Pilot Study of Digital Health Technologies for Managing Low Back Pain : Digital Therapeutics Value Assessment in South Korea

Yoo HY[1] , Bae E[1] , Lee DY[1] , Choi WJ[1] , Shin C[1]

[1] National Evidence-based Healthcare Collaborating Agency (NECA), Seoul, Rep of Korea
Dayeon Lee (day@neca.re.kr), Acceptance Code: HTA107

1. Abstract

Objective

The Digital Therapeutic (DTx) Evaluation Toolkit was established by the Digital Therapeutics Alliance (DTA) to provide a common language and process for decisionmakers and DTx manufacturers to jointly use through DTx product evaluation and implementation processes.

This study aims to present the operationalization and piloting of the value framework in the South Korea DTx ecosystem.

Methods

This work was carried out collaboratively with a variety of stakeholders. Three sequential phases were undertaken: (1) Quick validation of the evaluation framework on the local market and implementation, (2) piloting of the evaluation criteria through applying the framework on low back pain digital technologies, (3) validation of the result on the value evaluation, where usefulness and implementation aspects of the framework were assessed.

Results

The advisory board of Digital therapeutics conducted the framework's operationalization. They highlighted the need to improve ambiguous distinct among criteria, and the potential for added complexity. The value framework was applied in a technical document on low back pain management digital technology. The result showed that the 'Clinical Impact' was the highest priority criteria, while the 'DTx Product Technical Consideration' was the lowest. This is consistent with the view that it is difficult to clearly describe and verify the process of cognitive behavioral therapy interventions and the implementation of AI algorithms in technologies used for therapeutic interventions.

Conclusion

This study has shown that different technologies can have diverse priorities for consideration, reflecting the need to consider technology-specific importance when assessing value evaluation.

2. DTx Value Assessment Tookit

The Digital Therapy Association(DTA) developed 36 value assessment tools for 12 different categories, as shown in Table 2. Among these value assessment tools, a framework for evaluating the essential foundational components of a digital therapy device was identified under the category 'Develop, or refine, a formal process to evaluate DTx foundational components'.

Table 2.1 Evaluation tools for clinical decision makers to consider to evaluate and implement DTx products

STEP	Resource
Understand the digital health technologies(DHT) that are available to patients, caregivers, and clinicians today)	· Fact Sheet: DHT Ecosystem Categorization (2023) · Comparison Guide: Patient-facing DHTs (2023) · Report: Guidance to Industry: Classification of Digital Health Technologies (DHT) (2023)
Account for DHT products that have multiple functions and components)	· Proposing a Harmonized Multi-Functional DHT Approach (2023)
Know how to define a digital therapeutic(DTx)	· Fact Sheet: International Organization for Standardization (ISO) Digital Therapeutic Definition (2023) · ISO Technical Report (TR) 11147: Health informatics-Personalized digital health-Digital therapeutics health software systems (2023) · Fact Sheet: DTA's Adoption & Interpretation of ISO's DTx Definition (2023)
Recognize DTx industry core principles and policy positions	· Fact Sheet: Digital Therapeutics Industry Core Principles (2018) · DTx Industry Code of Ethics (2019) · DTx Product Best Practices (2019) · Fact Sheet: DTA Policy Positions (2022)
Understand DTx place in clinical therapy	· Fact Sheet: DTx Intended Uses & Mechanisms (2023) · DTx Disease State Targets (2023) · 'Is This Product a DTx?' Flowchart (2022) · 'Where Do Digital Therapeutics Fit into Healthcare?' Flowchart (2022)
Identify specific DTx products to consider, review, and evaluate	· DTx Product Library (2023)
Review existing regulatory and reimbursement pathways for DTx products	· European DTx Regulatory & Reimbursement Pathways (2023) · Fact Sheet: Australia DTx Regulatory & Reimbursement Pathways (2022) · Fact Sheet: China DTx Regulatory & Reimbursement Pathways (2022) · Fact Sheet: Japan DTx Regulatory & Reimbursement Pathways (2022) · Fact Sheet: South Korea DTx Regulatory & Reimbursement Pathways (2022)

	· Fact Sheet: United States DTx Regulatory & Reimbursement Pathways (2022)
Develop, or refine, a formal process to evaluate DTx foundational components	· DTx Value Assessment Dossier: DTx Product Benchmark Questions (2022) · DTx Value Assessment Dossier: DTx Product Evaluation: Clinical Impact & Intended Use (2022) · DTx Value Assessment Dossier: DTx Product Evaluation: Regulatory & Security (2022)
Develop, or refine, a formal process to evaluate DTx clinical impact	· DTx Value Assessment Dossier: DTx Product Evaluation: Clinical Evidence (2022) · Publication: Digital Therapeutic Clinical Evidence Basics (2022) · Publication: Digital Therapeutic Clinical Evidence Quality & Timing Recommendations (2022) · DTx Real-World Evidence in Practice: Pragmatic Clinical Trials as a Compelling Approach to Inform Healthcare Decisions (2023)
Educate target end users, including patients, caregivers, and clinicians	· Fact Sheet: Demystifying DTx (2023)
Develop, or refine, a formal process to evaluate DTx health economic impact	· DTx Value Assessment Dossier: DTx Product Evaluation: Economic Assessment (2022) · Report: Digital Therapeutics: Reducing Rural Health Inequalities (2020)
Implement and scale DTx products to enable appropriate patient access	· DTx Integration Guide: Implementing Digital Therapeutics in Practice (2022) · US DTx Workflow & Integration Report (2023) · Fact Sheet: DTx Market and Patient Access Pathways (2023) · Fact Sheet: DTx Prescription vs. Non-Prescription Pathways (2023)

