11 The AI-Powered Digital Health Sector: Ethical and Regulatory Considerations When Developing Digital Mental Health Tools for the Older Adult Demographic

Camille Nebeker, Emma M. Parrish, and Sarah Graham

11.1 Introduction

Globally, the population of older adults is rapidly growing with estimates of those over 60 years of age doubling by 2050—an increase from representing 12% to 22% of the population—and it is predicted that 80% of these older adults will live in low-to-moderate–income countries [1]. Mental illness affects nearly 20% of the older adult population (60 years above) in the United States and approximately 15% globally with 6.6% of all disabilities facing older adults attributed to mental and neurological disorders [1]. Moreover, older adults are less likely to perceive the need for or use mental healthcare [2]. The majority of these individuals have limited or no access to mental healthcare and those who potentially have access may not be able to afford care [3]. These data support careful consideration of how information and

C. Nebeker (✉)
Herbert Wertheim School of Public Health, University of California, San Diego, La Jolla, CA, USA

Research Center for Optimal Digital Ethics in Health (ReCODE.Health), University of California, San Diego, La Jolla, CA, USA

Sam and Rose Stein Institute for Research on Aging, University of California, San Diego, La Jolla, CA, USA

Design Lab, University of California, San Diego, La Jolla, CA, USA
e-mail: nebeker@eng.ucsd.edu

E. M. Parrish
San Diego State University/University of California, San Diego Joint Doctoral Program in Clinical Psychology, La Jolla, CA, USA

S. Graham
Sam and Rose Stein Institute for Research on Aging, University of California, San Diego, La Jolla, CA, USA

Department of Psychiatry, University of California, San Diego, La Jolla, CA, USA

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communication technologies (ICTs) that support digital health research, including the use of AI-powered tools, can be used to support older adults generally and, particularly, those with mental illness.

The use of digital strategies to advance health promotion, disease prevention, and treatment research has exploded over the past decade. A recent study that assessed funding for digital health research by the National Institute of Health (NIH) revealed that the National Institute of Mental Health was among the top investors across all NIH institutes, along with the National Cancer Institute and the National Institute of Drug Abuse [4]. Based on NIH funding and the scientific literature, digital tools employed in health research are used to support observational and intervention studies via mobile apps, remote and wearable sensors, and social media platforms. As examples, one study used a SenseCam device, which is an outwardly facing wearable camera that records a first-person point of view and can help the wearer with recalling events of the day to assist older adults with memory loss [5]; smartphones are ubiquitous tools that can be used for brief assessments like real-time ecological momentary assessment (EMA), an alternative to retrospective self-report that is used for repeated sampling of users' current behaviors and experiences [6]; and social media platforms are being leveraged to identify and mitigate health risk factors like social isolation and loneliness; for example, a study conducted by Quinn (2018) enrolled residents of a retirement community to evaluate the effects of social media use on cognitive decline and found positive effects on information processing and cognitive function [7]. There is evidence to suggest that higher social technology use is associated with better self-rated health, fewer chronic illnesses, higher subjective well-being, and fewer depressive symptoms [8] and that older adults have similar levels of online social connectedness to younger adults [9]. Yet, the literature also reports that high use of social media among teens and young adults may be detrimental to mental health and well-being [10–12]. Clearly, more research is needed to better understand both potential benefits and risks to health.

Digital health research has increased among the older adult demographic due, in some part, to the increased adoption of smartphone technologies by those over 60 [13]. Smart phones can host apps designed to improve mood, avert loneliness, and promote self-reliance, the latter which is critical for aging independently [14]. However, while there is increasing interest and growth in the use of technology to support independent and healthy living, it is important to consider both the potential benefits in the use of assistive technologies along with risks of potential harm—especially when involving older adults combined with mental illness. Factors that influence willingness to adopt technology among older adults include trustworthiness of the vendor, practices that align with privacy expectations, and usability of the product [15, 16]. For example, a study conducted by Andrews et al. (2019) found that mobile app graphics and jargon familiar to digital natives negatively impacted adoption for the older adult demographic; whereas Wang et al. (2019) identified privacy preferences and control of data to be important factors in technology adoption [14, 17].

