages of digital therapeutics is their potential to save money on the cost of traditional health interventions. For instance, a narrative review reported that digital mental health interventions may overcome the barriers of travel and time, which are the primary reasons why conventional therapy is often out of reach for many individuals (Tremain et al., 2020). Therapy can reduce the costs of the in-person visits by providing the services through digital platforms. The decrease in therapeutic costs is especially relevant to mental health because traditional therapy is resource-intensive and usually requires more sessions than are possible for each patient (Tremain et al., 2020). In fact, the use of digital therapeutics for the management of

chronic diseases is found to be cost-effective. An example would be a hybrid cost-effectiveness intervention in knee osteoarthritis: having fewer sessions of the digital component compared with the traditional physical therapy intervention could potentially yield a low intervention cost while maintaining equal health outcomes (Shah et al., 2022). The implication of this finding is that DTx could offer treatment alternatives that are resource-scarce, which could be an alternative to traditional interventions.

The economic evaluations for the digital therapeutic care apps targeting low back pain also have been positive. In one cost-effectiveness analysis, the digital interventions emerged as compared to the standard rehabilitation programs which often are quite more expensive and resource-intensive Lewkowicz et al. 2022). It reduces the costs for the unit and provides greater convenience to the patient, which is a huge concern for treatment adherence and overall satisfaction, by reducing the number of in-person visits that are needed to provide appropriate care. Generally, the health outcomes of digital therapeutics are better compared to the traditional interventions. For instance, a prospective case-control study reported that a smartphone application with an activity tracker-wearable device successfully prevented the relapse of mood disorders, and this was considered to show that DTx may be at least as effective or even better than other interventions in providing health outcomes (Cho et al., 2020). This is more especially in the mental health sphere, as there are interventions which, sometimes, do not show consistent effects to all of their patients. This flexibility, plus the digital availability of such interventions, is what will eventually enhance engagement and adherence, therefore ensuring better results in health care.

However, its limitation in the care process should not be overlooked. Despite the fact that DTx offers a standardized intervention as an evidence-based practice, such treatment can become worthless to the patient since individual engagement is not found in the delivery if it involves a therapist (Cho et al., 2020). In this regard, it is sensible to combine both digital therapeutics and the traditional approach into one model that provides the best of both practices. This also gives the scope for improving patient engagement and adherence through the incorporation of digital therapeutics in the existing healthcare delivery system. A systematic review drew attention to the

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fact that DTx could improve treatment adherence through continuous support and reminding that do not occur with traditional treatments (Kessel, 2023). This can subsequently result in improved health outcomes and also diminish healthcare spending since the patients are most likely to comply with a treatment regimen since they are always guided through online platforms.

Digital therapeutics may capture real-time data about the behavior and outcomes of patients that are then used in more targeted treatment approaches. Application of digital biomarkers, such as information captured by wearable devices, can track patients' progress and then interventions be adjusted at the point where necessary (Strauss et al., 2022). Although this has been quite beneficial, digital therapeutics is accompanied by certain challenges. Digital interventions would have to ensure high-quality regulation along with a uniform method of assessment (Smits et al., 2022). Furthermore, the divide regarding digital availability would have to be bridged since the discrepancies between technology use and access can broaden health inequalities, which it already does for different groups and social classes in societies (Hall et al., 2020).

2. Implementation Barriers

One of the main problem is lack of a clear, systematic framework and guiding principles on how to use digital health interventions. A qualitative study indicated that mental health practitioners expressed their apprehensions about the unclear nature of ethical, legal, and procedural rules accompanying the integration of digital mental health services in their professional activities Mendes-Santos et al. (2022). Uncontrolled chaos brings inconsistencies in its application, such that the ability of DTx to be more effective and helpful in the provision of care among providers and clients may be limited. The ambiguity of standardized care protocols also allows confusion among caregivers on best approaches to using various digital tools: this limits health care providers to adopt these health technologies.

