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RECONCEPTUALIZING THE ETHICAL GUIDELINES FOR MENTAL HEALTH APPS:

VALUES FROM FEMINISM, DISABILITY STUDIES, AND INTERCULTURAL ETHICS

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RECONCEPTUALIZING THE ETHICAL GUIDELINES FOR MENTAL HEALTH APPS:

VALUES AND CONCEPTS FROM FEMINISM, DISABILITY STUDIES, AND INTERCULTURAL ETHICS

EXECUTIVE SUMMARY

Existing ethical guidelines that aim to guide the development of mental health apps tend to overemphasize the role of Western conceptual frameworks. While such frameworks have proved to be a useful first step in introducing ethics to a previously unregulated industry, the rapid global uptake of mental health apps requires thinking more deeply about the diverse populations these apps seek to serve. One way to do this is to introduce more intercultural ethical perspectives into app design and the guidelines that aim to encourage best practices. In addition to this, existing ethical guidelines can also benefit from the ethical scholarship from the feminist and disability traditions, both of which highlight specific ethical considerations for vulnerable users. Rethinking the ethical responsibilities of mental health app designers through the prisms of feminism, disability studies, and intercultural philosophy leads us to a more global and inclusive set of ethical considerations in app design. This white paper explores what existing guidelines for the regulation of mental health apps are missing. It also explores how these guidelines could be improved for users who inhabit an increasingly diverse and globalized world.

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1. CHALLENGE: ETHICAL GUIDELINES FOR A DIVERSE AND GLOBALIZED WORLD

Mental health apps are increasingly being proposed by governments, industry, and medicine as a digital solution to the growing need for mental health care across the world. The advantages of mental health apps have inspired app designers to create a vast number of products that are only partially governmentally regulated and often only in the country where the app provider does business. There have been some attempts at regulation by the European Commission's Digital Services Act (DSA) and optional regulation by major industrial players. Nevertheless, the creators of these initiatives concede that they are responding to a dynamic and fluid range of technical solutions to the clinical needs of app users and are poorly equipped to guide app developers from an ethical point of view.

The current regulatory mandates that attempt to guide the development of mental health apps focus on legal issues, with a heavy emphasis on efficacy, privacy concerns, and data safeguarding, which, this report argues, can be usefully supplemented with greater attention to the nuanced ethical value conflicts that regularly arise in this space. Where ethical guidelines have been drafted (Burr and Powell [18]), it has been acknowledged that they draw from predominantly mainstream European or Northern American rights-based ethical frameworks. This white paper attempts to remedy this by broadening the scope of normative frameworks that inform regulations. The so-called "next billion internet users" (Arora [4]) will predominately come from the Global South, with mental health apps showing exponential growth in non-Western regions. To better serve this growing number of users, a new set of ethical considerations drawing on the conceptual resources of what have been often underrepresented traditions are introduced (Singh and Sagar [75]). A broad representation of ethical traditions is important for many reasons, but in this case, the traditions on which this paper focuses stand to directly benefit the growing number of users of mental health apps.

The first set of traditions drawn from are intercultural ethical ones. Given that many users of mental health apps will come from non-Western countries, it is vital to ensure that Western ethical notions do not exclusively inform the regulation of these products. This means that the ethical regulation of these apps should explore normative frameworks that are non-Western, those that have developed in traditions outside the Western world. This white paper certainly lays no claim to be exhaustive here. Instead, it takes a selection of non-Western ethical concepts to illustrate how mental health app developers can improve their products by thinking beyond the Western ethical canon. The hope is that the usefulness of these concepts will inspire developers and regulators

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to think more widely about the ethical frameworks they draw from. Moreover, this aims to make the ethical guidelines that will inform the design of mental health apps more familiar to the ethical interests and concerns of non-Western users, while also providing ethical direction in this space.

