mHealth Research Applied to Regulated and Unregulated Behavioral Health Sciences

Camille Nebeker

I. Introduction

Technology, applied to the health sector, is referred to as "mobile health," "mHealth," "digital health," "e-health" and "digital medicine." Not only are we experiencing a new lexicon to describe this new health sector but, not unexpectedly, the terms are used interchangeably and definitions are not standardized. For example, the World Health Organization (WHO) defines mHealth as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices,"[1] whereas Park suggests an alternative of "the use of mobile devices to monitor or detect biological changes in the human body,"[2] and the National Institutes of Health (NIH) has been credited with describing mHealth as "mobile and wireless devices used to improve health outcomes, healthcare services and health research."[3] While a standard definition may not exist, the term "mHealth" is used in this paper and described in the domain of behavioral health research. In this context, mHealth involves the use of wearable and remote wireless sensors, mobile apps and social media platforms for the purpose of observational research and deploying behavioral interventions designed for health promotion and/or disease risk reduction.[4]

In addition to sensors and platforms that capture behavioral, environmental and social data, behavioral scientists utilize existing data from the electronic health record (EHR), including genetic information.

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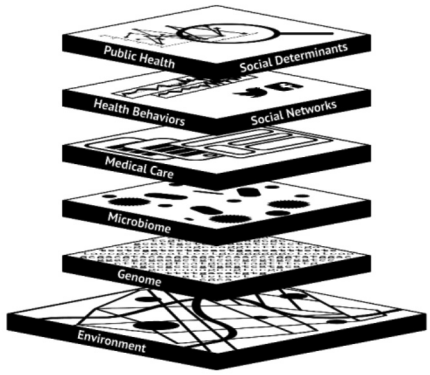
Figure 1

Overview of Influences on Human Health and Disease



(Source: Kevin Patrick, M.D., M.S., UC San Diego)

With genetic, behavioral and environmental data combined with new computational tools and novel methods, behavioral scientists are better able to make sense of and, subsequently, intervene to improve human health (see Figure 1). Clearly, the rapid escalation of digital health research has occurred more quickly than the science[5] and regulations[6] have been able to accommodate.

Those in the mHealth research sector find new digital tools and strategies exciting as they facilitate opportunities to answer research questions; yet, several factors make the design and implementation of mHealth research somewhat challenging. For example, how to safely use sensor technologies and ubiquitous computing to respect the rights of research participants is essential; however, qualifying and

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quantifying potential harms is challenging.[7] Additionally, the technology, be it a passive sensor or mobile app, needs to produce valid and reliable data, which is variable across products.[8]

Technology is also contributing to a shift in the research ecosystem and, subsequently, new actors are involved in the conduct of health research. Traditionally, research was carried out by professional scientists who received extensive training in a specific discipline and were then guided by conventions and norms deemed acceptable to respected professional societies as well as federal laws and regulations. While these professional researchers are active in mHealth, increasingly, research is conducted by people, also known as "Citizen Scientists." Those operating under the broad Citizen Science umbrella often have little or no formal research training and, unless working in partnership with professional researchers, may not be governed by professional standards or regulatory bodies.[9] For example, in "Rise of the New Bio-citizen," Pauwels and Denton share stories from eight health innovators who are solving their own unique health issues through self-experimentation and technology development.[10] These activities range in risk from benign to life-threatening and may occur in silos or in collaboration with organizations including non-profits and higher education. The novelty of tech-enabled health research, combined with increased access by largely unregulated non-traditional "researchers," has opened the door for new research methods (e.g., adaptive intervention, N-of-1 self-study) as well as unique ethical and regulatory challenges that are ripe for examination and discussion.

To better understand how mHealth is occurring in the behavioral sciences and related ethical challenges, this paper introduces sources of data along with the types of tools and methods used. Use cases are included that portray authentic activities complemented by a brief analysis designed to elevate awareness across: (1) governance including conventions, norms and regulatory structures; (2) formal research training; and, (3) acculturation with respect to widely accepted ethical principles of respect for persons, beneficence and justice found in the Belmont Report[11] and respect for law and public interest as described in the Menlo Report.[12] To conclude, questions for further empirical research are posed with recommendations to advance responsible behavioral mHealth regulated and unregulated research.