Smart homes offer another potential digital solution for the ongoing mental and physical healthcare of aging adults. Smart home technology is designed to gather

data about the dweller's health, location, and environment. Smart homes first emerged in the late 1990s and can serve to monitor various aspects of a person's activity, behavior, and health through digital technology, particularly the use of video, audio, wearable, and environmental sensors combined with artificial intelligence analytic techniques. Due to the complexity of collecting these data, most research is in the pilot or planning stage and sample sizes are limited [18]. Many smart home applications are focused primarily on monitoring the daily activities of an older adult within their home environment to aid in the clinical detection and/or diagnosis of aging-related impairments like dementia in a real-world (as opposed to laboratory) environment, such as the Dem@Home platform [19, 20].

Key features of a smart home are: (a) automation (ability to accommodate automatic devices or perform automatic functions), (b) multifunctionality (ability to perform various duties), (c) adaptability (ability to adjust to meet the needs of users), (d) interactivity (ability to interact with or allow for interaction among users), and (e) efficiency (ability to perform functions in a time-saving, cost-saving, and convenient manner) [21]. In order to provide support for an individual with dementia, and promote aging in place, a smart home could advance beyond monitoring and assist with routine things like self-care, medication adherence, meal preparation, and safety support (e.g., prevent falls, wandering behavior, or dangerous situations like a fire) and provide socialization [22]. Problems with the detection and diagnosis approach include lack of evidence that sensor signals, activities, behaviors, etc., and are indeed causal to diagnosis of dementia or other mental health disorders, lack of standardization across algorithms that evaluate these data, and the fact that these platforms do not necessarily interact with the individual with dementia in a meaningful way that could promote aging in place [18, 23–25].

In this chapter, we describe regulatory and ethical frameworks used in the US and challenges with conducting ethical digital health research including special considerations when developing tools to meet the needs of older adults, particularly those who suffer from a mental illness. We narrow the scope of mental illness to those with dementia, as dementia is one of the most common mental illnesses affecting older adults [26, 27] and is a priority target of the digital therapeutic sector [28]. Dementia is defined as a major neurocognitive disorder by the DSM-5 that affects six cognitive domains: complex attention, executive function, learning and memory, language, perceptual-motor function, and social cognition [29]. People living with dementia are a particularly vulnerable group who may warrant additional protections from harms associated with biomedical and behavioral research studies due to reduced cognitive ability impacting decisional capacity [30]. Furthermore, cognitive impairments may impact their ability to provide true informed consent, highlighting the need for special protections [31].

What may be unique about big data and digital technologies that are powered by AI-tools is the extent to which our existing regulations apply to, and are able to be carried out by, ethics review boards. First, we briefly reflect upon regulations that guide current human research protections and speak to gaps exposed when not all involved in the digital health research sector are bound by regulations. We then describe three commonly accepted ethical principles used in the review of

biomedical and behavioral research (Belmont Report) [32] and introduce a fourth principle advanced by authors of the Menlo Report in response to increased availability of information and communication technologies (ICT) (e.g., smartphones and wearables) [33]. To contextualize challenges introduced by digital health research designed for use by older adults, we provide a use case based on smart home technologies. We then apply a decision-making checklist developed to assist behavioral scientists that includes five intersecting domains including ethical principles, risk/benefit assessment, access and usability, privacy, and data management [34].

11.2 Regulatory Gaps

As health research is an international endeavor, it is important to acknowledge global efforts to elevate ethical practices in research involving humans. The Declaration of Helsinki developed by the World Medical Association [35] governs much human research globally. The Common Rule is the rule of ethics that governs research supported by the US Department of Health and Human Services [36]. Globally, there are standards and procedures for operationalizing ethical health research involving humans that are country and/or organization specific [37], each with a goal to communicate expectations that speak to the ethical and responsible conduct of biomedical and behavioral research. In addition to regulations, professional societies (e.g., American Psychiatric Association, World Health Organization) have established codes of ethics that address professional expectations and in addition speak to research participant protections specific to the discipline to foster norms among affiliated members [38, 39].