The Framework for evaluating the essential foundational components of digital therapeutic devices (DTx) is based on the 'Develop, or refine, a formal process to evaluate DTx foundational components' tool, which consists of three main tools, and a breakdown of the purpose of each tool is shown in Table 2.2.

Table 2.2 Tools for formally identifying the basic components of DTx and their separate purposes

STEP	Resource	Purpose
Develop, or refine, a formal process to evaluate DTx foundational components	· DTx Value Assessment Dossier: DTx Product Benchmark Questions (2022)	- Provide healthcare decision makers (HCDMs) with a high-level understanding of the development stages and real-world use of digital therapy (DTx) products - Does not replace a full product evaluation - Enables HCDMs to more easily compare multiple products side-by-side
	· DTx Value Assessment Dossier: DTx Product Evaluation: Clinical Impact & Intended Use (2022)	- Provides a basic framework for healthcare decision makers (HCDMs) to evaluate digital therapeutic products - Patients see the impact, including the benefits of therapies that use software in addition to chemical or human-centred interventions to achieve treatment goals - DTx products typically go through some sort of approval process before being used in patients to ensure that each therapy is used appropriately - DTx products can be used independently or in combination with drugs, devices or other therapies to optimise patient care and health outcomes - Helping HCDMs determine which end users may benefit from a particular DTx therapy - When considering patient experience and needs, the following considerations guide HCDMs to optimise product suitability - Enable HCDMs and IT teams to ensure optimal use of DTx therapies - Provide HCDMs with an

		overview of the manufacturer's reliability, governance, and services
	· DTx Value Assessment Dossier: DTx Product Evaluation: Regulatory & Security (2022)	- Depending on the region and jurisdiction, regulatory bodies have different levels of regulatory and market authorisation requirements for digital therapeutic devices, depending on the intended use and risk level of the product - Confirmation of compliance with various international and national security standards - Ensure patient privacy, governance and consent processes are in place for the use of DTx products

In order to establish a basic framework for the evaluation of digital therapeutic products, three main types of tools were identified, as previously outlined. Each tool has been designed with a specific purpose in mind. The creators of the product (technology) evaluation frameworks were consulted extensively regarding the value of their tools and the necessity of utilising them to inform clinical value judgements.

In the context of the frameworks, it was proposed that the tool 'DTx Value Assessment Dossier: DTx Product Evaluation: Clinical Impact & Intended Use (2022)' be employed for the purpose of assessing value within the clinical domain.

3. Framework

The finalised framework evaluation metrics are presented in Table 3 for reference.

Table 3. DTx Value Assessment Dossier: DTx Product Evaluation: Clinical Impact & Intended Use (2022)

[Clinical Impact & Intended Use] Evaluation Consideration
① Product Basics
· Target patient population (including approved indications)
· Duration and frequency of treatment
· Details of product use, such as risks and side effects
· Detailed product features for disease management or prevention
· Environment for treatment initiation and ongoing management
· Current development and commercialisation and insurance stage of the product
② Clinical Impact
· Improve Health
· Coping with illness-related challenges in everyday life
· Deliver care in line with current guidelines
· Outcome metrics
③ DTx Product Authorization and Distribution
· The process for granting access to digital therapeutic interventions
· Procedures for Approving or Terminating Patient Use
· How to use the product
· Where to deploy your product and who has permission to deploy your product
④ Patient Facing Technical Consideration
· Hardware or software components
· Required network connectivity
· Product software compatibility with mobile operating systems
· Types of technical support and customer service available to patients or clinicians
⑤ Product Usability
· User characteristics required for proper use
· Improve health literacy
· Improving access to care

· Patient-centred usability aspects of product
⑥ Patient Centricity
· Patient requirements for appropriate use
· Product costs and insurance
· Clinical, environmental, and social benefits of products for patients
⑦ Technical Aspects
· Standalone/combined with hardware
· The product's core algorithm (system)
· Built-in processes to prevent bias and manage misbehaviour
· Data infrastructure for product
· Who is responsible for data storage and where it is hosted
⑧ DTx Manufacturer Evaluation
· How to review vendor technical quality
· Ability to launch, scale, and maintain long-term
· How to create and manage data
· How to get customer support

Digital Therapeutics Alliance, DTx Value Assessment Dossier DTx Product Evaluation: Clinical Impact & Intended Use