II. Behavioral Science in mHealth Promotion and Disease Prevention: Methods and Tools

The behavioral sciences are grounded in public health, anthropology, sociology, psychology and cognitive sciences to examine organisms, in our case humans, and their interactions within social and environmental system.[13] In the context of health promotion and disease prevention, behavioral scientists conduct observational studies to learn how people behave in their natural environments.[14] These data are used to develop hypotheses and design experiments to study behavior and behavior change. Behavioral mHealth has received steady support from the NIH to identify, for example, how to influence smoking cessation among pregnant moms,[15] decrease sedentary behavior among youth,[16] increase physical activity,[17] and to control appetite,[18] to name a few. Behavioral strategies are also used in studies of mental health including substance use among adolescents,[19] management of bipolar disorder[20] and, monitoring of self-harm.[21]

Over the past decade and, in response to the explosion of new technologies, behavioral scientists have developed new methods and frameworks to guide how best to use technology to optimize individual level change.[22] Pervasive sensors and mobile apps allow researchers to passively observe human behaviors "in the wild" 24/7 and supports delivery of personalized interventions in the real-world environment.[23] A Just in Time Adaptive Intervention or JiTAI is one approach being used today, whereby an mHealth technology is programmed to deliver the intervention at the time and location that is optimized for that particular individual.[24] For example, a JiTAI might combine the use of wearable sensor technologies and text messaging to carry out behavior change studies tailored to an individual in their natural environment.[25] This novel ability to collect temporally dense, longitudinal, and personal data is possible because of the increased ease and access of smartphone sensors and connectivity. First passive data, information collected automatically from sensors, offers a wealth of behavioral related data without any active engagement from the user.

This is all possible because smartphones contain an incredible array of sensors that allow applications to constantly record where users are, and in what direction they are moving using Global Positioning System (GPS) and magnetometer, or how the device (and likely the user) also moves in space with accelerometers and gyroscopes.[26] Smartphone technologies are capable of contextualizing and "understanding" the current environmental conditions through barometers, thermometers, and ambient light sensors, and by capturing audio and video of the user or the surroundings through multiple integrated high-definition cameras and microphones. Cameras and microphones are also pervasive in the environment, or on wearable devices, and cutting-edge computer vision and speech processing techniques combined with new machine learning

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algorithms are enabling unprecedented research with active data in the form of smartphone surveys, also known as Ecological Momentary Assessment (EMA), it is increasingly possible to assess behaviors, mood and experiences in real time within the persons real-world context.[27] Unlike passive data, active data requires the engagement of the user for information to be captured. The advantage of EMA is that it minimizes retrospective recollection and allows for behaviors to be easily recorded over days and, even years. Combining both active and passive data, it is now possible to understand behavioral cues in people affected by a variety of health problems such as stroke,[28] Parkinson's disease,[29] or autism.[30] The realm of mixed passive and active data includes social media platforms, where natural language processing is enabling researchers to mine textual data exchanged online for example to characterize HIV risk[31] to study social ties related to smoking[32] or to identify outbreaks of disease.[33]

III. Existing Governance and Norms

Digital technologies in behavioral health research are currently outpacing the regulatory structures and, potentially, ethical guidelines that typically support and inform responsible research practices.[34] In this section, challenges introduced by mHealth research tools when applied to behavioral sciences are described across: (1) regulated academic research organizations; and (2) unregulated citizen science.

1. mHealth in Regulated Academic Research Organizations

A recent study looked at NIH's support for mHealth research at three time points over a 10-year timespan (2005, 2010 and 2015) and found 12-fold increase in the number of mHealth projects.[35] Organizations hosting these mHealth studies have been slow to respond as public facing guidelines directed to researchers are, for the most part, non-extant.[36] Because organizations supported by NIH to conduct health research are required to comply with federal regulations for human subjects protections (45 C.F.R. 46), these entities must utilize a process of review to ensure that research is conducted consistent with the regulations and accepted ethical principles. While behavioral mHealth research is becoming more common, there is a knowledge gap among those designing the research as well the institutional review boards (IRBs) charged with evaluating the probability and magnitude of harms to participants against possible benefits.[37]