An exception to these regulatory requirements has emerged over the past decade. New forms of research have emerged that are un- or underregulated as organizations began leveraging big data from a plethora of sources to conduct predictive analytics concurrent with the emergence of direct to consumer mobile apps and passive sensor technologies [40]. As noted, US federal regulations are in place to guide research supported by the federal government and that which falls under the US Food and Drug Administration's oversight (e.g., developing drugs or devices, including some digital therapeutics). This means that regulations apply to those in the more traditional research settings like universities yet do not necessarily apply to research being planned or carried out by citizens or digital therapeutic (DTX) start-ups and technology giants that have entered the digital health sector. In fact, much of the research taking place in the digital health sector is unregulated because the products fall under the "wellness" domain (e.g., Fitbit), which the FDA may not evaluate [41]. The FDA considers a product to be a medical device when the intended use refers to a specific disease or condition [42]. For regulated researchers who include wellness devices or apps as tools for research, they do receive review by an ethics review committee. This regulatory gap is problematic for many reasons including inconsistency between regulated and unregulated researchers specific to: (a) formal training in research design and methods and (b) acculturation with respect to

awareness of ethical norms and practices. The potential impact on society is important to consider, especially to vulnerable populations, as consumers are not likely familiar with these regulatory gaps nor the potential risks of harm introduced by AI and sensor technologies [43]. Furthermore, the FDA requires patient engagement in device development for those products that will be used in digital medicine [44]. The involvement of patients in the development of digital health devices is a critical step forward, as historically patients have not had a voice at the table, particularly older adults [45].

11.3 Ethical Principles

The ethical principles that undergird much of biomedical and behavioral research described in the Belmont Report include Respect for Persons, Beneficence, and Justice [32]. These principles, published in 1979, later inspired the US federal regulations for human research protections [46], which were adopted by 18 federal agencies and are now referred to as the Common Rule. These principles were deemed relevant for guiding ethical research practices and have, for the most part, stood the test of time. Several years ago, and in response to the increase in information and communication technologies (ICTs) and related ICT research (ICTR), the Menlo Report was developed, which applied the three Belmont principles to ICTR and added a fourth principle of Respect for Law and Public Interest [33].

The important contribution of the Menlo Report is its attention to how existing regulations and practices are not sufficient to address the current challenges introduced by interactions between people and communication technologies. Those developing the report included cybersecurity experts working with the federal department of homeland security and who were familiar with the potential impact of ICTs. Digital research is built upon complex and ubiquitous computing communication technologies, and our discordant regulatory structures, law, and social norms create ethical gaps. The Menlo Report speaks to our limited understanding of the scale and speed with which risks can manifest and begins to elevate awareness of these gaps and potential harms as well as provide solutions. A key factor in the Menlo Report is recognizing that ICTs create distance between the researchers and people who participate in the research, elevating the potential risks of harm beyond an individual human research participant to include a range of stakeholders who may be affected. As such, the report encourages contemplation of harms that extend beyond the direct research subject and suggests that researchers and ethics review boards carefully evaluate the impact of technologies and information communications across various stakeholders, including bystanders. This includes becoming familiar with laws (e.g., information privacy, trespass statues) and regulations and committing to accountable practices. The overlay of ICTR consideration to the existing principles is to both enhance awareness and increase understanding as we use these tools to support health research while at a crossroads of policy and governance gaps. A revised Ethical Impact Assessment has been created to reflect new principles added in the Menlo Report [47].

Collectively, the principles, each briefly described below, are useful in making the research process more transparent and for engaging in dialogue about the ethical dimensions of research.

Respect for Persons. The principle of "Respect for Persons" speaks to study participation being voluntary and that people are recognized as autonomous agents who are able to determine what is in their best interest. It is demonstrated through the informed consent process whereby a person who is eligible to participate in a research study, and has the decisional capacity, is given information deemed necessary to make a choice about volunteering as a study participant. Even in more conventional biomedical research, there is much debate about the effectiveness of the consent document and communication process as well as efforts to make improvements [48]. The concerns primarily focus on how complex study information is delivered, who delivers the information, and how information is influenced by culture, religion, and literacy [49]. In digital health research where thousands of people can be enrolled via a mobile phone, the consent delivery may be occurring via an e-consent process which introduces a number of new challenges, primarily how users process information on a screen and their tendency to click and agree without reviewing the content [50]. While e-consent is feasible for older adults, additional challenges are introduced specific to technology-enabled research that may compromise their ability to provide informed consent, including unfamiliarity with terminology used and lack of technological literacy [51].

