Review Articles

In-home monitoring of persons with dementia: Ethical guidelines for technology research and development

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Abstract

Innovative technologies are rapidly emerging that offer caregivers the support and means to assist older adults with cognitive impairment to continue living "at home." Technology research and development efforts applied to older adults with dementia invoke special grant review and institutional review board concerns, to ensure not only safe but also ethically appropriate interventions. Evidence is emerging, however, that tensions are growing between innovators and reviewers. Reviewers with antitechnology biases are in a position to stifle needed innovation. Technology developers who fail to understand the clinical and caregiving aspects of dementia may design applications that are not in alignment with users' capabilities. To bridge this divide, we offer an analysis of the ethical issues surrounding home monitoring, a model framework, and ethical guidelines for technology research and development for persons with Alzheimer's disease and their caregivers.
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1. Introduction

Residential monitoring technologies are applications designed to be used in consumers' personal living spaces, ranging from private homes to multiple-unit dwellings including commercial apartments, independent senior housing, and assisted-living facilities. The goal of these technologies is to help vulnerable people live more safely, more capably, and longer in their location of choice. While the approach will vary from a single task to a suite of multiple offerings, the technologies support a person's ability to conduct normal activities of daily living and maintain well-being. This is usually accomplished by integrating the technology into the home environment, thereby creating a "smart home" that proactively monitors and reports undesirable events. The technology is designed primarily to serve the "person" as the consumer of this service. By contrast, home telemedicine technologies view the clinician as the consumer of the service, and the person at home as his or her "patient." That technology focuses on disease management and the monitoring of physiologic data for aberrant indicators necessitating clinical treatment. Telemedicine technologies are usually subject to medical-device standards and approval from the Food and Drug Administration (FDA), whereas there are no regulatory standards for home residential monitoring. Thus, consumers and developers of innovative technologies may benefit from a thoughtful re-

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view of home monitoring technologies for persons with Alzheimer's disease (AD).

Specifically, this review adopts an ethical perspective, and offers guidelines to apply an ethical model to in-home technology research and development. Moreover, grant reviewers, funders, and members of institutional review boards (IRBs) may also use this content to help analyze the relevant risks and benefits associated with home monitoring technologies. In part, this paper emanated from the funding recipients of the Everyday Technologies for Alzheimer Care (ETAC) program, who reported multiple occasions when Federal or international grant reviewers demonstrated marked inconsistencies in scoring and interpreting study risk for the same proposal. For example, a secondary reviewer at the National Institutes of Health rated a proposal highly, but the primary reviewer cited major "ethical concerns" that were expressed in statements such as "technology is a-humanistic and has no place being an intervention for frail elders," or "this technology will only further isolate home bound elders and decrease critical telephone connections with their families," despite preliminary data that showed otherwise. This polarization demonstrated passionate responses based on personal beliefs, but not necessarily supported by true ethical concerns or objective data. Why does this occur? The traditional medical, clinical psychology, and socio-behavioral models that underpin patient care are grounded in office-based, in-person encounters for face-to-face assessment and treatment. Underlying these professional models is the general assumption that the provider's in-person contact is the critical component of care, and the more, the better. Since most review panels consist of researchers from one or more of these fields, it is not surprising that an antitechnology bias may occur. As Slack [1] noted:

> "The onset of computers in medicine a few decades back provoked Orwellian fears about doctors being replaced by machines. Today, of course, computers are everywhere, and doctors have survived yet there remains a persistent fear within medicine and society in general about an over-reliance on computers and other technologies, as if by too heartily embracing the future we might forfeit the essentially human within ourselves and cede control of our lives to machines."

