VILNIUS UNIVERSITY
MEDICAL FACULTY

The Final Thesis

Ethical Issues in mHealth

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2024-05-10

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SUMMARY

Substantiation: Mhealth is a growing field that uses mobile technology and network communication to revolutionize healthcare delivery. It encompasses wearable and non-wearable devices, smartphone applications, and machine learning algorithms. While mHealth offers promising solutions for improving healthcare accessibility, especially in mental health, it also presents ethical challenges that need consideration.

The aim of the work: To examine ethical issues surrounding the application of mHealth in a mental healthcare context and explore the ethical challenges, this thesis aims to shed light on the complexity of the ethical landscape of mHealth.

Methods: This is a narrative review of the topic and given the novelty of the subject, the search was conducted for recent, 2019-2024, peer reviewed articles via Google Scholar, PubMed, and the Web of Science and recent blogposts. For definitions and historical facts, older sources were used. The following terms were used to locate articles relevant to the topic*: Ethical Issues in mHealth* and *Mental Health* and *What is mHealth* and *Ethical Principles in Healthcare* and *Evolution of Mobile Technology*. Variations of these terms were used to ensure adequate results.

Results and Conclusions: Privacy and Confidentiality emerge as significant concerns due to potential data breaches and the misuse of personal information by mHealth apps. Informed consent processes are often inadequate, raising questions about user autonomy and comprehension. Issues of equity and accessibility consist, while certain populations face barriers to accessing mHealth services. The impact on the doctor-patient relationship is nuanced, with remote communication offering convenience but compromising personal connection. Data security remains contentious, with regulations often failing to adequately protect user data.

Mhealth holds promise for transforming healthcare delivery. Ethical considerations must be prioritized to ensure patient privacy, autonomy, and safety. Regulatory bodies must implement stricter guidelines to address ethical challenges posed by mHealth applications. Developers must prioritize user privacy and security and healthcare providers must be adequately trained to navigate the ethical dilemmas in mHealth interventions to maintain the patient trust and safety.

Keywords: Mobile Health, Mental Health, Ethical Issues, Ethical Principles

INTRODUCTION

Mobile health (mHealth) stands at the front line of a digital revolution in healthcare, influencing mobile technology and network communication to transform the way we approach medical treatment and health management. The unity of wearable devices, smartphones, tablets, and

innovative applications has introduced a new era of accessible and personalized healthcare. It has the potential to improve patient care and increase efficiency. Mhealth has emerged as an avenue for addressing current health care challenges.

The development and application of mHealth technologies span a wide array of functions. These can include the prevention, care, monitoring, or surveillance of diagnosed diseases. By using its abilities for ongoing monitoring, feedback mechanisms and predictive analysis, mHealth is revolutionizing healthcare and helping individuals take control of their help and thereby empowering them.

In recent years, mHealth has expanded to encompass mental health. It recognizes the usefulness and need for innovative solutions in this area. Especially during the COVID-19 pandemic the new necessity of remote contact expanded access to healthcare and made it more widely available digitally. During this time, mobile applications turned into a standalone market. Mental health disorders, such as depression and anxiety disorders, are global burdens and need new approaches to aid diagnosis, treatment, and support. The interconnection between mHealth and mental healthcare has great potential for closing gaps in access, lowering costs and for being effective.

Although it has transformative potential, mHealth causes many ethical considerations and challenges. From issues of privacy and confidentiality to data security and even patient safety, the ethical issues are complex. As the adoption of mHealth advances, it becomes more important to examine the moral consequences of how it is made, used, and put into action.

This thesis aims to explore the ethical considerations at the junction of mobile health and mental health, centering on privacy, informed consent, equity, and the doctor-patient relationship, leveraging case studies and regulations.

Objectives to reach the aim:

Primarily to examine ethical issues arising from the crossroads of mHealth and mental health. To focus on understanding the ethical principles guiding mHealth interventions and their implications for clinical practice. To reach the aim the following objectives were raised:

1. Examination of Privacy and Confidentiality concerns and analysis of real-world examples of ethical dilemmas.
2. Analysis of Informed Consent and the doctor-patient relationship in mHealth interventions.
3. Investigation of Equity and Accessibility in mental health.

