Closed Health Systems As Early Adopters and Incubators for Digital Behavioral Health Therapeutics

Poster #HSD52

Saber J[1], Lee E[1], Johnston M[1], Gandhi H[2], Waters H[2]

[1]Innopiphany LLC, Irvine, CA, USA, [2]Otsuka Pharmaceutical Development & Commercialization Inc., Princeton, NJ, USA

Contact: junko.saber@innopiphany.com

STUDY OBJECTIVE

- **Situation:** Digital behavioral therapeutics represent a promising new therapeutic modality for many behavioral health conditions such as PTSD, autism, anxiety, depression, and opioid addiction.
- **Challenge:** Despite the therapeutic potential, the United States has been surpassed by other countries in adoption of digital health as many digital health products face potential coding, coverage, and payment hurdles.
- **Question:** This study sought to examine the role and opportunity for evidence-generation partnerships with potential use by a range of stakeholders (including payers, providers, and regulators) to aid in future decision-making on adopting digital therapeutics.

METHODOLOGY

Secondary Research	Companies & Policies	Primary Research Validation
Secondary research assessing adoption-driving policies of key US healthcare stakeholders, including government stakeholders (n=7), provider organizations (n=3), industry groups (n=2), health networks (n=5), payers (n=5), and patient advocate organizations (n=2).	**Assessed 468 digital, behavioral health companies in the US** (excluding wearables) from PitchBook[1], **12 were selected for in-depth review** of access and coverage based on company size (Series C \$30M+, total raised equaling \$100M, or IPO).	**Expert interviews** (n=2) were conducted to supplement and verify findings. Perspectives from an industry group executive and digital therapeutics manufacturer are represented.

Acronyms: PDT = Prescription Digital Therapeutic, IDN = Integrated Delivery Network, FFS = Fee For Service, DTx = Digital Therapeutics, D2C = Direct to Consumer, Payvider = Healthcare model that includes both payer and provider services such as IDNs

RESULTS & DISCUSSION

Health System Type	Policy Drivers	Current Level of Clinical Evidence Generation	Current Impact on Access
Payers + Employer plans	Payers and employers offering D2C wellness tools are largely content and educational driven materials to capture cost savings (e.g., through productivity capture).	**Moderate** (Limited participation by payers, mostly as pilot programs)	**High** (<86M covered lives in Talkspace, coverage leader)
Closed Health System (a.k.a., Payvider Models)	Closed healthcare systems such as some large commercial IDNs are developing models to evaluate impact with a strong influence on adoption.	**High** (Established partnerships & internal evidence generation frame-works)	**High** (<16M covered by IDNs for several products)
	Government: The VA has an established track record in developing evidence for digital mental health apps and is the third largest IDN in the U.S.	**High** (Established partnerships framework through innovation ecosystem)	**High** (12M covered lives for several products)
Open Health Systems (e.g., Traditional Models)	Adoption of DTxs is more difficult under traditional FFS model.	**Moderate** (Limited participation, mostly pilot programs)	**Low** (Inconsistent coverage & reimbursement)

- **Developing High-Quality Evidence is Foundational to Access:** As of today, no gold standard has been established for evidence development for digital health tools.
- **Payers & Employer Plans**: The majority of payers believe PDTs to be experimental and investigational, however, traction in employer plans for mental wellness and teletherapy adjacent tools has provided substantial access and coverage.
- **Closed Health System (a.k.a., Payviders):** Innovative private integrated care delivery networks (IDNs) have taken a partnership approach to test products within networks, allowing for evidence generation of clinical efficacy, appropriate use-case testing, cost savings, and cost effectiveness. These partnerships serve to generate health economic, clinical, and real-world data which are used by other healthcare stakeholders, including regulators. Despite innovative partnerships and pilot trials, no products have received widespread coverage. As of now, limited large commercial insurers cover PDTs on the basis of FDA approval.
- **Open Health Systems**: Providers in open health systems cite increased work and responsibilities, lack of integration, and non-uniform reimbursement as barriers to PDT uptake.[2]

CONCLUSIONS

Conclusion:
- Closed health systems lead in digital behavioral health access, partly due to partnerships with digital therapeutics companies for evidence development.
- Open health systems with FFS models face challenges to adoption given lack of provider incentive to utilize PDTs and uncertainty in provider reimbursement.

Path Forward:
- Increased transparency on pilot programs and publication of clinical and financial outcomes may positively impact the adoption of behavioral health DTx.
- Payers, manufacturers, and policy decision-makers should commit to a standardized evidence-generation "gold-standard" to ensure appropriate digital therapeutics adoption without the need for extensive, repetitive pilot studies for each payer or health system.

References: 1) PitchBook Database; 2022 [cited Oct 5 2022] 2) Whitelaw S, Pellegrini DM, Mamas MA, Cowie M, Van Spall HGC. Barriers to and facilitators of the uptake of digital health technology in cardiovascular care: A systematic scoping review. European Heart Journal - Digital Health. 2021 Feb 4;2(1), Pages 62–74, https://doi.org/10.1093/ehjdh/ztab005

Disclaimer: This study was funded by Otsuka Pharmaceutical Development & Commercialization, Inc

Presented at ISPOR Annual Meeting, May 7-10, 2023, Boston, Massachusetts