Our contemporaries, however, continue to worry and ask [2], "What about the hands-on situation when you go to your physician and she's holding a laptop. Is there going to be a disconnect in that sacred patient physician interaction?" Others highlight the tension between privacy and surveillance when using home monitoring technologies. As Tate [3] noted, "We must constantly balance the need for intervention with infringements of personal control and autonomy." Even a recent article in the *Wall Street Journal* that objectively covered a technology and aging showcase of home monitoring technologies, and documented the positive aspects, carried a negative subtitle [4]. If one believes

that technology is a problem, then there is little likelihood that one can view it as a solution. A negative technology bias by grant reviewers undermines funding, and stymies innovation. For institutional review board (IRB) members overseeing research studies, this bias can result in delayed study approvals while the researcher satisfactorily addresses concerns of questionable relevance. This busy work increases the administrative burden and costs due to postponed commencement of projects. Importantly, even comments that reflect the antitechnology bias with no substantive merit rightfully trigger special IRB concerns, because cognitively impaired elders are entitled to additional protections due to their diminished autonomy. Since IRBs are being prodded to take their roles as protectors of the public and individual good even more seriously, the very real possibility exists that such biases may intrude ever more deeply into the research approval process [5].

New questions are arising as home monitoring technologies are being increasingly tested for people with AD. What level of surveillance is helpful, and what infringes on personal dignity? Can automation maintain or improve human functioning without frustrating the user? At what point does reality become overwhelming to a person with cognitive impairment, and at what point does virtual reality become a comfort? The key point missed by the Orwellians is that humans design the technology. If a technology is dehumanizing and takes away personal control, it is because of the way that humans envisioned and developed the application. This should be the focus of a technology review and critique. How well do the designers understand cognitive impairment and show respect for the persons targeted as the end-users of their technology by designing realistic applications? Moreover, reviewers should be concerned that there is a multidisciplinary team that blends expertise from social, clinical, and technical disciplines. When such a perspective is adopted, truly critical issues may be revealed that assist the researchers and ultimately benefit the project. For example, the following comments, by a grant reviewer regarding a proposal aimed at introducing assistive pocket personal-computer technology into homes where one family member was caring for another who had AD, demonstrated an excellent understanding of the technology and the human setting:

> "No process measures or patient safety/quality measures are suggested that relate to problems to be addressed by the proposed intervention." [For example,] "In an institutional setting, many factors are taken care of (medication administration, hygiene, daily activities, etc.)—aging in place presumably places the patient at risk for these not occurring. This is not mentioned at all as a patient safety concern and shows a lack of understanding of the MEDICAL domain."

The reviewer was entirely correct. The authors had failed to take into account the very real possibility that medical

compliance by the caregiver might decline as a consequence of the presence of professional researchers. Review panels might also ask how well the researchers have integrated personalized control and privacy features when caregivers are in charge. That leads to the follow-up question: how is personal freedom infringed upon if the persons involved (residents, guardians, or caregivers) give their assent or consent, and have control over the surveillance options? Reviewers should strive to address, in an unbiased manner, the truly ethical issues that need to be the focus of human-subject reviews for people with cognitive impairment who are using technology. Unfortunately, there are no guidelines to aid reviewers in this approach. In response to this need, this paper aims to 1) review the relevant literature specific to ethics and home monitoring technology, 2) present an ethical model for technology development, 3) raise pertinent issues for reviewers to consider in assessing applications, 4) discuss strategies to address IRB concerns, and 5) recommend ethical guidelines to direct the research and implementation process.

2. Relevant literature

Most previous research on home monitoring technology has focused on the effectiveness of the interventions, and very little of it specifically addresses the ethical issues in research or in routine clinical practice [6]. Marziali et al. [7] conducted a systematic review that shed considerable light on the practice standards and research ethics in technology-based home healthcare intervention programs for older adults. Utilizing the MEDLINE (1966–2003), CINAHL (1982–2003), and PsycINFO (1974–2003) databases, the authors identified 107 English-language original studies involving ethical considerations in applications of home-based technologies with persons aged ≥65 years. Of these, the vast majority were conducted in North America (70%) or Europe (20%), involved management of chronic disease conditions (60%), and were published in peer-reviewed journals (64%). Nonrandomized, controlled trials accounted for >50% of the studies, while randomized, controlled trials and descriptive studies comprised another quarter of the study sample. The most common interventions included medical symptom monitoring (67%), cost-benefit or effectiveness analysis (14%), individual counseling (12%), support groups (11%), and self-help groups (1%). Synchronous technologies permitting real-time communication via the use of audio or video were the most common form of intervention.

