Digital Health Tools and Mobile Applications in Healthcare

Shriya Das

Introduction

The appropriate selection and utilization of technology in healthcare facilitate patient enrollment, trust, and willingness to participate in the study. Moreover, the current challenges in the successful recruitment of participants also include difficulties in reaching the participants. This comprises ethnic and racial minorities, geographic disparities in access to healthcare, and underrepresentation of minorities in pandemic settings. (1) Over the past several years, digital health technologies and mobile applications have allowed the exponential growth of health applications as well as the utilization of healthcare services. The increase in access to digital technologies in recent years has served as a nidus for approaches to counter challenges to the utilization and adoption of technology. (2)

In traditional settings, patient recruitment and participation in healthcare are subjected to logistical and financial hindrances. The evolution of the use of digital health tools in healthcare has allowed for data acquisition, remote patient monitoring, digital phenotyping, and the development of precision medicine strategies. (3) Mobile health applications and digital health tools are also useful in reducing the overall costs of healthcare. These tools are also crucial to feedback provision in order to enhance the efficacy of clinical trial interventions. (4) Nonetheless, digital health technology is a transformative force that drives improvement in efficiency, accuracy, and patient engagement in healthcare. There are several key areas where digital health tools and mobile applications can be applied to clinical trials.

The main objectives of this review are to comprehensively explore the role of digital health interventions in enhancing patient engagement, optimizing data collection, and evaluating the overall impact of these interventions on healthcare. Additionally, this review will examine the regulatory considerations involved in the deployment of digital health tools, addressing compliance with data protection and healthcare regulations. Through this review, the authors seek to provide a thorough understanding of the current landscape, highlight the benefits and challenges, and offer recommendations for future research and implementation strategies in the domain of digital health in healthcare.

Development and Deployment of Health Applications

Patient Engagement

During recent years, the research investigators, clinical research sponsors, and other stakeholders have worked on introducing novel

solutions to improve the recruitment, engagement, and satisfaction of patients. With the establishment of the coronavirus disease 2019 (COVID-19) pandemic, the interest in technology development and its integration into healthcare has spiked given the role of these technologies in remote patient monitoring in healthcare. (5) Moreover, the interventions also increase the adherence of participants to the intervention but also increase the efficacy of the clinical trial intervention by increasing patient engagement. (6) Digitally enabled studies provide the added benefit of facilitating higher quality and more efficient data collection of the trial participants, allowing closer engagement with the patients. An increase in patient engagement also allows for reducing patient burden and enhancing the data sets of healthcare. (7)

Patient engagement driven by the use of digital health tools and mobile applications further mediates patient engagement and compliance in drug healthcare. Electronic monitoring technologies refine the quality and accuracy of adherence data. This can be achieved by the dissemination of daily reminders, review of patient data, patient counseling for compliance with the trial intervention, and data review. Access to real-time data also allows for better patient outcomes, ultimately, enhancing their engagement and compliance. (7)

Data Collection

Mobile health applications are a great tool for user data collection and several measures can be undertaken in order to ensure adequate privacy and security of this data. The data that can be transmitted to the physicians includes the medical history of the patients, biometric data, and the list of pharmacologic agents. By facilitating data collection and exchange of information, digital health tools and mobile health applications allow improved physician decision-making processes. (8) Electronic patient-reported outcomes and other relevant digital health tools are crucial to improved patient-physician communication, treatment monitoring, and informing patient care. By contributing to patient-centered care, digital health tools and mobile health applications enhance the accessibility and generalizability of research in clinical settings. (9)

Wearables and sensors are becoming increasingly popular in the field of clinical and biomedical research. These tools can be utilized for several purposes including monitoring, screening, detection, and prediction of health-related participant outcomes. (10) Wearable bioaffinity sensors mediate the detection of biomarkers in body fluids. This data can be extracted via a smartphone dock, allowing real-time diagnosis. (11) The portable and wearable devices allow the systematic acquisition of data and biological measurements for monitoring health-related activities, which can further guide recommendations and treatment-related decisions. (12)

Evaluating the Effectiveness of Digital Health Interventions

The pharmacological and non-pharmacological clinical trials utilize digital health technologies for patient engagement, home- and telehealth visits, healthcare applications for data collection pertaining to patient-reported outcomes, wearable and portable devices, and patient screening and recruitment on the basis of electronic health records. (13) Clinical trials and other forms of research designs can measure the attribution of digital health tools and interventions based on the usability, efficacy, cost, and effectiveness of these interventions. (14) The evaluation and appraisal of digital health interventions and mobile health applications involves defining certain research questions and also taking into consideration the opinions of the authors. Moreover, the benefits of digital health interventions in clinical research can be assessed by understanding the nature of the problem and evaluating whether the intervention addresses the problem. (15) Compared to randomized controlled trials, observational studies provided a greater quantity of reliable evidence to demonstrate patient-related outcomes and patient satisfaction with digital health interventions and mobile health applications. (16)