An example of this gap was reported in a 2015 study evaluating IRB determination letters in mHealth research that involved wearable sensors. Specifically, eight protocols were obtained that used a combination of sensors to: (1) record the participant's first-person point of view using an outwardly facing wearable camera, (2) location via and a waist worn GPS device and, (3) movement using an accelerometer. For each protocol, the IRB determination letters were coded for patterns and themes with results revealing that risk identification and management strategies were inconsistent across the several IRBs involved.[38] One inconsistency was whether the IRB expanded its charge beyond human subjects to include protections of bystanders. Bystanders are people who are not research participants, yet may become part of the research record if their image or other personal information is captured by a device used by the research participant. Also noteworthy in this review was a consistent lack of concern about how GPS data would be managed. The granularity and volume of location data generated from wearing a GPS sensor can reveal sensitive and personal information about the participant. Lacking standards for storage of these data, both researchers and IRBs should be aware of the sensitivity of location data and think carefully about how to securely store these data. This is especially true when not covered by privacy protection regulations like HIPAA, for example.

Needless to say, mHealth research conducted within a regulated environment may have advantages because the infrastructure exists; however, the need for both the researchers and IRB members to become knowledgeable about the technologies being used as well as the types of data produced is critical. The example above is based on a 2013 NIH study and the use of "research" grade technologies as opposed to clinically tested and/or commercial products. As such, the researchers had full control over data collection and storage — no third party or platform was involved. Following launch of these observational studies, commercial wellness products were deployed in the marketplace (e.g., Fitbit initially and now, Apple Watch) and are now used in behavioral research. With these commercial products, the researcher lacks direct access to and control of the "research" data which, introduces new potential risks for research participant protections around data management and privacy protections. In addition, the federal regulations for human subjects protections conflict with the standard language found in the Terms of Service (ToS) agreements specific to exculpatory language (45 C.F.R. 46.116); making use of the product nearly impossible without introducing potential compliance issues for research organizations operating under the Common Rule.[39]

When it comes to mHealth strategies, it is critical that we not assume those involved in the design or use of health technologies are well versed in the

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risk assessment process. The new technologies used in mHealth research are powerful and sophisticated and, in many cases the risks assessment is difficult to calculate.

2. Unregulated Citizen Science

Unregulated health research carried out by citizen scientists continues to rapidly expand. While there are various terms to describe this category of researcher such as lead innovators,[40] quantified self,[41] bio-citizens,[42] do it yourself,[43] and participant-led researchers[44] — one thing they all have in common is taking health matters into their own hands. Another commonly used term is N-of-1, which can be attributed to the labels introduced above, as well as systematic cross-over studies that are carried out by the individual or, in partnership with their physician/clinician.

Should there be guidelines or guardrails that support those who are embarking on PLR or otherwise conducting research that is not federally regulated? Should the research definitions be expanded, or would most agree that self-study is human nature and any regulation might compromise agency? And, are trained researchers who provide support to PLR studies acting responsibly?

Those taking part in citizen science, broadly speaking, are highly motivated people who are either looking for solutions to pressing health problems or are genuinely curious about their health and factors that influence wellness.[45] Regardless of whether they are conducting self-tracking, self-experimentation or building solutions, they are doing this work without regulatory or ethical frameworks to guide practice. Well-documented harms from this type of research, for example with brain stimulation, highlight risk especially as such "do-it-yourself" efforts can be rapidly spread via social media leading to exponential risk.[46] Initiatives to explore the related ethical dimensions and concurrent development of guidelines and/or regulatory infrastructure are emerging, but nascent. One pressing question, and the objective of the overarching study,[47] is whether we can build from existing structures and norms to offer guidance on responsible mHealth research practices to this group.

Because these researchers may not be affiliated with an organization that receives federal funding and, subsequently, not subject to the Common Rule or FDA regulation there is no requirement to involve an IRB prior to launching a study. Another point of consideration when evaluating whether or how to regulate people conducting self-study are the definitions used to define a human subject. The current regulation states that a human subject is a "living individual about whom an investigator (whether professional or student) conducting research…"[48] A person involved with self-tracking or self-experimentation is both the researcher and the participant, as such, the regulatory language must adapt if expanded to include those conducting this form of citizen science.

