Problems with the Regulation of Mobile Mental Health Apps: Contrasting Developed and Developing Countries with Special emphasis on India

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Abstract
Mental health Apps can be seen as intangible formulations of visually directed care discharging vectors maintaining emotional and mental health. They are centered around interdisciplinary perspectives of technology, psychological support delivery, clinical healthcare and communication. However, what challenge the rightful implementation of mobile mental health technology are its weak regulations globally. The following paper seeks to review the problems around the loopholes pertaining with these weak regulations, contrasting developed and developing countries, with special emphasis on India. This paper aims to contribute towards the advancement in understanding the curation of regulated mobile mental health apps by all its stakeholders (healthcare professionals, mental health experts, developers, regulatory bodies etc.) through exploration of the issues and weaknesses in their regulation and thus help in showcasing the need to create opportunities for regulated future apps, by suggesting few recommendations that improve health outcomes for app users and the benefits the society.

Keywords: Mental health Apps, regulations, psychological support delivery, clinical healthcare, mobile mental health technology

1. Introduction

1.1. Mobile Mental Health Apps:

We outline mobile mental health apps as technical coded/software applications constructed to impart and/or support mental health and well-being through the use of mobile devices such as smartphones and tablets. Mobile mental health apps target a broad range of psychological issues in various settings with function and design based on use of the app [1]. They offer anonymity, convenience, cost-effectiveness, support, accessibility, consistency, and ease to user. Mobile mental health apps have been classified through several ways. One way of doing that is by dividing them into six categories, based on what the app claims to do. These include: self-management apps, training of skills cognitive improvement oriented apps, apps directing social support, apps tracking symptomatology, and apps used for data collection passively [2]. Their typology can range from simple tools that provide relaxation techniques, tracking for example, emotion to other apps that impart motivational support. While there are also more complex ones like the apps that relay therapy and support through licensed mental health professionals. These apps can either be managed by the user all by themselves (self-management) or be aided by a professional. Curating technology that can foster self-management of the symptoms related to mental health may help people/users by motivating them to direct a more active participation in their well-being, along with enhancing the accessibility of resources related to mental health delivery [3]. Mobile phones are widely used by all people including the ones experiencing mental health issues [4] and they find it easily accessible to take use of their phones so as to explore treatment opportunities [5]. The market penetration for mental health apps is increasing every year. In 2023, it was valued more than $6 billion and has been growing at a ‘compound annual growth rate’ of more than 15% and by the year 2027; it might be a valuation of more than $11 billion [6]. The accessibility and wellbeing outcomes of digital technology, including mental health apps, may be influenced by dispositional demographic and usage factors, such as social and economic background, individual motivations underlying the use of mobile mental health apps, perceptions of how useful the app may be, and preferred use of mobile technology [7,8]. We suggest that such factors help segregate the differences in reasons behind usage of mobile mental health apps in developing and developed countries and throw light on the implementation of the regulations of mobile mental health apps across nations. A point to note is that despite these apps being handy, innovative and useful, no matter what typology they may have, the fact that they are poorly regulated or the compliance to regulation remains flawed is a cause of concern around mostly all nations. We support the cause and the need for the establishment of universal guidelines which regulate the ethical use of mobile mental health technology across the globe. Health apps do not respect national boundaries, which is one reason why international collaboration between academics and policy creators might be beneficial [9].

In this paper, we attempt to review the issues, challenges and difficulties associated with regulatory failures/loopholes associated with mobile mental health apps providing an insight on how regulation enforcement can help solve these problems and build sustainable future apps. A contrast between developing and developing counties as to what regulations they have, for the use of mobile mental health apps, specially discussing the regulatory policies in India will help understand the need for growing markets in healthcare to use technological aids for the benefit of the society.

The review protocol for the analysis can be seen as more integrative in nature, as it needed to be comprised of both experimental and theoretical studies along with an analysis of ongoing policies governing mobile mental health technology to understand and draw conclusions with greater overall comprehensive understanding of technology based healthcare's implementation-related challenges. We selected the sources of information carefully from leading scientific databases making sure that the criteria of inclusion with respect to the type and quality of information, dates, language and other criteria is effectively fulfilled. Keywords and subject terms were mindfully drawn to broaden/narrow down search results as we worked towards the synthesis of rightful understanding, available on how mobile mental health apps fall short in terms of regulations and their potential as a healthcare aid and to see how enforcement of effective regulations can solve these issues and guides practice of these apps based on ethical and scientific foundations.