LITERATURE SEARCH STRATEGY

This is a narrative review of the topic and given the novelty of the subject, the search was conducted for recent, 2019-2024, peer reviewed articles via Google Scholar, PubMed, and the Web of Science and recent blogposts. For definitions and historical facts, older sources were used. The

following terms were used to locate articles relevant to the topic*: Ethical Issues in mHealth* and *Mental Health* and *What is mHealth* and *Ethical Principles in Healthcare* and *Evolution of Mobile Technology*. Variations of these terms were used to ensure adequate results.

Keywords: Mobile Health, Mental Health, Ethical Issues, Ethical Principles

1. UNDERSTANDING MOBILE HEALTH- DEFINITION, DEVELOPMENT, APPLICATION

Mobile health is the use of mobile technology and network communication in healthcare (1). These can include wearable devices such as smartwatches or smart finger rings and non-wearable devices such as smartphones, tablets, and smartphone applications. Machine learning constitutes a part of its functions aspects as well as medical platforms. In other words, mHealth is the use of wireless communication technologies and its applications in medicine and public health (17). MHealth technologies and applications may have the possibility to store data or may be used for purposes such as collaboration between doctors, collaboration between researchers of studies and the interactions between the doctor and the patient by appointment scheduling, remote consultations, and patient education, which are accessible through the above-mentioned devices (1). The applications of mHealth are aimed to be used by healthcare professionals as well as patients (2). They are considered secure, readily available, effective, and affordable (32). This is achieved by ongoing monitoring, feedback, and predictive analysis of behaviours. Therefore, they can be used for the prevention, care, monitoring, or surveillance of diagnosed diseases (59). This is achieved by for example tracking symptoms, physical activity, nutrition and promoting healthy behaviours and providing personalized health care. The collected live data feed from these apps can be viewed by the patient and in other cases the corresponding doctor, nurse, or researcher (1). This continues to have an impact on healthcare as its availability, usefulness, ubiquity, and ease of use make it compelling and increasingly more patients are receiving information and patient care via mHealth devices and applications.

Mobile health is seen as a new and innovative way of health management, covering sectors of information transmission, diagnosis, monitoring, and telemedicine. Mobile Health has influence on costs, as it has the potential to lower them in health care, to increase personalization of health care for each patient, which increases quality and own responsibility. It thereby increases efficiency and facilitates access of the information by its stakeholders (6).

During the 1960s, the first technology that would later constitute a part of the fundamental technology of mHealth – computers – were subject of discussions as potential to be implemented (9). It seemed promising for improving of health care but were not being implemented in health care at that time.

Starting from the 1980s, mHealth started to see accelerated development (5). Network technologies and visual graphic user interfaces started seeing widespread adoption. Regardless, most health care facilities in developed countries were unable or unwilling to make financial investments.
During these and the following years the goals were to increase maturity of digital health, including mHealth, health information technologies, wearable devices, and telemedicine (6) driven by the International Medical Informatics Association (5) and the American Telemedicine Association (5) from the 1990s (8).
The first mobile phone to enter the market commercially was released in 1983 (10), laying the groundwork for the following centuries to improve upon them. At the same time, the internet became operational but was not available to the general population of the developed countries until the early 1990s, which is when the world wide web was developed (12) and the mosaic browser (13) by making it more user friendly and popularizing it.
Apart from the internet and hardware devices, Electronic Medical first developed as a concept in the 1970 (14) and saw adoption into health care in the 2000s.
Mobile Health as we know it today has made a large progress in the last decade (5). During the COVID-19 pandemic a new necessity made itself apparent to expand access to health care and make it widely available digitally. During this time, mobile applications in healthcare have developed into their own separate market. The application of 5G networks around many parts of the world enable quicker and reliable internet access and facilitate the ease of monitoring real-time patient data in health care (4).

2. APPS IN MENTAL HEALTH

There are many thousands of health-related apps in the app stores of major operation systems (33, 34). Of these, there are between ten thousand and twenty thousand mental health related apps as of beginning of 2023 (53).

2.1. Issues with apps in Mental Health

In contrast to regulated healthcare professions, the development of mental health apps lacks standardized licencing procedures, regulatory oversight or required knowledge (61). Consequently, individuals with programming skills can create apps, leading to an abundance of offerings providing mental health mental health guidance without empirical evidence. Moreover, many apps fail to disclose the qualifications of their creators, potentially misleading users about their effectiveness and safety. Further, some apps simplify mental health treatment, potentially discouraging users from seeking professional assistance. They might not have warnings or advice for handling crises, which could make mental health problems worse. Also, many of these lack sufficient evidence and backing from scientific studies (53).