There are two other major bottlenecks in the practice of DTx: funding resources and resource

shortage. Funding to support public health in most healthcare systems, including emergency departments, is relatively low (Egerton-Warburton et al., 2015). This may hinder the development and launch of digital therapeutics because health care organizations may favor older interventions that do not demand much initial investment. The cost of new technologies in the introduction to existing systems discourages organizations from embracing DTx, especially in budget-sensitive environments. The digital divide is a critical issue in the fair implementation of digital therapeutics. It has been researched that differences in access to technology can significantly affect the impact of digital health interventions (Asthana et al., 2019). Therefore, DTx can afford to exclude populations without or with very limited access to smartphones, reliable internet, or digital literacy. This is very serious in the public health domain, where one expects equitable distribution of care. Bridging this digital divide would thus require focused efforts in making vulnerable populations resource and skill equipped enough to participate in digital therapeutics.

Cultural resistance also acts as a barrier to implementing digital therapeutics in health care settings. The majority of the health care practitioners are afraid to embrace new technologies because they may not be effective, increase their workload, or are against traditional therapeutic techniques (Brantnell et al., 2023). Such resistance may be due to lack of knowledge on digital tools or skepticism about the effectiveness of these interventions in contrast to the traditional ones. This cultural barrier has to be crossed by giving health care providers the right extent of training and education so they can believe in the concept of DTx and how these can be supplemented with already practiced procedures. The adoption of digital therapeutics is facilitated by the motivation and engagement of both the health care provider and the patient. For instance, the intentions and motivations for healthcare providers in using DTx have been proposed to sometimes facilitate and at other times work as a hindrance in this regard (Brantnell et al., 2023). Implementing digital interventions by the health care provider may not work efficiently if the professionals do not consider digital tools worthwhile or are too preoccupied with many responsibilities. Another critical aspect is patient engagement; if the patients are not motivated to use digital therapeutics or do not perceive them as beneficial, treatment adherence may decline. Critical strategies in transcending the barrier above would involve individualized

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guidance and education towards enhancing commitment.

Table 2: Comparison of Implementation Barriers and Facilitators.

Aspect	Barriers	Facilitators	References
Digital Divide	Limited access to smartphones, reliable internet, and digital literacy in underserved populations.	Increased smartphone penetration and targeted digital literacy programs.	Asthana et al. (2019), Khoong et al. (2021)
Regulatory Frameworks	Complex and fragmented regulations, lack of clarity in reimbursement policies.	Clear guidelines and streamlined regulatory processes.	Kim et al. (2022), Iyamu et al. (2022)
Cultural Resistance	Skepticism toward new technologies, preference for traditional therapeutic techniques.	Comprehensive training programs for healthcare providers.	Brantnell et al. (2023)
Infrastructure	Lack of EHR systems compatible with digital therapeutics platforms.	Investments in robust health IT infrastructure.	Francombe et al. (2022)
Patient Engagement	Low adherence due to perceived lack of personalization or benefit.	Use of real-time data and patient-centered designs to boost engagement.	Strauss et al. (2022)
Economic Feasibility	High initial investment costs and lack of financial incentives for providers.	Demonstrated long-term cost savings and scalability of digital interventions.	Nordyke et al. (2019), Sweet et al. (2023)

Regulatory and reimbursement issues pose an added complexity to the roll-out of digital therapeutics. Policymakers and health care organizations may face difficulties handling the regulatory environment of digital health technologies (Neher et al., 2022). This can be a

significant challenge for the adoption of digital therapeutics by providers where the reimbursement models, including how it is billed as a service for which they expect reimbursement, lack clarity. Providing clear policies regarding reimbursement pathways makes it easier for the environment to thrive through adoption of these interventions and treatments. Finally, infrastructural challenges in health care systems could be a huge challenge to implementing DTx. Many organizations would lack the proper technological infrastructure needed to support integration of digital health solutions, for example, EHR systems which can interface with DTx platforms (Francombe et al., 2022).

Regulation and reimbursement policies are a critical factor that affects the implementation of DTx in public health settings, posing a myriad of challenges. Such challenges therefore pose a hindrance toward integrating and implementing DTx into the already existing systems of healthcare. This thereby affects access to health care and the ultimate health outcomes for patients. This synthesis will address the major areas of challenge that regulation and reimbursement policies pose for digital therapeutics on evidence derived from different studies. However, one of the significant challenges is that the regulatory frameworks for digital therapeutics are relatively complex. Compared to pharmaceuticals and medical devices, the former often land in a grey area that involves dealing with numerous regulatory bodies and guidelines (Iyamu et al., 2022). This complexity is furthered by the transdisciplinary nature of digital health interventions since developers need to adhere to a variety of regulations which are specific to region and application (Iyamu et al., 2022). Digital therapeutics, for instance, require clinical evidence to be prescribed and therefore come under tight regulatory scrutiny, thus delaying entry into the market and increasing cost development (Kim et al., 2022). This complexity may deter innovation and limit the effective availability of digital solutions in public health.

