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Angaben zur Veröffentlichung / Publication details:

Hendl, Tereza, Bianca Jansky, Victoria Seeliger, Ayush Shukla, and Verina Wild. 2023. “Ethical aspects of mHealth technologies: challenges and opportunities.” In Digital medicine: bringing digital solutions to medical practice, edited by Ralf Huss, 101–28. New York, NY: Jenny Stanford Publishing. https://doi.org/10.1201/9781003386070-7.

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Ethical Aspects of mHealth Technologies: Challenges and Opportunities

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The chapter investigates major social and ethical implications raised by mobile health (mHealth) technologies. Our investigation draws from our interdisciplinary expertise, spanning across political philosophy, public health ethics, sociology, STS, and law. We discuss major ethical concerns in the mHealth field, such as issues relating to ontologies and epistemologies used in mHealth, accuracy, safety, efficacy, support for user decision-making, questions of security, the need for preventing physical and mental harm from mHealth, the importance of health benefit and the need for intersectionality and justice within mHealth technologies.

5.1 Introduction

Mobile health technologies (mHealth) are often perceived as a sector with the potential to transform individual and public health, including by global health agencies, such as the World Health Organization (WHO) [78]. mHealth is an umbrella term for a variety of digital and mobile health technologies. These technologies include mobile devices, such as mobile phones, apps, wearables and sensors in medical and health care, and they are often based on machine learning (ML) and artificial intelligence (AI) [26] Beside mobile smartphone applications, mHealth also includes such variable technologies as sensors for clothing [62], or smart lenses [106]. Practices, including self-tracking can also be understood as part of mHealth. The WHO therefore defines mHealth quite broadly as a "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" [78]

The application area of mHealth is rather large and ranges from technologies in the wellness and fitness area [57] to certified medical devices.[1] Recently, particularly in the course of the Covid 19 pandemic, mHealth technologies have been becoming increasingly integrated into governmental public health policies and measures [1, 18, 39, 122]. While in some areas, such as chronic disease management[2] or mental health support,[3] mHealth technologies already are an integral part of healthcare, in other areas governmental policies are aiming to accelerate the integration of mHealth. In some countries, such as Germany for example, mobile applications (apps) can now be prescribed by physicians and are then reimbursed by health insurances.[4]

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[1] According to Article 2(1), Article 51 in conjunction with Annex VIII of Regulation (EU) 2017/745), software with a medical purpose falls under medical device law and must be approved by a notified body for distribution on the market [125].

[2] For example App SiDiary Diabetes Management: https://www.sidiary.de/.

[3] For example App Deprexis:https://de.deprexis.com/; App Novego: https://www.novego.de.

[4] So far, only in Germany is it possible to obtain apps on prescription or to have them prescribed by the health insurance company if there is a medical indication. These apps are called "digital health applications" and are legally anchored [59] in §§ 139 e, 33a Social Code Book V (SGB V) [39].

These developments are transforming both individual and population-based healthcare. mHealth introduces or reinforces many new aspects into healthcare, for example the constant availability of large amounts of data, constant monitoring and measuring of bodily processes, tech-based health and body interventions, self-diagnosing and tech-mediated health guidance, connectivity to social media and patient communities, as well as a focus on self-management and individual responsibility.

Big hopes and expectations are placed on mHealth technologies [4]. MHealth is expected to improve individual access to health services, particularly in patients living in remote areas [32], improve user health-management as well as increase patients' participation, autonomy and self-determination in health care decision-making [32, 117]. In regard to the healthcare system, mHealth is expected to improve the quality and efficiency of healthcare processes [51], reduce healthcare spending [32, 40, 121] and relieve medical professionals in their daily professional routine [29].