2.2. Examples of mental health apps

There are several popular mental health apps popular with users. According to Forbes Health, the application *Headspace* may have benefits in gaining a more productive and stress-free life by offering meditation guidance, breathing exercises and relaxation tools (54). It has been downloaded around 80 million times from 2016 to 2023 (56). Another app— called *Talkspace*— functions as a platform for text- and video-based therapy, experiencing a surge in new users during the COVID-19 pandemic (62). It offers convenient access to mental health counselling, yet ethical concerns arise which will be discussed in section 5.

The similar app *BetterHelp* is an app that provides mental health counselling (62). It has several thousand therapists and several million users while claiming affordable and convenient therapy in almost all countries and offering therapeutical services for a wide range of conditions (67).

PTSD Help is an app intended to assist individuals coping with post-traumatic stress disorder. It provides psychoeducational resources, tools for managing emotions, functions for targeting different symptoms and self-assessments (65).

3. OVERVIEW OF ETHICAL PRINCIPLES AND THEIR APPLICATION IN MENTAL HEALTH

Ethical frameworks exist to guide certain individuals such as healthcare providers, researchers and policymakers in certain situations that may involve taking decisions that can cause ethical dilemmas (21) by providing principles and metrics by adhering to clinical guidelines and regulatory standards. There are four widely recognized principles of ethics (20). These include beneficence, nonmaleficence, autonomy and justice. They were formed by philosophers Tom Beauchamp and James Childress in their work called the Principles of Biomedical Ethics of 1979 (52).

In mental health care, these ethical principles are likewise important and applicable. Psychiatrists have the moral obligation to respect ethical principles regarding their patients just like other physician groups (28). It is applicable to all these principles that in some situations one principle might be more important or relevant than another and may override another existing principle for a more just outcome. Certain components and clinical practices applicable to ethical principles are also relevant to making ethical decisions or to design health care in accordance with ethical principles.

3.1 Beneficence and Non-Maleficence and their application in mental health

Beneficence states that the physician must act in a manner to ensure a benefit to the patient, promoting their well-being and avoid negative consequences (20). In mental health care the principle of beneficence aims to alleviate the effects of mental illnesses by improving mental and

overall health (66). Providing effective and advantageous treatment for patients is key (29). So called evidence-based treatment that has been researched is important to minimalize any possible suffering of the patient, due to the treatment having been shown to have effective outcomes. It is furthermore important to have in mind cultural, individual, or family backgrounds and differences and challenge one's personal biases as health care- and mental health care professional. A sensitive approach to an individual's different background enables the physician to adjust the treatment and care to the specific needs and understanding of the patient and improve the outcome. The principle of beneficence is also tied into the principle of autonomy in mental health care. By granting autonomy by providing comprehensible information and the patient's own decision making, the doctor ensures that the treatment plan is lined up with the patient's own values and may thereby increase a positive outcome. The principle of beneficence is directly related to the principle of non-maleficence because it is a risk-benefit ratio (30), in which providing the maximum possible benefit is closely related to the obligation of minimizing disadvantages or harm to the patient. Nonmaleficence refers to the obligation to do no harm (20). According to this principle, the physician is to weigh the benefits over potential harms and to avoid unnecessary negative outcomes. It is important to avoid treatments of inadequate clinical validation, insufficient effectiveness and have in mind patient vulnerabilities especially in the field of mental health (66).

3.2 Autonomy and its application in mental health

The principle of autonomy states that a patient above a certain age and mental capability has the right to choose their own course and strategy (15) by being able to implement self-determination and thereby being able to decide for an act or against an act (23). In mental health care it is especially important to assist individuals in need and improve their mental status with available tools by recognizing a person's right to choose a treatment that aligns with their goals and preferences (66). Intervening mental health specialists are bound to disclose information to the patient for example about how the psychotherapy will be conducted and make it comprehensible, including upsides and downsides. Providing sufficient and understandable information and requiring an informed consent to be signed enables the patient's sovereignty and aids them to make their own decision and balance risks and benefits (28).

