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Perspective

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Mobile apps for real-world evidence in health care

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ABSTRACT

The use of real-world evidence for health care research and evaluation is growing. Mobile health apps have often-overlooked potential to contribute valuable real-world data that are not captured by other sources and could provide data that are more cost-effective and generalizable than can randomized controlled trials. However, there are several challenges that must be overcome to realize the potential value of patient-used mobile health app real-world data, including data quality, motivation for long-term use, privacy and security, methods of analysis, and standardization and integration. Addressing these challenges will increase the value of data from mobile health apps to inform real-world evidence and improve patient empowerment, clinical management, disease research, and treatment development.

Key words: real-world, evidence-based practice, mobile applications, telemedicine, US Food and Drug Administration

INTRODUCTION

The role of real-world evidence (RWE) in health care is growing. The 21st Century Cures Act permits the U.S. Food and Drug Administration (FDA) to allow the use of RWE instead of randomized controlled trials (RCTs).[1] The FDA defines real-world data (RWD) as "data . . . from electronic health records (EHRs), claims and billing data, . . . product and disease registries, patient-generated data . . . and . . . other sources that can inform on health status, such as mobile devices."[2] RWE is the analysis of these data to assess the use, benefits, and risks of products, medications, and interventions.[2]

RCTs are the gold standard in health care research. They allow causal inferences and control for potential sources of bias, providing strong evidence of effectiveness.[3] However, RCTs are expensive and time-consuming. More worryingly, because of strict eligibility conditions, their conclusions often fail to generalize to real-world populations.[4] Patients whose multiple prescriptions, comorbidities, age, or disease severity make them "outliers" are often excluded from RCTs.[3] Therefore, the study population does not necessarily reflect the intervention's target population. Efficacy in a controlled sample does not necessarily imply real-world effectiveness. These concerns have increased focus on the potential of RWD to provide more efficient, cost-effective, and representative evidence.[3,5]

RWE COLLECTED THROUGH MOBILE DEVICES

Electronic health records (EHRs) and claims data are currently the primary sources of RWE.[6] However, mobile apps have the potential to collect a wide variety of data on patients' daily experiences and decision motivations that are often missing in other sources of RWD.[6,7] There are many mobile health apps that track patient data or help consumers change health behaviors. These apps can also collect active and passive sensing and task-based data to measure daily activity and mental state, physiological status, and performance on physical or cognitive tasks.[8]

RWE from patient-used mobile apps can help evaluate the safety, effectiveness, and satisfactoriness of medical interventions in a more representative sample at a lower cost, and monitor symptoms, behaviors, and quality of life to improve patient care and reduce strain on medical services.[6] These consumer-focused mobile health apps could provide valuable RWD to inform research and patient care. However, there are several challenges in the use of mobile health apps for RWE that must be overcome before this potential value can be realized.

Table 1. Relevant laws and regulations relating to the safety, effectiveness, data protection, and privacy of mobile health apps and their data

Country	Law/regulation	Covers
United States	Health Insurance Portability and Accountability Act (HIPAA)[27]	Data security and privacy of health information, health information breaches
United States	Federal Food, Drug, and Cosmetic Act (FD&C Act)[28]	Safety and effectiveness of medical devices (includes some mobile apps)
United States	Federal Trade Commission Act (FTC Act)[29]	Privacy, data security, validity of claims about safety and effectiveness
United States	Federal Trade Commission's Health Breach Notification Rule[30]	Personal health information breaches
Europe	General Data Protection Regulation (GDPR)[31]	Data protection, privacy, sharing of personal data outside the European Union/European Economic Area
Europe	Medical Device Regulation[32]	Safety and effectiveness of medical devices (includes some mobile apps)
United Kingdom	Data Protection Act 2018[33]	Data protection and privacy

CURRENT USE OF MOBILE RWE

The FDA is evaluating the use of RWD to provide evidence for drug approval and postapproval studies, support clinical trials, and develop decision-support tools for clinical practice, primarily using EHRs, patient registries, and claims data.[9] Mobile health apps are also collecting a wide variety of RWD on patient health.[10,11] However, data quality is not consistent. Validated questionnaires are available for measuring patient-reported outcomes such as quality of life, abilities, symptoms, health behaviors, and quality of care.[12,13] PROMIS (Patient-Reported Outcomes Measurement Information System) contains validated questionnaires that have already been integrated with EHRs.[14] However, many apps adapt these questionnaires or develop their own without validation. Objective measures also need further data validation—step count and blood pressure data vary in accuracy and precision depending on the app or sensor being used.[15–17]