In addition, payment policies are major barriers to the embracing of DTx. DTx is not a service that most healthcare systems reimburse for currently; hence, it becomes a cost burden to providers and patients alike (Kessel, 2023). For example, Poland has very few reimbursement pathways for digitally delivered health services only covering consultations between medical doctors and patients but not the full gamut of digital therapeutic interventions(Kessel, 2023).

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This may lead to a dis-incentive of healthcare providers to integrate DTx in their practice, given that it might not improve nominal reimbursement rates for them. That gap between the nominal and real reimbursement rates might still introduce another complexity dimension to DTx's financial feasibility. The actual rates, even in the presence of reimbursement policies, fail to meet the requirements for offsetting the delivery cost in the digital therapeutic service (Zhang et al., 2015). That incongruence might further lead to the problem of healthcare providers facing financial hardship in their delivery services. Therefore, if the provider is not able to recover its cost by reimbursing DTx, they are likely to shy away from its use. Consequently, it would mean a failure to develop sustainable reimbursement models, which in turn would undermine the growth of digital therapeutics in public health settings.

The need for clinical evidence to support the efficacy of digital therapeutics is another barrier that affects their regulatory approval and reimbursement. Unlike wellness apps or wearable devices, DTx require robust scientific validation to demonstrate their effectiveness before they can be prescribed or reimbursed (Kim et al., 2022). Additionally, there is also limited standardization of the methods of evaluating digital therapeutics, which also limits the uptake of such interventions in health care systems. The existing frameworks for economic evaluations may not suitably capture specific aspects of DTx, for example, its delivery mechanisms and engagement with users (Michie et al., 2017). Thus, adoption uncertainty may ensue among the stakeholders in determining the value of digital therapeutics than older interventions. Evaluation methods for DTx are standardized, thus considering the variations of such products and consequently facilitate their acceptance in the public health system.

The culture of resistance within healthcare organization also slows the process of adoption of the digital therapeutics. Other health workers are also reluctant to use the new technology since they will not be assured of its efficiency, additional workload, or considered a threat to traditional treatments. This may be on top of an unfamiliarity with digital tools and scepticism over how effective they could possibly be by comparison to traditional interventions (Iyamu et al., 2022). Educating and training in broad form, among other things, healthcare professionals in all matters will overcome cultural barriers and show how much value DTx can add to what already exists. Lastly, clear policies and guidelines must be in the commercialization and globalization of DTx

in order to foster an enabling environment that supports adoption. Policymakers should develop frameworks that help in developing and integrating DTx in healthcare systems but support patient safety and data security at the same time (Kim et al., 2022). Unclear guidance can leave developers uncertain about the regulatory landscape, thereby discouraging innovation and limiting the availability of effective digital solutions.

Equity and access issues significantly affect the scalability of digital therapeutics for diverse populations. These issues might even determine the efficacy and reach of digital therapeutics, and these can also determine whether innovative solutions in this area are likely to be fully realized to improve health outcomes for all people. This synthesis will discuss various dimensions of equity and access issues impacting the scalability of digital therapeutics, basing its discussion on relevant evidence from the studies. The digital divide is one of the primary concerns. This term simply refers to inequalities in the availability and use of the internet and the technological equipment at different levels among different demographic populations. Studies indicate that poor demographics, who have relatively low socioeconomic statuses, are generally comprised of racial and ethnic minorities without easy access to smartphones, robust internet connectivity, and adequate levels of digital literacy (Khoong et al., 2021). In a similar way, lack of access can prevent these populations from benefiting from digital health interventions and thus extend already existing disparities in health. For example, systematic reviews indicate that fewer studies on mHealth included participants older than the age of sixty-five, and lower educational levels as well as being non-White, among the populations generally most vulnerable to bad health (Khoong et al., 2021).