At present, longitudinal l empirical evidence substantiating benefits of the use of mHealth could only be identified in the context of chronic disease management and therapy, where digital mobile technology has already been in use for over 10 years [60]. In this case, clinical trials show that the use of mHealth technologies can both improve clinical outcomes, as well as quality of life for a wide group of users [5, 10, 28, 41, 87, 116]. However, this is only one small (and highly regulated) area of application of mHealth technologies. For the most parts the hopes and expectations associated with mHealth cannot clearly be substantiated with empirical evidence, especially with regard to long-term and population effects [42, 124].[5] Rowland et al. (2020) point out that currently there are over 30.000 hits in the pubmed database of scholarly articles when one searches for "mHealth," but "only a handful of clinical scenarios where use of mHealth apps is supported by the highest levels of evidence [93]. The quality of the mHealth literature is highly variable with few studies registered on clincaltrials.gov and many of the apps studied not available on the iOS or Android app store" [98]. Issues regarding evidence base and quality standards are even more pressing, owing

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[5] Some small-scale studies also point to evidence to the benefits of mHealth for smoking cessation [16] and rehabilitation therapy in relation to certain diseases, such as breast cancer [93].

to a current lack of robust and clear regulations to guide mHealth technology users and manufacturers [2].

Hence, while the mHealth field is rapidly growing and the technology is being used in a wide variety of healthcare settings, a robust evidence base and well-defined quality standards and effective quality control assessment and implementation measures are still lacking [95]. Rigorous research is still needed to ensure that mHealth technologies will be safe, efficacious, and beneficial to large and diverse populations of users. The impact of mHealth – on individual health as well as on the healthcare system – depends on many factors, including individual health status, the quality of the mHealth technology and its ability to provide health benefit in various user groups, the type and appropriateness of a treatment method, the duration and extent of mHealth use, a variety of individual, socio-economic and environmental factors, the cost of a particular technology or the conditions for replacing a specific therapy or doctor's visit with mHealth technologies [107, 111]. Moreover, the success of mHealth technology depends on user adherence. Evidence shows that many users stop using apps after a short period of time and positive benefits do not have a long-term impact [48, 112]. Socioeconomic disadvantage and inequalities can also play a role in user adherence, as activities such as self-tracking are time consuming and various population groups might not have the conditions to participate in them – or to the extent that might be required for a successful therapy [46]. This shows that the positive effect of mHealth must always be considered contextually and can vary depending on individual factors, the patient's health condition as well as lifestyle, socio-economic conditions, and one's living environment.

In this chapter, we will delve deeper into the social and ethical implications raised by mHealth technologies. We will discuss a variety of concerns, including approaches to health and design that shape innovation with mHealth, concerns of safety, efficacy and security, discuss the need for preventing physical and mental harm from mHealth, the importance of health benefit and proceed to argue that there are important concerns of equity and justice that ought to be integrated into ethical assessments and frameworks for mHealth technology.

5.2 Ethical Implication and Challenges

As digital health technologies provide health information and services, they are part of healthcare and as such, need to comply with the same requirements and expectations in the field of medicine, health care and public health. Just like other health services, mHealth needs to promote health and wellbeing, be safe to use, medically founded and efficacious, eliminate detrimental impact on users and provide health benefits to users/patients. In our approach, we hold that mHealth ought not only benefit an individual user but also advance public health, and whenever possible and applicable, also global health [9]. But how to ensure that these ideals are realized, which issues are most pressing and how to ensure that these challenges are resolved in the ethically most appropriate and effective way that often requires finding balance between competing concerns?

An ethical analysis of mHealth should be informed by value frameworks from the fields of medical ethics [67, 82, 89, 103], Philosophy of technology [27, 45, 64], public health ethics [77, 88] and theories of social justice in health [21, 37, 104, 115]. The latter theories are particularly well adapted to investigate health in the contexts of broader concerns of structural inequalities, such as justice, fairness and power, and particularly well positioned to guide debates on how to ensure that mHealth will have a positive impact from social and ethical perspectives [63, 104, 115]. In the following text, we take a closer look at some major ethically relevant issues and challenges raised by mHealth and discuss their implications and viable responses to them. We begin with considering the broader ontologies and epistemologies[6] shaping mHealth.

