Diversity and Inclusion in Unregulated mHealth Research: Addressing the Risks

Shawneequa Callier and Stephanie M. Fullerton

I. Introduction

Racial and ethnic minorities are much less likely than their white counterparts to be included in biomedical research, even when the health conditions studied disproportionately affect minority communities.[1] According to the 2018 U.S. census, about 40 percent of people living in the U.S. report Hispanic, Pacific Islander, African, Asian, or Native-American heritage, yet these groups combined represent a dramatically lower proportion of all participants in health research.[2] These disparities in research participation, which represent longstanding biases in recruitment and enrollment, threaten to undermine the equitable translation of research for broad public health benefit.

Mobile health (mHealth) technologies could aid in the recruitment and engagement of a broader array of research participants and citizen scientists.[3] mHealth research encompasses the use of mobile phones, wearable sensors, and related internet-linked services (e.g., social media, email, video streaming, web-based counseling) for health communication and monitoring.[4] To the extent that individuals typically underrepresented in research are able to access and use mHealth technologies, these tools could help address persistent barriers and transform the inclusiveness of biomedical research.[5] Unregulated mHealth devices and applications, however, present risks to underrepresented minority populations that have yet to be fully evaluated.

This article considers important questions surrounding the adoption of unregulated mHealth technologies for the purpose of enabling more diverse research participation.

Potential risks to minority participants and their communities arising from disproportionate surreptitious enrollment, the promotion of secondary (often commercial) uses of applications and participant data, discriminatory profiling,[6] inaccurate health inferences due to algorithmic biases,[7] and unrepresentative reference data,[8] may undermine trust in this new form of (largely unregulated) research, exacerbating rather than resolving current inequities. First, we elaborate on the potential benefits and challenges involved in the use of unregulated mHealth technologies for promoting diversity and inclusion in biomedical research, and second, we discuss preferred approaches to address these challenges moving forward.

II. Promise of mHealth to Advance Equity and Inclusion in Research

A number of important publicly funded research efforts aim to improve the participation of individuals historically underrepresented in research, including the All of Us Research Program,[9] the Population Architecture Using Genomics and Epidemiology Consortium,[10] the Human Heredity and Health in Africa initiative,[11] and the Trans-Omics for Precision Medicine Program.[12] Private companies, including direct-to-consumer genetic testing companies, have also launched a number of initiatives to increase the diversity of their customers.[13] These and related efforts have drawn attention to numerous barriers to the enrollment of diverse study cohorts. mHealth

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technologies hold potential to address barriers to recruitment and engagement (although there is still much work to be done to realize this potential)[14] and have already demonstrated success through text messaging programs.[15]

With respect to recruitment, prior analyses have underscored the ways in which members of racial and ethnic minorities are less likely to be invited to participate in research than their white majority peers.[16] Virtual advertisements, distributed via social media and mobile phone applications, may be one means of overcoming this recruitment barrier.[17] Participants who see online advertisements for health improvement studies may be more likely to enroll if they can bypass their daily constraints (e.g., time to travel to the research site, the desire to go to work, family obligations, and caregiving).[18] Further, in order to ameliorate unequal power relationships between participants and researchers,[19] participants can be given wearable devices and mobile applications that afford them greater control over the terms and limits of their participation, potentially addressing latent power differentials and feelings of distrust. Studies showing that African Americans expressed willingness to participate in mHealth studies and were more likely than any other groups to use mobile health-related applications[20] provide some evidence that the adoption of mHealth tools could be acceptable depending on the underrepresented population.

Once members of underrepresented populations are successfully recruited to a study, ongoing engagement, particularly for longitudinal investigations requiring repeated research interactions, can also be challenging and lead to attrition.[21] Here too mHealth devices and applications may provide important tools for promoting ongoing engagement. mHealth applications can collect information from users wearing or using wireless devices either actively[22] or passively (e.g., through a wearable accelerometer sensor that measures sedentary behavior).[23] Studies have successfully engaged patients who share medical data with researchers using web-based platforms, log their exercise activity and meals on smartphones or Facebook, and participate in cell phone-based smoking cessation counseling.[24] At a minimum, these types of mHealth applications, which may be accessed from personal smartphones and at times and locations convenient to the participant, can limit attrition.