Beneficence. The goal of the principle of "Beneficence" is to minimize possible harms and maximize possible benefits. This occurs when an ethics review board systematically evaluates the risk of harms to the individual participant against the possible benefits of knowledge gained from the study to those represented by participants and society [32]. Evaluating the probability and magnitude of potential harms is challenging, yet ethics review boards typically have the expertise necessary to make risk assessment and management decisions that allow the research to move ahead. If not, they can outsource to obtain the necessary expertise. If the risk to benefit determination identifies risks that are unacceptable in relation to possible benefits, reviewers may decline approval such that a study will not be conducted. When ICTs support digital health research, it is often difficult to identify possible risks in advance and subsequently understand how best to manage those risks, and moreover, the appropriate expertise may not be readily available. This is in part due to the scale and speed at which a risk can develop and our limited understanding of the dynamics between the physical and connected world. The Cambridge Analytica fiasco is one example of ICTR with unknown downstream risks of harm. In this case, an academic researcher deployed a personality survey via the Facebook platform. Responses were then used to profile participants, including those who were contacts of the initial participant and ultimately were believed to have influenced how citizens voted in the US 2016 presidential election [52]. In the connected world of today, there are information-centric harms that need to be considered with respect to data confidentiality and sensitivity of information, recognizing that the potential risk of harm will vary by individual and also extend beyond the individual. When it comes to older adults, there

are privacy considerations to incorporate when assessing risk. In a recent study of older adult privacy preferences, researchers noted a significant difference in privacy attitudes when compared to younger adults and adolescents, with older adults being significantly more likely to identify as fundamentalists (40%) compared to younger adults (6.7%) [53]. What this means is that older adults: have a high value for privacy, believe they own and have control of their information, support laws and regulations to secure privacy rights, and may be willing to share personal data with a trusted entity [53]. While technologies can add value to aging in place and may be acceptable due to the potential benefits, privacy, and the risk of privacy violations, is an important factor to consider [54]. Clearly, applying the principle of beneficence will require input from diverse stakeholders to better understand the potential risks of harm and how best to mitigate those in digital health research targeting older adults.

Justice. The principle of "Justice" is to encourage the fair selection of research participants and equitable distribution of risks and possibility of benefit [32]. Those who are included in the research should represent people who may benefit from the knowledge gained. In conventional regulated research, it is possible to review the research protocol and evaluate the study inclusion and exclusion criteria to determine alignment with the principle of justice. However, in unregulated digital health, the idea of justice is difficult to evaluate in that those who have access to a product or app are those who become the data source upon which algorithms are derived [55]. Issues of bias in training data used to inform algorithm development are well documented [56, 57]. That being said, managing the bias is dependent on organizational standards for accountability and transparency that drive fair and ethical decision processes—these standards are only now being developed (see Ethically Aligned Design, IEEE) [58]. Recently the National Science Foundation in the US allocated funding to examine Fair, Ethical, Accountable and Transparent AI [59], and there are a number of initiatives globally working to advance ethical AI [60]. There are studies underway to assess the acceptability of in-home monitoring systems that can communicate cognitive changes and other health problems to caregivers and clinicians [25, 61, 62]. The promise of tech-enabled health research, particularly, digital geriatric mental health research, is the potential benefit of creating greater access to services needed by a growing older adult demographic [63].

Respect for Law and Public Interest. The Menlo Report, published by the Department of Homeland Security in 2012, applied the Belmont Report principles (above) to ICT and cybersecurity research and added this fourth principle of "Respect for Law and Public Interest." The goal of this report was to encourage those involved in ICT research to engage in legal due diligence and be transparent and accountable in methods and results. This principle, if and when applied, may bridge the gap in our current regulatory environment where wellness products are unregulated and not bound by existing regulations for human research protections. That being said, there is no requirement for any unregulated research to adhere to either the Belmont or Menlo Reports. This is concerning, especially when considering digital geriatric mental health research and the vulnerability of this

demographic. The future of this research is of critical public health relevance, and plans to advance this work need to be supported [63].