5.3 The Ontologies and Epistemologies Shaping mHealth

Every inquiry into the ethical implications of digital health technologies shall begin with broader questions about the foundations the technologies are based on. Whose approaches to

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[6] The term ontology refers to how the world is and functions and epistemology relates to way we gather knowledge about the world and its character.

and conceptualisations of health and illness shape digital health and mHealth technologies? Which socio-cultural views on healthcare, the organization, delivery and provision of health services do these technologies incorporate and promote? Much of technological innovation is driven by companies located in the US Silicon Valley [33, 63] while mHealth technologies are utilized by users of a wide-range of socio-cultural backgrounds and across national borders. Whether and how well these technologies accommodate various approaches to health (care) and wellbeing is an important factor, which can have a vast impact on their representativeness, uptake, and efficacy. Consider, for example, health prevention and how different strategies will have different relevance and success in different social contexts.

These broader concerns should also motivate inquiries into the participation and composition of the workforce in the tech industry and particular health technology developer teams. Many mHealth technologies are implemented on a population level, locally and often globally. Thus, it is important to ask how mHealth developers represent and reflect on the diversity of mHealth users? Current evidence shows a striking lack of diversity within the tech sphere, a whole 82.8% of employed ICT specialists in Europe are men [17] and major tech companies show a similar disparity, for example, Google's workforce is 69.1% male and 53.1% white, with only 25.5% women and 33.1% people of color in leadership positions [19], Apple's (2019) workforce is 77% male, with only 29% women in leadership and Intel (2019) reports 76.1% of men in the workforce. These disparities represent a problem, particularly because a growing pool of research shows that technologies designed by a partial segment of the population do not have high chances of serving as diverse a population as possible [22, 83, 86]. Sociologists and Science and Technology Studies (STS) scholars have argued that technologies carry the ideas and assumptions of those who develop them. A classic STS approach is to describe this as "user configuration" [3, 84, 113], in which the developer envisions the user as similar to them. Technology is often designed in a one-size-fits-all approach, with the developer as a reference category. This approach to design is often described as I-Methodology [84]. The problem with this narrow design is that it often translates into a selective benefit and a risk of harm in structurally marginalized populations [6, 49]. To benefit a diverse population, technologies need to be developed by diverse developer teams and under conditions promoting the approaching of design from a variety of perspectives (building on a diversified research evidence-base), enabling better solutions [100, 114]. In the case of mHealth, it has been shown that "members of low-income and racial/ethnic minority populations have had a limited role in the development and implementation of mHealth interventions designed to impact them" [118]. As such, digital behavioral interventions that aimed at increasing physical activities were effective in people of high socioeconomic status, yet, have been found to lack benefit in people of low socioeconomic status [92].

Bigger questions also ought to be asked about socio-cultural design of apps: which socio-cultural approaches to health and medicine do mHealth technologies involve? Much of innovation with mHealth has been done in the Global North [33, 63]. Digital humanities theorist Roopika Risam [92] has argued that the centering of these ontologies and epistemologies decentres those of the Global South, which is a significant problem should this be happening in technologies that are placed on a global market.

Overall, the involvement of target populations in the design process is key to ensure the relevance, efficacy and safety of digital health as well as user benefit [35, 47]. Particularly members of structurally marginalized and underrepresented populations should participate in expert and leadership roles in which they can set health priorities and agendas crucial to their communities. Scholars have argued that access to the ownership and governance of technology is also paramount to ensure that said technology will support the agency of various target populations and enable user empowerment [35].

5.4 Concerns of Accuracy, Safety, and Security

In general, some of the most crucial concerns regarding healthcare involve the accuracy and safety of particular health tools, technologies, therapies, health interventions and guidance associated or generated by them. Accuracy and safety are paramount for ensuring that health technologies provide user benefits and prevent harms (we will discuss these issues in more detail below). To guarantee that mHealth technologies will work properly and will be safe to use for all, it is crucial to secure that they will be evidence-based, informed by the latest medical research and other relevant scientific expertise, employ clinical and training data representative of the whole (diverse) target population, be clinically tested and approved particularly when providing diagnostic and therapeutic advice. Different approaches such as User-Centric Design and Values Sensitive Design (VSD) have been proposed to operationalize diverse user needs, incorporate their values and align the technological product to their expectations [24, 43].

