Time to Have Effective Regulation of the Mental Health Apps Market: Maximize **Gains and Minimize Harms**

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apidly increasing smartphone ownership among the majority of the world's population and increasing internet penetration through relatively cheaper mobile data usage plans have led to the development and popularization of various mobile applications (apps).¹ These apps are third-party software apps that utilize mobile and/or other related devices' hardware (e.g., wearable sensors, such as a smartwatch) along with or without internet communication technology and enable users to perform a wide range of different tasks related to varied fields, such as trade, commerce, education, entertainment, or health, through their smartphones. The increased levels of psychological distress in the population and the disruption of traditional mental health services during the COVID-19 pandemic have widened the mental health treatment gap that already existed even prior to the onset of the pandemic.² Additionally, there is significant stigma attached to mental-health-treatment seeking, especially in low- and middle-income countries.3 The culmination of these different factors has provided a fertile ground for



the mushrooming of mobile health apps for mental health disorders and wellbeing.⁴ People advocating the use of mental health apps (MHapps) often describe the potential of these apps in delivering mental health services discretely to people living in even remote and rural locations,

in turn reducing the huge mental health treatment gap. Also, MHapps could help increase the effectiveness of traditional mental health treatments by assisting people in self-monitoring of symptoms of mental disorders (early detection and initiation of treatment) and improving adherence to treatment (e.g., sending

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reminders for taking medication, helping in scheduling follow-up with a psychiatrist). Furthermore, the potential of MHapps in promoting healthy lifestyle practices and building resilience among the general population (primary prevention) has been acknowledged by various researchers.5 India has the second-largest number of smartphone and internet users globally, with more than two-thirds of India's total internet traffic contributed by mobile phone users.6 Thus, the potential market for MHapps is huge and merits careful examination. The advantages of increased accessibility, affordability, convenience, anonymity, and immediacy offered by MHapps make a compelling case for widely using them to meet the population's mental health needs.7 However, a careful evaluation of the claimed benefits and potential risks associated with MHapps is a must prior to recommending their use.8 In this paper, we discuss concerns and challenges associated with the use of MHapps and provide suggestions for addressing some of them.

Equivocal Evidence for the Effectiveness

The available literature suggests that although more than 20,000 MHapps are currently available to consumers, less than 5% of them have any empirical research studies backing their claimed effectiveness.9 This is also reflected by the relatively small number of MHapps available to treat mental health problems (e.g., depression and anxiety) being actually approved by the Food and Drug Administration.10 Moreover, a recent metareview of seven meta-analyses assessing the efficacy of MHapps for treating any mental health problems suggested that the available evidence was of poor quality and did not provide support for recommending them as a standalone treatment to the general public.11 However, studies on MHapps for the treatment of anxiety and/or depressive symptoms were of moderate to high quality and reported small-to-medium effect sizes. Furthermore, the use of MHapps for guidance and adjunctive treatment was more effective than the standalone use of MHapps for self-management. It also pointed out the need for more quality studies prior to recommending the use

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of MHapps for different mental health disorders/symptoms. There is a need to conduct double-blinded randomized control trials (RCTs) assessing the efficacy of MHapps with an active control arm (a sham app version is used) instead of waitlisted controls to control for the digital placebo effect and have follow-up assessments to see the longterm impact of MHapp use. In theory, an ideal sham app would appear similar to the test app but lack active components of intervention delivered through the test app in such a manner that the participants remain blinded to their allocation group status. For example, the sham app used in an RCT assessing the efficacy of an MHapp (which used principles of cognitive behavior therapy) for the treatment of depression-delivered placebo intervention using the same digital format as that of the test app (e.g., the psychoeducation section elaborated on common-sense strategies for overcoming depression, such as positive thinking or listening to music; only a sticky notes tab was provided in the exercise section, providing participants with an option to add content).12 Similarly, another RCT testing the efficacy of a digital game designed to improve symptoms of attention-deficit hyperactivity disorder in children used a sham game (as control) that matched the test game on expectancy, engagement, and time on task domains in the form of a challenging and engaging digital word game. The sham game targeted cognitive domains that were not primarily associated with attention-deficit hyperactivity disorder and were not targeted by the test game.¹³ However, it could be challenging to design appropriate sham apps for control groups for certain types of MHapps, such as those delivering yoga-based treatment or simply claiming to provide symptom tracking or monitoring feature. In such scenarios, an active control arm (e.g., aerobic exercises instead of yoga) or nonplacebo controls (e.g., waitlisted arm, treatment-as-usual group) could be used. Finally, an independent group of researchers (and not app developers) should evaluate the efficacy of MHapp in a sham-app-controlled trial among different groups (e.g., nonclinical vs. diagnosed mental disorder) and models of usage (e.g., standalone treatment vs. adjunctive treatment).