Cultural and linguistic barriers will probably hinder the adoption of digital therapeutics in diverse populations. Many digital health solutions are designed primarily for a predominantly Western audience and will not do as good a job of capturing nuances and preferences from other populations (Crawford & Serhal, 2020). This lack of regard often results in low interest and also low acceptance rates of DTx among individuals having different cultural backgrounds. Furthermore, language restrictions even pose the hindrance of digital therapeutics' applicability, and this is due to the reason that some of these applications are found without language support other than one's mother tongue (Groom, 2024). Toward full scale-up, accordingly, the designers

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of the developers must ensure the culture-sensitive design and implementation of the digital therapeutics. Usability and acceptability of digital therapeutics among diverse populations are also key determinants of their scalability. Research has indicated that unless app developers evaluate the usability and validity of their tools in underserved communities, the potential of digital health products to overcome barriers to entry into diagnostic and therapeutic pathways may be severely compromised (Ponzo, 2023). For example, in the case of digital biomarkers for autism, they must be validated using balanced sex populations to ensure equitable access to early interventions (Ponzo, 2023). Making DTx user-friendly and targeted to diverse populations' specific needs is therefore key to getting most people involved and adopting DTx.

Secondly, how health literacy influences people's ability to engage with digital therapeutics is paramount. Low health literacy populations may find it difficult to use digital platforms, understand health information, and participate in digital interventions appropriately (Groom, 2024). Such a challenge limits the scalability of DTx since those who are unable to understand or use such tools will not benefit from health improvements. To address this end, digital therapies need to be designed to be intuitive and, therefore, also easy to implement with clear, step-by-step instructions, accompanied by support mechanisms that may provide users with needed guidance through utilizing these technologies themselves. Regulatory and reimbursement policy also plays into the scalability, as these actions determine who should have access. DTx are not yet recognized in many healthcare systems as reimbursable services, meaning financial barriers for providers and patients; many health care providers will be slow or unwilling to invest in offering DTx without adequate reimbursement models (Lyles et al., 2021). Moreover, the regulatory frameworks become complex, and uncertainty is the result in the aspect of digital health interventions, which stifle innovation and limits diversity available DTx (Lyles et al., 2021). Clear and supportive policies on regulatory and reimbursement should be established for widespread adoption of digital therapeutics. Therefore, the alignment of stakeholder priorities ensures that different population groups meet the needs from these digital health solutions. It helps mitigate the situation if there exists an imbalance amongst funders, digital health companies, providers, and payers (Lyles et al., 2021). There has to be interaction and

collaboration to bring together diversified groups to support designs from which DTx shall benefit while boosting scalability as well as impact.

4. Broader Economic Implications

One of the significant economic benefits from digital therapeutic integration is cost savings through the management of chronic diseases. An economic impact study regarding digital therapeutics on the management of type 2 diabetes and hypertension brought out that DTx may significantly reduce healthcare expenditure for better self-management and better adherence to treatment regimens Nordyke et al. (2019). DTx would allow patients to track their condition from distance and implement early interventions in time, thus eliminating the requirement for routine expensive visits and hospitalization, which would go a long way in curbing the aggregate healthcare costs. Further, digital therapeutics would also result in efficiency gains for healthcare systems. With DTx, routine tasks such as monitoring a patient's status, gathering data, and then consolidating that information would be machine-based, reducing the tedium required to then focus on complex cases (Laurenza et al., 2018). Healthcare professionals will have more time and be more productive while treating patients, and care will be of superior quality. For instance, evidence exists that digital health interventions led by a pharmacist reduce transport costs and time to diagnosis, therefore making care accessible earlier and with more effectiveness (Park et al., 2022). On the other hand, remote provision of care decongests health facilities whenever demand is up, such as in public health emergencies.

The economic evaluations on digital health interventions help to know the cost-effectiveness of interventions as compared to the traditional modes of care. A systematic review has reported that economic evaluations can make the comparison between DTx and existing interventions easier, so that the decision-makers could clearly decide if the implications of adopting a digital solution are worth the cost (Iribarren et al., 2017). The standardized reporting frameworks, such as the CHEERS checklist, can facilitate stakeholders to determine whether DTx is economically sound

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and thus enable prudent decision-making for healthcare systems to incorporate it in their systems (Iribarren et al., 2017). Health outcome benefits also have downstream economic benefits for such integration. For example, the digital interventions in weight management have proved to boost healthy behaviors and thus lower the rate of prevalence for obesity conditions, which would subsequently reduce the development of the resultant chronic diseases (Shoneye et al., 2020). Improved health results in decreased utilization and costs in healthcare associated with complications from chronic disorders. In fact, the long-term economic impact of better health outcomes may be substantial because healthier populations usually have lower health care costs and higher productivity levels.