The different digital health interventions and tools described in the existing medical literature include web-based patient health records, asthma management electronic health tools, mobile health applications for continuous patient care, electronic health educational tools, mobile phone-based prevention programs, and telemonitoring. (17,18) The digital health tools allow progress monitoring and reminders for treatment-related goals. (19) For instance, mobile health applications such as the applications connected to wearable blood glucose meters allow obtaining high-frequency data and improve patient adherence to self-monitoring and self-management practices. (20)

There are several barriers to the implementation of digital health tools and mobile health applications. The most common hindrance is inadequate patient engagement, leading to reduced utilization of digital health tools. Studies have indicated that individuals who are more frequent users of digital health tools and mobile health applications tend to experience better patient-reported outcomes compared to individuals with a low utilization rate of tools and interventions. Other challenges to the adoption of these interventions and tools in clinical trials include the lack of participant and physician motivation, time constraints, poor training, and inadequate physician engagement. (17)

Regulatory Considerations and User Experience Design

Regulatory Considerations and Participant Compliance

The traditional regulatory practices are not sufficient to facilitate the integration of digital health interventions and mobile health applications in healthcare. This results in the emergence of regulatory challenges, which shall be addressed in order to keep pace with the current trends in

technology. The advancements in the field of digital health technology are supported by the US Food and Drug Administration (FDA) and the European Medical Agency (EMA) for regulatory decision-making. The organizations have devised several strategies to facilitate regulatory acceptance in order to include digital health tools in clinical trials and permit the use of acquired data in the trial. The measures undertaken by the FDA in the US to improve regulatory acceptance include the drug development tools (DDT) qualification pathway, the investigational new drug (IND) pathway, and the critical path innovation meetings pathway. The measures undertaken by the EMA to promote the acceptance of digital health tools and mobile health applications in healthcare are the innovation task force training and scientific advice during different stages of the drug development program. (21) The Health Insurance Portability and Accountability Act (HIPAA) regulations are implicated in the protection of identifiable health information. (22)

In order to ensure compliance of the study participants with the mobile health applications and digital health tools and the transmission of information to the physicians and other stakeholders, the principal investigators should ensure compliance of participants with the health application development and utilization. (23) The Clinical Trials Transformation Initiative recommends ensuring compliance of the digital health tools with the state regulations and establishing a record-keeping protocol for further contributing to compliance. (24)

Process and Importance of Used-Centered Design of Digital Health Tools

User-centered designs and usability approaches are useful in the identification of issues and acquiring information pertaining to the experiences of the patients in order to ensure the quality of digital health tools and interventions in healthcare. (25) The notion of user-centered design implies that the study participants are involved in every phase of the clinical research and digital health intervention design process. The four stages of this process include the generation and ideation of the digital health intervention concept, the design, and development of the prototype, evaluation, and deployment of the tool. The implementation of this approach in the development of digital health tools and mobile health applications is pivotal to user engagement and the effectiveness of the intervention in improving patient outcomes and adherence. (26)

There are, however, several challenges to the implementation of user-centered design and the development of a digital health intervention. The development of a digital health tool is a time-consuming process and different interactive components of the mobile health applications and digital health tools require the assistance of software engineers. Moreover, the data acquired from patients can be subjected to data breaches since the general data protection regulations do not always apply

to data storage on digital platforms. Moreover, the complex process of the development of a mobile health application is subjected to time and financial constraints. The costs are dependent on the degree of complexity of the user interface, application functions, and the potential additional costs. Furthermore, digital health tools and mobile health applications are subjected to existing and potential technical problems, which primarily arise at the time of software updates, which prompts the availability of technical support to maintain the applications throughout the period of clinical trials. (27)