Further concerns about safety relate to data and ways through which they are collected, handled, and stored. Just like standard and digital health records, mHealth gathers health data of sensitive nature, which raises concerns about the need for ensuring the privacy of mHealth users and preventing harmful and unethical management of data. There is much evidence that mHealth providers commonly commercialise user data, particularly those who offer 'free' health services in exchange for data, which in turn can affect already disadvantaged populations more [13, 35, 68, 97]. This evidence points to the practice of 'data mining,' often without the knowledge of mHealth users (we will discuss the implications in a section on preventing harm). A growing body of empirical evidence shows that users of mHealth technologies are not aware of how third parties use the data they collect, have little knowledge about data privacy and protection and express little concern in protecting their personal data [38, 52, 56, 126]. This evidence points toward the need for better protections of mHealth users, their data and health needs. A crucial part of this debate should lead to questions regarding whose interests does data collection serve and how does mHealth ensure the protection of mHealth users, their data and health needs. Such protections are also important for a better safe-guarding of data security, including with respect to dangers of data thievery or cyber-attacks, including dangers stemming from malware and the un/intentional manipulation of medical devices and unauthorised changes in the dosing of drugs [11, 54, 99].

5.5 Support for User Health Decision-Making

A major part of the transformative potential of mHealth is seen in its participatory effects, associated with increased user autonomy and empowerment in the health sphere [108, 119]. Through the utilization of various digital technological features, mHealth users (healthy individuals and patients) are perceived as engaging in a more active participation in the maintenance and improvement of their own health, with less oversight by health professionals or the healthcare system [70]. According to this view, patients are becoming "digitally engaged" [48] and empowered to be in charge of their health. Health-related knowledge is no longer exclusively held within the boundaries of medical facilities or in the hands of medical experts, which raises hopes for the democratization of the doctor-patient relationship and healthcare more broadly.

However, the notion of user empowerment in debates on mHealth warrants critical scrutiny. Many scholars have raised concerns that the conceptualisation of empowerment largely amounts to an individualistic notion of self-empowerment, for example in self-tracking for individual health benefit [47, 94].[7] Yet, the collection and handling of data can involve ethically concerning power imbalances and asymmetric relationships between those who provide data and those who process and use them in large quantities [15, 34, 69, 72, 101]. Beside already mentioned concerns about data safety and security, crucial questions need to be investigated regarding how to best guarantee that digital health data are collected in ways that empower and support users' health decision-making as well as their health and wellbeing? Consider again concerns of data mining and commercialization, which generate worries about the guiding of mHealth by users' health needs or common good. Some of the issues involved are often discussed as concerns of informed consent, yet, scholars have emphasized that it remains unclear how informed consent can be achieved or whether it is even possible to speak of it when standards of informing users fall short on, e.g., how health data is processed, monetised, or otherwise used [30, 101, 111]. These worries point towards broader issues of benefit and governance, including strategies for ensuring user's individual and collective agency over their own health data and the data of their communities and control over the purpose for which the data are collected and used [35] (more on these issues below).

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[7] We have already noted that for technologies to be considered supportive of user health decision making, they first and foremost need to be grounded in the latest, scientifically supported and diversified evidence base that justifies the health information, guidance and services provided by these health technologies. We will discuss related concerns in more depth below in sections on the need for preventing harm and providing benefit.