The most frequently cited ethical concerns in these reports included clarification of informed consent (50%), mechanisms for monitoring participants (38%), confidentiality and protection of privacy (27%), IRB approval (26%), and a mechanism for contacting the healthcare provider (22%). While these findings are not dissimilar to those in large reviews of ethical considerations in nontechnology-
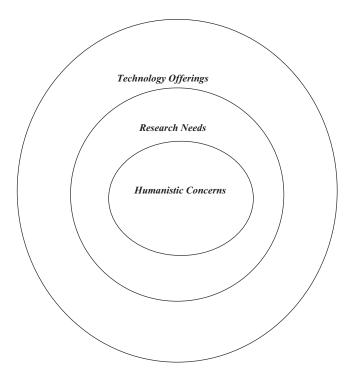

Fig. 1. Ethical Model for Technology Research and Development. © R. Purito. Used with permission.

based clinical research, the enormous scope of the problem is readily apparent [8,9]. Moreover, to our knowledge, no controlled study has examined the impact of such home-based technological interventions on family caregivers whose lives clearly would be impacted by the ethical and practical encroachments of such technologies. Indeed, as Bauer [6] pointed out, much remains to be done in shifting the patient-centered ethical decision-making framework of office and institution-based service settings to a family-centered approach, because the impact of home healthcare technology interventions is not limited strictly to the patient at hand.

3. Ethical framework and model

From the inception of a project designed to yield as much promise as real-time residential monitoring for AD, an ethical framework is essential to guide the direction of research as well as the hoped-for applications of the technology. The framework should not be used as a substitute for the principles presented in this review. Rather, it allows such principles to become incorporated into guidelines, consistent with the concerns reflected in the framework. This model, as depicted in Fig. 1, keeps humanistic concerns as the core priority, while keeping research and societal concerns (related to the promise of the technology) in their proper perspective. A sample annotated framework is presented below.

3.1. Humanistic concerns

3.1.1. Respect for persons with conditions warranting residential monitoring

Respect should pervade all of our encounters with research participants, but the physical and cognitive manifestations of AD require that investigators engage in special vigilance against falling into disrespect, because societal attitudes toward such "disability" are often skewed toward unduly diminishing an individual's autonomy and quality of life.

3.1.2. Autonomy through respect for individual differences

Society tends to view "disabled" persons as being less capable generally than their "able" counterparts. The investigator's intent is to engage in research to improve independent (or more effective interdependent) functioning in the home. But this intent must be cast against the core concern that individuals with AD vary widely in their preferences and capacities to act on information when being approached about participation in a study.

3.1.3. Quality of life through respect for the person's healthfulness

Society tends to view persons with cognitive impairment as being "sick and disabled." However, persons with AD may vary widely with respect to social, mental, physical, and spiritual healthfulness. They may also be fit physically. Investigators must be mindful to approach potential subjects and their families with reassurances that they recognize areas of strength and health in the person. If not visibly acknowledged with each encounter, the person's self-esteem risks becoming compromised, and family members, friends, and others close to him or her may be influenced. Moreover, if extensive home monitoring systems are viewed by society as having utility within the sickness framework of healthcare only, an unintended side effect may be to foster social attitudes and social policies designed for sick populations at the price of addressing other important quality-of-life challenges imposed by AD in the residential environment.

3.1.4. Respect for family caregivers and family relationships

The vast majority of persons with AD and their family members find their roles within the family significantly altered. Any added variable, such as those imposed by conditions of a research protocol, has the potential of injuring workable, healthful arrangements or destroying fragile ones. Therefore, protocols for monitoring systems must be developed with acute sensitivity to how family relationships will be affected in the home and other family environments. Data show that the introduction of devices such as percutaneous endoscopic gastrostomy tubes and left-ventricular assist devices has increased stress on family caregivers, and therefore on the relationship.

3.2. Research needs and concerns

3.2.1. Proportionality

The investigator's goal must be to make the opportunity for research participation available in the least intrusive and least restrictive (yet adequate) manner, exercising sensitivity to the amount of disruption in the residential environment. For example, cumbersome or extremely complex instruments should continue to be simplified to the highest degree possible, to optimize use and minimize invasiveness in the residential setting.