1.2. Problems with mobile mental health apps:

Mobile technology centered on development of health aiding software currently experiences much less regulatory weightage as it should [23]. It is frequently not possible for users to study or cross examine again and again, the scientific references highlighting the effectiveness of treatment paradigms or self-management tricks given through mobile mental health apps [10]. According to a survey, close to only 30% of the topmost mobile health apps had 'crisis-specific resources 'in them [11]. Hence, in cases of immediate and highly demanding mental health emergencies, a currently in use mobile mental health app's reliability can be deemed questionable. The content on many of the mobile mental health apps accessible is not always clear. It is generally seen unspecified if anyone with experience dealing with mental illness or conditions or subject matter experts in the field of psychological care were involved in the development of these mobile mental health apps [12]. The description of the app that is made public in the app store's download screen segment or the subjective material that developers highlight sometimes seems like advertised content. Often, mobile mental health apps are promoted this way by claiming goals that the software cannot fulfill. All this is done for the sake of maximizing app downloads [10]. Almost usually without consent, websites leave electronic traces behind. These digital trails consist of data that might put forward the user's

crucial information. Let alone demographical and feature driven information, records of an individual's religious bent and wardrobe styling too might be revealed. Information about health status can be very inimical. Apps tend to share private user information with third-party enterprises like Google and Meta. According to a study, around 85% of reviewed mobile mental health apps for easing users with depression and smoking did this but the data on privacy policy of only 50% of them made this information public [13]. This undisclosed data sharing problem therefore, becomes worrisome because it is not very clear how these third parties use the data provided to them and the very fact that this private information is supplied to them in the first place. With the use of cookies, app browsers may be marked with distinctive identifiers that make it easier for them to instantly recognize users so as to protect their activity based data or information submitted. Such information can be used to develop user profiles like browsing history [14]. This is how the internet creates algorithms as well. Looping entries and records with analysis of content (automated) and with the use of artificial intelligence, this profiling can be nurtured to generate probable outcomes by itself. A history of mental health and reports of issues related to it or current mental health status of an individual can foster the creation of predictive algorithms online along with targeted marketing and advertising [15]. One significant moral and legal quandary related to the use of mobile mental health apps can arise with users under the age of 18 years [12]. This is the question of proper comprehension of the potential hazards indirectly conveyed while addressing the need of clearly defined regulations. Through the use of ‘special digital identifiers’, the information gathered through mobile mental health apps might be found adjoined with information from other questionable sources. This compiling foresees the creation of user profiles that can be further misused for marketing etc. without the knowledge of the user [16]. Digital health solutions continue to fall short of their potential despite notable developments in healthcare technology [17]. This is because most apps, created with lack of scientific comprehension, cannot actually be solutions. Some apps on mental health might even encourage the medicalization of daily experienced texts based digital reminders about maintenance mental health by themselves [18].

These challenges of mobile mental health technology can be summed up as following: The lack of clear definitions and standards for mobile mental health apps which can lead to inconsistent or insufficient regulations, The difficulty in enforcing those regulations, especially for apps developed and distributed globally, The rapidly changing technology and development of new apps is making it difficult for regulators to keep up, The potential for conflicts of interest for example, app developers having financial ties to pharmaceutical companies, Limited research on the efficacy and safety of many mobile mental health apps and many more. These challenges and many more highlight the need for ongoing efforts to improve and update regulations to ensure that mobile mental health apps provide safe and effective support for mental health. Since users have little to no control over sensitive profile related information if it gets leaked, there are typically no restrictions that may guarantee the privacy and

security of personal and health information, even if the developer has established an extensive privacy policy [19]. The general public therefore, has to be made more aware of the potential risks connected to the incorrect use of mobile mental health apps like in these conditions and the usage of subpar ones [20]. Technical curators of mental health apps generally lack security related understanding. This lack of knowledge is typically attributed to a variety of issues that challenge safety of app user's data [21]**.** To lower the danger of online fraud, people with mental illness should be therefore, taught safe online hygiene when using mobile mental health apps. Therefore, the promotion of deeds like developing curated health app libraries and centralized repositories, mechanisms for quality based evaluation for simple reporting of any harms or adverse events experienced by app users of mental health apps is what the studies centered around problems associated with mobile mental health development should highlight [20]. It is challenging to formulate and bypass research-based, optimal quality apps in health segment because of the increasingly rising fast speed at which new apps are being developed compared to the a lot more time (in several folds) it takes to produce excellent data demonstrating their usefulness [22]. Therefore, the use of mobile mental health apps faces several challenges which can be solved by properly regulating mental health apps in practice.