Contemplations on mHealth's potential for user empowerment also ought to investigate the conditions on which these technologies work. What enables and drives many of these technologies? Some have argued that much of mHealth is 'powered' by unpaid and invisible digital labour supplied by their users [15, 91, 119]. Yet, is it ethical, fair, socially sustainable, or indeed, user-empowering for health technologies to rely on free labour performed by users, some of whom are also patients? Many would argue that it is not and such critical inquiries appear particularly pressing considering the commercially profitable nature of many mHealth technologies for providers [47, 76]. It seems important that healthcare systems incorporating mHealth should ensure that these technologies are provided in ways that eliminate the exploitation and commodification of mHealth users/patients as part of their quest for healthcare.

Last but not least, the individualised notion of empowerment implicit in debates on mHealth involves a greater focus on individual rather than shared responsibility for health outcomes, which has troubling social and ethical implications. Such increased individual 'responsibilization' for health outcomes can shift attention away from social determinants of health and illness (e.g., economic inequalities and poverty, discrimination, gender-based violence, climate change, [7, 21, 71, 96, 104] and the need to investigate social responsibility for health, involve the promotion of individualistic rather than systemic solutions to structural health problems, and subsequently, lead to the attribution of blame to individuals for poor health outcomes that may not be under their control to avoid.

5.6 Protection from Physical and Mental Harm

The very increase in self-tracking and self-management via digital health platforms can have a variety of socially and ethically challenging aspects. Some of the concerns relate to how the digitization of health and the tracing and surveillance of bodily health data and measures impact on the relating to an individual's health and ways of knowing about it or the perception of oneself and the body.

Digital self-tracking and self-management can also involve unrealistic body and health norms, which can result in higher social pressures, exclusion or decreasing solidarity [69, 89, 102]. When mHealth generates constant surveillance, areas of human lives, such as nutrition, (un)healthy behaviour, sexuality or family planning can become more increasingly associated with feelings of bad conscience, guilt and shame [75].

A greater incorporation of mHealth into routine health care can have detrimental impact on mental health and wellbeing. You might have heard about the Quantified Self Movement, an online community of mHealth users who share and compare health data [80]. Such initiatives can exacerbate peer pressure and the need to compare and conform to dominant notions of health or appearance and the need for manifesting them in online communities and on social media [58, 103]. Some argue that constant information updates can have an addictive potential [50]. Self-optimisation through mHealth technologies could potentially cause depression in users, doing more harm than good [101, 110].[8]

Some have argued that mHealth involves the prioritisation of data generated digitally and outside of the body, with this data being ascribed more validity than one's own bodily sensations and judgements [48, 85]. This can present social and ethical problems, particularly considering evidence that much of mHealth lacks accuracy [12, 47, 98]. What justifies the assigning of epistemic authority to digitally generated data? There are various issues that challenge the notion that digital data is unambiguously more reliable, accurate, "objective" or free from harmful or discriminatory effects and we will discuss these issues below. To begin with, the prioritization of digital data assumes that calculations are independent of space-time and social conditions [45]. However, not everyone will have the socio-economic conditions and time to engage in regular self-tracking and this can in turn undermine the quality of mHealth generated data [48, 74, 79]. This suggests that efforts to minimise risk of inaccuracy and harm in mHealth also need to be committed to the investigation and mitigation of social inequalities as much as concerns of technological accuracy.

mHealth technologies also raise concerns regarding harm to structurally disadvantaged and vulnerable groups. The design of health technologies often mirrors social inequalities, e.g., by prioritizing a particular user group over other population groups,

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[8] Some scholars also suggest that mHealth can have a placebo effect, see: [110].

their health concerns and needs [21]. Some have argued that certain technologies are congruent with oppression and have materially discriminatory impact [12]. A recent example of such technology involves the pulse oximeter, a small digital health device that clips onto a fingertip like a clothes peg and records a patients' oxygen saturation, helping health professionals to assess patients' health. The tool was widely used during the COVID-19 pandemic when hospitals had to triage patients [12, 105, 109]. Less urgent cases were sent home to self-monitor, however, the pulse oximeter was found to record darker skinned patients better off than they were.[9] These empirical findings raise serious concerns about how many patients with darker skin tones have been deprived of hospital care and how many lives may have been lost owing to the bad design of the pulse oximeter. Further concerns have been raised about the accuracy of the pulse oximeter in women because the tool was not calibrated to fit women's on-average smaller fingers [45]. These concerns generate particular worries regarding the extent towards which women – particularly women of color – might have been exposed to a disproportionately negative impact from the medical tool.