However, it is worth noting that the initial investments for digital therapeutics are expensive. Such investments may include setting up technology infrastructure, training healthcare providers, and support and maintenance (Park et al., 2022). Stakeholders are going to need to make comparisons between front-loaded costs versus value of these digital solutions through these economics evaluations so as to clearly look at these things, both immediate short-term savings that can add to long term as well for digital solutions from DTx. Further, the economic context of healthcare systems influences the scalability of digital therapeutics. In resource-poor settings, the implementation of DTx is likely to be limited by budgetary constraints and competing priorities (Laurenza et al., 2018). Long-term cost-saving potential through the addition of digital therapeutics to chronic disease management is indeed a very complex phenomenon. Such evidence of the interventions leading to a major reduction in the costs of health care while patients' outcomes improved, adopting DTx as part of their healthcare systems might be the key for healthcare providers. These dimensions of savings related to cost by DTx in chronic disease management will be discussed based on relevant studies within this synthesis.

One of the key ways in which digital therapeutics can create savings is through disease management and conformity to regimens of treatment. As an instance, digital health interventions for chronic diseases, such as type 2 diabetes, have been observed to enable

continued remote monitoring and daily assessments that may improve the strategies of disease management and yield better patient results Oliveira et al. (2023). By allowing the patient to constantly interact with the health information of the patient, DTx might improve adherence to prescribed therapies; thus, this would lower complication rates that always occur at the cost of some significant expense to hospitals and emergency departments. Moreover, studies have indicated that weight loss from digital health interventions saves patients with chronic diseases such as diabetes, hypertension, and arthritis a significant amount of medical care costs (Thorpe et al., 2021). For example, researchers have established that weight loss contributes to reduced prescription costs because patients have better control over HbA1C, blood pressure, and cholesterol (Thorpe et al., 2021). The monetary implications of the studies are so high because maintaining control over these chronic diseases prevents further progression toward conditions that later would cost individuals higher healthcare service provision.

The other critical factor behind the long-term cost savings of DTx is the reduction in healthcare utilization. A digital diabetes prevention program was assessed for its impact on healthcare utilization, and it led to reduced utilization and substantial cost savings (Sweet et al., 2023). In fact, the intervention group had an accumulated savings of approximately USD 2,277 in direct medical care over two years compared to the usual care group. This conclusion means that DTx is likely to relieve the burden of healthcare systems as it minimizes the need for expensive interventions and hospitalization. DTx may also be efficient in the delivery of healthcare services. DTx can liberate the time of healthcare providers for more complex cases by automating routine tasks, such as monitoring patients and gathering data (Venkateswaran et al., 2022). This can improve the aggregate productivity of health care professionals and the quality of care for patients. For instance, electronic health registries have been reported to reduce the time used in health information management, hence giving providers ample time to take care of their patients (Venkateswaran et al., 2022). Such efficiency gains might thus result in cost savings for health care systems.

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Additionally, DTx is scalable because of the low financial and safety risks associated with its implementation. The fact that smartphones are nearly ubiquitous and the fact that more people are increasingly literate regarding the effective use of digital technologies means that DTx can be scaled to various populations across the country (Swift, 2024). That is significant, especially for chronic diseases where timely access can make all the difference between avoiding complications and reducing long-term costs. With the inclusion of DTx in healthcare systems, providers can allow patients with chronic conditions to gain greater access to care. This will result in improved health outcomes and reduced healthcare spending. A second factor that will affect the economic impact of DTx is reducing hospital readmissions. It actually helps patients. Patients are made to have adequate management of conditions with the kind of tools that DTx delivers, and all those complications related to readmissions are prevented. For example, digital interventions on chronic pain have been found to improve education in patients, encourage shared decision-making between the healthcare providers and the patient, improve compliance with the set treatment plan, and therefore prevent exacerbation cases that are readmitted into hospitals (Ma et al., 2023).

