Digital twins: hype or hope for better health outcomes?

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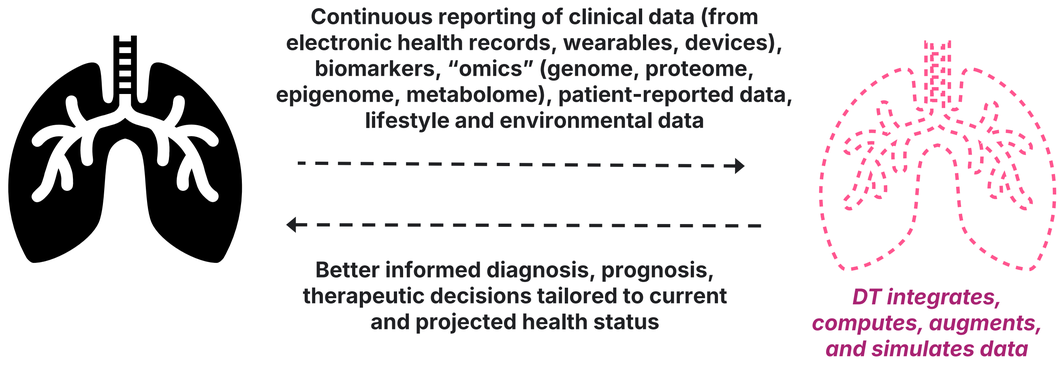
Introduction

- Digital twins (DTs) are complex systems involving physical and virtual models that exchange information in real time. Not just virtual copies of a system, DTs are sophisticated models with analytic and predictive abilities,[1] often harnessing the Internet of Things, cloud computing, artificial intelligence (AI), and virtual reality (VR).[2] Medical DTs consist of five key components: a patient (or part of the body), patient-in-silico, data connection between the physical and virtual patient, an interface, and digital twin synchronization[3] (Figure 1).
- DTs are widely used in the manufacturing, aerospace, and automobile industries. Rapid development in the healthcare and pharmaceutical industries is facilitated by the availability of large amounts of health data, advances in cybertechnology, and continuous development of AI.[1,4] However, some existing AI and mechanistic models have been re-labeled as DTs, diluting the true impact of DTs for patients.[3]

Figure 1: **Example digital twin model**



Objectives

- To identify the current and potential uses of DTs in the healthcare and pharmaceutical industries.
- To consider the key benefits and challenges of DT use/implementation.

Methods

- A targeted literature review was conducted to identify current and potential uses of DTs in healthcare.
- Google and PubMed were searched to identify relevant published and gray literature. Searches used combinations of the term "digital twins" with "healthcare," "health," and "pharma." Articles published in the past 5 years and in the English language were considered for analysis.
- Categories of DT use reported in the literature were identified, and the key benefits and challenges of implementation were considered.

Results

- Within the past five years, the concept of DTs has been increasingly explored in literature; the publication volume was negligible in 2016, with a consistent upward trajectory to over 400 publications in 2023.[1,4]
- The potential uses of DTs in healthcare vary widely and fall broadly into two categories: "clinical applications" and "operational applications."[5] Clinical applications directly involve patients through modeling parts of the body or diseases with a clear direct impact on health, while operational applications indirectly benefit patients through system planning, hospital management, and care coordination, even digital twins of doctors themselves.[1,6] (Figure 2)

Figure 2: **Potential uses of DTs in healthcare**

Clinical applications

- Optimizing treatment pathways
- Personalized care/precision medicine
- Patient prognosis and diagnosis
- Predicting disease evolution
- Disease or organ models to predict treatment/medical device effect
- Clinical trials (*in silico* design, patient selection)

Operational applications

- Hospital management and care coordination
- Surgical planning
- Digital twins of doctors
- Biomarker and drug discovery
- Pharmaceutical manufacturing

DTs have been applauded as the pathway to precision medicine[4] or personalized medicine[7], transforming patient-centered care through more effectively involving patients in care decisions and better-informed diagnosis and treatment,[8,9] particularly as DTs evolve alongside the patient.[3]

One of the most prominent areas of existing DT use was in clinical trials through "in silico" design.

Research projects exploring DTs to support patient outcomes are already in progress, with more than 20 trials registered.[10]

DTs can support preclinical to pivotal trials by simulating how a treatment may work on a specific pathway, dosage or formulation adjustments, and predicting how patients with specific characteristics or comorbidities may respond.[1,11]

DTs have many reported benefits in clinical trial design, including:[1,7,9,11-13]

- More cost-effective drug development
- Reduced control arm sizes while reflecting real-world diversity
- Shorter trial duration with higher certainty of evidence for drug approval
- Generating a larger evidence base for efficacy and safety data
- Overcoming recruitment barriers, eg, in rare diseases or for patients with comorbidities typically excluded from trials
- Reduced exposure to ineffective or harmful treatments, particularly in pediatric populations.

Figure 3: **Challenges impacting feasibility and wider uptake of DTs**

Amount, quality (accuracy, completeness), and type of **data inputted into the model**
Data frequently have gaps and biases

Data privacy and security
Including data ownership and control

Complexity of models
Real-time synchronizing of multiple sources of accurate, patient-specific data and large quantities of data must be computed

Access to data and **data management**
EHR are heterogeneous and difficult to inter-operate

Trust in AI applications and liability for decision-making

Ethical and societal concerns
Consent, patient autonomy, and confidentiality

Lack of clear, harmonized guidance on use of computer-generated evidence despite regulatory and HTA agencies supporting innovative trial design

Adapted from: 1,2,4,5,7,9,14

Conclusions

DTs have the potential to revolutionize the pharmaceutical and healthcare industries, resulting in better health outcomes for patients through realizing the promise of personalized medicine, optimized treatment pathways, and *in silico* trial designs.

Excitement over innovation must be weighed against costs, the complexities of the human body, and inherent data quality issues. Inaccessibility of existing data, bias in datasets, and trust in AI may be the first hurdles for the uptake of DTs.

Although DTs are starting to be used in clinical trials, how payers will consider the use of DTs during pricing and reimbursement decision-making is unclear and creates more questions than solutions.

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