Inconsistent or Inadequate User Engagement with MHapps

The degree of user engagement with MHapps is one of the most crucial factors mediating their success in realworld settings. The available literature suggests that most people quickly lose interest and stop using mobile apps just after three days and uninstall them within a week of downloading.^{14,15} This is likely to be applicable to MHapps being used by people without any recommendation or collaboration from mental health professionals. A sustained good user engagement (e.g., adequate duration and/or frequency of use) is a prerequisite for any MHapp to be effective in alleviating mental health problems. Furthermore, how successfully a person can understand the instructions or suggestions provided in the app is also an important determinant of user engagement. Thus, researchers have recommended that developers should focus on developing MHapps with simple and intuitive user interfaces (e.g., user-experience design methods), not include tasks or instructions requiring high cognitive load (e.g., using pictures and shorter sentences), and utilize gamification and usage reminder strategies to increase user engagement.16

Privacy and Data Safety Concerns

There is a lack of transparency related to the data collection, storage, and sharing practices followed by different MHapps. A survey of MHapps available in the app store revealed that more than 50% of them did not display a privacy policy for people to read before downloading the app.¹⁷ Even when a privacy policy was provided, it was often written in a language with a much higher reading grade difficulty than that of an average layperson and often included technical terminology and legal language, which was difficult to comprehend for users.18 Thus, informed consent from users about how their sensitive personal data are handled and shared with third-party companies or institutions is often not sought in the true sense. Importantly, most health app (including MHapp) developers consider collecting and selling personal data for commercial purposes as an essential part of their business model.¹⁹ A recent study reported that 33 of the 36 top-ranked (by app store ratings) MHapps for depression and smoking cessation shared user data with third-party commercial organizations, such as Google and Facebook. Only about half of them disclosed this in their privacy policies.20 Furthermore, there is often no information about how this personal information collected through MHapps would be shared and/or used by third parties. The data collected through MHapps could be combined with data obtained from other sources through the use of unique digital identifiers (e.g., the mobile number entered for MHapp registration and the mobile number provided for securing a Facebook account) and in turn help in collating and creating a comprehensive customer or user profile without their explicit knowledge or consent.²¹ This could lead to targeted advertising, causing increased distress (e.g., people with mental health problems being bombarded with tailored mental health treatment options online) and even discriminatory practices against people with a history of mental health problems (e.g., personal information about mental health status used to populate predictive algorithms for making decisions about employability).²² Another potential area of concern involves the quality of encryption used by MHapps to store and transmit sensitive personal data of users. A study had reported that most health and wellness apps listed as clinically safe and trustworthy at the UK National Health Services (NHS) Health Apps Library did not use any encryption to protect the personal information of the users while storing or transmitting it online, making users vulnerable to hacking and online frauds.23 This also led to the subsequent shutdown of the NHS Health Apps Library for some time. Thus, there is a need to have uniform minimum data safety standards for MHapps. At the same time, the general public and mental health professionals need to be made aware of the potential risks to privacy while using MHapps. In a recent study exploring the views of general people and health professionals in India

about using MHapps, both the groups expressed concern about their data safety and privacy.24 Furthermore, the policy of linking the unique identity number (i.e., Aadhaar) with digital health records as a mandatory requirement to avail benefits under a government program for tuberculosis and Acquired Immunodeficiency Syndrome (AIDS) resulted in a significant proportion of beneficiaries to drop-out, possibly because of the fear of unintended breach of privacy and sharing of sensitive health-related information and subsequent discrimination.²⁵ Both these health conditions are considered highly stigmatizing, like mental illness, in Indian society. Hence, privacy and data safety issues are likely to be an important area of concern while adopting the use of MHapps as well among the Indian population.