1.3. How the regulation of mobile mental health apps cater to these challenges:

Regulation of mobile metal health apps means setting rules and codes to be stringently adhered to while using mobile mental health apps. We reckon that many problems related to the use of mobile mental health apps can be fruitfully fixed by regulating them. Adhering to the APA's hierarchical framework, which stresses upon a clinician's' duty to study phases of the structure with clients, attend to questions, and motivate shared decision-making on proper utilization of the app, would be one effective risk management technique in this direction [23]. But these do not cover all types of mobile mental health apps. Issues with the use of mobile mental health apps revolve mainly around concerns related to their quality, safeguarding shared information/data and security [24]. We reflect upon this idea to suggest that the regulation of mobile mental health apps should involve establishing standards for their development, content addition, and usage directions. This may include: Data privacy and security measures to protect users' personal and health information, Clinical standards for the accuracy and effectiveness of app-based treatments, transparency about the qualifications of app developers and the sources of their funding, Clear and accessible information about app features and limitations, Regular monitoring and review of apps to ensure continued compliance with regulations and other concerns and making sure that these instructions are followed. Now it is high time that society must decide whether and how to govern the innovative services that software programs offer [25]. An important challenge with ethical compliance to mobile mental health apps is the absence of unity among all stakeholders. Knowledge about

how an alliance would function, will improve mental health outcomes, mostly all dimensions of healing [26]. As much as we stress on that ethically regulated mental health apps have the potential to be healthcare aiding vectors, we also believe that the goal of these regulation should be to protect users and ensure that mobile mental health apps provide safe and effective support for mental health. How we see it, the regulation of mobile mental health apps is important because it can guarantee the protection of user privacy and security. For example, App stores can increase the 'thorough investigation'/'vetting' for medical and other health related apps as these section of apps can be termed as high-risk for the fact that they contain private user data [27].Mobile mental health apps often collect sensitive personal and health information, regulation can help ensure that this information is protected and not misused. It may ensure better quality control of app settings and usage. In a recent report on the econometrics of the digital health industry, it is claimed that the use of mobile and linked technology in the field of mental health is advancing and the plurality mobile mental health apps are seen as profitable in terms of monetary outputs to grow significantly [28]. Regulation can help ensure that mobile mental health apps meet minimum standards for accuracy and effectiveness, providing users with safe and effective support for their mental health. Despite the absence of transparent usage guidance or clinical evidence for the majority of applications, app users are nonetheless interested in and utilizing them today [29,30]. Therefore, importantly, regulation of these apps can resolve issues related to transparency since the regulation can help ensure that users have access to clear information about the qualifications of app developers and the sources of their funding, so that users can make informed decisions about which apps to use. Consumers, technology companies, clinicians, policy makers, and researchers are all becoming more and more interested in mental health apps due to factors like the rising prevalence of smartphone use, the accessibility and sometimes no or low cost of apps, the convenience of app use, and the potential to provide evidence-based care [28]. Regulation of apps may also foster to improve consumer protection as regulation can help prevent false or misleading claims about the benefits of mobile mental health apps and protect users from potential harm and strengthening of regulations may support ongoing innovation and development of the craft. We also stress upon a streamlined and effective practice and implementation of the regulations. The regulatory agencies take fragmented measures to manage digital mental health care. There can be seen a relative inability of system based healthcare and their financial structures to combat the rising populations with mental health problems [24]. Hence, implementation becomes equally important. We believe that by establishing and implementing clear standards and regulations, the field of mobile mental health can continue to grow and improve, providing users with a wider range of safe and effective options for managing their mental health.

Regulation enforcement would mean that the user is more in control. Stringent privacy-protecting demands should come from mental health app users [27]. Apart from this, enhancement in the roles of mental health professionals along with other stakeholders in app

development would create an ecosystem where these users are able to actually demand more safety. With better regulation in force, app developers will study app security nicely before app development. Much health related apps encourage users to provide a lot of personal information which might be the source of endangered demographic, geographical and medical data [19]. Mental health apps have similar concerns. With efficient regulations for mental health mobile apps in place, systems and bodies comprising of all stakeholders, will have segments that will actively work to improve implementation of what mental health app promises to deliver and maintain adherence to the most ethical and acceptable practices in this area. In one study, a framework was devised that explained that, for the implementation of policies on mental health apps, the responsibilities can be categorized stage-wise like a filtration process. For example, government guidelines can be the first-stage filtration, which would select 'legally complaint' mental health apps, followed by the second-stage filtration, which will have the 'guidelines by app store' for app developers, where app curators have to submit their apps for a good review before they are commercially available for users. This will be followed by a final filter that would retain 'high quality' apps as they would certify apps that fulfill a pre-defined criteria of standards [20]**.** We support such segmentation and division of regulatory labor so that the app user is relieved and healthcare is served best. Although, in coherence, enforcement of regulations should foresee more active participation of mental health professionals and end app users in certain decision making situations. Mental health experts can carefully assess and study the mental health apps so that they can recommend privacy-confirming and safe to use apps to their patients and clients [27]. Better regulations will enforce more participation of these stakeholders so that better apps are created that benefits humanity. Overall, regulation of mobile mental health apps is important to ensure that they provide users with safe and effective support for their mental health.