3.2.2. Privacy and confidentiality considerations

As in all human-subject protocols, those designed for residential monitoring must embrace every precaution to assure that the research design honors the subject's and family's privacy and confidentiality. This may require additional vigilance with respect to home monitoring research. For instance, according to every indication, monitoring devices may include data regarding such "private" functions as using the bathroom, acts of sexual intimacy, or other activities never intended for others to observe. Both in the home and in the investigator's laboratory, the gathering, storage, and retrieval of information from such systems must have safeguards built in, to ensure that they meet legal and ethical standards. Research protocols should include specific statements about how privacy and confidentiality considerations will be handled.

3.3. Technology: promises and concerns in societal context

In addition to the ethical framework that guides concerns related to our common humanity and to the role of investigators, there are ethical considerations related to the investigator's role within the larger societal context:

3.3.1. Justice and distributional fairness

Increasingly, clinical and other human-subject investigators are viewed by society as moral agents whose accountability does not end with data collection, analysis, and reporting. Investigators are not mere cogs in the sequence from a good idea to the implementation of technologies that become a standard of care. From its inception, a research protocol must be crafted with the goal of developing home monitoring devices or systems that will help meet the needs of all who eventually might benefit from them. The increasing incidence of AD and related dementias across the globe militates that research collaborators, funding sources, and protocols be chosen with commitment to how they will benefit affected populations worldwide. As with AIDS and other global conditions, special attention must be given to populations in those parts of the world facing extreme scarcity of resources for realizing the benefits of research participation and the implementation of technologies that result from such research.

3.3.2. Truthfulness, prudence, and humility as virtues

The specter of AD can make almost anyone's blood run cold. Any promise of prevention or relief from its symptoms makes for headline news. Therefore, unreasonable societal expectations wait to take root with every reportable finding. The AD research community and individual investigators must take every precaution to truthfully describe capabilities (or potential capabilities) of residential monitoring technology for persons with AD. This includes especial prudence in telling the cautionary tale of limitations along with positive results, emphasizing safety concerns and other social burdens that often ride on the heels of small or large indications of scientific progress.

No investigator privileged to work in such a groundbreaking area of scientific, technological, and healthcare advances remains immune to societal praise and rewards. The high human and social stakes require the AD research community to stay the more humble course of what investigators and science itself have to offer through the laborious, precise, step-by-step process whereby reliable discovery unfolds.

4. Safety issues: the ethical imperative to "do no harm"

When planning research endeavors that bring technology into the lives of aging adults, safety concerns may be underestimated. For most researchers, the promise of technological innovation represents a very positive improvement in the environment and quality of lie for older adults. For example, the simple aim of introducing older adults to the Internet can be viewed as adding virtual mobility to the daily life of people with mobility restrictions [10]. Opportunities are provided for activities such as shopping and acquisition of knowledge. Particularly for homebound persons, this simple innovation can be life-altering, and has the potential to vastly improve quality of life. So where does safety come in? If the target population were the introduction of children to the Internet, public concern over Internet sexual predators would present itself as a crucial issue that demanded attention. Controls over access to websites, the monitoring of sites visited, and ongoing discussion with children regarding Internet-related behaviors all would (or should) occur. With older adults, an introduction to the Internet with no lessons regarding scams and "phishing" would place them in danger of financial exploitation. This would be both unsafe and unethical. The naive investigator proposing such a project who planned only to provide the technology along with instructions on the use of the hardware and software would not have planned well. The safety of older adult participants, who may be considerably more trusting and gullible than their younger counterparts, has not been assured, and review panels for granting agencies and IRBs might rightly raise concerns [11].

In another scenario, a researcher proposes a project that will introduce communications technology into the homes and lives of older, mostly homebound adults. The purpose is to broaden the communication options for the older adult, and provide a new means of offering the family and the physician electronic data about the elder's activities. The investigator sees increased safety because participants are now in better communication with important others in their extended environment, including their doctors. When grant reviewers respond that the investigator has not taken steps to ensure participant safety, the investigator is perplexed. But the failure to tell participants directly of their need to continue their usual type of physician interactions could create a safety issue. The technology may imply to the participant that "someone is minding the store," i.e., I can stop attending to things. The investigators are the new wizards, and the technology appears mysterious and magical. Older adults who agree to participate in studies tend to be more trusting than others in the elderly community [11]. They are quite likely to assume that the combination of technology and a learned researcher means that they are in good hands, and that they and their caregivers can reduce their normal vigilance [12].