There are other cases of mHealth technologies that have been badly designed and risk causing harm or have been shown to have caused harm to particular user groups. Recently, concerns were raised about a Google dermatology app, which was certified as Category I medical tool by the EU. Concerningly, this was done without a clinical trial and the data provided about the app by Google shows that the development of the app involved only one person of the darkest skin type and only 2.7% of the second darkest skin type [8]. The calibration of the app towards whiteness raises concerns over the potential of the app to harm racialized people through misdiagnosing or over-diagnosing them or being unable to diagnose them at all – options which could have negative implications for one's health and wellbeing.

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[9] Sjoding and his colleagues [105] conducted a follow-up study, investigating 48 000 pulse oximetry readings in 8675 US White patients and 1326 US Black patients, while comparing the results with more precise arterial oxygen saturation measures taken nearly contemporaneously. They found that pulse oximetry failed to detect occult hypoxemia (low level of oxygen in blood) almost three times more frequently in Black compared with White patients.

The inability to diagnose structurally marginalized patients has also been a concern in the use of algorithms more broadly. Many have argued that algorithms are never neutral because the data they are trained on are shaped by patterns of structural disadvantage and the coding can represent designers' partial viewpoints, prejudice, and preferences, creating distortion effects and often magnifying social inequalities [9, 27, 61, 81]. Moreover, algorithms also replicate and can magnify persistent social inequalities. Recent evidence has shown that in the US, an algorithm used by US hospitals was found to interpret Black patients as healthier that they were based on their lower health spending, which itself was an effect of discriminatory structures [14]. As a result of the decision-making software, millions of Black people were affected and deprived of adequate healthcare. Similar concerns have also been raised in radiology [90], where the use of AI was also found to skew diagnosis based on lower healthcare spending on racialized people and in mammography [36], where concerns were raised about digitizing already skewed data as a study has found that doctors tended to spend less time with women of colour, particularly of low socio-economic status. As such, there was a higher likelihood that the doctors also failed to diagnose the women properly and subsequently, fewer accurate diagnostic images and data for those groups of women were available for digitized datasets. Examples like these show that remedies to structural problems in digitized medicine and healthcare ought to go much further beyond 'bias' in data and datasets and address patterns of discrimination shaping medicine and healthcare. These issues also point towards the need for a greater focus on the elimination of structural vulnerability of already socially disadvantaged groups, including through a greater emphasis on the fundamental importance of benefit in the health context.

5.7 Increasing Benefit

The problems regarding narrow and discriminatory design of mHealth technologies and related harms and selective benefit suggest that the sector needs a systematic focus on health benefit and user-benefit oriented quality control. As technologies that are part of healthcare and offer health services, mHealth technologies ought to provide health benefits to users. User benefit should be facilitated in the population as a whole, in all diverse groups and disadvantaged groups in particular.

Yet, which empirical evidence exists to substantiate that mHealth technologies provide such population wide benefit and that they also benefit the most vulnerable and disadvantaged populations? Studies which supposedly provide evidence of benefit from mHealth commonly do not provide data disaggregated by specific population groups, e.g., with regard to gender and mHealth users' racial/ethnic self-identification or socioeconomic factors [23]. It is thus not clear who exactly do the mHealth technologies benefit and indeed, whether the reported benefit also relates to structurally disadvantaged populations or not – and why. However, the evidence of issues and concerns regarding harm or a risk of thereof in mHealth highlight the need for a different approach to benefit – a population-specific and intersectional conceptualization and measuring of benefit. Intersectionality is a theoretical framework that allows to examine how categories of social dis/advantage, such as gender intersect with other social identities, including socioeconomic status, racial and ethnic background, sexuality, or disability [65]. Such population-specific and rigorous approach research enables researchers to not only investigate and capture crucial differences among different population groups but also diversity within particular population groups – such as women – who are often falsely perceived as homogenous. By paying attention to issues of different social positionality or socioeconomic conditions, intersectionality allows to track and monitor how different categories of social disadvantage combine and investigate issues, such as barriers to accessing or receiving health services, which impact on health and wellbeing and can result in marginalisation, social disadvantage, and poorer health-care outcomes.