Although different nations are at different stages of development and have different ideas about how centralized the review of health apps should be, there are some things that they all have in common, such as ongoing projects involving a number of national agencies and the use of pertinent existing and emerging international regulations. We tried to understand how different nations respond to mental health apps and its technology.

2. The contrast of regulations: Developed versus Developing countries:

2.1. The regulation of mobile mental health apps in developed countries:

There are less evident extremely strict universally recognized minimal guidelines or clear directions to direct the creation and use of health and wellness apps in the high-income nations for example, there are no clear regulations in Canada, the UK, or the US defining what kinds of mobile applications are even considered medical devices. But these countries have put more efforts and funds in creating bodies and committees which can regulate mobile

mental health technology. There is ongoing reduction in the use of intermediaries of conventional employed attendants like healthcare units, and governments that may be constrained with the implementation part [9]. However, these developed nations try to abide by willingness to pursue regulations of mobile mental health apps and hence, some progress has been made, there is seemingly not much fruitful policy standardization in this direction. We tried to understand how these nations regulate mobile mental health technology.

1. **United States:** In the US, the Food and Drug Administration (US-FDA) regulates certain types of mobile health apps, including those that are marketed as medical devices. However, many mental health apps do not fall under FDA jurisdiction and are not regulated by it. The potential advantages provided by Mobile mental health apps are encouraging, but it is urgent to involve all the stakeholders (mental health app developers, mental health professionals, individuals with mental health problems, and data safety experts) in the development of minimum standards and regulatory framework for improving the quality of mobile mental health apps and lowering the risk of potential harms related to mobile mental health app use. The 'software precertification program' progressed by the US-FDA makes it important to assess evaluating the credibility of the methods and techniques that app curators and developers use in place of evaluation of the app itself. Another body that regulates health apps in the US is the US Federal Trade Commission (US-FTC). It has the authority to initiate legal action against apps and software oriented businesses that make unsubstantiated promises regarding their goods [25]. The methods used by these two regulatory organizations may be compared to learn more about the kinds of digital services that are now seen as deserving of regulatory monitoring. Since its main focus is on avoiding consumer fraud in general, the FTC is mostly concerned with the promises made by app's technical curators. However, based on what type of the app is in practice and the functions that it claims to fulfill, an app can stand at different degrees in terms of how much it has to be regulated. For instance, an app that shapes users to study skills to combat acute anxiousness, or more general tracking/enhancing mood or cues to motivate for better sleep hygiene may face less oversight as compared to apps that link illness/condition related to emotional and mental functioning by the US-FDA [25].

2. **Australia:** 'The Australian Commission on Safety and Quality in Health Care's publication of National Safety and Quality Digital Mental Health Standards', sets goals to safeguard service users from potential frauds thereby strengthening the quality of mental health inputs and offerings like digital apps [32]. The Australian government has established a framework for the regulation of digital health, including mobile mental health apps. The framework includes standards for data privacy and security, as well as for the quality and effectiveness of these apps. The National Safety and Quality Digital Mental Health Standards created by the Australian Commission on Safety and Quality in Health Care offers a pathway for quality control of the mobile mental health apps that verifies whether the necessary inclusions are in place to

guarantee that the desired levels of safety and quality are fulfilled in the offering. It presents a uniform national statement for the level of care that clients and others who give them with assistance, may anticipate from a digital mental health service [32] but compliance to implementation is unclear.

3. **European Union**: The European Union has established regulations for medical devices, including certain types of mobile health apps. However, the regulation of mental health apps specifically is still in the early stages. According to a study, a survey was conducted in the United Kingdom by the National Health Services. Most wellness apps that were rated reliable and clinically safe in the Health Apps Library actually do not encrypt information that is transmitted and stored on the internet and hence, the user's data can be threatened to be hacked [33]. The European Commission asked industry participants to develop a privacy code of conduct for mobile health apps after this consultation. European data protection authorities had formally approved the code. This 'General Data Protection Regulation' in the European Union represent a leap in app user's transparency and accountability in regards to the privacy of the user as well. Under the European Commission's 2014 consultation, the European Data Protection Board had the authority to evaluate codes under the current General Data Protection Regulation. Codes that have been accepted by the Board give EU-wide universal validity. The main requirements for app developers include: security measures; publicity for mobile health applications user approval; by default, and by design, the rights of data subjects and information needs; transfers of data; minimizing data and purpose limiting and the retention of data; releasing information to other parties for processing; breach of personal data; and use of personal information for unrelated purposes [34].