From a more generic standpoint of safety, investigators should always ask themselves: How will the introduction of this technology affect the behavior of the participant? The question must extend past the behaviors that form the dependent measures for the study, and cover behaviors that are unanticipated, i.e., the behavioral "side effects" of introducing technology. For example, an investigator has introduced a "smart viewer" into the home of a caregiver of an AD patient. The device is activated by movement of individuals in the home. Through a series of remote webcams, a streaming video of the room where the movement takes place is projected to the viewer. The caregiver assumes that the technology works. Yet the project is an initial "proof of concept" study to see if the system can really work as intended outside of the laboratory setting. If a sensor fails and the caregiver assumes it is functioning correctly, then his or her usual "checking" behaviors may not occur, and the patient may enter a dangerous situation.

From the viewpoint of reviewers of grant proposals and IRB members, human-subject safety is of foremost concern. However, some members' unfamiliarity with technology can translate into an inappropriate sledgehammer that stymies innovations. For example, if a personal digital assistant (PDA) is introduced into a home environment so that a caregiver can keep track of critical daily events, a reviewer may be concerned that the participant, who is encouraged to carry the PDA on his person, might drop it into the bathwater of family members and electrocute them. An investigator who sees such a comment may cringe, wondering how that reviewer believes that the power of two AA batteries will spark a life-threatening current in the bathwater. It is easy to ignore such a comment as representative of technological ignorance. However, what about the possibil-

ity that such a device is plugged into the AC charger in the bathroom or kitchen, and that it then falls into the bath or sink? There really may be an issue of safety which should be addressed as a potential concern. Ultimately, researchers should include safety among the myriad ethical and technological issues that are considered in the development of a proposed study.

5. Strategies to address IRB concerns

In essence, a research study relies on the integrity and respect of a diverse group of individuals in order for the process to be safe, successful, and productive. Perhaps few research participants, or their guardians/caregivers, are aware of the existence of an IRB until reviewing the informed consent or other study documents. Yet the IRB is an intimate and vital partner in the research paradigm. As per FDA regulations, IRBs are formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in protecting the rights and welfare of human research subjects [13].

In addition to an IRB's commitment to protecting their human-subject research populations, they also provide training and guidance for investigators and research teams, and have the authority to monitor and audit investigators and their studies regarding protocol/consent compliance and adherence to accepted research codes and regulations (21 CFR 56.109 (f)). Moreover, the IRB has a relationship with every member of the research team that submits a project for review. The IRB's voice is assured in the decision-making associated with the moral and ethical issues of all human research approved and conducted under its assurances. As such, the IRB also has a profound relationship with the human-research participants, and are invested in a project's success, and in investigators' responsible conduct. These relationships are ultimately built on faith, trust, respect, and honesty; this implies that researchers represent not only themselves, but their organization and their IRB (and more subtly, their subjects) in every project in which they engage. However, the underlying regulations, laws, guidelines, and principles infuse IRBs with their charge, their vested authority, and their ability to hold an assurance. It is these very charges and authorized consignments that create the bridge between the promises and concerns associated with technology, research, and humanism, with the individual and society at the core of this ethical model. Therefore, research participants, or their guardians/caregivers, are (perhaps unknowingly) invested inherently in the ethical integrity with which each IRB operates, including the manner in which the committees understand, review, approve, and provide oversight for each investigator's protocol and consent requirements. Further, the participants,

guardians, and IRB rely on the investigators and research teams to be transparent, thorough, responsible, respectful, and ethical in the development of their research project, and in the study's strategies, methodologies, management, and conduct. Furthermore, the investigators and their research teams rely on the IRB to offer scientifically objective and ethically relevant reviews.

There is great benefit to knowing and understanding the IRB, the roles it plays, its authority, and the underlying doctrines that have shaped human research and participant-protection policies. Such understanding informs the successful development of technologies which are to be used in clinical trials, and allows the creation of an effective strategy for IRB approval, participant recruitment, minimization of risks and intrusiveness, reliable confidentiality practices, suitable data security measures, and optimum project-management strategies.