5. Challenges in Economic Evaluation

One limitation is there is no standard that applies to all economic evaluations of digital health interventions. It has been evident in a systematic review that most studies fail to adhere to well-established guidelines, such as the Consolidated Health Economic Evaluation Reporting Standards, often abbreviated as CHEERS, thereby leading to inconsistencies in reporting and consequently in the interpretations of results Benedetto et al. (2022). This absence of standardization complicates cross-study comparison of findings and the establishment of a more holistic perspective of the economic effects of DTx. Additionally, most of the economic assessments of digital therapeutics are also constrained by short-term outcomes, not long-term ones. It is difficult to identify the long-term economic implications of DTx since there has to be constant monitoring and evaluation (Dong, 2023). Most studies focus on only short-term cost

savings and health outcomes; in fact, some studies do not even consider the possibility of long-term benefits. This brings about reduction in the effective economic value in the case of digital therapeutics, more so those used in the management of chronic diseases because long-term maintenance and health recovery are essential components.

The differences in strength and volume of evidence for conducting economic evaluations are added to the previous limitation. A. Systematic review notes that even if many digital mental health interventions were proven to be cost-effective, most studies from high-income countries on their effectiveness mean there is a paucity of applicable evidence for low-and middle-income settings (Villarreal-Zegarra et al., 2021). It applies a biased geographical standpoint to limit the generalizability of findings and raises concerns over the applicability of DTx in such diverse healthcare settings. Moreover, the evaluation that is done in high-income countries may not fully take into consideration the problems and cost structures which are quite unique for low-income regions. However, data quality and availability weaken the economic evaluation of DTx. Finding reliable information on cost, utilization, and health outcomes is often difficult, which weakens the findings of the researchers (Dong, 2023). Most research relies on self-reported data from the participants, which creates biases and inaccuracies in such assessments. The lack of comprehensive health records as well as standardized reporting mechanisms adds complexity to evaluating the strength of the impact of DTx on the economy.

Moreover, heterogeneity of digital therapeutics complicates economic evaluations. DTx is a broad group of interventions ranging from smartphone apps to telehealth platforms, different in complexity, target population, or method of delivery (Greenhalgh et al., 2017). Thereby, these aspects create complexities in coming up with an all-encompassing framework for their economic evaluation. Therefore, specific digital interventions' unique features and benefits may not be captured by economic evaluations, leading to incomplete assessment of their value. Lastly, most of the time, contextual factors are absent that could indicate how external factors are likely to impact economic evaluations of DTx. Reimbursement, regulation, or other features of a country's health care system have significant impacts on cost-effectiveness analyses of DTx,

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according to Hao (2023). Such factors are rarely incorporated in studies, which leads to biased outcome estimations and application outside the boundaries of a setting for healthcare research.

6. Future Directions

One of the major advances would be standardized frameworks for economic evaluations that are unique to digital therapeutics. Currently, the evaluations that are done reflect a lot of inconsistency in methodology, thus making it challenging to compare results from one study to another. For instance, adherence to the use of CHEERS ensures that best practices of conducting economic evaluation are followed but still, many studies do not follow these rules Benedetto et al. (2022). That is why developing standardised frameworks to address the nuances of DTx can enable the researchers to come up with more comparable and reliable economic appraisals. Longitudinal studies are essential to capture the long-term economic impact of the digital therapeutics. Most of the recent reviews concern short-term effects, which probably do not reveal the long-run benefits of DTx. To illustrate, longer follow-up would be necessary when reporting the impact of diabetes prevention interventions on cost-outcomes, where one would expect additional savings up to 10 years after treatment was received (Sweet et al., 2023). In longitudinal designs, it will be more complete to include in economic evaluations, which will show the long-term value of DTx.