3.3. Justice and its application in mental health

The principle of justice refers to fairness, access to resources and clinical practices as much as possible (15). People should be treated with the treatment plan appropriate to them (20).
The principle of justice stands for fairness in mental health and equitable distribution (15). To uphold it, only feasible interventions should be considered, especially since resources may be limited in mental health. Further, if an individual's privacy and confidentiality is respected, as well as their autonomy, this contributes to fairer mental health treatment or research. In addition, by

utilizing the process of informed consents, mental health professionals may ensure that the patients receive sufficient information about the intervention and the way their data is used and may make voluntary and knowledgeable decisions aligning the treatment to the principle of justice.

3.4. Informed Consent, Truth Telling

Informed Consent is also an ethical principle which is required by law for procedures of clinical practice or research in medicine with human participants (24). It ideally requires a patient to comprehend the procedure that is to be undertaken as well as the risks and benefits and should be an educative method to help the patient make the most beneficial decision (25). It is therefore vital to ensure patient autonomy in health care. In mental health care, drugs prescribed bear certain negative consequences. Certain treatments for the depression have negative side effects. Before these treatments can be undertaken it is ethically compliant to ensure that the patient understands the risks to be undertaken.

Truth-Telling is vital for the ongoing trust of the doctor-patient relationship (20). The doctor-patient relationship is especially vital in the field of psychiatry, due to the importance of verbal interactions in ensuring optimal treatment outcome.

In addition, the presence of confidentiality is of importance in medicine for a well-functioning doctor-patient relationship (27), fortifying the trust in the physician or in the researcher that they will not reveal confidential information if not necessary, helping the patient open about their condition.

1.5. Privacy and Confidentiality

The presence of confidentiality is of importance in medicine for a well-functioning doctor-patient relationship (27), fortifying the trust in the physician or in the researcher that they will not reveal confidential information if not necessary, helping the patient open about their condition. Privacy is an important ethical principle in healthcare. It’s paramount for fostering open communication and creating a safe space for individuals to seek help without fear of judgment or exposure.

4. ETHICAL ISSUES IN MHEALTH MENTAL HEALTH

4.1. Privacy and Confidentiality

Privacy issues have been presenting themselves as an ethical issue to the patient’s autonomy, dignity and right to control their personal information in mHealth since the advancement of mHealth services (16). Many applications used in mHealth can potentially access and share personal information to third parties (31). This information may entail the users contacts, the users’ location as well as identifiers to distinguish different devices. Further, many apps collected the so-called Media Access Control addresses as well as cookies, facilitating tracking and storing users’ activities. In the Google Play store, for example, there were over 54 thousand health care and

medical apps as of December 2023 (33). In the Apple Store, it was over 41 thousand as of the third quarter of 2022 (34). About one third of mHealth apps lacked a valid privacy policy text (31) even though various regulatory bodies state rules around privacy, most likely since privacy standards are not sufficiently enforced on a global scale. This proposes a failure to comply with standing rules. A small number of app users can be found to have raised concerns of privacy issues.

Although some personal information is needed for the application to function as desired, there are protective measures like de-identification to make it more difficult to associate with individuals' specific mobile devices (35). The information that would reach app developers, researchers, doctors, or other third-party service providers can likely be bypassed. De-identified information may potentially be merged with alternative sources such as social media accounts or public records, which introduces multiple risks. These risks apply especially to people with health challenges. If these people could be identified due to a breach in privacy, it might lead to the revelation of sensitive health information. This in turn could lead to stigmatization or discrimination as employers or insurance companies could utilize the information to make decisions that might affect these individuals negatively.

Further, if information from social media is combined with de-identified information from mHealth apps, individually targeted advertisement or marketing could be performed without the user's consent, which might not be in the user's best interest. Data infringement is possible because consumers may not always have control of the collection of their health and medical data (16). This can cause the so-called privacy-personalization paradox (16). The privacy-personalization paradox is the result of consumers desiring personalized experiences and services but being unwilling to disclose health data or personal information due to privacy concerns. This has an impact on the readiness to adopt mHealth services as it increases reluctance. Users are concerned about their information being misused or their privacy leaked or abused, leading to the above-described dilemma.