Special Considerations for Using MHapp in the Indian Context

The limited available literature qualitatively exploring the transcultural differences in uptake and response to mobile-delivered digital mental health interventions in the Indian context points out some encouraging similarities and important differences from the western context.^{24, 26} The majority had a positive response toward the use of MHapps for a multitude of things, such as seeking reliable information related to the mental health disorder symptoms, its treatment, and practical aspects (e.g., help in accessing local resources, such as ambulance or legal services); self-monitoring of symptoms; or providing reminders for taking medications and doing daily routine activities (e.g., selfcare-related tasks). However, most of the Indian users endorsed the use of MHapps as complementary and not substitutive to direct therapeutic care provided by mental health professionals. Focus group discussions with potential user groups (e.g., patients and caregivers) and service providers (e.g., psychiatrists and counselors) in India have shown that "self-help" is not a culturally congruent concept for the majority of Indian adolescents, with most of them reporting a preference for direct instruction from parents,

teachers, and other elderly. Furthermore, a significant proportion of participants reported a preference for apps with offline support or functioning, because of the lack of uninterrupted access to highspeed mobile internet.27 Importantly, the need for the use of simple language (e.g., regional language support, having the text written at a readability difficulty level of up to sixth grade) and concrete examples to explain concepts around psychological-theory-driven therapy delivered through mobile apps or games has also been highlighted for improving relatability and engagement among the Indian population.27-29

An overwhelming number of MHapps currently available in India fall short of providing customized content relevant to a majority of people in India, especially those from lower socioeconomic backgrounds and/or those with little or no knowledge of the English language. ³⁰ There is a need to have MHapps with an option to provide support in multiple regional languages commonly used in India (e.g., Hindi, Marathi, and Tamil). Furthermore, as most of the currently available MHapps have been created in Western developed countries (e.g., USA and UK), the creators use situations such as feeling lonely at a cocktail party to contextualize the mental health problem(s) and/or present potential solutions, which are less likely to resonate with the majority of the Indian population.³¹ There is a need to have MHapps with content presented in a manner that is in sync with the cultural norms of the Indian population and customizable to the life situations (e.g., a housewife living in rural India or a young man working in a metro city) of the person using the app.

Possible Harms with MHapp Use

There is a lack of clarity about the authorship of content available on many available MHapps. It is not clear whether any mental health expert or people with experience of living with mental illness or problems were involved in the development of the MHapps. The references for scientific evidence supporting the usefulness of interventions or self-management strategies delivered through MHapps are often not provided

for users to read or confirm in case of doubt.¹⁷ Furthermore, content analysis of MHapps available for helping people with mental illness (e.g., bipolar disorder) or substance use disorders revealed that many of them contained information or features that could be potentially harmful to the users.^{32,33} Similarly, MHapps that provide self-monitoring or self-assessment tools for mental health problems might wrongly diagnose people with mental health disorders and lead to wrong or unnecessary mental-health-treatment-seeking behaviors. This is even more problematic if we consider the loss of money and resources because of this at the population level.³⁴ For example, a person with normal stress could be misdiagnosed as having depression and start taking treatment by using a paid MHapp or seeking treatment from a health care provider and unnecessarily burden the existing limited resources. Importantly, most of the MHapps currently available are not adequately equipped to help people in crisis situations, such as a person with suicidal ideations. A recent study reported that only about one-third of the top MHapps assessed provided crisis-specific resources in their app interface.35 Similarly, a study that systematically assessed the MHapps for depression management and suicide prevention available in Google Play and Apple's App Store reported that only about 7% of them incorporated all six suicide prevention strategies commonly recommended in the standard international clinical guidelines.³⁶ Finally, users might also be at risk of developing a problematic smartphone use disorder because of excessive use of MHapps to manage depression and/or anxiety.^{37,38} Critically, the issue of adequate understanding of the possible risks associated with the use of MHapps by young children and adolescents under the age of 18 years and their ability to provide valid consent by using the "I agree" option provided at the time of downloading MHapps are some of the other important ethical and legal dilemmas associated with their use.

The app description available at the app stores or information provided on websites by app developers is akin to advertising and tends to maximize the number of downloads for the MHapp.