How significantly could mHealth technologies improve if intersectional thinking about benefit could be integrated already into the research stage preceding the design of a technology? Which materially beneficent impact would such a shift carry for the diverse target population? It seems plausible that an intersectional conceptualisation of benefit would increase the likelihood of actual user benefit in a diverse mHealth target population. What is also becoming obvious is that poorly and narrowly designed technologies risk magnifying health disparities and inequalities. A focus on intersectional benefit could change this by prompting technology designers and providers to improve design and seek heterogeneous and evidence base as well as test technologies in a manner sensitive to the specific needs of specific populations, rather than falsely assume that one mould fits all. Thus, intersectional thinking should be implemented into technology testing, assessment, safety, and quality control. These steps would then also provide a more accurate and evidence-based feedback on whether a particular technology was well equipped for large-scale application and use or more narrowly able to serve a very specific population.

5.8 Intersectional Benefit and Health Justice

Many of the issues mentioned in this chapter relate to issues of justice in the health context. In bioethics concerns of justice have commonly been associated with questions considering the allocation of resources and access to services [20, 53, 55]. These issues are relevant in the mHealth context too. For example, while some populations might access health services more easily thanks to the digitization of healthcare, others might not be able to receive the same services, owing to a digital divide, lack of funds to own a smartphone or difficulties with the accessibility of digital information [9, 66]. However, as we have shown throughout the chapter, concerns of justice are broader and include issues of structural disadvantage, vulnerability, and oppression, and the need for healthcare to provide equitable and just health outcomes across the whole population and facilitate health justice more broadly [21, 104].

A focus on health justice in mHealth also suggests that a different approach to design, assessment, implementation and maintenance of mHealth technologies is needed, i.e., one that would be concerned with mHealth quality control and particular health outcomes individual technologies bring about in specific populations. A focus on intersectional benefit would complement this endeavor well, as the intersectionality framework enables to collect empirical evidence and test the hypothesis that mHealth is able to provide broad and wide population benefit and revolutionize healthcare. Another advantage of a strong focus on benefit is that such an approach goes significantly further than a sole focus on harm. This is because a mere absence of harm does not ensure that a technology will provide a significant enough likelihood of improving user health, a threshold important in standard healthcare (Article 2 (1) of Regulation (EU) 2017/745).

A stronger focus on health justice in mHealth would also warrant the inclusion of quality control and provision of intersectional benefit into ethical and regulatory frameworks for mHealth. As we have noted, there currently is a lack of clear guidance regarding many mHealth technologies (or their specific sub-categories, such as apps) and testing and assessment criteria often do not involve concerns of non-discrimination and intersectional impact of mHealth technologies, with regards to safety, efficacy, harm and benefit. The current legal framework only provides legal regulations for a small selection of mHealth technologies. At the European level, only software that requires to be approved as medical devices (including apps and mobile applications, for example) is covered by law (Article 51 of Regulation (EU) 2017/745). Medical device law ensures that the software is technically and functionally safe – but not whether it is safe for health or whether it might have detrimental impact on particular population groups. Depending on the risk class into which the software is categorized based on its impact on health status (§ 33a, 139e, SGB V) an official conformity assessment procedure must be carried out before a notified body in Europe. Software, such as medical devices, is recognizable by the CE mark. However, since the classification and certification procedure does not check the intersectional health impact of mHealth technologies, potentially discriminatory software applications can also be certified and distributed on the European market.