Drawing on ethical principles along with factors relevant to digital research, Table 11.1 presents questions that researchers, ethics boards, research participants, and technologists may consider across the research cycle of development, implementation, and reporting. This list is not intended to be comprehensive, but more practical ideas for how to think about ethics when involving older adults in digital mental health research.

With this background on our current regulatory environment and ethical principles developed to guide responsible research practices, we present a use case to contextualize how digital health research, including AI-powered tools, are deployed. Our use case describes the development of a smart home platform intended to be interactive with the user—it simulates a type of assisted-living facility in the home environment that may enable aging in place for older adults with dementia.

11.4 Smart Home Use Case

Amiribesheli and Bouchachia in 2019 introduced a smart home platform specifically tailored for three end users: persons with mild dementia symptoms, their caregivers, and geriatric psychiatrists. These researchers first identified problem scenarios specific to this population including repetitive speech, dehydration, loneliness, learning to use new devices, nighttime wandering, forgetfulness, and challenges with vision. They developed smart home technology that can intervene on five different levels to assist with these problems: (1) inviting awareness, (2) suggesting, (3) prompting, (4) urging, and (5) performing. For example, in the case of monitoring dehydration, the system would be preprogrammed by a caregiver regarding the number of times an individual should drink per day; environmental sensors would detect movements; software would recognize the activity of drinking; the system would log the number of times this activity occurred throughout the day; if the individual was not drinking enough, the system would prompt the individual to drink more through inviting awareness and suggesting; if the individual ignored these prompts, the system would send an alarm to the caregiver; and finally, the system would maintain logs over time that could be viewed by the individual's physician to assess trends.

11.5 Discussion and Case Analysis: Ethical Dimensions of Smart Home Technologies

With this use case as an example of technology and AI at the intersection of geriatric mental health, we evaluate responsible practices across the key domains of consent, access and usability, risks and benefits, privacy, and data management.

Table 11.1 Prompts to guide application of ethical principles to geriatric digital mental health research

Key factors	Access and usability	Risks and benefits	Privacy	Data management
Ethical principles				
Respect for persons	Consent provides: Relevant information within Terms of Service/Privacy policy in plain language Access to definitions Access to visual and audio versions of information Possibility of bystander involvement	Consent conveys: Risks and risk management strategies Evidence unknown risks possible benefits to the person, people like them, and to society	Consent conveys: Nature of personal information collected Data sharing plan Privacy policy risks	Consent conveys: Data collection process Data storage and security who will have data access protocols for data sharing
Beneficence	Includes a plan for return of group and individual study information Study design includes features to increase access and usability for older adults Short and long-term use has been or will be tested with older adults Rights of all stakeholders are considered	Study design is responsive to privacy preferences Evidence to support tech reliability/validity Evidence is peer-reviewed Risks are known and mitigated Risks are unknown Potential benefits outweigh possible risks of harm	Privacy expectations are respected Participant data are not shared or sold to a third party Participant contact information is not exploited	Data collection by party external to the research team Potential of data collected on or about a bystander Data are accessible to the participant Data are transferrable to the EHR Data ownership is clear
Justice	Device or App tested with older adults Requires internet Requires smartphone AI trained on data inclusive of older adults	Legal harms are known Potential risk of discrimination is transparent Risks of harm no greater for 65+ demographic	Bias is managed to reduce: Economic harm Social harm Discrimination Profiling	System vulnerabilities are publicly disclosed Data are not used to target groups or people

(continued)

Table 11.1 (continued)

Key factors	Access and usability	Risks and benefits	Privacy	Data management
Respect for Law and Public Interest	AI is accountable Algorithms are documented and transparent	Data and privacy protections are compliant	Increase trust Protect privacy	Data encryption meets expected standards Storage is HIPAA compliant Data are deidentified

Source: This work is published with permission and reflects an adaptation of the Digital Health Checklist developed for Researchers (DHC-R). It was developed by Camille Nebeker, EdD, MS, licensed under a Creative Commons Attribution-Non-Commercial 4.0 International License 2018 [64]