One central foundation of participant protection is the Belmont Report, which establishes clear ethical principles, definitions, and boundaries to guide research involving humans [14]. This report provides a critical underpinning for the protection of humans who participate in biomedical and behavioral research, of the research endeavor itself, and of society as a whole. This report specifically addresses and elaborates upon the ethical principles of respect (including autonomy and additional protection for those at increased risk or vulnerability), beneficence (accessing and minimizing potential harm while maximizing possible benefits), and justice (as in just distribution of both the risks and benefits of the research to potential subjects or groups of subjects, so that no one group is disproportionately disadvantaged or benefited by the research). During the review process, IRBs assess all documents, as well as the technology and research team's training and expertise, to determine if they meet these and other requirements, as well as the investigator's delineation of all informed-consent elements, including financial interest in the technology and conflict-of-interest issues. Similarly, IRBs are charged with assessing the real and potential risks, balancing a risk-to-benefit measure against the maxim "do no harm."

Noninstitutionalized older adults living independently in the community are not necessarily regarded as a vulnerable population. However, cognitively impaired individuals are considered vulnerable. Although some individuals in the early stages of AD are competent and can make autonomous decisions, research participants exhibiting cognitive impairments that would interfere with an informed understanding of the research, their participation, and the risks involved would invalidate self-determination and require additional protections (Code of Federal Regulations, 45:46—Protection of Human Subjects, DHHS, June 23, 2005; Human Subject Protection Regulations 46.111 (a) (.3), 46.111 (b), 46.116; and Code of Federal Regulations, National Archives and Records Administration, April 1, 2006, 21 CFR 50, 21 CFR 56.111 (b)). The rigor of these added protec-

tions is related to, and dependent on, the level and types of risk and exposures the participant will face in the specific study protocol. Beneficial research can be classified as therapeutic research or as having a therapeutic component. Further, it is controversial for participants who are cognitively impaired, or otherwise incapable of providing informed consent, to participate in research that may cause harm or discomfort and is not of a beneficial nature to them. To participate in research, cognitively impaired individuals must have a designated and appropriate surrogate provide consent for them [15]. Surrogate consent is often provided by family members, including legally authorized adult children, a significant other, or a legal guardian. The surrogate and participant are, in essence, a team, each warranting respect and consideration of the principles within the Belmont Report. Interestingly, a recent study found that >90% of respondents who were at increased risk for AD were in favor of surrogate-based consent for minimum-risk research studies [16].

Whether consent is provided by the participant or the surrogate, the investigator and research team must be cognizant of the issues of respect, beneficence, and justice for these individuals. As such, there are many participant-related issues to consider during the planning phases, including the potential diversity of the subjects and the types of consents which may be warranted, including advanced informed consents [15,17]. Investigators should have a clear delineation of any leeway the subjects or surrogates are allowed in controlling the technology, such as who determines when the technology will be used, or whether it will be continuously on, or if the control to shut it off is given to caregivers. Further, sensitivity and adaptation to changes that may agitate or upset the subjects improve the quality of the data collected, and are direct applications of the principles of respect and beneficence. Similarly, great attention is warranted during the phases of technology conceptualization and development to ensure that the design maximizes benefits, such as promoting autonomy and safety for the subjects and surrogates, while using the least intrusive means and minimizing risks (including safety issues such as electrical shock, fire, and physical components that might trip or injure those involved). Technology should be as robust and reliable as possible, given the stage of development. Further, it should be determined whether there is to be an interventional aspect of the study to be tested, and if so, to what extent, and how, will this be measured and validated? Research using monitoring technologies may identify neglect or abuse issues. How such circumstances are to be handled, in accordance with appropriate local and regional laws and reporting standards, should be determined and disclosed in the consent form.

Using research populations that are in residential settings or nursing homes requires investigators to determine whether these facilities are to function as partners in the research, e.g., as co-investigators or consenting members of research populations. If the facility is engaged as a research partner in federally sponsored studies, the facility needs Federal Wide Assurance (FWA) certification, and members of the staff serving as co-investigators or interviewers would need certification in human-subject research. Alternatively, if staff members serve as subjects to be interviewed or to test a technology, they need to participate in the consent process, with the clear specification that they can refuse to participate without any negative reprisals in the workplace.

