ESTABLISHING ETHICAL GUIDELINES FOR TELEHOMECARE RESEARCH ON CHRONIC DISEASES

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Extended Abstract

Introduction

Telehomecare technologies are applications designed to be used in patients' personal living spaces ranging from private homes to assisted-living facilities. The goal of these technologies is to help physically and/or mentally vulnerable people live more safely, more capably, and longer in their location of choice. 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 technologies into the home environment, thereby creating a homecare that proactively monitors and reports undesirable events. The technologies focus on disease management and the monitoring of physiologic data for aberrant indicators necessitating clinical treatment.[1]

Such technologies have been developed for a wide range of clinical applications to manage mostly chronic diseases (CD), such as monitoring of asthma (eg, a home asthma tele-monitoring system, which assists patients in the daily routine of asthma care with personalized interventions), diabetes (eg, a diabetes care management support system to support care delivery to diabetic patients), and coronary heart disease and sleep apnea (eg, a tele-device which monitors throughout the nights as patient sleeps, and sends information to a diagnostic testing facility, where a report is run and delivered to patient's physician.)

Most previous research on telehomecare technology has focused on the effectiveness of the devices, and very little of it specifically addresses the ethical issues in research.[2] This paper employs an ethical perspective, and offers guidelines to apply an ethical model to telehomecare research.

Humanistic concerns-- respect

Respect should pervade all of investigators' encounters with research participants. The physical and cognitive manifestations of CD 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]

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Society tends to view "disabled" persons as being less capable generally than their "able" counterparts. The investigators' 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 CD vary widely in their preferences and capacities to act on information when being approached about participation in a study.

The vast majority of persons with CD 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 telehomecare systems must be developed with acute sensitivity to how family relationships will be affected in the home and other family environments.[4]

Research needs and concerns—proportionality, privacy and confidentiality

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.

As in all human-subject protocols, those designed for telehomecare 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 telehomecare research. For instance, telehomecare 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.

Promises and concerns in societal context-- justice and distributional fairness

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.[5]

The accountability of clinical and other human-subject investigators does not end with data collection, analysis, and reporting. From its inception, a research protocol must be crafted with the goal of developing telehomecare devices or systems that will help meet the needs of all who eventually might benefit from them. 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.

Nowadays any promise of prevention or relief from CD's symptoms makes for headline news. Therefore, unreasonable societal expectations wait to take root with every reportable finding.

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The CD research community and individual investigators must take every precaution to truthfully describe capabilities (or potential capabilities) of telehomecare technology for persons with CD. 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.

Safety issues: the ethical imperative of "non-malfeasance"

When planning research endeavors that bring technology into the lives of physically and/or mentally challenged persons, safety concerns should never be underestimated.

Telehomecare technologies are usually subject to medical-device standards and approval from the Food and Drug Administration in the U.S. But, from a more generic standpoint of safety, investigators should always ask themselves: are there any behavioral "side effects" of introducing technology. For example, an investigator has introduced a "smart viewer" into the home of a caregiver of a CD 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 may assume that the technology works even when the project is at an initial stage 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.

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.

IRB concerns-- informed consent

IRBs are formally designated to review and monitor biomedical research involving human subjects. 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.[6]

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 the basic ethical 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 principle "do no harm."[7]

Although some individuals in the early stages of CD 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

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invalidate self-determination and require additional protections.[8] The rigor of these added protections 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. Surrogate consent is often provided by family members, including legally authorized adult children, a significant other, or a legal guardian.

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. 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. In addition, 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. Furthermore, 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.

Case study

An 85-year-old woman with osteoporosis is monitored 24/7 throughout her home by sensors that check for signs that she has fallen. The information is sent via a wireless network to a home health monitoring facility, which adheres to a confidentiality agreement disclosing information only to a nearby son, and only when a fall or other emergency has been detected.

Conclusions

This paper sought to identify research issues relevant to telehomecare of patients with CD from an ethical perspective. It suggests that this area presents particular challenges, with the need to address multiple perspectives. Researchers should duly consider humanistic concerns as central amidst the complexities of technology research, and families and other end-users should not overestimate the capability of new technologies and letting down their vigilance. It offers basic guidance in attaining a ethical approach to technology research.

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