4. **Canada:** The regulation of mobile mental health apps in Canada is still in its early stages, with no specific regulations in place. However, some provinces have established guidelines for the use of technology in mental health. Canadian regulation on mobile mental health delivery through apps is governed by 'Health Canada'. Governments (federal and provincial) depend upon NGO's and partially funded (by government) units for relay of this technology. An example of such a unit is the 'Canadian Agency for Drugs and Technologies in Health'. Two key areas of Canada's regulatory framework are lacking: the precision of legislation for mobile mental health app release, and the clarity of the regulations for implementation of aims of these apps [35]. Before marketing for apps involving higher-risk categories, like for diagnosis or treatment of inimical medical disorders, 'Health Canada 'must grant a medical device license to these apps. However, less dangerous applications like the ones which promote healthy living are exempted from such licensing requirements but they are still subjected to some regulation and Health Canada's enforcement, which may include recalling them from the market until a license has been obtained [35].

2.2. The regulation of Mobile Mental Health Apps in developing countries:

In many developing countries, the regulation of mobile mental health apps is still in its primitive and premature stages. This may be due to a lack of resources, limited access to technology, or a lack of awareness about the potential benefits and risks of these apps. There is sadly a prominent seeming stigma around psychological and mental-health related consultation of treatment especially in developing nations [36]. However, many nations (including India) currently lack a solid structural/regulatory agency to monitor the standard of the mobile mental health apps industry for example, data privacy. Similar to this, there are no universally recognized minimal guidelines to direct the creation of health and wellness apps [12].

The implementation of regulated use of mobile mental health apps in developing countries can face several challenges. Some challenges pertaining to the use of mental health apps that can be addressed with proper regulations may include: Enhancing customer satisfaction with users, The app must be able to communicate the necessary data with systems created by other suppliers, The accompanying system architecture must be scalable and allow interaction with other systems, and User data confidentiality- data must be sent over secure channels and stored in a safe location and more [37]. We also figure out some of these challenges. The major include: Developing countries often have limited resources for the implementation of regulations, which can make it difficult to enforce regulations for mobile mental health apps; Many individuals in developing countries do not have access to technology, including mobile devices and internet, which can limit the use of mental health apps; There may be a lack of awareness among individuals and healthcare providers about the potential benefits and risks of using mobile mental health apps, which can make it difficult to ensure the proper use of these tools; The regulation of digital health, including mobile mental health apps, often involves the collection and storage of sensitive personal and health data. In developing countries, there may be limited infrastructure and resources to ensure the privacy and security of this data; Developing countries may have limited healthcare infrastructure, including a shortage of mental health professionals, which can make it difficult to ensure the quality and effectiveness of mobile mental health apps. A major difficulty in mobile health technology regulatory implementation and delivery is how to assure safe and successful health apps by tracking, manipulating, and examining [9]. Despite these challenges, some developing countries are taking steps to regulate mobile mental health apps which might not be well implemented yet.

1. **South Africa:** The South African government has established a framework for the regulation of digital health, including mobile mental health apps. The framework includes standards for data privacy and security, as well as for the quality and effectiveness of these apps. In South Africa, mental health apps are mainly sought to be regulated through the Health Practitioners

Council of South Africa (HPCSA). The developer, owner, proprietor, or operator of the software curated by the healthcare practitioner is not required to register with the HPCSA. Thus, the HPCSA limits the liability of digital health apps, but other laws, including the Consumer Protection Act 68 of 2008, the Medicines and Related Substances Act 1965, and the South African Health Products Regulatory Authority, may also confer liability on a software provider in relation to a digital health app. However, it is established that all apps must be registered with the South African Health Products Regulatory Authority, or legal use and the Medicines and Related Substances Act provides for fines and/or custodial summons and prohibitions of any operation for the sake of business inclined with export, manufacturing, marketing or distribution of an app without the license but no present compliance or future awareness is found with respect to the use of future legal developments that concerns with using health related apps in South Africa [38].

2. **Brazil:** The Brazilian government has established a framework for the regulation of digital health, including mobile mental health apps. The framework includes standards for data privacy and security, as well as for the quality and effectiveness of these apps. According to a Federal Medical Council Resolution, doctors who advise patients via telemedicine are held legally responsible in Brazil. Other parties, such the makers of digital appliances, are also jointly accountable for the harm they contributed to. Producers of software or the finished app are accountable for flaws under the Consumer Code. The Brazilian Civil Code Law establishes broad guidelines for civil liability; the General Data Protection Law controls the protection of personal data; the Consumer Protection Code Law regulates consumer interactions; and the Internet Law regulates internet use [39]. But, there is little awareness about any ongoing legal advancement in the implementation of regulations. Brazilian telemedicine policy is still being improved as many interest groups, both within and external to the Ministry of Health, continue to debate and discuss the priorities and consensus. Despite the abundance of laws and rules, it doesn't seem as though Brazil's legal foundation for it has been appropriately established [40].