Contact with IRBs unfamiliar with technology research should start in the very early stages of planning, in order to brainstorm and discuss the concepts, planned direction of research, compliance issues, concerns, questions, and review process. Providing clear answers to the questions that arise about various facets of the proposed study can prove educational, and important information can be exchanged between all parties involved. For instance, "what the IRB members think" or perceive regarding technologies, and what that technology "really is," may be dramatically different. With education, what begins as unsupported or biased perception gives way to knowledge and understanding; thus, educating members of IRBs becomes a desirable proactive component of the pre-submission procedure. Should the IRB decide that the technology to be used requires submission of an application to the FDA, as a medical device, the IRB can be a powerful ally in clarifying this necessity and facilitating the process.

When developing IRB applications, investigators need to focus on subject protection, elements of the Belmont Report, data quality, reduction of risk to participants, use of the least invasive technology or techniques, and addressing any issues previously raised by or discussed with the IRB. Issues related to Health Insurance Portability and Accountability Act, data security, or privacy should be appropriately detailed in the IRB application. Building in an acceptable degree of flexibility allows for dealing with unforeseen issues, and for conducting studies in an approved stepwise fashion (if indicated by study type, design, or subject population). This allows investigators to address expeditiously certain variances without having to return to the IRB for multiple approvals for the same project.

With an open, ongoing IRB relationship, researchers will know the IRB's concerns and expectations. In much the same way, the IRB will come to know how researchers will address these concerns, and how they will make a concerted effort to minimize risk, maximize benefits, and respect the privacy of their research populations. This minimal upfront time investment significantly outweighs the time needed to rewrite and resubmit an IRB application, the wait for the IRB to meet and review the application, and the associated, costly idle time of the research facility and research team.

Table 1
Ethical principles and guidelines for gerontechnology research & development for persons with Alzheimer's disease and their caregivers

Respect
For persons with Alzheimer's Disease (AD) by appropriately matching the technology to their capabilities.
For family caregivers and fragile family relationships by minimizing the intrusiveness and performance demands of the technology & study protocol.
For clinical providers by mitigating technology generated information overload. (Systems that generate a plethora of data points may not only be clinically non-useful but also distracting and burdensome to review).
For participants safety by stipulating that usual elder safeguards need to remain in place or as backup to the technology being tested.
Autonomy & Informed Consent
Assess the elder's capacity for decision making using a standardized measure; consent may be possible in early stage AD with non-complex decision making, assent in midstage, and guardian as proxy in late stage or for complex decision making at any stage.
Anticipate multiple consents for AD technology research: the elder, their family caregiver and or legal guardian, and if data are exchanged with others, then the professional caregivers, residential staff, clinicians or other involved parties.
Consider cultural differences wherein the head of household or other key decision maker in the culture is involved even if the participant has the capacity to consent.
Comply with federal regulations governing protections of human subjects (Http:///www.hhs.gov/ohrp/humansubjects/guidance/45CFR46.htm)
Beneficence (Do Good)
Include a variety of experienced technical, social science, and clinicians to foster technologies that realistically match with the targeted needs of AD participants.
Write technical directions for users in lay language at an elementary reading level.
Train technology installers and staff on how to interact with people with AD and how to avoid upsetting them when installing the technology especially on them or in their home.
Justice & Distributional fairness
Provide equity of participation in testing and use of new technologies.
Conduct small pilot feasibility studies initially rather than large scale RCTs to reduce economic waste from buying expensive technologies that do not work in your setting.
Disclose all sources of commercial and public research funding.
Make transparent any commercial or other influences that might bias the findings.
Aim to develop devices and systems affordable to all who can benefit from them.
Non-Abandonment
Ensure that the elders and families are aware from the beginning if the technology will or will not be available for continued use upon study termination. If not, prior to concluding, share information about other relevant resources.
Non-malfeasance (Do no Harm)
Avoid frustrating users due to upkeep needs of technology or its complexity, i.e. frequent battery changes to enable the components, daily resetting of the system or other burdensome demands requiring elder or family active involvement.
Avoid language that implies the technology does more than it actually does, i.e. "wakes up" and "provides assistance" when in reality it does not.
Inform users that technology generated prompts, alerts, or transmissions may not happen when there is a loss of telecommunications /power outages/ web access.
Privacy & Confidentiality
Honor the moral dictates of the participants' rights.
Provide participants /guardians control over whether and how their data are shared.
Comply with HIPAA Privacy Standards if a covered entity and exchanging personally identifiable health information (Http://www.hhs.gov/ocr/)
Install security measures to safeguard access to technology data.
Identify if monitoring may reveal questionable patterns of care such as neglect and abuse and if so how the field study protocol will address these situations.