There have been steps toward purposefully using patient-generated mobile health data in research and improving integration between platforms. Apple's HealthKit collates health data from various apps, wearables, and EHR platforms. Since HealthKit's release, Apple has also developed ResearchKit and CareKit—open-source frameworks for building apps to help researchers recruit patients and help patients manage their health conditions.[18,19] A study of the app Asthma Health demonstrated that data shared with a pulmonologist could be effectively used to identify and address deviations from patients' norms.[18] This type of access for health care professionals (HCPs) can improve patients' quality of life and reduce clinic and emergency visits, reducing the strain on those services.[18] Standards are being developed to improve interoperability, notably the Fast Health care Interoperability Resources Specification, which aims to integrate EHRs and other RWD across a variety of systems.[20,21] Patient-powered research networks are another driver of improvement of mobile health apps for RWE.[22] ArthritisPower is one example of these patient-guided registries that uses a mobile app to collect standardized patient-reported data more frequently than could be done at a clinic, but there are similar patient-powered research networks for many different chronic conditions.[6]

REGULATION OF MOBILE HEALTH APPS

Regulation of mobile apps depends on whether they are considered medical devices, and many are not.[23–25] The FDA defines mobile medical apps as "[accessories] to a regulated medical device [or apps that] transform a mobile platform into a regulated medical device."[24] However, even mobile medical apps are not regulated if they are considered low risk.[25,26] There are also a number of federal laws that address data privacy and security (see Table 1).[34] The FDA and other regulatory agencies are working to update certification guidelines and processes for mobile medical apps.[35]

Regulation is similar in the EU, with comparable conditions on what makes software a "device"—being an accessory, influencing treatment, or being used for diagnosis.[36] These apps must meet the standards of the Medical Device Regulation, which applies to Europe and the United Kingdom,[37] although this may change after Brexit.[38]

BENEFITS OF MOBILE HEALTH APPS FOR RWE

Apps empower patients to take an active role in managing their health, and their RWD contribute to the development of diagnostics, preventions, and treatments. This RWE is valuable for patients in the short term and long term because it aids self-management, clinical care, and the improvement of treatments. For clinicians, mobile health app RWD can provide a more comprehensive picture of a patient's condition and allow timely interventions. Economically, this can reduce clinic appointments and emergency visits by addressing issues early. RWD from mobile apps can provide payers (eg, insurance companies) more demographically specific information on effectiveness, safety, and value that can inform risk-benefit and payment calculations.[39] It can also help governmental agencies and medical companies with postapproval monitoring and regulation of new treatments.[39]

For research, health app RWD are valuable because they provide more representative and realistic evidence without the time and monetary costs of an RCT. The ubiquity of mobile phones and the relative low cost of apps makes them a feasible, inexpensive way of collecting a lot of data. However, to be valuable, these data need to be high quality and standardized so that there can be interoperability between different sources of RWE in clinical care and research.

CHALLENGES FOR MOBILE RWE

The first challenge in using mobile health apps to collect RWD is an issue of purpose. Many health apps are not designed for research, which can affect data quality—a primary concern of patient-generated data. To be useful in research and health care, data need to be collected using valid and reliable measures.[7] This is a challenge for mobile health apps because many variables rely on self-reports that are vulnerable to missing data and reporting and recall biases.[6,7] Sensing measures are subject to technological failure or

variability, and task-based measures depend on the user correctly performing the procedure.[8] Additionally, as with all mobile apps, maintaining long-term use is a challenge but is crucial to provide valid longitudinal data. Patients will also be unlikely to consent to these data being used for research without confidence that their data are private and secure.[8] Most app users have concerns about privacy and data security and want to know how their data are being accessed and by whom.[40] These concerns are justifiable; a recent study found that health apps share data similarly to other apps, and some of the apps analyzed shared sensitive and potentially identifiable data that were vulnerable to access for commercial purposes.[41] There is little regulation of the quality and effectiveness of mobile health apps that are not considered medical devices,[26] and another study found that only 20% of apps examined were considered medical devices and therefore subject to regulation.[23]

Even if these problems are addressed, there is a lack of methods available to analyze the data concisely and comprehensibly so that it can be used by researchers, HCPs, and patients.[8] Standardization, so that data from different sources can be integrated, is essential to make mobile health app RWD useful. This requires standardized

Table 2. Summary of the challenges of using mobile health apps for real-world evidence