Emerging Digital Health Technologies and Mobile Health Applications

The integration of artificial intelligence and augmented and virtual reality enables reliable patient-physician communication for greater precision and efficient diagnosis. (28) artificial intelligence allows the development of precision medicine and digital health technologies based on a patient-centered approach. Moreover, the deployment of artificial intelligence tools integrated into mobile health applications and digital health interventions is significant for ensuring the compliance of participants with the trial protocols and maintaining the integrity of study outcomes. (29) The development and implementation of artificial intelligence-driven mobile health applications can mediate cost reductions and improve health management practices, ensuring prompt and early diagnosis, follow-ups, and tailored and personalized therapeutic approaches. The digital health applications can utilize machine learning algorithms for identifying the trends in health-related data, making health- and treatment-related predictions, and providing personalized treatment-related recommendations. (30)

Artificial intelligence-powered digital health interventions and mobile health applications can adopt machine learning algorithms to achieve different goals based on the objectives of clinical trials or other research studies. For instance, these digital health tools can be utilized to assess the changes in activities and behaviors and target the risk factors in the participant population. (31)

The development and implementation of computerized decision-making tools in tailoring digital health interventions provide support to the physicians and other stakeholders for the management and follow-up interventions. Compared to tools that are not facilitated by artificial intelligence and machine learning algorithms, digital health applications powered by artificial intelligence tend to demonstrate significantly greater improvement in patient outcomes. Machine learning-based predictive models can facilitate the development of mobile health monitoring systems for predicting intervention outcomes. Besides, these digital health interventions and mobile health applications allow for obtaining feedback from the participants in order to improve the quality of the intervention.

Predictive analytics also mediate the assessment of the risk of hospitalizing, aiding healthcare professionals in taking prompt and appropriate actions. The real-life digital health applications are useful in pharmacological and non-pharmacological clinical trials and have proved to be both useful and effective. (32)

Research Gaps and Interdisciplinary Collaboration

Despite the growing integration of digital health tools and mobile applications in clinical trials, several research gaps remain. Firstly, there is a need for more robust evidence on the efficacy and reliability of these technologies in diverse patient populations. Most studies to date have focused on specific groups, limiting the generalizability of the findings. Additionally, the long-term impact of digital health tools on patient adherence and engagement in clinical trials is not well understood, necessitating longitudinal studies. Secondly, issues related to data privacy, security, and ethical considerations in the use of mobile applications in clinical trials require a more thorough investigation to establish trust and compliance with regulatory standards. Lastly, there is a lack of standardized metrics and methodologies for evaluating the performance and outcomes of digital health interventions in clinical trials, making it difficult to compare results across studies and settings. Addressing these gaps through targeted research efforts will be crucial for maximizing the potential of digital health tools and mobile applications to enhance the efficiency, inclusivity, and quality of clinical trials.

Interdisciplinary collaboration in the development and implementation of digital health interventions is critical for creating effective and comprehensive solutions. The healthcare professionals ensure clinical insights and ensure interventions are medically sound and relevant to patient care. They also contribute to designing interventions for different health conditions and ensure that overall well-being is considered. On the contrary, technologists and engineers are responsible for designing and improving wearable devices and health monitoring systems. Interdisciplinary collaboration fosters innovative solutions that might not emerge within a single discipline. By leveraging the expertise of diverse professionals, it is possible to create innovative, user-friendly, and effective health solutions that improve patient outcomes and advance public health. (33–35)

Conclusion

The integration of digital health tools and mobile applications in clinical trials holds significant potential for transforming the landscape of medical research. The key future implications include enhanced quantity and quality of data to ensure more robust findings and more rapid identification of health trends and patterns. Mobile health applications and digital tools allow remote participation and increase the enrollment and

retention rates of participants in clinical trials. These tools further streamline the trial processes and counter administrative costs to make clinical trials more affordable and accessible. More importantly, the increase in the knowledge and utilization of digital health tools necessitates the updating of regulatory frameworks in terms of developing guidelines and ensuring data integrity, safety, and privacy.

This study provides several strategic recommendations to maximize the benefits and health implications of digital tools and health applications. These include the development of standards to ensure the consistency and operability of tools and mobile applications in clinical trials. The investigators and other stakeholders should also address the ethical concerns associated with data privacy, patient-informed consent, and digital equity among ethnic and racial minorities. By continuous evaluation and improvement of digital health tools and mobile health applications, the trial investigators can collect user feedback to address the issues.

Digital health tools and mobile applications are poised to revolutionize clinical trials, offering numerous advantages in terms of data quality, patient engagement, cost efficiency, and trial timelines. However, realizing these benefits requires careful planning, collaboration, and adherence to ethical standards. By embracing technological advancements and fostering an ecosystem of innovation and cooperation, the clinical trial industry can advance toward more efficient, inclusive, and effective research methodologies, ultimately leading to better healthcare outcomes for patients worldwide.

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