III. Potential Pitfalls of Unregulated mHealth Research

Despite the promise of mHealth research to address persistent barriers to research recruitment and engagement, unregulated mHealth technologies pose risks to underrepresented and minority participants within the contexts of regulated and unregulated research.

A. Marketing Masquerading as Research

mHealth applications are often designed by and for for-profit companies seeking to recruit individuals to research, collect data, and expand their marketing[25] and, as such, their unregulated adoption for other research can be problematic. Andrews argues, for instance, that companies recruiting for virtual clinical trials may claim to be providing a health service (e.g., drug safety alerts) while targeting people for clinical trials.[26] Pharmaceutical and health marketers are also integrating both data collection and digital marketing tools with mHealth devices, such as wearables.[27] Data aggregators assist marketers by creating digital profiles of individuals based on behavioral factors, health conditions, and social identity, including race, gender, health condition, and socioeconomic status.[28] The profiles used for marketing purposes may represent individuals or groups, and rely on stereotypical and stigmatizing frameworks.[29] The risks of digital profiling, which are described further below, are likely to be disproportionately borne by historically marginalized groups, including underrepresented populations (e.g., women, disabled, poor, homeless), minorities (e.g., racial, ethnic, sex and gender), and the poor.[30] Without oversight, these types of harms are likely to go unchecked and unevaluated within the context of unregulated mHealth research.

B. Promoting Use of Unregulated Secondary Applications

Appropriately directed and regulated mHealth research may nevertheless lead potentially vulnerable research participants to seek out and use secondary unregulated applications that pose additional unanticipated risks, especially to underrepresented and minority populations with limited access to medical care.[31] Participants enrolled in regulated biomedical research who receive results, such as genomic sequencing data or health related information, may seek out mHealth applications unrelated to the study, such as those provided by their insurance companies or sold in the app stores, to help understand those results. Unfortunately, mHealth commercial vendors offering services related to sensitive mental health conditions, heart health, and other bodily monitoring applications reportedly use unsecured internet communications and third-party servers, placing participants and their data at risk outside of formal research participation.[32]

In many cases, the devices and applications employed in a regulated scenario could themselves be unregulated and outside of the reach of the major biomedical

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research laws designed to protect research participants (i.e., the Common Rule, FDA laws, and HIPAA).[33] Since digital health resources enable a collaborative and accessible research environment, diverse regulatory regimes can co-exist for multiple mHealth applications, and in some cases, instances of no regulation at all. Research participants may disclose sensitive details about themselves on one application and then on another by interfacing fluidly in what they perceive as a uniform digital environment. The consequences, which are too soon to predict entirely, could breach the trust of research participants and impact future minority recruitment and engagement in mHealth research.

C. Discriminatory Profiling

Data aggregators may also be incentivized to invade privacy and collect data in an attempt to identify or create profiles of potential research participants.[34] In addition, consumer health data are continually fused with financial, geographical, behavioral, and social data.[35] Montgomery argues that these risks to individual privacy are accompanied by profiling and discriminatory practices that span across fields and impact employment, education, insurance, social services, criminal justice, and finance.[36] Unregulated mHealth platforms can enable data collection related to location, environment, and health in "real time."[37] Since data collected from mHealth devices are unprotected by the medical privacy laws that govern covered medical entities and federally funded researchers,[38] these data can be sold to additional marketers and third parties.

Underrepresented research participants and minorities who own smartphones are more likely to be dependent on them[39] and may be subject to more surveillance than majority groups, extensive data collection, and monitoring in ways that are not disclosed to them.[40] Research programs that provide discounted products and services in exchange for private data, might even create a "privacy divide"[41]: people who are more likely to experience discrimination due to low socioeconomic status are also more likely to take advantage of such incentives and to be exposed.[42]

Discriminatory stereotyping may deny individuals the opportunity to access relevant or broader studies advertised to people who are grouped differently—a practice which is unlawful within the context of regulated research. Investigators have the tools to target research participants based on smartphone ownership, zip code, and other factors[43] in order to improve the likelihood of success, which could lead to the unwarranted and unfair segregation of participants in unregulated contexts.[44] A national survey of health app use among mobile phone owners found that whether someone downloaded a health app was significantly correlated to younger age, Latino/Hispanic identity, a higher income, a high school education or more, and obesity.[45] Evidence suggests that African Americans tend to be more likely than other groups to use health apps,[46] and that their preferred mobile device is an Android.[47] Thus, there are sometimes links between racial and ethnic identity and the types of devices commonly used (i.e., androids versus smartphones, smartphones versus flip phones). Underrepresented and minority communities may be particularly vulnerable to discriminatory practices if they reside in low-income communities.[48]

