The Monitor Intervene Predict Value Framework: A Structured Approach to Demonstrating How Digital Health Can Improve Health Outcomes and Reduce Burden of Illness

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Major hurdles will need to be overcome if digital health is to deliver value for all stakeholders (eg, patients, payers, physicians, pharmaceutical companies, and diagnostic/digital device/software developers)

Value attribution will become increasingly important for informing who should pay or be paid (reimbursed), how much, for what, and when

These issues need to be addressed if multi-element "personalized" approaches (involving both digital and genomic technologies) are to enhance the efficiency of healthcare delivery and make disease management more effective

Digital health, by linking patient-level real-world/real-time data–sourced through digital monitoring, interventional disease management, and predictive analytics, together with precision medicine/biomarker informed treatment–is likely to improve economic, clinical, and humanistic outcomes

Healthcare is evolving rapidly. Last year, ISPOR published its "2022-2023 Top 10 HEOR Trends."[1] These included using real-world evidence in healthcare decision making, value assessment to inform value-driven healthcare decisions, artificial intelligence, and advanced analytics. Complementary research[2] undertaken by Ipsos indicates that healthcare is becoming more "connected" with multiple components (eg, digital patient-level, real-world/real-time monitoring; software, algorithms, and apps informing interventions; analytics predicting outcomes; and genomics/biomarkers informing therapy choice) In the future, value will increasingly be delivered by multicomponent disease management rather than by drugs or interventions in isolation.

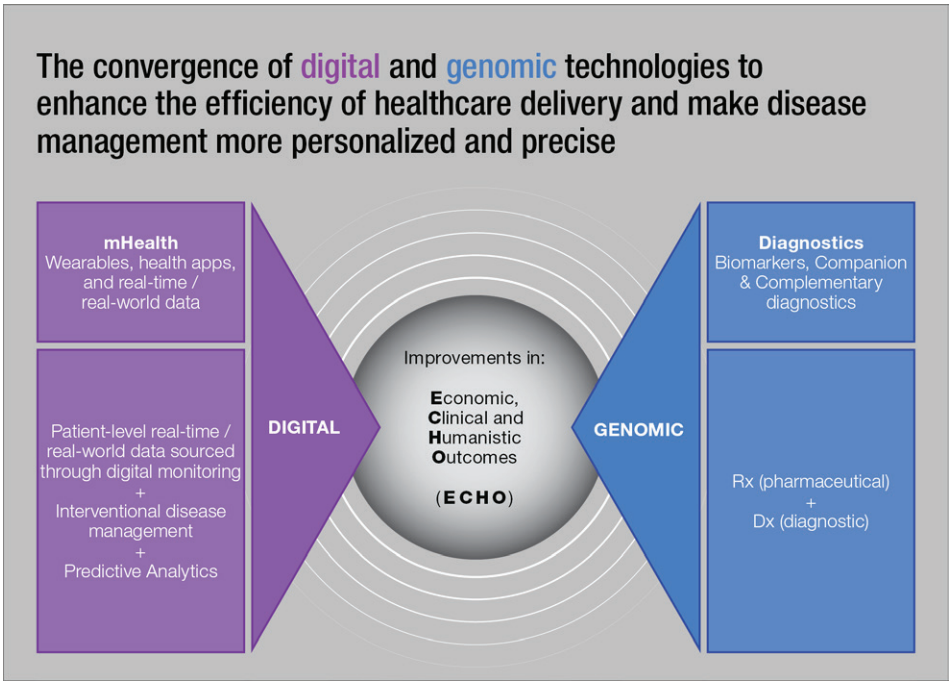
The gradual evolution and fusion of biomarker-informed disease management (eg, genomics/proteomics with companion and complementary diagnostics indicative of disease or treatment response), real-time informed disease management (eg, digital health technologies and wearables), and intelligent smart disease management (eg, advanced analytics, software, algorithms, and artificial intelligence), with all components having both diagnostic and predictive elements, is opening up opportunities to enhance the efficiency and effectiveness of healthcare delivery by making treatment more personalized and precise (**Figure 1**).

This will create challenges for value, price, and health technology assessment and will require new approaches to value evidence generation and value attribution. Of increasing interest are digital health technologies addressing monitoring, intervention, and prediction (see left-hand side of **Figure 1**).

The first challenge surrounds speed of evolution

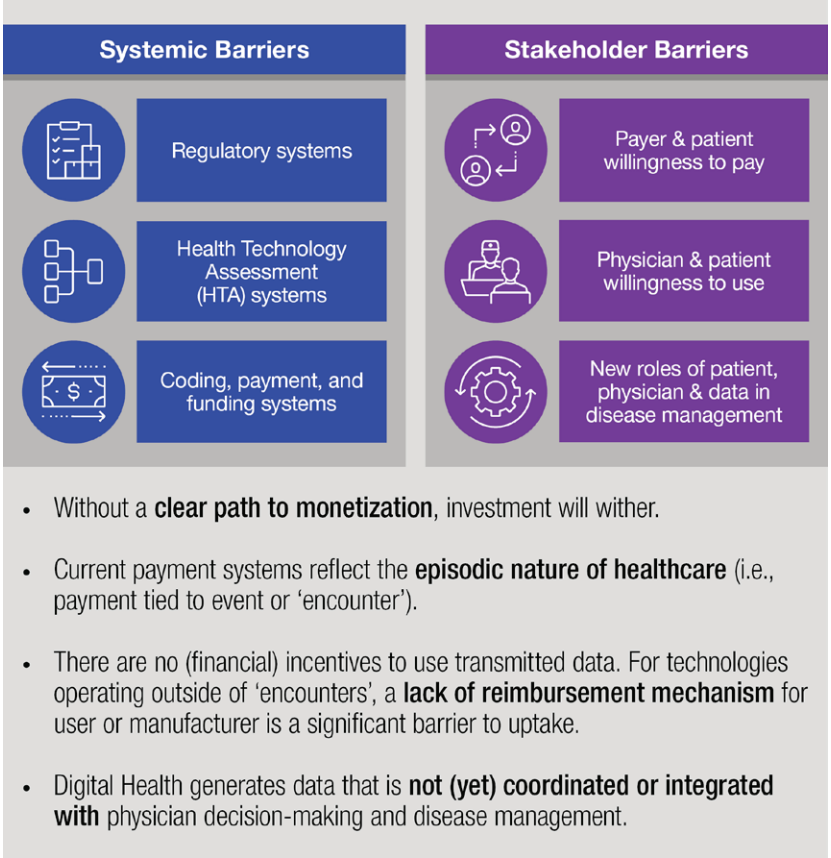
Technology is evolving faster than the regulatory, behavioral, healthcare funding, and health technology assessment (HTA) systems that are required for successful implementation.