3. **Poland:** There are no precise guidelines regarding responsibility in Poland while using telemedicine or digital health applications, and we are not aware of any pending legal changes. Legal frameworks that might apply to digital health software include the Copyright Act, Electronically Supplied Services Act, General Data Protection Regulation, and Telecommunications Law (1994). The Polish Act on Competition and Consumer Protection may apply to several features of digital health software [41].

4. **India:** In terms of mobile phones and internet users, India is internationally the second largest user base of internet using individuals and that is why the discussion becomes important. Of all these users, more than 70% use internet on their mobile phones and this ser-

vice penetration is expected to grow further [42]. In many nations (including India), there is yet no strict and definitive framework or regulatory agency in place to monitor the standards and data privacy policies of the mobile mental health apps market but with respect to health apps, as a whole and the health aid they can offer, there are certain central bodies that may have a role that can dictate their uptake and usage. Mobile internet penetration in India is expected to reach close to around four hundred and fifty million users by this year [43]. In India, the Ministry of Health and Family Welfare has been working on the practical impartation of standards for maintaining electronic health records as it simultaneously also works on refining drafts of regulations for mobile mental health technology. It is important to note that apps in India should comply with the requirements for electronic health records. The National Digital Health Mission has been created by NITI Aayog in India to manage consent, legislation behind regulations for mobile mental health apps, user privacy and other important sectors of digital health care [44]. Some criteria for safeguarding user's data and privacy are provided by the Information Technology (I.T. Act) of 2000 and its guidelines issued like the Sensitive and Personal Data Information (SPDI) Rules, 2011 and Intermediary criteria, 2021. According to SPDI guidelines, the data and information on a person's sexual orientation, medical records, physical health problems, physiological issues, mental issues, and or past is treated as sensitive or personal digital data that must be secured in accordance with the act. The National Digital Health Mission's Health Data administration Policy also offers standardization inducing guidelines for the administration of health records and related digital data [45]. Subject to extraordinary circumstances, the Mental Healthcare Act of 2017 recognizes the right to secrecy of people with mental illness. There may be new potential to broaden the reach of digital mental health care centered technology as the availability and use of smartphones and mobile based internet continue to grow in many parts of developing nations like India [17]. In light of the coronavirus induced COVID-19 pandemic, it becomes even more relevant than ever to create and evaluate technology based solutions that can foster the hidden potential of digital health and care to its maximum [46]. The legislative system in India managing data security and privacy can also be deemed deficient in its requirements for reducing the hazards connected with software-oriented mental health therapies. For instance, the Ayushman Bharat Digital Mission (established in 2020 with the goal of digitizing the nation's entire healthcare system by giving each person a unique digital health identity) creates centralization of personal data to make access to qualitative essential healthcare for people minimizing financial burden [47]. This centralization of a person's information recorded in all dimensions however, may arguably increase comprising privacy of data as the records include financial, biometrical and health history related information which cannot be termed safe as there is little or structural framework for the protection of such information in the Indian legislation [48]. It can also be argued that leakage of data can impart deleterious effects due to information breaching. There isn't yet a complete legislative formulation of codes in India that can actually guarantee safeguarding of all sorts of personal and public data. In

2019, the Personal Data Protection Bill which had the purpose to create authorities so as to safeguard an individual's right to privacy of information and security and to offer further protection for the preservation of their personal records was held back and withdrawn [49]. This was because the implementation of the policies of the bill were themselves prone to many security concerns regarding mismanagement of personal points of person's information providing the state with the accessibility to process the bill without safeguarding essential data points, which may have also given access to the head offices to exercise control over those records [48]. Concern over data security and privacy has been raised in some studies across India that examined their perspectives on utilizing mobile mental health apps for example, a study revealed so after experimenting with a co-designed app to be used cross culturally in India and the US. In it, it was found that both the general public and health professionals raised such concerns [17]. In another study, it was found that majority of Indian users responded favorably to the use of mobile mental health apps for a variety of purposes, including self-monitoring, seeking accurate information about the symptoms of mental health issues, their treatment, and practical aspects, like, providing reminders for better health management checks [12]. Recent initiatives in India to use technology, like apps to raise awareness of mental health in remote areas have been productive [50]. But sadly, there is no solid proof of the fact that smartphone use can help with the treatment of people with severe mental issues [51]. Alarmingly, there exist large inequalities among Indians between individuals who have access to proper care and those who don't and continue to live with mental illnesses [52]. We were not able to find any research that attempted to translate apps between cultures and health systems as diverse as those in India. The majority of Indian users, however, supported the use of mobile mental health apps as an additive tool, not a replacement, for the direct delivery therapy related care provided by mental health experts [12]. Numerous professionals in all dimensions in the field of mental health care claim that few internet and hardware based health tools are created majorly with their wished inclusion and requirements in perspective [53]. In India, there is currently limited regulation of mobile mental health apps. The Indian government has not yet established specific regulations for these apps, though they fall under the broader category of e-health services, which are governed by the Ministry of Health and Family Welfare. India allocates around 1% of the overall healthcare spending on mental health. More than 90% of the money allotted for the National Mental Health Program (2019–2020) fiscal year was not used. India currently lacks a thorough data protection legal framework too [45]. Despite the lack of specific regulations, some steps have been taken to ensure the quality and safety of mobile mental health apps in India, such as: The Indian government has launched the 'mDiabetes program', which includes a mental health component and uses mobile technology to provide mental health information and support, the Indian Psychiatric Society has developed guidelines for the use of technology in mental health, including the use of mobile apps, private healthcare providers in India are starting to incorporate mobile mental health apps into their practices, often working with app developers to en-