An example of a citizen science activity in the behavioral health sector can be found with a group of patients who have formed a Participant Led Research (PLR) initiative in southern California called Project Apollo. These individuals have a common frustration with the healthcare system and have experienced difficulty getting an accurate diagnosis. Few in the group have received formal research training or been exposed to what might influence its ethical conduct, yet regardless, they are embarking on a journey of becoming better informed patients. They have come together to support one another in the process of learning how to self-track and, potentially, self-experiment with an overarching goal of building their health literacy, research literacy and agency. To this end, they are learning how to review the scientific literature, form a research question and test a hypothesis. Given these are behavioral health studies, the questions focus on lifestyle and environment with hypothesis testing on topics of sleep, nutrition, pain and stress (e.g., stopping screen-time two hours prior to bedtime will improve my sleep). The majority of Apollo participants are using a commercial product called an Oura ring to monitor their sleep duration and quality along with heart rate variability, respiratory rate, body temperature and resting heart rate.

Another example is the Gut Instinct project, a PLR involving a citizen scientist recruiting other citizens to participate in research.[49] The Gut Instinct platform, developed by a doctoral student at UC San Diego, facilitates the ability for non-professional researchers to design and deploy studies. Whereas the Project Apollo PLR is a within subject, N-of-1 design, Gut Instinct studies are design by an individual who then recruits others to participate. In one case, a study

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was designed and implemented to answer a question about whether using less social media increased optimism; another looked at weather drinking beer in the evening helped people go to sleep.[50] The research team behind Gut Instinct has a goal of helping people to learn about themselves and solve their own problems.[51]

Since regulated researchers are, at times, involved with Apollo and Gut Instinct, they have obtained IRB approval for some of the research associated with these citizen science projects. However, in these examples, the citizen scientists are learning how to conduct a systematic investigation but, not necessarily with a goal of contributing to generalizable knowledge. They envision teaching others how to learn about their health through PLR in the form of self-tracking and self-experimentation. Using the formal definition of "research," which is "a systematic investigation designed to contribute to generalizable knowledge" and "human subject," defined earlier, it is unlikely activities carried out by these PLR activities would qualify as something to be regulated based on current definitions.[52] That being the case, should there be guidelines or guardrails that support those who are embarking on PLR or otherwise conducting research that is not federally regulated? Should the research definitions be expanded, or would most agree that self-study is human nature and any regulation might compromise agency? And, are trained researchers who provide support to PLR studies acting responsibly?

Use Cases — Un-Regulated. Since unregulated research is typically not evaluated by an external body, the following examples provide an opportunity to consider the application of ethical principles to unregulated behavioral health studies.

Use Case #1: Lipids, Diet and Exercise: Participant Led Research
Digital Products: Commercial
Sector: Unregulated Citizen Science
Funding: Private Foundation

In 2018, a group of people affiliated with Quantified Self formed a PLR group with a collective goal of supporting each other in the process of learning to self-track blood lipid levels.[53] For this study, each participant developed a research hypothesis related to a personal interest (e.g., does training for a marathon influence my daily blood lipids? does a keto diet influence my lipid values) and conducted an experiment using a within subject, single-subject, self-study design. All used a medical grade blood testing device called CardioChek.[54] While most in this PLR had received an advanced degree, few had formal academic training in research and, as such, subject matter experts assisted the PLR with study design, developing a research protocol and data management strategies.[55]

ELSI Analysis: This activity does not involve research on human subjects based on the federal definitions (see 45 C.F.R. 46.102). That being said, it may be useful for those opting to join the group PLR to think about what participation might involve including potential physical risks associated with finger sticks, how to best collect and store data and, if an experiment is involved, whether the activity introduces potential harms. In this PLR, the organizers requested my involvement, as a research ethicist, to facilitate group dialogue about study risks and potential benefits, which served a secondary purpose of creating a "self-consent" process.[56] In addition, it would be useful to participants to know whether their involvement poses any legal concerns. For example, if a group PLR activity involves a physician or, might a liability issue arise if other participants are unclear about the physician's role? At study completion, each individual involved participated in a semi-structured interview which led to development of governance principles that can help to guide future PLRs, including transparency about roles and responsibilities. [57]