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Often, unrealistic claims about the efficacy of MHapps are made in order to encourage people to download them.¹⁷ Furthermore, many MHapps describe symptoms of mental disorders as synonymous with adverse life events or stressors of modern-day living and suggest the use of MHapps by everyone to improve their mental health. This might promote medicalization of normal stress and excessively shift the responsibility of attaining and/ or maintaining mental health onto the individual himself/herself.39 MHapps repeatedly encourage users to manage their symptoms of psychological distress themselves and put undue stress on them for not being able to use the MHapp better. This might also lead to neglect of other important socioeconomic determinants of mental health (e.g., adequate housing, food security, employment, and education opportunities) and shift the responsibility for maintaining mental health from the government and other welfare organizations to predominantly the individual.¹⁷

MHapps might also paradoxically increase inequality in mental health service delivery by excluding certain groups of people in society. For example, older adults might not be comfortable using mobile apps and are less likely to avail care through MHapps.⁴⁰ Similarly, a vast majority of MHapps available in the market do not support use by people with disabilities (e.g., visual or physical impairments). Also, most MHapps currently available in the market are in English and do not support the functionality in local or regional languages (e.g., Hindi, Tamil, etc.). Furthermore, people from lower socioeconomic status and other vulnerable population groups (e.g., homeless people) are less likely to have easy and uninterrupted access to a personal smartphone with internet access. Thus, the widespread and predominant use of MHapps for delivering digital mental health services would exclude certain sections of society and increase inequality in mental health care.41 There is a need to develop MHapps with features that enable usability by different groups of people and promote diversity. These include steps like providing features such as talkback to support voice- and/ or touch-assisted functioning for people with disabilities, providing the option to modify or customize MHapp features as per the need of the user (e.g., regional language support, option to have a virtual trainer with preferred gender or ethnic background of the user), among others.

The Way Forward

There is a need to increase public awareness about possible harms associated with improper use of MHapps and the use of poor-quality ones. People with mental illness should be educated about safe online practices while using MHapps, to reduce the risk of online fraud. The available literature supports the promotion of steps such as creating curated health app libraries, developing mechanisms for postmarketing quality assessment, and having a central repository for easy reporting of any harms or adverse events experienced by users of MHapps, to guide the market forces toward the development of apps with good credibility and usability.42 Although several tools and assessment frameworks are available for quality assessment of MHapps, most of them are relatively complex, require downloading and trial use of the MHapp, and are designed keeping in mind the mental health professionals or experts. However, there is also a need to educate consumers about things to check when selecting an MHapp for download and precautions to keep in mind while using them.43 In this regard, based on the authors' own professional experience and review of relevant literature, we have provided a nonexhaustive list of things the general public should consider prior to downloading the MHapp as an onlineonly appendix (see supplementary file).

There is also a need to have a greater number of evidence-based MHapps with proven safety and efficacy, similar to the scientific standards set for approving other available mental health treatments (e.g., cognitive behavior therapy or a new medication for a mental disorder). However, the fast pace of new app development (in weeks) compared to the time required to generate quality evidence supporting its efficacy (in months) and the rapidly changing nature of the MHapp market make it difficult to have evidence-based quality apps.⁴⁴ Thus, there is a need to develop consensus upon newer frameworks for assessing and ensuring the quality of MHapps.⁴⁵ Recently, some Western countries have taken welcome steps in this regard. Examples include the United States of America Food and Drug Administration's software precertification program focusing on assessment of the quality of processes and practices followed by health app developers rather than the app itself ⁴⁶ and the release of National Safety and Quality Digital Mental Health Standards by the Australian Commission on Safety and Quality in Health Care to improve the quality of digital mental health services (including MHapps) and to protect service users from possible harm.⁴⁷ However, there is still no framework or regulatory body in several countries (including India) to oversee the quality and data privacy practices of the MHapp market. Similarly, there are no international or widely accepted minimum standards to guide health and wellness app developers. The potential benefits offered by MHapps are promising; however, there is an urgent need to involve all the stakeholders (MHaap developers, mental health experts, people with mental health problems, and data safety experts) in the development of minimum standards and regulatory framework for improving the quality of MHapps and reducing the risk of possible harms associated with MHapp use.

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