How ready a user is to utilize an mHealth application depends on their internal analysis weighing the benefits of receiving health advice by providing personal information versus the anticipated loss of the information (36), assuming they are aware of the risk of privacy loss. If a user has the attitude that the benefits are greater than the losses, meaning that the user shows interest or is concerned about their sensitive information being lost to third parties, certain factors like trust in the provider become relevant. If an mHealth application user does not show concern about privacy, these factors are of little importance due to the user being disinterested in their information being used by third parties or in a way they are not aware of. This might be the case if a user believes they are in control of their information and personality traits such as attitude.

Only in recent times have developers and consumers started showing concerns about the protection of personal data (37). Since companies are managing vast volumes of data, with the potential exposure of users' sensitive information, governments have been establishing safeguards to protect users' privacy. At the same time, privacy has been overlooked in favor of rapid technological developments, meaning that the advancement of technology has been being favored over adequately being able to address arising privacy issues.

A different situation could cause a privacy breach and a dilemma with giving adequate patient care (15). For example, in the situation of a patient being treated by a health care professional in psychiatric care the physician may have a moral obligation to keep track of the patient's activities through mHealth aspects to reduce the possibility of harmful negative effects on the patient or other people. They might have an obligation to intervene if such a situation is observed, but at the same time have the moral obligation to preserve the patient's autonomy and privacy, leading to a dilemma that may cause a breach in private information or patient autonomy.

4.2. Cases of Privacy and Confidentiality issues in mental health apps

Headspace—a beforementioned app—may cause issues regarding privacy protection. For example, *Headspace* collects data from various sources about its users, which is then used to advertise to others (57). This data may include personal details, usage patterns and sensitive health information. In its case, *Headspace* collects the user data about their meditation habits, the frequency of usage and preferences within the app. The data collected could reveal information about a person's stress level as well as mental health status. There is a chance that this information could be accessed by unauthorized people and be misused (35). Privacy violations or leaks can negatively affect the users' trust in the app and its developers (16). Users can have feelings of betrayal or deception if they find out that their sensitive information is being used without their knowledge. For example, if users found out *Headspace* were sharing their data with third parties for advertisement purposes without having been fully aware, they might lose trust in the app and its privacy. This may negatively influence user engagement and may be caused by incomprehensible privacy agreements or incompliance of the application with privacy regulations.

Further, privacy leaks may have an impact on the users' mental health and their well-being (58). Negative feelings may be the cause from the privacy being compromised. Therefore, if *Headspace* were to violate private information rules or users found out that *Headspace* is providing information to third parties if they were not aware before, it could exacerbate feelings of distress or distrust. This may be the case even if users are only thinking about the possibility, due to some users being particularly vulnerable if they are suffering from a mental condition.

The app *Talkspace* collects user data with third parties, potentially compromising the confidentiality of therapy sessions and personal information. Users may not comprehend the extent of data

collection and sharing when using Talkspace. The app *BetterHelp* also shares data with third parties, raising concerns about privacy and confidentiality and leaving users vulnerable to ethical violations (62). In 2023 the Federal Trade Commission in the U.S. confirmed that the company handled its users' data deceptively (63). Despite assuring that the data would remain confidential, *BetterHelp* shared this information with major advertising platforms like Facebook, Snapchat, Criteo and Pinterest without obtaining proper consent. This breach of trust led to a proposed FTC settlement, including a $7.8 million fund for partial refund of affected customers.

4.3. Informed Consent in mHealth interventions

To understand potential liabilities of user privacy and confidentiality in applications of mHealth, so called Terms and Conditions are usually implemented to explain the policies and purposes of collected data to the user (38). These are typically long and lack comprehensible language. This may lead to users not fully comprehending the risks of the application or research if they are participating in one, leaving their autonomy of making an informed decision questionable (39). Further, there is a lack of clear guidelines proposed by regulatory bodies which raises questions about if there is sufficient protection of the participants or users (38) and about possible conflicts with the ethical principle of nonmaleficence (15), since researchers or application developers are left without clear guidance (38).

In addition, there are different viewpoints and perspectives held by the various stakeholders about the attention to detail given in these terms and conditions because different stakeholders might prioritize different aspects of the research process or an application's risks and benefits. This raises questions about both maleficence and beneficence (15), since the most beneficent care to the patient and most possible protection from harm cannot be guaranteed.