Use Case #2: Sleep Study: Participant Led Research
Digital Products: Commercial
Sector: Unregulated Citizen Science
Funding: Unfunded

In 2018, the Project Apollo group initiated a self-tracking project. A goal for several members was to learn what behaviors might influence their sleep quality. They purchased an Oura ring to begin self-tracking of their nightly heart rate, heart rate variability, hours of deep, light and Rapid Eye Movement (REM) sleep as well as awake time.[58] Once they had a baseline of their sleep data, PLR members developed a research hypothesis related to what might influence their sleep quality (e.g., does a daily nap influence my nighttime sleep quality? Does caffeine use in the afternoon influence my sleep quality?). Similar to the lipid study, the Apollo participants conducted a within subject, self-study "N-of-1" design. All used a commercially available wearable sensor, the Oura ring, designed to measure biometric data during sleep. Most in the Apollo cohort had earned a college or graduate degree, yet, few had formal academic research training and, as such, subject matter experts assisted the PLR mem-

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bers with study design, developing a research protocol and data management strategies.

ELSI Analysis: This activity does not meet the criteria for research on human subjects based on the federal definitions.[59] That being said, those involved in this PLR may want to prospectively evaluate potential benefits and harms associated with their self-study. Given individuals in the PLR decided to use a direct to consumer product that is marketed as a wellness product, it may be useful to review the vendor's terms of service and privacy policy to identify the extent to which personal health information is collected, stored and shared. Moreover, since the product does not claim to be a medical device it may not have been reviewed by an external regulatory body to evaluate safety and efficacy. This means that the consumer who uses the product must evaluate whether the product has documentation proving its value. This information may be available on the product website but, should also be discoverable via the scientific literature. By reviewing the scientific literature, a PLR member can identify whether studies have been conducted to evaluate the validity and reliability of the product (i.e., does it measure what it claims to measure (validity) and is the measurement consistent over time (reliability)). By gathering data about the product, an individual essentially creates the body of knowledge needed to make an informed decision about whether to move forward with their self-study. This form of self-consent can be carried out as a group process or individually.

Limitations

The digital health sector is a rapidly growing multibillion dollar industry with health products available either through employers and insurance companies or directly to consumers.[60] As these companies are not federally funded to conduct research or not marketed as a medical device, they are not required to have an IRB review. Several behavioral health programs in the marketplace have adopted programs supported by scientific evidence (e.g., diabetes prevention, mental health management), yet there is scant evidence that the apps, platform, and delivery of these services have received adequate empirical testing. In addition, these entities may be conducting research in concert with the deployment of a commercial product to improve service delivery, yet little is known about how this occurs and whether consent is obtained from end users. The use cases selected for this paper include how an unregulated or regulated direct to consumer product may be used in behavioral health research and not how these consumer products are tested prior to consumer access.

Discussion: Behavioral Science Research, ELSI, and Next Steps

When designing mHealth research studies, considering the Ethical, Legal/Regulatory and Social Implications (ELSI) early is essential. As with any research involving human participants, risks of harm can vary and, typically will depend on the individual, the type of information collected and how the personal health data are managed — including storage and sharing protocols. Novel with digital strategies applied to behavioral health research, is the variety of methods and tools being used to capture and/or combine personal health data along with whether the activity is conducted by those who are regulated or not. The case studies presented in this paper were developed to showcase diverse ethical challenges associated with unregulated behavioral health studies. They can be used to prompt conversations about: (1) what a technology maker may need to consider when creating an app or device; (2) what a researcher may need to consider when designing a study and selecting a digital strategy; and (3) what those involved in governance might consider — be it a registered IRB or informal discussion among a DIY or PLR community. To make the ethical analysis process more concrete, a framework anchored to longstanding ethical principles of respect for persons, beneficence, and justice outlined in the Belmont Report[61] are used. The principles are augmented by an additional principle of respect for law and public interest described in the Menlo Report.[62] The Menlo Report was initiated in 2009 with support from the Department of Homeland Security to align the Belmont principles with emerging cybersecurity challenges introduced by Information and Communications Technologies Research (ICTR), which includes platforms and network systems that collect, transmit and store data. By including the Menlo Report's lens on technology that undergirds mHealth, we may improve our analysis of the ELSI. Table 1 lists the four principles and identifies areas for reflection across the ELSI domains. The ELSI program was developed in 1990 to guide research and practice in genetics and genomics research and may be useful for thinking through mHealth research broadly, as well as behavioral health studies more specifically.[63] The combined Belmont/Menlo principles and ELSI framework depicted in Table 1 is a work in progress with a goal of prompting reflection and discussions about, for example, whether: (1) study participants have access to the information needed to inform their decision to volunteer (respect for persons), (2) risks are reasonable in relation to potential knowledge to be gained and managed (beneficence), (3) burdens of participation are fairly distributed (justice) and, 4- the