Similarly, one should consider all available means and alternatives to demonstrate the technology. For instance, researchers can invite IRB members to open houses for demonstrations of the technology and educational purposes. This discussion assumes an open, receptive, and personally interactive IRB. In cases where there is no personal contact with the IRB, such as automated e-submissions, we recommend that study protocols be developed in accordance with the ethical principles and guidelines recommended in Table 1, and that they be submitted in the application to inform reviewers of the ethical areas relevant to the technology research. By remaining cognizant of the pivotal core of the Ethical Model for Technology, i.e., the humanistic risks, benefits, and concerns, one can expedite the process of obtaining IRB approval, while ensuring a quality research design that will protect the research population and provide valid data.

6. International perspective

The ethical frameworks that are applied to the design, evaluation, and implementation of technology for people with dementia are not the same across the world. For instance, European researchers are working in a different context from their colleagues in the United States. There are different cultures, legal systems, and regulatory environments that reflect and sometimes define the ethical framework within which research is conducted.

Fig. 2. The "Forget-Me-Not" calendar and display.

Cultural differences and expectations influence the design of devices and technical and personal support. The following example from the European ENABLE project illustrates the impact of cultural differences when implementing research across national and cultural boundaries [18]. The ENABLE project was run according to the ethical framework developed by Bjorneby et al. [19]. This example is of the impact of small cultural differences on device configuration. In this case, the device was a calendar for people with dementia that showed the day, date, and time of day in words. The display would resemble that as shown in Fig. 2.

Eight calendars were supplied to each of the five countries taking part in the evaluation project. The English-language calendars from the United Kingdom and for Ireland were sent to the United Kingdom. The calendars for Ireland were then forwarded to Dublin. The calendars for the United Kingdom were distributed to their evaluators and installed successfully. Not long after the arrival of the Irish calendars, a call was received from Dublin asking why the time-of-day display included "evening." It was explained that the usual sequence of time of day in English is "morning," "afternoon," "evening," and finally "night." The Irish partners responded by explaining that in Ireland, the usual sequence is "morning," "afternoon," and "night," and that "evening" is not a time of day, but something that one does. For example, one "goes out for an evening" to the theater or a club. This small difference in culture has since been confirmed many times by Irish visitors to a smart home in the United Kingdom.

Had the United Kingdom version of the calendar been used in Ireland, a person with dementia might have thought that he or she was being reminded to go out "for an evening" at a certain time every day, leaving the house when prompted to do so. It is important to be thorough in checking details such as these when working across cultural boundaries, even across cultures as similar as the United Kingdom and Ireland that share a language and some of their history.

Projects encompassing more than one country can be complex organizationally and financially, but there are also complications based on maintaining consistency of experience for user-evaluators. The experimental design for such evaluations should anticipate these variations in user experience. This may be achieved by measuring changes in user experience rather than making absolute measurements. The design of devices also needs careful consideration when working across national and cultural boundaries. Features of a human interface that appear trivial can be significant when introduced into an unknown culture. Interfaces should be checked with people from the region of evaluation prior to introduction, to ensure that they will be understood in the intended way. Working with people from other countries and cultures is rewarding and challenging, but requires attention to detail, linguistics, and flexibility at the point of delivery.

7. Conclusions

This review sought to identify research and development issues relevant to the in-home monitoring of older adults with dementia from an ethical perspective. We suggest that this area presents particular challenges, with the need to address multiple perspectives. We caution: 1) researchers to duly consider humanistic concerns as central amidst the complexities of technology research and development; 2) grant reviewers and IRB members to avoid stifling technology innovations out of personal bias; and 3) families and other end-users against overestimating the capability of new technologies and letting down their vigilance. We offer case examples and an ethical model with related guidelines (see Table 1) to offer guidance in attaining a humanistic and ethical approach to technology research.

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