11.5.1 Informed Consent and Agency

Informed consent becomes especially important when such a large volume of personal data is collected in digital research and needs to account for both the content of the information to deliver and the process for delivery and cognitive capacity. When it comes to enrolling in a smart home study, it may be that our norms and practices for obtaining informed consent need to change—especially in the era of big data [31]. To be effective and to mitigate low technology literacy, informed consent needs to be adapted to the unique needs of older adults. A qualitative study of older adults found that adults are concerned about the potential intrusiveness of smart home technologies, but may not be aware of the extent of security risks, highlighting the need of informed consent that is adapted to technological literacy [65]. This suggests that presenting information so that the text is visually accessible and incorporates options for accessing unfamiliar terms (i.e., cloud storage) is needed. Moreover, how data is collected, transferred, stored, and shared must be clearly stated in the consent delivery and in a manner that conveys the granularity, volume, and personal nature of the data collected. How to do this well is a topic for further research.

11.5.1.1 Content and Delivery

An example of how informed consent can be improved was the subject of an exercise conducted with residents of a retirement community in southern California who were enrolled in a longitudinal study designed to assess the extent to which AI could detect cognitive and physical decline. The study received approval from the local ethics review board and used a traditional method for obtaining informed consent—which being several pages of paper with a 12-point font and little white space. Several residents were asked to take that consent form and imagine what it would look like if it was designed for them. Comments included less information, adjustable text size, clearly defined sections, progress indicator, video explanations, definitions, and electronic receipts. This human-centered design process