The second set of traditions this paper examines has also been neglected and historically marginalized. This is the ethical theorizing of feminist and disability studies scholars, both of which have transformed the landscape of moral philosophy over the last four decades. Feminism has emphasized the role and importance of vulnerability, social relationships, interconnectedness, and relational autonomy. For example, it has rehabilitated the notion of care ethics, which emphasizes context in moral deliberation and the relational connections people have toward vulnerable members of the human community.

Disability studies also offer a challenging perspective on traditional ethical conceptions of human well-being and morality. Like feminism, this tradition emphasizes that humans are embodied beings but points to the diversity and variety of human embodiment, which is often neglected or judged critically.

As explored in the first section of this white paper, "The Regulatory Status Quo" (1.1), regulatory guidelines for mental health apps are currently highly limited from a geographical and cultural point of view, as there are no ethical codes for the designers of these products that draw on non-Western ethical traditions. Like the objection to the overarching use of Western ethical perspectives in the design of these apps (instead of intercultural ones), the same point can be made to plead for the increased use of feminist and disability studies in this domain. The use of apps is unequally divided along gender lines, and some of the most vulnerable users of the apps are non-able-bodied. This white paper proposes that listening to these traditions and actively incorporating their ethical insights into future guidelines for mental health apps will improve the design of these apps for tomorrow's global audience.

1.1. REGULATORY STATUS QUO

Summarizing the regulatory status quo in a concise yet useful way is challenging because of the breadth of existing regulations as well as their inconsistent level of depth and detail. Nevertheless, it is possible to map the key contours of the regulatory landscape in an informative way to show what is missing. To do this, this paper will make some broad observations before doing a deep dive into three approaches to regulation across specific regions (Europe, Germany, and the USA). The significant voids in regulatory frameworks necessitate caution, particularly in areas where app developers operate in a regulatory "wild west," encompassing much of the Global

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South. It is also important to note that current regulatory approaches prioritize approaches with a medical background and a strong preference for apps that are based on cognitive behavioral therapy (CBT). Various reasons can be attributed to this, but one key factor is the relative ease with which CBT approaches lend themselves to the online format as well as how they can be tested for effectiveness easily.

1.1.1. MENTAL HEALTH APP REGULATION IN THE EUROPEAN UNION

In the European Union, mental health apps are primarily regulated by the Medical Devices Regulation (MDR) and the General Data Protection Regulation (GDPR). The MDR, which came into effect in May 2021, classifies mental health apps as medical devices if they diagnose or treat mental health conditions. These apps must have a CE mark to comply with EU safety standards.[1]

The GDPR, effective since 2018, regulates how health data are processed. Mental health apps that collect, store, or handle personal information must adhere to strict data protection, security, and user consent rules. Health data are considered sensitive, requiring explicit consent and additional.

The European Data Protection Board (EDPB) has provided specific guidelines that stress transparency, user control, and data minimization, ensuring mental health apps align with GDPR principles.[2].

Furthermore, the European Commission has created mHealth assessment guidelines to ensure the safety, quality, and reliability of health apps. They offer a framework for assessing the clinical effectiveness, data protection, and usability of these apps. Additionally, individual member states have their own regulations. For instance, Germany's Digital Health Applications (DiGA) program allows certain apps to be prescribed by doctors and reimbursed by health insurance.[3]

1.1.2. MENTAL HEALTH APP REGULATION IN GERMANY

In addition to the European-wide regulatory guidelines discussed above, it is useful to focus on Germany to see how a national government within the European Union is responding to the challenge of regulation. Mental health apps in Germany are specifically regulated by the Digital Health Apps Directive [Digitale Gesundheitsanwendungen-Verordnung (DiGAV)], which is the leading directive for any manufacturer of digital

[1] Available at https://eur-lex.europa.eu/eli/reg/2016/679/oj
[2] Available at https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-032020-processing-data-concerning-health-purpose_en
[3] Available at https://www.bfarm.de/EN/Medical-devices/DiGA-and-DiPA/DiGA/_node.html