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work is compliant with relevant laws and is accountable and transparent. Suggestions for further research that touch upon several, although not all, of the cells in Table 1 are proposed below.

Respect for Persons Challenges

The regulations and ethical principles dictate that informed consent to participate in research include a statement that the activity involves "research" and continues with a description of study activities, data collected and strategies for mitigating risks of harm.[64] A rarely acknowledged flaw in the consent process is the assumption that the public is familiar with the scientific method and research design — most are not.[65] With the collection of granular and voluminous data that can occur using digital strategies, we should be considerate of the need for education and formative assessment of understanding as part of the consent process.[66] In addition to low research literacy, there is a need to develop both data and technology literacy in order to increase the likelihood that a person understands the nature and granularity of the data they may provide as a research participant. The need for education and research funding to examine how to better prepare participants, their caregivers, and potential bystanders for mHealth research should be a priority. Moreover, recognizing that culture and context will influence how best to engage diverse populations in research needs to be studied. Likewise, research is needed to better understand whether the e-consent process can be used to accurately authenticate study eligibility, convey information in a manner that is accessible and supports quality decision-making and, to what extent the process of conducting research using digital engagement methods facilitates ongoing study retention.[67] Lastly, the same technology that has created new threats, may offer benefit in providing personalized education and learning plans to improve technology and data literacy and, ultimately, authentic informed consent.

Bystanders

Technology-enabled studies to observe participant behaviors via wearable sensors or research on social network platforms can inadvertently capture information about people who are not research participants and who have not provided consent.[68] These data, while potentially sensitive, may not be covered by data security or privacy protection regulations. New rules and regulations to guide ethical research and protect bystanders is needed moving forward.

Return of Information

The idea of returning study information to a research participant is relatively novel but not uncommon in behavioral science research. Returning lifestyle data

Table 1

Dimension	Ethical	Legal/Regulatory	Social	Implications
Respect for Persons	• Informed Consent • Tech Literacy • Data Literacy • Sensitivity • Culture	• Regulations – HIPAA – OHRP – FDA • Public/Private	• Bystander Rights • Culture • Caretakers • Family • Society	• Need for: – Stakeholder education – Research funding – Informed consent
Beneficence	• Risks vs Benefits • Unknown Risks • Individual Agency • Return of Value	• Privacy protections • Data sharing • Harm mitigation	• Population health • Evidence-based • Rapid acceleration • Surveillance risks	• Need for: – Transparency – Informed risk assessment
Justice	• Access • Fair distribution • Digital divide • Data quality • Social score	• Legal harms • Bias • Policy implications • Discrimination	• Access • Health disparities • Economic harm • Social harm • Discrimination • Profiling	• Need for – Equal access to technology studies – Transparent sharing of results – Community input
Respect for Law and Public Interest	• Accountability • Transparency • Disclosure	• Compliance • Data protection • Consumer protections • Privacy protections	• Reduce bias • Increase trust • Protect privacy	• Need for – Public engagement

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(e.g., sleep, steps) may be useful in conveying feedback and can be used as a motivational tool in Just in Time Adaptive Interventions to promote behavior change.[69] The mechanics of returning information back to study participants can be labor intensive and, as such, feasibility in terms of staff time and additional costs is a potential barrier.[70] There are also ethical challenges that are important to consider, including whether the information to be returned to participants is actionable or not (e.g., early onset Alzheimer disease).[71]