Challenge	Problem	Potential solutions
Intended purpose	Many mobile health apps are not designed to collect data in a way that is useful for health care and research	• Involve medical and research experts in app development process
Data quality	Lack of validated and reliable measures through mobile health apps	• Use previously validated questionnaires • Test validity and reliability of newly developed questionnaires before use • Further studies to validate sensor data • More transparent reporting of how data were collected, so validity can be accurately evaluated
Privacy and security	Lack of patient trust and willingness to share data	• Provide clear explanations of what information is being collected, who it is being shared with, and how it is being secured • Provide an easy way to let patients consent to and control this data sharing over time • Better technological security within apps for sensitive patient data
Methods of analysis	Data are overwhelming and difficult to use in research, in clinics, and by patients	• More research into improving methods of analyzing and visualizing the types of real-world data collected by mobile apps
Standardization and integration of data	Real-world data cannot all be combined and assessed as a whole	• Standardize methods of collecting and reporting data so that data can be shared • Further develop infrastructures that allow integration of electronic health records, mobile health app data, and research databases
Health equity	Use of mobile health apps is weighted toward younger, more educated, and more e-health–literate people	• Design app interfaces for older users with less technological experience • Address privacy concerns, particularly for apps focused on reproductive health and other sensitive medical issues • Target nontypical health app users to increase uptake and data representativeness • Use purposeful sampling and appropriate statistical analyses to improve representativeness of real-world evidence in studies
Regulation of mobile health apps	Little regulation of mobile health apps that are not classified as "medical devices" with potential risk to public health	• Design an international system of regulation of the quality and effectiveness of mobile health apps that are not regulated by the Food and Drug Administration, Medicines and Health care products Regulatory Agency, or other national bodies
Long-term use	Loss of motivation to keep using a mobile health app	• Provide something of value that will motivate patients to continue use (eg, useful information about their health, specific behavior changes that could improve health, transfer of information to health care professionals for better treatment, a clear link between data and research) • Easy-to-use apps that integrate into their daily lifestyle • Personalizability of app features and availability of goal setting for health improvement
Integration into established routines	Lack of understanding of how new technology can best fit into existing workflows	• Innovation in methods of assessing user needs to account for the amount and variety of patient-generated data • Account for the context and established systems of all stakeholders when designing new or adapting current mobile health apps for real-world data collection

reporting and interoperability between digital platforms, which are by no means universal features of apps.[42] Additionally, older, less educated, and less e-health–literate people are less likely to use health apps in general, although they were more likely to use vital sign tracking apps.[43] To successfully use mobile health apps for RWE, the needs and contexts of all different groups of users must be considered. This will require integrating these new technologies into established frameworks for patients, HCPs, researchers, and other stakeholders.[44] These challenges are summarized in Table 2.

Other sources of RWD share many of these challenges.[45] For instance, EHRs, one of the main sources of RWE, are designed to record clinical interactions and aggregate data from other sources. However, much of the data collected are unstructured and incohesive.[46] These challenges—intended purpose, standardization, and integration—are similar to those described for mobile health apps. However, because the intended purposes and data collection and analysis structures of apps and EHRs are different, solutions to each will need to be specifically tailored.

IMPROVING MOBILE HEALTH APPS FOR RWE

Health care is beginning to transition toward a value-based system that pays providers according to patient outcomes. Value-based health care will depend on technology to evaluate costs and outcomes from an individual to a population level and must sufficiently address privacy and security concerns.[47] Mobile health apps are well suited to contribute to a value-based system because of their potential to cost-effectively collect a variety of RWE and integrate with existing systems. However, to achieve this potential, the challenges identified regarding data quality, privacy and security, analysis, standardization, and interoperability need to be improved.

The standards mobile health apps must meet to be valuable for RWE can be extrapolated from the challenges identified. To collect high-quality data, health apps should be purposefully designed for research data collection.[48] This includes the use of valid and reliable measures and the clear reporting of how data were collected so that quality can be accurately evaluated.[7] Mobile health apps for RWD also need to be convenient and easy to use; have strong privacy, anonymity, and security features; and provide motivation to maintain engagement and data reporting.[8,49] For patients, this could include supporting health behavior changes, improving communication with HCPs, and personalizing apps to suit their needs; for HCPs, this could include improved data analysis to deal with the abundance of data.[50] Apps must also address the specific needs of different demographic groups to improve the representativeness of the RWE.[43] Finally, to contribute to the body of RWE from other sources—such as EHRs, genomics, and claims data—health app data should be reported in a standardized and comprehensible way and integrated into existing databases.[8]

CONCLUSION

The potential of mobile health apps for RWE is great but currently unrealized. To be valuable sources of RWE, mobile health apps need to meet a variety of standards that differ depending on the user. Patients want control over their data and their health and observable benefits of participation. HCPs can benefit from reduced time and monetary burdens, as well as more data that can improve care. For research, the amount and variety of data and participants that can be studied at a low cost are valuable for understanding diseases and developing new interventions. To be beneficial in these ways, data need to be high quality and able to integrate with other systems, methods of collection need to be reported, mobile apps need to be easy to use and provide a benefit to the user, methods of analysis need to produce a clear and concise interpretation of a large amount of data, and privacy and security of sensitive information must be guaranteed. Striving to meet these standards, and adopting regulatory policies that ensure that they will be met even from mobile apps that are not classified as "medical devices," will vastly increase the value of mobile health apps for RWE.

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AUTHOR CONTIBUTIONS

EM conceived the article topic. MM-I drafted the initial article, which was subsequently revised by EM and MHvV. MM-I redrafted the article following feedback. MM-I responded to peer-review feedback under supervision of EM and redrafted the article.

CONFLICT OF INTEREST STATEMENT

None declared.

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