Furthermore, the question whether informed consent has been adequately given in the form that mHealth applications do in terms and conditions, oftentimes cannot be assured due to their complexity and lengthiness (38). Because they might not fully understand the supposed informed consent, user autonomy cannot be guaranteed for each case (39)

Lastly, assessing ethical implications while reviewing these user agreements may require expertise that some researchers or developers may not have (38). This is the case especially if external experts are not consulted to review terms and conditions, leading to queries with the above-mentioned ethical principles.

4.4. Equity and Accessibility in mental health services

Mobile Health has great potential in the realm of mental health (40). In terms of equity and accessibility of mental health, there are some apparent imbalances between different populations groups. Despite the need for mental health services, racially and ethnically disadvantaged groups, rural residents and people that are socioeconomically disadvantaged, may not always reap the

advantages of mHealth. There is unmet need in the mHealth design process to understand all users' needs in case of disabilities, language considerations, health literacy or technological proficiency. In addition, there is an inequitable distribution of mental health services between rural and urban areas, and mental health issues are more present and substantial rurally (45). There are certain blockages preventing fair and adequate care in those areas, such as scarcity of professionals and higher distances to treatment facilities and higher concerns about stigma in mental health diseases and concerns about privacy in those regions. MHealth can offer an effective alternative to bring mental health care to rural areas. However, it is possible that certain populations predominantly in rural areas lack the financial means to afford a device that can support mHealth care applications (46). Also, the lack of connectivity to cellular coverage and technological infrastructure may present an issue for live consultations or appropriate mHealth application use, leading to imbalanced mHealth equity between rural and urban communities.

Additionally, the bias in machine learning models of mHealth applications may affect individuals of certain population groups negatively (41). This may be due to the training data of the machine learning system which has biases programmed within the algorithm as human experience may be biased and humans create the algorithm (44). Datasets that mirror biases stemming from race, sex, ethnicity, skin color or other factors lead to biased predictions when utilized by the program (43). For example, ethnic and racial minorities may be disproportionately harmed if biases in training data contain factors like race, sex, ethnicity, or skin color. These biases can affect all mHealth applications that use a type of AI learning algorithm (42). Although these biases may be minimized or eliminated, it seems that bias is natural and inherent to the human brain do to our experiences and perceptions., explaining the ubiquity of machine learning bias in mHealth applications (44).

4.5. Impact on doctor-patient relationship

About three decades ago, the internet started demonstrating the potential for medicine and developed countries since that information would become available ubiquitously and up-to-minute. Physicians were able to communicate more effectively in real-time using internet-capable devices. This effectively changed the doctor-patient relationship because physicians began using the devices more. Nowadays, we have a situation where treatment plans and test results can be transferred electronically. Patients and healthcare providers increasingly communicate using messaging platforms or telemedicine, due to facilitated remote contact. This has both positive and negative consequences.

A recognized downside to remote communication is the reduction of personal or face-to-face interactions (14). It offers increased convenience but sacrifices personal connection, clarity, quality, and accuracy.

The possibility of online consultations may create certain issues (47). For example, it is questionable whether information transmitted to patients during online consultations have the same accuracy and entail the same comprehensive information as face-to face interactions (47), which may not lead to full compliance with the ethical principle of beneficence (15).

In the case that a mobile consultation is text based, the doctor may not fully comprehend the patient's needs, making a helpful intervention more challenging (47). This can be due to a lack of explanation coming from a patient. If a patient uploads images or texts to a mHealth platform or application concerning their condition, there might be diagnostic hints missing in that information, leading to potential inefficient care or potential harms to patient's due to a false diagnosis from failure of interpretation by the doctor.

Further, the doctor or therapist might not be able to fully comprehend or read the emotional signs and needs of a patient through online consultations, leading to possible strained relationships if the patients feel they are not adequately understood, meaning that they will not be able to be helped to the same degree as in in-person consultations.