D. Poorer Quality Feedback Due to Biased Data or Algorithms

Even well-intentioned and non-duplicitous mHealth research (both regulated and unregulated) has the potential to expose minority research participants to unanticipated risks due to relying on unrepresentative reference data or biased algorithms. As noted above, many minority and marginalized persons are significantly underrepresented in biomedical research studies and databases.[49] As a consequence, reliable reference data against which to contextualize and interpret personal health and lifestyle information may be limited, a problem that has been described in the context of genomics research as the "input/output problem."[50] Whereas many forms of biomedical research have not, until recently, offered individual research results to participants, norms are changing[51] and mHealth applications are poised to enable routine feedback. With evidence accumulating that what constitutes a "normal" laboratory value for healthy individuals may vary by demographic characteristics, such as age, race, and sex,[52] there are significant concerns that minority users could receive inaccurate or misleading information due to inadequate reference data.

Similarly, "black-box" and potentially biased algorithms for associating individual information with specific health risks, such as newly emerging polygenic risk scores to predict complex disease outcomes, may significantly underestimate risks when translated to individuals drawn from populations different from those on which the algorithms were built or trained.[53] The impact of such biases are only beginning to be recognized in other areas of data science and artificial intelligence.[54] How best to identify and address related concerns in unregulated mHealth research remains an open question.

E. Other Limitations and Capacity-Related Concerns

Finally, it is important to acknowledge that general adoption of mHealth technologies may not be able to address all barriers to recruitment and retention. Cur-

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rently, it is unclear whether mHealth apps will be successful among populations that require careful attention to cultural influences and literacy on uptake.[55] Wearable fitness products, such as Fitbit or MapMyFitness, and other research tools may require access to data hotspots and sufficient Wi-Fi connections that are not readily obtainable in some communities.[56] Minorities who are elderly, disabled, and chronically ill may require special assistance or additional investment in resources and time in order to effectively use mHealth applications. Digital communication about research findings with implications for emergent health issues, however accessed, may be inadequate without follow up with an informed healthcare provider. Given these difficulties, advanced digital strategies will need to consider whether it is possible — and, if so, how — to increase participant access to technologies compatible with individuals' and communities' resources.

Further, the exclusion of some communities traditionally rendered invisible by medical health systems could be helped by unregulated mHealth research if approached through the use of careful community engagement strategies described elsewhere in this article. Sexual and gender minorities, for instance, are difficult to identify because their sexual orientation and gender identity information is often not captured by clinical research, as well as federal and hospital surveys.[57] Still, concerns among immigrants, individuals, and families that feel vulnerable to bias, cultural incompetence, and surveillance may avoid enrollment in mHealth research altogether. These concerns may be valid among all vulnerable groups encouraged to use unregulated mHealth devices.

IV. Unraveling the "Gordian Knot": Promoting Inclusion While Minimizing Risks

Despite the clear promise of mHealth devices and applications to address persistent barriers to recruitment and engagement of historically underrepresented individuals and communities, the risks outlined above make the uncritical promotion of unregulated mHealth approaches for such purposes problematic. Nevertheless, we should not regard the implied intractable tradeoff (symbolized with respect to the "Gordian Knot" that confronted Alexander the Great) as unresolvable in practice.[58] Instead, specific ethical considerations and policy approaches can reduce potential risks, allowing interested mHealth researchers and communities to maximize participation of currently disenfranchised groups and, ultimately, promote the broadest possible public health benefit.

Elsewhere in this symposium, the main research team makes recommendations for a series of measures, including education, consultation, transparency, self-governance, and regulation to address the welfare and interests of research participants, as well as the broader public, in mHealth research.[59] Our intent here is not to duplicate those recommendations (which we endorse), but rather to elaborate on the types of measures that should be considered when unregulated mHealth approaches aim to promote more diverse research participation. Because past research abuses have disproportionately impacted communities of color,[60] there is a heightened obligation for unregulated mHealth researchers to anticipate and, wherever possible, actively minimize such risks. The failure to do so may undermine participant and community trust[61] and further exacerbate already unacceptable disparities in research participation.