Similar situation is in place in Germany. A distinction is made between digital care applications and digital health applications, the second of which can be prescribed by doctors and health insurers and reimbursed (§ 40a, 40b, 78a SGB XI, § 33a Abs. 1 S. 2 Nr. 1 – 2 SGB V, § 139e Abs. 4 S. 1 SGB V). While digital health apps must meet special criteria, such as proof of positive care effects, the regulatory framework, however, does not require the apps to be proven to be medically effective, only to improve healthcare processes. Moreover, digital health apps that cannot provide evidence of positive healthcare effects at the time of application can still be approved for a trial period of 12 months in accordance [25]. Thus, digital health apps that potentially do not meet the requirements of the law may also be prescribed. Beside health apps, care apps are provided by care insurers, without certification. Neither digital health apps nor digital care apps are tested and assessed for population specific and intersectional health impact or benefit.

Ethical frameworks for mHealth can also come short of integrating structural concerns of health equity and justice. Much of mHealth ethics has been disproportionately concerned with issues focussing on the individual user such as autonomy, privacy, transparency or uptake [31, 120, 123]. While these investigations can offer important insights, when ethical inquiries are disconnected from structural concerns of justice, then they aren't well equipped to research, map, capture, tackle or resolve complex problems regarding specific patterns of harm and benefit to health, or health disparities and inequalities replicated in and through mHealth, even globally. Neither can such approaches sufficiently identify and examine the roots of these problems and identify effective remedies.

The lack of focus on justice and equitable health outcomes in mHealth in ethical and regulatory approaches to mHealth is a major downfall but simultaneously, also a major opportunity for improvement. Such improvement is indeed necessary for the ensuring of high standard and quality of public healthcare, which would be relevant and beneficent to a wide cohort of the human population, locally and globally. Furthermore, scholars have also argued that these efforts for improving the relevance and quality standards of mHealth also ought to be better integrated with broader efforts to enhance social equity and justice. Currently, much of mHealth does not address the social factors, causes and inequalities that fundamentally shape human health. For example, mHealth apps responding to gender-based violence only rarely address gender inequalities and power structures which fuel and generate specific hierarchies and patterns of violence, most commonly men's violence against women and girls [31]. Most of the mHealth apps currently on the market offer one-off solutions and promote strategies to 'avoid' rather than mitigate and prevent such violence. This example illustrates that effective health interventions to socially generated health problems ought to go further beyond individualistic one-off and short-term solutions towards structural response strategies, which address the root causes of health problems and change oppressive and health-undermining social structures, inequalities and norms. In this regard, mHealth technologies ought to be better integrated with broader health and social efforts to address the social determinants of health and mitigate the causes and contributing factors generating and exacerbating health problems.

5.9 Conclusion

We have discussed in this chapter some of the major ethical issues raised by mHealth. We've discussed that while the field is rapidly growing, a robust long-term and population-specific evidence base is still lacking. We discussed a range of ethical concerns, starting with whose approaches and conceptualizations of health and healthcare shape mHealth and which impact it has on how they function and to whom the technologies offer beneficent results. We further discussed concerns of accuracy, safety and efficacy and the need for preventing physical and mental harm from mHealth and the importance of health benefit. We have argued that empirical evidence showing that digital technologies have the ability to magnify structural inequalities in marginalized and vulnerable population groups suggests that we need to think about harm and benefit in ways that are intersectional. Such intersectional approach to harm and benefit ought to take into account the differential position of various individuals and groups within social structures and inequalities that are dominant within them and find systemic solutions that will mitigate these structural problems. We argued that a greater focus on health justice in mHealth is needed and also warrants an intersectional approach to design, assessment, implementation and maintenance of mHealth technologies, that would ensure quality control and beneficent health outcomes across various specific populations. There are many more concerns and issues that remain to be addressed regarding equal access to mHealth or concerns of solidarity with those who may not be able or willing to use mHealth technologies. A well-functioning healthcare system should still make sure that such people will have access to appropriate health care services. The concerns and approaches we have described shall guide the development of ethical and legal frameworks, socially sustainable and responsible innovation with mHealth technologies.

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