Figure 1. The convergence of digital and genomic technologies



For digital health to deliver on the promise, developers will need to produce relevant robust evidence regarding the technology for assessors; systemic changes will be required in regulatory and HTA assessment systems; the roles of the physician and data in disease management, payment systems, and the pricing of healthcare will need to change (**Figure 2**).

Figure 2. Barriers to delivering the promise of digital and genomic technologies



The second challenge surrounds evidence

There are various challenges to evidence development in this environment, including:

- relevance, robustness, and rigor
- difficulty and cost of evidence development
- timeliness of evidence delivery
- continued validity of evidence in a rapidly evolving environment
- measurement and attribution of codependent value between developers of the different disease management components

Evidence development will increasingly depend on input from all stakeholders. Responsibility will, however, depend on the nature of the challenge. Funding of evidence development (fully or in part) may be the responsibility of the manufacturer, whereas attribution of value (linked to reimbursement) may be the responsibility of the payer.

One approach to delineate how much or what kind of evidence is needed is to apply a functional classification of digital health technologies. Classifying digital health technologies by function allows them to be stratified into evidence tiers (typically A, B, C). The evidence level needed for each tier is proportionate to the potential risk to users from the digital health technologies in that tier.

Under current NICE guidance[3] in England, for example, the evidence tiers are as follows:

- **Tier A: System impact**
  - — system services: digital health technologies with no measurable patient outcomes but which provide services to the health and social care system
- **Tier B: Understanding and communicating**
  - — inform: provides information, resources, or activities to the public, patients or clinicians; includes information about a condition or general health and lifestyle
  - — health diaries: includes general health monitoring using fitness wearables and simple symptom diaries
  - — communicate: allows 2-way communication between citizens, patients, or healthcare professionals

The most relevant to future digital/wearable technologies, **Tier C involves monitoring, intervention, and prediction elements**. Tier C interventions typically include:

- preventive behavior change: address public health issues like smoking, eating, alcohol, sexual health, sleeping, and exercise
- self-management: allows people to self-manage a specified condition; may include behavior change techniques
- treatment: provides treatment; guides treatment
- active monitoring: using wearables to measure, record, or transmit data about a specified condition; uses data to guide care and intervention
- calculation: a calculator that impacts treatment, diagnosis, or care
- diagnose: diagnoses a specified condition; guides diagnoses
- prediction: indication of the likelihood of an event occurring based on monitoring and intervention

For Tier C interventions, best-practice evidence standards include:

- high-quality interventional study which incorporates a comparison

group, showing improvements in relevant outcomes, such as:

- **patient-reported outcomes** including **symptom severity** or **quality of life**
- other clinical measures of **disease severity or disability**
- healthy **behaviors** and physiological measures
- **user satisfaction and engagement**
- health and social care **resource use**, such as admissions or appointments.

There are, however, limitations and barriers for success to this approach. For example, a reluctance to develop evidence by the manufacturer of the digital health technologies, which may be caused by issues of feasibility, affordability, and risk. In addition, a reluctance of the healthcare system to adopt and fund the digital health technologies, which may be caused by issues of infrastructure. Current payment systems reflect the episodic nature of healthcare (ie, payment tied to an event or "encounter"). For many digital health technologies that operate outside "encounters," there is no mechanism to reimburse the user or the manufacturer.

The third challenge involves the assessment and attribution of value

Value frameworks are becoming increasingly useful and important for structuring the value of multicomponent disease management. Although traditional payers still focus on economic, clinical, and humanistic outcomes, they anticipate that—driven by advances in digital health and a shift in costs and healthcare responsibility onto patients—this will need to evolve with value being analyzed in different ways[4]:

- **value contribution** of 3 different elements: Monitoring, Intervention, and Prediction, MIP paradigm
- **value segmentation** based on 3 outcome types: Economic, Clinical, and Humanistic
- **value perception** based on 3 stakeholder groups: Patient, Payer, and Physician
- **value attribution**, informing value-based reimbursement allocation, will become increasingly important as multiple stakeholders (eg, drug, diagnostic, and device manufacturers; software and app developers) become involved in more holistic disease management. This will be needed to inform who pays/is paid (reimbursed), how much, for what, and when.

Payers see value in all elements of the MIP paradigm but see potential ethical, legal, and regulatory challenges emerging from an intervention element that is driven by automated analytic algorithms/machine learning/artificial intelligence, rather than "traditional" healthcare provider-driven decision making. Ethical and legal challenges may arise from the question of where responsibility lies for the consequences of decision making around interventions such as dosage or therapy change. Regulatory challenges may relate to the balance between risk and benefit.

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