sure their products meet quality and safety standards. In all, the regulation of mobile mental health apps in India is still premature, but there are efforts underway to improve and expand the use of these tools for mental health support.

Overall, the regulation of mobile mental health apps in developed countries has catered to some policies and regulations that these nations abide by despite being certain implementation related loopholes. Some countries have collaborated with leading global agencies and practice toolkits. For example, The Ministry of Health, New Zealand piloted the "Global Governance Toolkit for Digital Mental Health: Building Trust in Disruptive Technology for Mental Health, 2021" which claims to help make better informed decisions about mental health and motivates for strategic growth in ethically regulated digital mental healthcare with the collaboration of all stakeholders [54]. While in the developing nations, the status of mobile mental health technology can be deemed less stringently regulated and actionable as seen from the description of the countries above but there are efforts underway to improve access to these tools and ensure their quality and safety for users. Standards and permissive regulations may be crucial in directing mental health app's usage [9]. There are more factors than covered in this paper that contribute to challenges faced by developing nations. It is essential for economic, social, and other facets of human development, not only mental health, to bring mobile solutions to the lesser served regions of the world [45]. The implementation of regulated use of mobile mental health apps in developed and developing countries requires a comprehensive approach that takes into account the unique challenges and resources as per the requirements of the countries.

3. Conclusion and Discussion:

In conclusion, this review article illuminates the issues with global regulations governing mobile apps for mental health, differentiating how they fathom in different countries, contrasting developed and developing countries explaining India as an example. The challenges with the regulations governing mobile mental health apps need immediate action and attention with respect to requirements based on their geography. The regulation of mobile mental health apps varies by country, with some countries having specific regulations (mostly developed countries) in place but less followed and others still in the process of developing regulations (mostly developing countries). India is a good example to understand that a developing country can be assumed to be weak with respect to regulations but because of a good potential market of mental health app users, the authorities seem to employ some worthy codes to be considered while using the apps. However, implementation still remains a cause of concern like everywhere else. Breeches in regulation can create seemingly small but resourcefully inimical consequences and proper education and research is required to curate appropriate regulations and then successfully implement them for ethical use. The absence of uniform global standards across nations governing mental health apps has created a scenario

where welfare of users is still a far reality. Around the globe, new ethical concerns regarding the ease of use, security, effectiveness, safety and sustainability of digital mental health apps, are on the rise.There are already more than ten thousand mental health apps available online, however restrictions and regulations do not completely prevent the exchange of sensitive and private customer information or guarantee qualitative relay of healthcare [54]. Proper uniform (globally) regulating mobile mental health apps are the way forward towards minimizing challenges that the implementation of this technology faces today. As mobile health apps continue to flourish further, it will remain substantially necessary to include developments in 'case law 'and 'regulatory guidelines' [25]. Usage based user engagement with health apps depends on technology, which is a supplement to care provided by a professional, not a replacement for it [17]. All the issues and challenges discussed in the paper can not only potentially erode user's confidence slowly about using the app for their welfare but can also create serious ethical dilemmas and fears in their minds. The assessment of regulations in different nations given here, also gives hope that with effective regulatory control, these apps may actually begin to express their true potential as digital mental health solutions and can be established into healthcare systems as effective technological aids. Research on digital mental health has generally been focused on particular areas or health systems up to this point, with little collaboration across various settings, cultures, or nations. Collaboration between scientists, doctors, engineers, people who have lived through a particular situation, policymakers, and other stakeholders is clearly necessary [55]. Nevertheless, new efforts should involve participants from both developing and developed nations. Users of the apps also need to be made aware of the precautions to take when using mental health apps, as well as the sections/inclusive items to look for when choosing one to download [56]. There is a sizable potential market for mobile mental health apps that warrant serious consideration. The benefits of mobile mental health apps, including their range of accessibility, low cost, ease of convenience, maintenance of anonymity, and functional immediacy, present a strong argument for their widespread use in addressing the general population's mental health concerns [57]. The method of delivering healthcare can be made better thanks to mobile mental health apps. But the obstacles their ethical and safe use faces today, it's important to concentrate on what needs to change exactly. Prior to advising their usage, it is necessary to carefully assess the alleged advantages and potential hazards regarding the use of mobile mental health apps [58]. Identification of storage locations, usability analysis of mental health apps and improvements made as a result, consideration of standards for interoperability, and reliability analysis of mobile mental health apps prior to use are a few of the practical solutions to these problems [37]. Using mobile applications to offer psychological therapies (using them as technological aids) may help with a variety of mental health issues [59]. They have the ability to enhance commitment towards treatment and serve as a transitional tool between mental health related therapy sessions [60]. Many researchers have recognized the caliber of mobile mental health apps in motivating the adoption of healthy living choices and fostering resilience among the