In a qualitative study that was conducted interviewing participants several weeks after they had received the app *PTSD Help*, patients' experiences were recorded after the patients had used the app as stand-alone treatment before psychotherapy (65). Three main themes emerged: app usage, patient perspectives, and overall app evaluation. Patients shared both positive and negative encounters with the app, with some finding it beneficial for symptom awareness and distraction, while others faced challenges like increased distress and the wish for a more personalized experience. The study underscores the need for further research to identify which patients could derive the most benefit from mHealth apps and more personalized app interventions to minimize user distress. It highlights the importance of understanding patient experiences with mHealth apps and remote communication, as well as the need for personalized interventions and further research to optimize their effectiveness. Considering patients' feedback is crucial, and a patient-centered approach can enhance the doctor-patient relationship. Further, the positive and negative encounters described by patients with the PTSD Help app emphasize the need for open communication between patients and healthcare providers. Any questions, concerns or experiences that will be discussed with a healthcare provider might foster collaboration and can strengthen the doctor-patient relationship by creating a supportive environment.

Lastly, the study highlights that not all patients benefit equally from mHealth interventions. This suggests the importance of personalized treatments. Healthcare providers can play an important role in assessing patient suitability, providing potential guidance on app selection, and offering additional support or interventions. This may reinforce the doctor-patient relationship positively.

4.6. Data Security and Ownership

In addition to the above-mentioned issues that may compromise the ethical compliance in mHealth, data security and data ownership have shown to raise concerns (48). For example, there are risks concerning the security of a user's data when storing and transmitting it. This is because there can be vulnerabilities in cloud infrastructure security. Further, the possibility of physical security in terms of theft or loss of a device may present an issue of unauthorized access to information and cause potential harm to the patient if information was stored on it. Although there are safety measures in place and data leakage through cloud storage is improving, data integrity, deletion, leakage, and loss of privacy remain a risk (49).

4.7. Case on deceptive practices

In 2023, a class action lawsuit by the California federal court was launched against the beforementioned app *Talkspace* that alleges that the company has deceived customers regarding its therapist availability and has continued to sign them up for payments in spite of therapist unaivailability (64). This lawsuit outlines several other ethical issues arising from the practices of Talkspace. Talkspace was accused of misleading users about therapist availability and therefore practiced deceptive billing practices, enrolling users in new renewal payments without therapist availability. Users alleged that Talkspace ignored their preferences in therapist selection and matched them solely based on availability, leading to dissatisfaction or prolonged periods without therapy. Moreover, the lawsuit claims that Talkspace's checkout process was designed to trick users into signing up for recurrent payments without clear and transparent information about these recurring payments during the checkout process. Lastly, past controversies involved allegations that Talkspace breached user privacy by mining private chats for marketing purposes and pressuring therapists to give false positive reviews.

4.8. Case on patient safety

The app *BetterHelp* is an app that provides mental health counselling (62). BetterHelp, including other mental health apps, are often marketed as effective solutions for mental health concerns, potentially leading users into believing they can replace professional mental health treatment. BetterHelp lacks crucial information regarding emergency situations, including suicidal thoughts or self-harming actions which could jeopardize user safety if not addressed appropriately.
The evidence pool surrounding digital mental health interventions is limited at the time (18). MHealth in mental health is relatively new, which is why studies comprising a larger time span are necessary to evaluate potential unhidden lack of effectiveness or safety. Thus, potential unintended adverse effects or harms due to used techniques or excessive use could cause worsening of symptoms or induce dependence. This cannot yet be adequately excluded.

5. REGULATORY AND PRIVACY FRAMEWORKS

Current regulations from different governmental bodies help regulate and guide mHealth and especially mHealth applications to provide more security and privacy and thus facilitate improvement (37). The privacy of personal information has shown to have gained importance to its stakeholders in recent years. In the last decade the amount of information handled by companies and incidents of data leaks have caused governments to take stricter courses.

5.1. Regulation in Europe

In Europe, the so-called General Data Protection introduced changes in data privacy regulation since the year 2018 (51). It is a practical guide for developers concerning the principles of data protection and emphasizes data handling, specifying the purpose for data collection, the amount of data, and security measures to protect privacy. App developers are required to comply with this regulation.

5.2. Regulation in the U.S.

In the United States, the rules established under the Health Insurance Portability and Accountability Act, or HIPAA, aim to protect the privacy and security of information held by healthcare entities (60). The Food and Drug Administration enforces an Act that regulates the safety and effectiveness of medical and mobile devices and mobile applications. For most app developers, the Federal Trade Commission Act requires most app developers to implement reasonable privacy and security practices, setting privacy standards for most app developers. If for example an app developer shares information with third parties after they have stated or indicated that the information is kept private, the Federal Trade Commission Act could be violated, and enforcement brought against the app developer.

