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Balancing Innovation and Safety When Integrating Digital Tools Into Health Care

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Experienced observers hope that digital tools, such as software applications, personal sensors, and new types of data and data analysis, will stimulate innovation in health care delivery. They also hope that this innovation will change the way we diagnose and treat many diseases (1). We believe that now is the time to consider how to introduce these new tools into care safely and effectively.

Not all digital tools will require careful scrutiny. For example, fitness trackers and other applications that help people maintain healthy lifestyles are unlikely to require evaluation when used for educational purposes or to support personal goals, such as weight loss. However, protections are appropriate when applications alter the diagnosis or treatment of disease. The following 3 examples meet this description.

Example 1 is a dashboard that displays personal information about an inpatient on a screen in the hospital room and on caregivers' computers. The dashboard aims to make recovery goals visible to all. It shows daily schedules for tests and procedures and reminders about such activities as when to use an incentive spirometer. To produce these insights, the program takes information about the patient's demographics, medical history, clinical diagnosis, and care plan from the electronic health record and aggregates it with data collected from the patient. In this scenario, although risks to patients seem low and the effect on providers' work seems small, patient privacy and data security outside the hospital are key considerations.

Example 2 is a pharmacogenomics service that provides personalized recommendations for medication dosing according to genetic test results in a patient's hospital records. The program requires information similar to that in example 1, but genetic test data from institutional records must also be shared with the external service. This raises greater concern about privacy and security because genetic information is highly sensitive. Recommendations from the service might also disrupt physicians' ordering practices or contribute to alert fatigue. Moreover, evidence for dosing related to genetic variants is evolving rapidly, so updates may lead to higher maintenance costs for this program over time.

Example 3 is a service that recommends and monitors lifestyle changes for an outpatient with hypertension, prompts the patient to schedule clinic visits, and advises the clinician when to review the patient's treatment program. The service requires information about medical history, race, body mass index, serum creatinine levels, history of medication refills, and home blood pressure values. It analyzes these data to create recommendations, which it returns to the patient and care team in the health system's electronic health record. Some observers believe that this service is an example of the desired future for digital tools, but it also represents a very-high-risk model. The data requirements are substantial and complex, and the algorithms are often proprietary or are based on scanty evidence about safety and efficacy. Because the decision support is relatively "invisible," patients and providers may not notice errors quickly. Finally, if the service becomes unavailable because of technical or other problems, providing a backup service will be difficult and costly.

Our 3 examples illustrate key principles. A digital tool for health care requires scrutiny when it is intended to alter a patient's diagnosis or therapy as a standard part of care and, in the course of doing so, must interact with electronic health records to provide decision support to clinicians or patients. We suggest that such tools be evaluated by groups with specific key competencies. The existing model is pharmacy and therapeutics committees (2), which evaluate drugs and traditional biomedical devices. These committees can be modified to accommodate unique aspects of digital health tools in a new type of organization that we would call a "digital diagnostics and therapeutics committee."

Digital tools evolve rapidly (3, 4) and are unlikely to be supported by evidence from preclinical trials now or in the future (5). To ensure patient safety, digital diagnostics and therapeutics committees will need to include experts who can make judgments without rigorous validation data. In addition to clinical risks and benefits, such judgments may include the risks for bad clinical information, conflicting information, system inefficiencies, and provider distraction. As outlined in example 3, the risk for unexpected problems increases as tools become more automatic and less transparent. Next, to ensure adequate protection of data, committees will need information technologists, specialists in data privacy and security, and those who understand legal and regulatory issues. Third, to determine feasibility, these groups will need members who can evaluate costs. In today's financial situation, new tools will have to produce clinical or financial improvements that offset the considerable expenses associated with maintenance, upgrades, and replacements when vendors go out of business. Perhaps most important, the process should include plans for evaluation—either before implementation (in pilot studies or testing in simulated settings) or through careful postimplementation monitoring. Such local evaluation efforts will likely replace formal evaluations by the U.S. Food and Drug Admin-

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istration, although they are concordant with postmarket surveillance activities being considered (5).

Understanding the competencies and skills needed to maintain patient safety while accommodating the rapid adoption of novel digital health tools is an important first step in aligning the opportunity such tools provide with the need to preserve and enhance health care value and provider work. We believe that health systems, providers, and patients have good reason to be optimistic, and we anticipate that innovation in digital health tools will be transformational for all. This full potential will be met when we embrace these innovations locally, examine the risks and opportunities involved, and commit to continuous evaluation of the tools in practice.

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References

1. **Lewis ZH, Lyons EJ, Jarvis JM, Baillargeon J.** Using an electronic activity monitor system as an intervention modality: a systematic review. BMC Public Health. 2015;15:585. [PMID: 26104189] doi:10.1186/s12889-015-1947-3

2. **Tyler LS, Cole SW, May JR, Millares M, Valentino MA, Vermeulen LC Jr, et al; ASHP Expert Panel on Formulary Management.** ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. Am J Health Syst Pharm. 2008;65:1272-83. [PMID: 18589893]

3. **Mandl KD, Kohane IS.** No small change for the health information economy. N Engl J Med. 2009;360:1278-81. [PMID: 19321867] doi:10.1056/NEJMp0900411

4. **Shuren J, Califf RM.** Need for a national evaluation system for health technology. JAMA. 2016;316:1153-4. [PMID: 27398696] doi:10.1001/jama.2016.8708

5. **U.S. Food and Drug Administration.** Software Precertification Program Model. 2017. Accessed at www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM577331.pdf on 1 February 2018.

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