Beneficence Challenges

Evaluating the potential risks of harm to research participants or their communities against the potential benefits of knowledge gained is challenging with mHealth studies. This is primarily due to the variability of methods and tools used to implement these studies combined with the intersection of traditional research tools (e.g., accelerometry) with commercial devices (e.g., fitness tracking devices, mobile apps). The new issues presented with respect to types of potential harms (i.e., legal, economic, psychological, physical), characteristics of harm (i.e., duration, intensity, severity) along with data considerations (i.e., ownership, access and sharing practices) need to be examined with respect to behavioral mHealth research. When evaluating study risks and benefits, it is important to question what technologies may facilitate the research in the most minimally invasive manner, who has access and control of data and how/whether results are shared. As the research landscape changes, so do the ethical, legal and social implications — as such, a dynamic, transparent and accountable review process is essential.

Researcher Controlled or Commercial Products

As noted, commercial products (e.g., fitness tracking devices and mood management apps, social network platforms) are increasingly being used to support behavioral research studies. When using products that do not claim to be a clinical treatment, vetting processes (e.g., FDA) to ensure products are safe and effective are not required. As such, researchers take on an additional responsibility of needing to know and understand potential risks passed onto participants. Researchers and IRBs may need to review vendor terms of service and privacy statements to identify what participant personal data is collected, used and shared. Knowing this information may influence what digital tools are used in behavioral health research — especially if the type of information collected by the commercial vendor conflicts with federal regulations for human research protections. Because terms of service are written to reduce liability to the vendor, a disclaimer that speaks to whether the "user" is able to file a claim if injured is usually inserted. Language that limits a research participant's ability to seek damages that arise from their participation in research conflicts with the Common Rule — specifically 45 C.F.R. 46.117.[72] Moreover, once a product is selected, it will be important to convey how the commercial entity may use the individual's information outside of the research study for which they are being invited to participate. Guidance to help researchers decide what product may be a good fit for their research was recently published and includes five domains to consider: (1) "Participant Privacy," (2) "Risks and Benefits," (3) "Access and Usability," (4) "Data Management" and, (5) Ethical Principles, which are presented as intersecting relationships. [73]

Justice Challenges

The principle of "Justice" is applied by including people as participants who are likely to benefit from the study results — the goal being that research benefits and burdens are distributed appropriately. A potential benefit of mHealth technologies is that as these tools become more accessible and affordable, it is possible to engage groups typically under-represented in biomedical research. However, the nascent efforts to involve diverse populations in behavioral mHealth research are few and more research is needed to identify how best to approach diverse populations to participate in mHealth studies.[74] The major concerns map to bias in the algorithms created from data that are not representative of the populations and the potential for discrimination that may result.[75]

Respect for Law and Public Interest Challenges

This fourth principle of "Respect for Law and Public Interest" came to be through a grass roots initiative in 2012 to increase awareness of added vulnerabilities introduced by information and communication technologies (ICT). In that ICTs are a part of our daily lives and, as such, may become part of our research, the authors of the Menlo Report added this principle as a call to action for researchers to become familiar with the networks, hardware and software technologies that may be used in their studies. The challenge is how best to ensure accountability, transparency and consumer protections are integrated within research protocols and understood by all stakeholders.

Conclusions

Digital technologies are dramatically changing how behavioral health research is designed, deployed, and reported. The excitement is real — we now can use

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pervasive sensing technology and computational tools to collect and analyze personal health data 24/7, in real time and in a participant's natural environment. Digital tools are not only influencing how traditional professional researchers conduct health studies, but are creating opportunities for citizens to be actively involved as collaborators and partners with professional researchers. Separate from the professional research community, independent "citizen scientists" are using digital tools and strategies to monitor their personal health metrics and also to address their own health challenges. In summary, technology is advancing health research and beyond what our current regulations and guidelines support — whether that be regulated researchers or unregulated citizen scientists. Those of us involved in the digital health/mHealth research sector must collaborate to advance the development of ethical principles and responsible practices. Moreover, funding to support research on the ethical dimensions of unregulated mHealth must be prioritized.

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