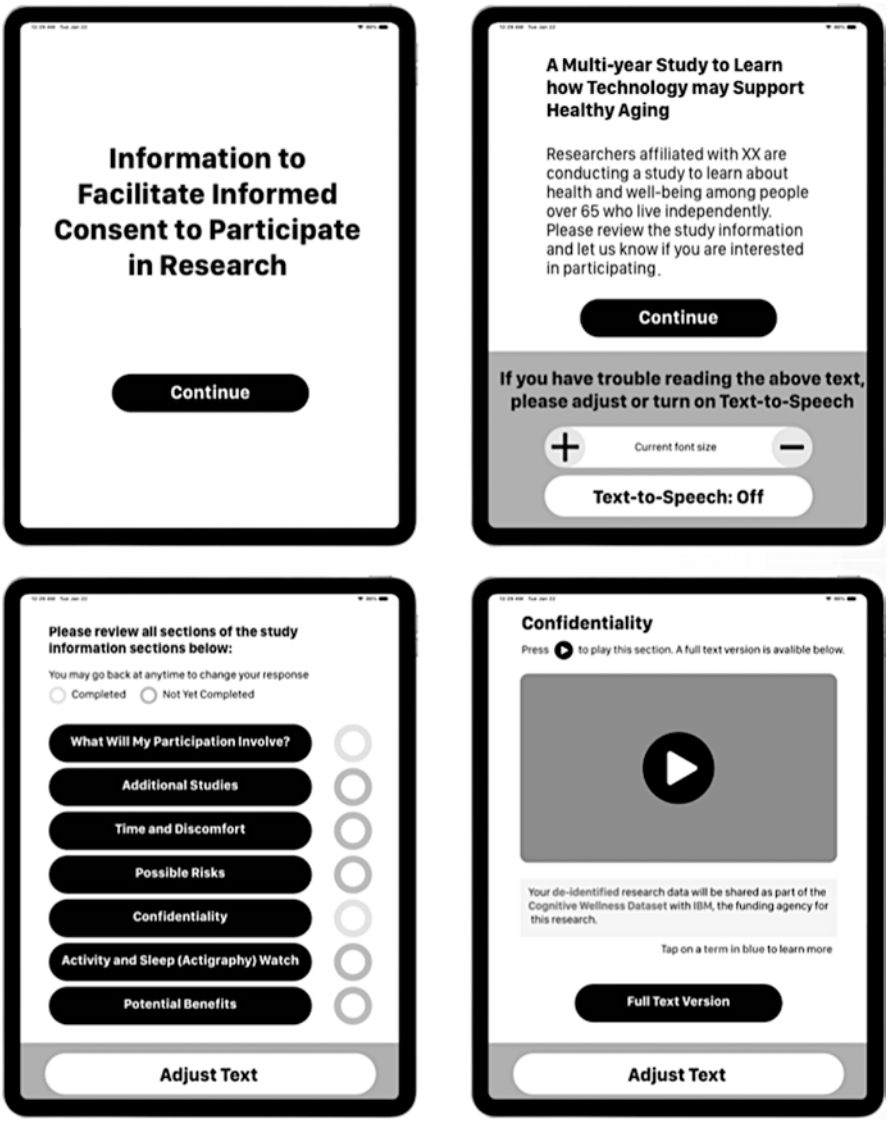

Fig. 11.1 Informed Consent Prototype. Informed by older adults, the panels show how information can be presented to increase accessibility to content that influences decision-making

resulted in a prototype (see Fig. 11.1) that is now being tested through design workshops [66].

11.5.1.2 Cognitive Capacity

Another consideration when obtaining consent to involve older adults is the potential for cognitive decline, either at the time of consent due to cognitive impairment

or over the course of a longitudinal study. Ienca et al. [31] suggest that the inclusion of advanced directives may be important at the time of consent. Perhaps there could even be a plan to assess decisional capacity regularly and consult with doctors to ensure that the individual is still capable of consenting. Tools developed to assist with assessing decisional capacity exist [67, 68] and could be adapted to detect barriers introduced by low technology and data literacy. For example, when an individual is no longer able to give ongoing consent, or when the initial decision to enroll in a smart home study is made by a caregiver or physician [69], the ethical principle of Respect for Persons entitles those with diminished capacity to added protections [32].

11.5.1.3 Bystanders

With smart home sensor technologies, the risk for bystanders to be captured and subsequent rights and agency comes into play [70]. A guest in the home of an older adult with an AI listening device may not explicitly consent to having their voice recorded and analyzed. If an older adult points out this device to see if the guest would consent to having their voice recorded, they then may need to self-disclose that they have smart home technology to monitor their physical and mental health. This could be an added burden, but also potentially stigmatizing to the individual who may not wish to disclose their personal health information. Perhaps one avenue around this would be to have the AI device turn off automatically when detecting the voice of an unfamiliar individual.

11.5.2 Usability and Accessibility

11.5.2.1 Usability

In the case of smart home technology, an individual may view the technology aides as unnecessary and, perhaps, intrusive. Assessing need and perceived usability is an important first step when designing technologies for older adults [17, 71]. Customizability may be important to help increase accessibility as an individual could tailor their smart home tools and functionality based on their desires and comfort. The research protocol and subsequent deployment of a smart home surveillance and intervention system must allow the user to make decisions about what actions are monitored and what actions remain private. The user could also have a dialogue with their healthcare provider to determine what interventions would be most helpful considering their comfort level.

11.5.2.2 Accessibility

Smart home technologies are costly to install and maintain. This presents a problem for the researcher, who will need to acquire large amounts of funding to acquire enough data to prove efficacy. Perhaps more importantly is that the users who may ultimately benefit from these technologies may not be able to afford them, further widening a healthcare gap across different socioeconomic statuses. Additionally, the smart home case begs the question of whether these technologies would be

appropriate for the non-technologically savvy individuals who may be overwhelmed by this technology in their homes.

11.5.3 Risks and Benefits

The first step is to identify potential risks of harm and determine if those harms are manageable and, if so, whether the benefits of knowledge to be gained outweigh these risks.

Risks, including physical, psychological, legal, and social risks, have their conceptual roots in traditional behavioral and biomedical research, yet remain relevant when using new technologies whether it be in research or in clinical care [47]. Specific to clinical applications, a user may be exposed to a physical risk if the equipment malfunctions or fails to perform as intended (e.g., fails to report critical data), resulting in harm to the user. A psychological risk might be the perceive threat of the technology invading their personal space. Another psychological (and physical) risk may be management of expectations that someone is "watching" in real time and will intervene if there is a need for assistance, which could be something agreed upon in advance or not [72]. Whether and the extent to which a clinical care team may intervene (or not) should be made clear during the informed consent process so that a user understands what to expect. With respect to the law, there is a lack of current legal guidance regarding smart home use, and thus, no solutions in place to address conflicts between smart home service providers and users [73]. Socially, users may feel as if the presence of the technology in their home is stigmatizing or fear it may reduce opportunities for face-to-face contact; however, more often than not, the benefits of increased social inclusion are thought to outweigh these risks [73].