First, there is a clear need to develop and disseminate education and other informational and consultative supports to help those not otherwise subject to human research regulations identify the interests of mHealth tool users or other stakeholders in order to address potential risks and concerns. While it is reasonable to envision general educational tools about research protections being made available through organizations such as the National Institutes of Health (NIH) or organizations of unregulated researchers,[62] more targeted consultation may be required when research is directed toward traditionally underrepresented populations. Ongoing and sustained engagement with a project-specific Community Advisory Board (CAB), which can represent the interests of both potential application users and other community members who might be impacted by the research process or its results, is especially important.[63] CAB feedback can help ensure that even unregulated mHealth tools are designed with the interests of specific communities in mind and promote trust in both the research and researchers.[64]

Second, in addition to regulatory mechanisms to ensure greater transparency with respect to the validation of mHealth application algorithms,[65] urgent attention must also be directed to inferential biases that can derive from the use of unrepresentative reference data; these biases are most likely to impact the very communities mHealth aims to engage in research.[66] This is a complicated issue that could possibly be addressed by making prospective participants better aware of the potential limitations of any feedback they might receive. Such transparency could discourage minority participation, however, further exacerbating existing evidentiary disparities. Alternatively, and far preferably, mHealth application developers could adjust the ways that their algorithms make use of reference data to ensure that individuals receive feedback of comparable quality and certainty.

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Third, while fears of commercial exploitation or other forms of discriminatory marketing may most effectively be addressed by consumer protections afforded by the Federal Trade Commission and the Consumer Product Safety Commission,[67] it is equally important to empower citizen scientists and other unregulated researchers to be attentive to potential abuses that disproportionately impact minority and marginalized groups. A distinguishing feature of citizen science compared to traditional research models is that research platforms include active participation by those who are normally the subjects of research.[68] This includes participants or "citizens" experiencing an illness or health issue. As mHealth devices and applications are deployed to attract a more diverse range of research participants, the ranks of citizen scientist sponsors of research must also be diverse. In both capacities, as participants and as sponsors of research, citizen scientists drawn from historically underrepresented communities will be well-positioned to identify objectionable data collection practices or adverse events and report such concerns to appropriate regulatory entities. In short, self-governance will become more effective as the unregulated research community widens to include diverse viewpoints and perspectives.

If unregulated mHealth research is conducted without oversight and due care, outcomes could resemble those of the subprime lending crisis: people already marginalized due to poor credit, low resources, and social and political exclusion may experience riskier, low-quality research engagement or feedback. While regulatory remedies can address some of these concerns, ensuring quality feedback when reference data remain skewed toward one or few (typically, white, higher income, and well educated) populations is more challenging and may require greater transparency on the part of investigators as well as more detailed engagement with citizen scientists from the communities that are the focus of research.

V. Conclusion

Despite the immense opportunity mHealth technologies present to bridge biomedical research divides,[69] there remain concerns that poorly managed and misguided "technical fixes"[70] can pave the way to inequity.[71] If unregulated mHealth research is conducted without oversight and due care, outcomes could resemble those of the subprime lending crisis: people already marginalized due to poor credit, low resources, and social and political exclusion may experience riskier, low-quality research engagement or feedback. While regulatory remedies can address some of these concerns, ensuring quality feedback when reference data remain skewed toward one or few (typically, white, higher income, and well educated) populations is more challenging and may require greater transparency on the part of investigators as well as more detailed engagement with citizen scientists from the communities that are the focus of research. At the very least, explicit detail about the dependency of unregulated mHealth research on commercial interests and current (often biased) data will be required to ensure understanding of the potential limitations involved and promote trust in the research process.

Unregulated mHealth research holds potential to widen and diversify the pool of research participants, and mHealth researchers should therefore proactively take into account location, income, and social identity of those with whom they seek to interact. Mobile devices present favorable mechanisms for capacity building to conduct inclusive mHealth research; new community-informed models can be created to broaden the reach of these technologies and limit harmful consequences, even when research and technologies remain unregulated.

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Note

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71. *Id.*, at 5-7.

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