Real-world evidence will also be an area for improvement in the inclusion of economic models. Most of the existing studies rely on data from clinical trials, which are not a full representation of the real world. This could also facilitate further representation of actual costs and effects of DTx in diverse populations by additionally incorporating actual real-world sources such as electronic health records and claims data within economic models (Dong, 2023). Subsequently, economic evaluations would become stronger in terms of their external validity and results, thus improving its usage even further for decision-making purposes. Dynamic modeling techniques are therefore necessary to be able to get an accurate calculation of the economic impact of DTx. Traditional

static models may not capture the dynamic nature of chronic disease management and the possibility of patient behavior change over time. For instance, Lewkowicz et al. used a discrete-time Markov chain model to simulate long-term effects on treatment and cost outcomes for patients with low back pain, showing the utility of dynamic modeling in capturing the complexities of disease progression (Lewkowicz et al., 2022). Expanded usage of such models will increase the accuracy of economic evaluations of DTx.

Health outcomes measurement requires more granularity. The current evaluation mainly depends on a broad measure of effectiveness and overlooks the specific changes in behavior, cognition, and environment that can be enabled by DTx. This emphasizes understanding how interventions affect these factors in order to potentially link them with health behavior change, as reported by Budney et al. (2020). More sensitive and objective measurements of treatment outcome can be generated by economic evaluations to better represent the multifaceted value of DTx. The thresholds for cost-effectiveness have to be tailored according to the context of digital therapeutics. Most economic evaluations rely on general thresholds for cost-effectiveness, which are less relevant to DTx due to mechanisms of delivery and potential scalability. Developing context-specific thresholds that will allow accounting for broader societal impacts of DTx will make more relevant studies toward economical evaluation. It further enables more-informed decisions (Sweet et al., 2023).

It is therefore important that the equity implications be considered within the economic models in order for full value realization from digital therapeutics. Current analyses do not measure disparities related to access and outcomes among populations. Economic models would reveal how integrating equity metrics would enable DTx to reduce disparities in health, increasing access for the disadvantaged, in care access (Villarreal-Zegarra et al., 2021). This will not only make the economic evaluations much more comprehensive but support equitable integration in healthcare systems as well.

7. Conclusion

Rawan Abdulsalam Albedeer[1], Sultan Muflih Alharbi[1]*, Ayman Saleh Saud Alramihi[2], Amal Dawd Alhawsa[3], Hassan Salem Alkalbi[4], Musa Hegab E Almohammadi[4], Ghazwah Abed Mohammed Alkuhayli[4], Hasan Hamid M Alharbi[5], Laila Dhaifallah Hamzah Aljuwayd[5], Sana Basheer Ali Alharbi[5], Abdulrahman Saleh Dakhilallah Alhawiti[6], Fatimah Abdullah Oudah Alatawi[7], Amal Ali Alshehri[8], Imtinan Talal Alrehaili[8]

Digital therapeutics are an innovative breakthrough in public health: personalized, scalable, and cost-effective management and prevention of a vast array of health conditions. In fact, the findings of economic evaluations reveal impressive savings in costs with better health outcomes for chronic diseases, mental illnesses, cardiovascular disorders, and cancer, among others. They offer promise for augmenting patient engagement, treatment adherence, and QALYs in addition to other more conventional therapy alternatives. Integration of DTx into health care faces major obstacles in the digital divide, complexities of regulations, cultural resistance, and infrastructure gaps. All of these issues impose restrictions on how the equitable diffusion and scaling up of digital therapeutics could take place, mainly in resource-limited settings. Addressing these barriers will require a multi-faceted approach involving investment in digital infrastructure, clear regulatory and reimbursement frameworks, and tailored strategies to enhance accessibility for underserved populations. More importantly, efforts to spread DTx widely will focus on developing patient and provider digital literacy to overcome resistance. The future of DTx will depend on continued work in the development of methodologies for economic evaluation that are strengthened by longer-term cost-effectiveness analysis and further linkage to real-world evidence to capture fully the impact. Dynamic modeling techniques and frameworks centered on equity should be used when assessing their social value. At the same time, collaboration will play a strong role among these stakeholders: policymaker, technologist, the healthcare provider, and the patient. Joint endeavors will ensure the alignment of these DTx toward existing healthcare structures while fostering the innovation and inclusions needed within them.

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Author contributions

The initial author wrote the original text, although all authors contributed significantly through data collection and literature searches. Each author engaged in the manuscript's critical revision, accepted full responsibility for the work, and gave their approval to the final draft.

Conflict of Interest

Authors declare they don't have any conflict of interest.

Ethical Approval

Not Applicable

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