Data-driven Digital Therapeutics Analytics

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***Abstract*—Digital therapeutics (DTx), in contrast to traditional treatments such as pills, use software installed in smartphones or wearable devices as a medical device to cure diseases and improve health conditions, which represents a significant departure from existing wellness products such as Fitbits. DTx requires clinical validation of efficacy through systematic clinical trials, as do conventional therapeutics. Mobile DTx apps transform conventional treatment approaches such as counseling, self-help, and self-tracking into app-based micro-interventions that can be *delivered* via notifications, short videos, and chatbots. This article presents a data-driven DTx analytics framework for analyzing and optimizing DTx delivery processes in everyday life contexts by leveraging passive sensor data analysis and human-in-the-loop interaction support.**

***Index Terms*—Digital therapeutics, DTx Data Analysis, Proactive Engagement Management**

I. Motivation

In traditional drug delivery systems, it was easy to evaluate the effects of drugs in controlled laboratory environments. However, in the case of mobile DTx apps, it becomes challenging to evaluate and improve the efficacy of DTx, because patients use mobile apps to receive micro-interventions in an uncontrolled daily environment [1]. Since typical clinical trials only look at differences in endpoints (e.g., patients' weight for weight management), it is non-trivial to examine which intervention components of the mobile DTx app were used and how they made the differences in the endpoints. Not surprisingly, such information in practice is essential for DTx improvement.

Another critical issue is how to keep DTx users involved during clinical trials or field deployment since users often stop using and leave the DTx apps. A recent review paper found that the average dropout rate in past clinical trials was about 43% [2]. This indicates that managing user engagement is also very important. Beyond just visualizing how user engagement changes over time, data-driven techniques such as availability and engagement forecasting may help proactively (thereby preemptively) manage and facilitate user engagement efficiently.

II. Data-Driven DTx Analytic Frameworks

This article extends the existing framework for DTx delivery optimization [3] by considering both context/causal analysis and proactive engagement management.

A. Context Analysis and Causal Inferences

Data-driven DTx analytics examines DTx mechanisms (e.g., goals and strategies) and the intervention contexts of a user (e.g., user traits and environments). Here, the context of an intervention includes both personal and contextual factors. An existing behavior change model for Internet-delivered interventions [4] considers (1) user characteristics (such as disease states, demographics, traits, beliefs and attitudes, physiological factors, and skills), (2) intervention experiences (such as user preferences, perceived burdens/fatigue, and habituation), and (3) intervention environments (such as personal, professional, and community aspects). This contextual model can be expanded using existing context representation models for ubiquitous computing, where mobile, wearable, and Internet-of-Things (IoT) devices are used to enable context-aware services [5]. Human factors (e.g., a user's cognitive and affective states, social environment, and tasks) and physical environments (e.g., location/place, lighting condition, and temperature) are examples of additional contextual information. User self-reports and machine-learned inferences from passively collected sensor data can be used for modeling the intervention context.

As the gold standard for clinical evaluation, a randomized controlled trial (RCT) aids in determining the efficacy of a newly developed digital intervention as opposed to the conventional method. However, it is difficult for RCTs to identify the most influential contextual patterns and intervention mechanisms. During RCTs (or even real deployments), passively collected sensor and interaction data can be used for contextual and causal analysis. Contextual analytics facilitates the exploration of contextual factors associated with DTx usage, such as lifestyle (behavioral routines), intervention contexts, and psychological states of the user (e.g., emotion and stress) during the intervention period. Causal analytics (counterfactual inference) aid in determining how individual intervention components and user engagement impact behavioral adherence (*i.e.,* proximal and distal outcomes).