Despite existing regulations in many parts of the world, gaps in the protection of user data is evident (61). Existing regulations like the HIPAA in the U.S. do not fully cover mental health products that are available to consumers. Regulatory bodies may assess certain technologies, but some platforms remain unregulated. There are app developers who inadequately address ethical and privacy concerns, and rather invest time in testing their app's functionality. For example, a recent report revealed that Crisis Text Line, a nonprofit organization offering support to those in crisis, shared user data with Loris AI, which develops customer service software. Initially regarded as ethical and abiding by the law, Crisis Text Line later terminated this data-sharing agreement. Loris AI claims to have deleted the received data, although it remains unclear if that also includes the algorithms trained on that data. This incident highlights regulatory uncertainty surrounding its use as well as the impact on the well-being, trust, and privacy of vulnerable individuals.

6. PERSONAL TAKE

MHealth offers a perspective for the future and helps people around the world. Yet, it stands in front of several challenges to overcome before being able to be considered ethically compliant. Privacy and confidentiality issues, transmitting information and consenting as a patient are challenges being faced and will be assessed for improvement by further studies over time. MHealth is not available or a valid option for everyone currently. The impact on the doctor-patient relationship is present, and potential side effects of using applications and devices are present and possible risk reduction is still to be studied. There are several challenges in the political, organizational, and technical field that require attention and investment.

The question remains whether mHealth will become ubiquitously available and accessible and have increased safety and confidence from its users with minimal downsides.

We as users of mHealth technology may implement several steps in our daily lives to help make mHealth more ethically compliant.

We may stay informed by educating ourselves and reading up-to-date literature from reputable sources about ethical considerations and current guidelines. We may consider attending courses or webinars to stay informed about the latest developments in the field, and even support advocacy groups through volunteering or donating to participate in potentially helpful ethical campaigns and raise awareness about issues. We may raise awareness about the current situation to our colleagues, friends, and family members, by aiding them in effectively use mHealth applications and services and teaching them about possible risks and benefits. We may get in contact by writing emails to policy makers and appeal to them to prioritize ethical standards and regulations, and advocate for better infrastructure in neglected areas.

Lastly for ourselves, we may research and choose applications that prioritize transparency and provide clear information about policies. We can ask questions about how the data is handled and how ethical guidelines are being implemented and provide feedback to encourage development and considerations for different people’s preferences and needs. When we have questions or concerns concerning trust and clarity with physicians, we can voice concerns and implement feedback as well as encourage others to do the same, for issues not to go unspoken.

Thereby, we may do a part to raise awareness about mHealth and ethical implementations. We can make ethical principles more widely seen and implemented.

7. CONCLUSIONS

This work explores the ethical landscape of mobile health in mental health. Focusing on key areas such as privacy, informed consent, and equity. It highlights the proliferation of mental health apps, noticing absence of standardized licensing procedures and regulatory oversight, leading to concerns

about the quality and safety of digital interventions. Examples of mental health apps such as *Headspace* and *Talkspace*, underscore a possible growing reliance on technology for mental support.

Privacy emerges as a central ethical concern, with discussions on data collection, sharing practices, and the potential risks of breaches. Despite regulatory effects, gaps in privacy protection persist, raising questions about user trust and autonomy. Similarly, the complexity of informed consent processes in mHealth interventions poses challenges to user comprehension and decision-making, underscoring the importance of transparent and user-friendly consent mechanisms.

The investigation into equity and accessibility, as well as the dynamics of the doctor-patient relationship in mental health care, reveals a complex landscape with ethical considerations and challenges. Disparities in access to mental health services, particularly among underserved populations and rural communities. As the relationship between doctors and patients changes over time, especially with remote communication and digital treatments, it's vital to grasp the positive and negative of digital interventions and remote communication.

Concerns about biases in machine learning and unequal distribution of resources emphasize the need for solutions that work for everyone and actions to solve unjust disparities.

Overall, this thesis aims to provide a comprehensive understanding of ethical considerations inherent in mHealth in mental health, with a focus on privacy, informed consent and equity. By explaining these complicated problems, it aims to guide future practices and rules in this fast-changing area.

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