With respect to possible benefits, smart home technologies can facilitate access to quality healthcare, enhance comfort, monitor health conditions, provide support to users, and foster social inclusion [73]. It is important to evaluate the probability and magnitude of potential harms against the potential benefits prior to making an informed decision. In a research context, the evaluation of risks and benefits associated with studies involving health technologies falls to the ethics review board (i.e., IRB in the US, REC in EU) and the research team. This risk to benefit evaluation includes consideration of the study design and the potential of the research to contribute new knowledge to the scientific enterprise. Within the healthcare application, the decision to adopt new technologies must put benefits of use ahead risks by selecting technologies, including smart home technology, that are properly vetted through rigorous research. Lastly, the informed consent process is critical to decision-making and information conveyed to the users, whether they be patients or research participants, must include a description of the possible risks of health technologies, how those risks are managed, and ultimately be acceptable by those choosing to accept. Moreover, it is important that not only consumers consider the direct and indirect effects of health technologies but that developers, clinicians, and researchers be aware of known and unknown downstream effects.

11.5.4 Privacy

The inclusion of new technologies expands the scope to include a broader conceptualization of risk specific to privacy [33]. Notably, new digital health technologies invite a risk of data security and privacy breaches [74, 75]. One of the primary categories of risk associated with ICTs are those of confidentiality, and the possibility that one's personal data may be stolen and misused, [47] which may become especially important when dealing with a technology that is in someone's home. There is also risk of third parties intercepting and subsequently modifying or falsifying personal data (e.g., cyberattacks) [76]. It is important that these risks are explicitly discussed with older adults when considering the use of new smart home technologies, along with risk mitigation solutions and related limitations.

One important consideration associated with pervasive sensor technologies in smart homes is the potential to violate privacy preferences for those who live in the home. It is necessary to understand the privacy attitudes of older adults in order to prevent privacy-related harm. Privacy may be a barrier to adopting technology for older adults, but that the practical utility of the technology outweighs this [69]. A 2008 participatory evaluation of smart home interventions found that older adults were not concerned about privacy in regard to smart homes [77]. However, the technology studied in this chapter does not include newer interventions such as AI, which should be examined. One study also notes that older adults found monitoring acceptable if they were able to decide who could view their data and the circumstances under which their data could be accessed [65]. However, it does not provide a clear guideline for how to establish this customized data sharing in practice. To best meet the needs of older adults, privacy settings should be transparent, adaptable, and customizable.

11.5.5 Data Management

Specific to data management and confidentiality, knowing how data are collected, transmitted, stored, and shared are factors that can influence the risk to benefit evaluation in deciding whether a smart home is suitable for a potential research participant. A careful assessment of who has access to these data (caregivers, physicians, social workers, family/friends, associations) as well as how data are transmitted and stored is important to convey during the consent process. Moreover, in the era of rapidly changing ICTs, data management must be dynamic and monitored as risks may arise due to instability within the platform supporting or other intermediaries supporting the research [47]. Dynamic data management can be achieved through continuous updating and monitoring of database management systems to ensure it is up to date, usable, and that the participant continues to be safe while using the technology. This will require development of new software and methods capable of managing and processing big data obtained from users (e.g., Health-cyber-physical systems) [78].

11.6 Conclusion

There is much promise in the use of AI and technological innovations to promote healthy aging [25, 62, 77]. However, the field must have a better gauge on the associated perils, including understanding what are known, as well as unknown risks of potential harms to move forward. All stakeholders must be mindful of barriers to obtaining meaningful informed consent for the direct, as well as indirect participants of research that intersects with information and communication technologies. Moreover, when considering whether potential research benefits outweigh the probability and magnitude of potential harms, evaluating the complex systems that are undergirding data collection, transmission, storage, and sharing of personal needs to be informed by experts through a dynamic "living" review process. Moving forward, considerations of diverse stakeholders, laws, and public interests are essential to informing ethical principles that will guide responsible digital health research across all demographics [31].

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