mHealth apps are mobile device applications intended to improve health outcomes, deliver health care services, or enable health research. The number of apps has increased substantially, and more than 40,000 health, fitness, and medical apps currently are available on the market. Because apps can be used to inexpensively promote wellness and manage chronic diseases, their appeal has increased with health reform and the increasing focus on value. The bewildering diversity of apps available has made it difficult for clinicians and the public to discern which apps are the safest or most effective.

The US Food and Drug Administration (FDA) has paid close attention to mHealth apps, because it has regulatory authority over their safety. The agency recently clarified that mHealth apps acting as medical devices or as accessories to medical devices will require FDA approval, whereas apps that provide users with the ability to log life events, retrieve medical content, or communicate with clinicians or health centers will not be regulated under its jurisdiction. For example, an app that tracks glucose levels and suggests insulin dosages would be regulated, whereas an app that tracks a patient's weight and makes general suggestions about exercise would not. In general, apps that provide precise treatment recommendations and diagnostic information will receive more regulatory attention. Although the FDA has focused on safety, it has largely left the review and certification of apps to the marketplace.

The currently available reviews of mHealth apps have largely focused on personal impressions, rather than evidence-based, unbiased assessments of clinical performance and data security. Although evidence-based reviews are not extensively available for mHealth apps, they are available for other categories of health information technology software. For instance, KLAS has successfully made a business out of producing report cards on the quality of health information technology vendors and enterprise software packages, presumably simplifying the lives of hospital leaders. This model has worked for enterprise software because users of expensive software are seemingly willing to fund unbiased reviews. However, this approach appears unlikely to work for mHealth apps because users of free and inexpensive apps are less financially invested in their decisions than hospitals. Furthermore, certification may be problematic in mHealth because certification companies ordinarily aim to generate revenues by charging the app developers they are evaluating—an inherent conflict of interest. Thus, there is a need for alternative models for app review and certification that are sustainable and free of conflict of interest.

However, given the sheer number of mHealth apps, it is unlikely that all will ever be meaningfully reviewed by a single organization. As a start, an organization could feasibly review the quality of the most widely used and clinically useful mHealth apps. Furthermore, guidelines could be established to help developers build high-quality apps and to serve as a basis for app review. The guidelines might include a broad range of categories, such as safety, accuracy, and security. By telegraphing these guidelines, as well as standardized approaches to achieving them, the organization will be able to influence mHealth app developers early in their planning process, enabling them to build their apps with these principles and a review process in mind.

App review organizations would likely need to include in their reviews a certification process to ensure that apps do not pose potential harm to their users or have significant security and privacy vulnerabilities. Certification entities in other industries are successfully protecting people from harm. For instance, the Health On the Net Foundation, a nonprofit, nongovernmental organization, plays an active role in evaluating the quality of online medical content and provides websites a certification that assures both consumers and clinicians of the accuracy of the medical content. Similarly, Underwriters Laboratories is a well-respected for-profit entity that provides meaningful but optional information that consumers can use to evaluate the safety of electronic devices. In mHealth, the startup Happtique began certifying the operability, privacy, security, and content of apps but ultimately suspended its operations after a developer discovered that 2 certified apps handled data insecurely. The attention that Happtique received suggests that many people consider the security of mHealth apps to be important and want them to be evaluated rigorously. From these cases, it appears that both nonprofit and for-profit certification are viable means of improving the quality of low-cost and free consumer products and services and that there is demand for mHealth apps to be certified. The Office of the National Coordinator for Health Information Technology (ONC) could help support the development of mHealth app guidelines and eventually commission app certification entities, as it is now doing for electronic health records (EHRs).

Another important role for app review organizations is illuminating the effectiveness of mHealth apps. Although more rigorous evaluations are needed across all mHealth, many apps share components (eg, reminders, logging, pedometer). Evidence for these common features might be cited in app reviews. For example, because countless apps use smartphone-based accelerometers as makeshift pedometers, it would be helpful to highlight that evidence suggests that pedometer-based walking interventions are associated with an average weight loss of 0.05 kg per week. Greater focus on outcomes may shift the focus of app develop-
ers to populations with the greatest medical needs—eg, chronically ill patients and elderly persons. The mHealth Training Institute of the National Institutes of Health is educating an interdisciplinary group of researchers about the potential for mHealth interventions to improve health and the need for robust evaluation. If this effort is coupled with increased funding for mHealth research, it may help galvanize a larger body of evidence to inform mHealth app development and certification.

As the popularity of apps increases, clinicians may wish to prescribe apps and to access the clinical insights apps generate. Many apps today collect data that could help inform patient care and medical decision making, but they fail to do so, as a result of how the data are presented and shared. Although it is difficult for a clinician to adjust an insulin regimen if shown hundreds of entries in a digital food diary, meaningful decisions might be facilitated if the information were shown as a summary report and integrated with the patient’s EHR. The development and use of standardized vocabularies and interfaces for data storage and reporting could make apps even more valuable tools in patient care. The ONC could support the development of these mHealth data standards to facilitate data integration with EHRs.

Although the mHealth app industry is still in its infancy, its future looks bright. With more rigorous certification criteria and unbiased accrediting bodies, clinicians and consumers could be more confident in their selection and use of mHealth apps. In a few years, the notion of a physician prescribing apps might no longer seem far-fetched. However, the potential of apps will only be realized if patients and clinicians trust apps, if apps are known to be effective, and if apps can communicate securely and meaningfully with EHRs and personal health records. Establishing an unbiased review and certification process is a key step in helping mHealth apps achieve their potential.

ARTICLE INFORMATION

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Powell reported receiving personal fees from mHealthCoach and Verbal Applications, outside the submitted work; these companies offer app-based solutions for care coordination and patient-clinician communication. Dr Landman reported that he developed 2 mobile health apps: ClinCam and NFC e-MAR. ClinCam was funded by the Brigham and Women’s Hospital (BWH) Health Information Technology Innovation Program and allows clinicians at BWH to securely capture and transfer clinical images to the patient’s electronic medical record. NFC e-MAR is a prototype app allowing nurses to perform electronic medication administration reconciliation (e-MAR) on a tablet using near field communication (NFC); this project was funded by the BWH Biomedical Research Institute Translatable Technologies and Care Innovation Grant. Dr Bates was supported in part through the Libretto Consortium, sponsored by the Gordon and Betty Moore Foundation, and reported receiving personal fees from Medicalis, outside the submitted work; receiving patent royalties from Medicalis for radiology decision support software; chairing the FDASIA workgroup, which has advised the Food and Drug Administration, Federal Communication Commission, and the Office of the National Coordinator on the regulation of health care information technology including mobile technology, and serving as a member of the Health Information Technology Policy Committee.

Additional Contributions: We thank John Halamka, MD, MS (Beth Israel Deaconess Medical Center), for his advice on this article. Dr Halamka received no compensation for his contributions.

REFERENCES