regular population [61]. We conclude that in order to ensure the safe , ethical and efficient use of mental health apps, numerous regulation implementation related challenges have to be combated by all stakeholders. We are in favour of stakeholders teaming up for easier and more effective app development and delivery. They should do this in a manner that they share more influence and power to dispense ethically regulated apps in the market so as to simplify the process of regulation thereby reducing the probability of harm that the app user faces [20].

4. Implications:

One of the implication of this paper is to promote interdisciplinary research for the study of implementation and immersion of globally connected digital mental health in practice across cultures with as less discrimination as possible so that mental health apps can be effectively and at the same time ethically be curated utilizing their full potential in all dimensions with the aim of generating maximum productive outcomes for humanity. Also, we suggest that curators of mental health apps, both technical and non-technical should stress more on the ways to make their apps more ethical in terms of usage and implementation. We suggest that a structural regulated framework should be used as standard which can be deemed inclusive for mostly all app typologies. Any regulation of mobile app related software must also support innovation while promoting safety [23]. There is a need to create, program and develop mutual agreement to construct novel structural frameworks for ensuring good mental health apps are released for public use [56]. We also want to add that this framework should be ethically built based on a standard regulation model drafted with consensus of all major regulating bodies around the world. The potential advantages provided by using mobile mental health app related offering is encouraging, but it is important and in fact urgent to assimilate developers, curators, psychologists, mental health advocates and cyber security experts to come together in the development of minimum standards and regulatory framework for improving the sustainable and ethical viability of mobile mental health apps. We suggest that it is not only beneficial but important to assimilate the work of all stakeholders as early as possible while curating the design and coded development of mobile mental health apps. This would facilitate narrowing the gap between individuals with mental issues and the accessibility of digital mental health care and provide guidance in the congruent deployment of digital solutions.

5. Recommendations for future:

Future issues for mobile mental health apps in terms of regulatory implementation can be divided into two categories: one, related to a structural and functional framework implementation and two, related to particular criterion-oriented factors [9]. Neither app developers nor

clinical professionals these days are sure what constitute "approved-for-use" apps. [57]. Hence, future research should focus on crucial aspects of mental health app regulation so that such confusion does not arise at all. These regulations should ensure aspects such as the availability of evidence-based methods for app efficacy assessment and the accessibility to emergency services communication. By doing this, app developers and mental health specialists may arrive at a consensus on the fundamental principles governing the assessment and oversight of mental health applications [58]. There is great scope in the use of mobile mental health oriented digital apps in all the countries but even nations like the united kingdom for example, where we can say that operationalization of structural and regulatory app frameworks is quite developed, the government and individuals struggle with effective implementation and use of regulations and safe practices to use health apps [9]. Mobile mental health apps have a special potential for enhancing mental health, though associated risks like user engagement problems, safety issues, a breach in confidentiality, and lack of evidence-based technique need to be better understood and managed. These risks can be managed through providing in-time support, cost-friendliness, narrowing stigma around aid-seeking, and improving treatment outputs [58]. Future studies should also concentrate on creating and assessing more evidence-based treatments, conducting in-depth analyses of regulations to follow, and on the status of formation of global partnerships that aim to exchange best practices and regulatory strategies/steps in order to solve these issues. Some more areas in which research in the upcoming years can focus on are: permissions that apps require from the users, data accessibility, and sharing related tendencies for longer periods of time [27]. Additionally, user education and awareness should be enhanced to enable people to choose their mental health app safely and wisely. We strongly support that regulation of mobile mental health apps are weak and deficiently followed across the globe with some countries doing better than the others but still not doing enough and there is no or little uniform code of conduct that is followed cohesively across all countries. These challenges should be taken seriously by all stakeholders in the future for us to benefit the most with the wonderful technology.

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