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health apps. The main aspect of this regulation is the set of prerequisites for the apps to be accepted in health insurance policies and cost redemptions. Specifically, DiGAV governs apps to do the following things:

- Follow the EU MDR (Medical Device Regulation 2017/745, with a strong focus on quality management, unique device identification, and risk
- Process data according to GDPR (EU General Data Protection Regulation)
- Prove effectiveness (proof of positive impact)
- Be committed to being listed in DiGA (directory of registered digital health apps)

Along with the DiGAV, mental health apps made and used in Germany must follow the Digital Supply and Care Modernization Act (Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz [DVPMG]), which is a regulation that applies to any kind of digital care apps (such as medication support apps, alarm systems, and guidance apps for fulfilling requests). The DVPMG requires the providers of these products to follow the following mandates:

- Provide electronic documentation according to the Electronic Patients Archive (ePA)
- Facilitate digital communication with governing interfaces
- Conduct and provide Data Protection Impact Assessment (DPIA) according to GDPR

DVPMG will ultimately impact almost any existing medical directive in Germany as a “digital addendum.”

1.1.3. MENTAL HEALTH APP REGULATION IN THE UNITED STATES

In the USA, the regulatory framework for mental health apps predominantly involves oversight by the Food and Drug Administration (FDA), Federal Trade Commission (FTC), and Health Insurance Portability and Accountability Act (HIPAA) compliance requirements that vary based on the app’s specific functionalities and how it handles user data. FDA generally divides mental health apps into the following three categories:

- General wellness products (GWPs)
- Medical products
- FDA-approved apps

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The FDA has outlined examples of "low-risk" apps eligible for regulatory discretion, particularly focusing on mental health apps. Regulatory discretion for low-risk GWP apps was emphasized during the COVID-19 pandemic following the Public Health Emergency (PHE) declaration.

The FDA oversees apps that function as medical devices. If an app solely provides educational information on mental health, it is not eligible for FDA approval. However, if an app offers therapeutic interventions, its creators may pursue FDA approval to certify it. To be considered a medical device, the software must be "intended for one or more medical purposes and achieve these purposes independent of a hardware medical device."[4]

The FDA enforces the FD&C Act that regulates the safety and effectiveness of medical devices, including some mobile medical apps. The agency focuses on digital health devices that could pose risks to consumers if they malfunction or if there are any breaches. Software functions that meet the definition of a device under section 201(h) of the FD&C Act are regulated as medical devices.

1.2. W.E.I.R.D DESIGN: CONNECTING INTERCULTURAL PERSPECTIVES WITH THE NEEDS OF MARGINALIZED USERS

As noted in Section 1 (Challenge: Ethical Guidelines for a Diverse and Globalized World), by far, the bulk of regulatory structures—mandatory guidelines, voluntary codes of conduct, and so on—are underpinned by Western ethical frameworks. The authors of this report wish to emphasize that such frameworks have been an effective way to begin the process of regulating mental health apps, although our aim here is to show why they are not comprehensive enough to accommodate the needs of the increasingly diverse users of these products. While we focus on the ethical frameworks that have informed the creation of apps themselves and their regulatory structures, it is vital to note that much of the empirical research that has informed their design is modeled on a subset—globally speaking—of users. Recently, the limits of research on this subset of users have become increasingly hard to ignore. Joseph Henrich's pivotal 2020 publication, "The WEIRDest People in the World: How the West Became Psychologically Peculiar and Particularly Prosperous," ignited discussions around the Western-centric bias prevalent in psychological research. This critique is centered on the fact that the majority of data is derived from Western, educated, industrialized, rich, and democratic (WEIRD) participants, highlighting a significant skew in the demographic profile of research subjects. Those who apply Henrich's

[4] See https://www.imdrf.org and consult "Software as a Medical Device (SaMD): Key Definitions."

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