B. Proactive Engagement Management

The treatment effect cannot be properly achieved if a user's DTx engagement declines over time [2]. It is advantageous to determine at what point or under what circumstances the user's engagement rate decreases, as well as in which user group (e.g., demographic information, symptom severity, and

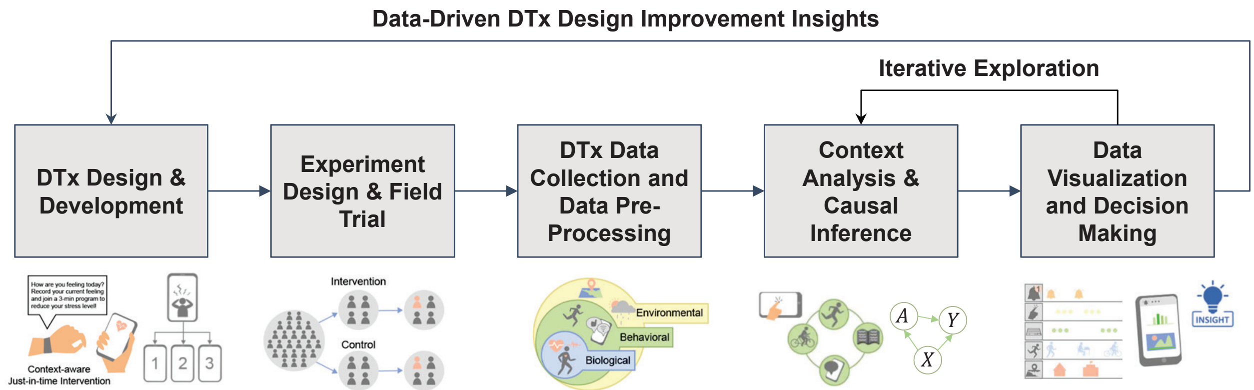

Fig. 1. Data-Driven DTx Analytics: Context Analysis and Causal Inferences

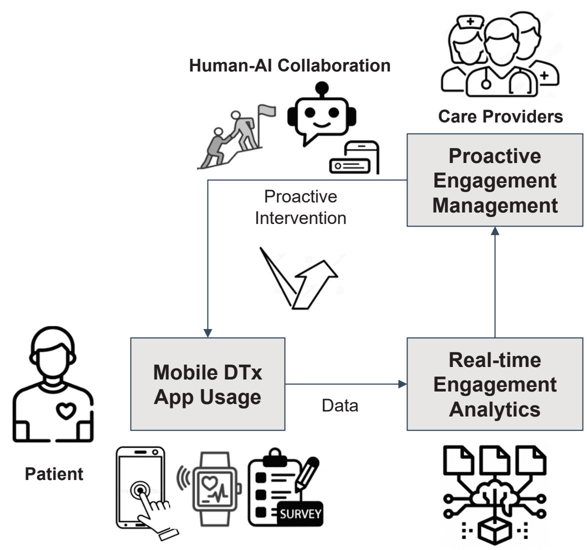

Fig. 2. Proactive Engagement Management

content preference), this phenomenon occurs [6]. Furthermore, it is necessary to classify the engagement according to the severity of the symptoms because the intervention content and the level of DTx usage should be customized according to the severity, as with the standard drug prescription dosage.

Managing user engagement can be further enhanced by differentiating the management strategy (e.g., in-app messaging, interactive agents, and human care coaches) based on the types of user groups and engagement patterns. When human resources such as care coaches are scarce, we can rely on a multi-level strategy to manage the engagement of a large number of DTx app users effectively. In other words, the engagement management of DTx app users is conducted through the collaboration of a human care coach and an artificial intelligence (AI) agent. The humbot structure [7], in which humans and AI collaborate to provide services, can be implemented. Through interactions and passively collected sensor data, AI learns the preferences and availability of DTx app users and care coaches. AI-Mediated Communication (AI-MC) strategies [8] can be used to automate care coaches' repetitive engagement management tasks that can be easily handled by the agent (e.g., requesting missing self-report data). AI agents can naturally take over control from a human coach in response to changes in engagement level. Overall, human-AI collaboration is expected to reduce the human workload.

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