GATHERING THE EVIDENCE: SUPPORTING LARGE-SCALE RESEARCH DEPLOYMENTS

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Abstract

Independent living technologies have tremendous potential to facilitate the study of aging and chronic disease. By collecting medical and behavioral data continuously as people live their daily lives, we are able to form a much clearer picture of the changes in people's health, and the efficacy of treatments over time, than is possible by using periodic clinical visits. However, deploying these technologies in large-scale clinical trials poses unique challenges. In this article we review those areas in which independent living technologies can provide significantly improved research data, and the challenges that must be overcome to effectively gather those data. We propose approaches, both technical and procedural, which enable efficient management of large-scale research studies, and we discuss scalability issues and their possible solutions.

Introduction

People aged 65 and older are the fastest growing segment of the United States population: it is predicted that this number will more than double by the year 2030. Forty-two percent of this age group reported some type of long-lasting condition or disability [6]. Furthermore, over 20 percent of people 85 and older have a limited capacity for independent living [5], requiring continuous monitoring and daily care. Almost 6 percent of private health expenditures and approximately 13 percent of all public healthcare expenditures in 2005 were spent on home healthcare and nursing-home care for older adults [4]. The convergence of growing numbers of seniors with attendant chronic illness, the rising costs and complexity of care, and the inability to effectively develop and apply increasing knowledge of how to treat or manage these health declines merge to create a well-recognized crisis of healthcare in America.

"Over 20 percent of people 85 and older have a limited capacity for independent living."

A major challenge to research into caring for the aged is the reliable assessment of behavior and clinical status across multiple related domains (for example, cognitive, social, physiological, environmental). Clinical research has not fundamentally changed its tools of conduct and assessment paradigm since the beginning of the computer age. Thus, clinical research is currently still rooted largely in traditional clinical practice methodologies, where the basic paradigm of assessment is a clinical interview or examination, relying on the recall of the volunteer, performed at a brief moment in time, at a location convenient for the researcher, not the volunteer. Even when technologies are deployed in the home, they are often used in a brief or episodic way (for example, 24-hour heart monitoring or two weeks of actigraphy) and not fully integrated into the clinical data stream and workflow.

There have been several research efforts that have developed solutions for monitoring and assessment of individuals in their homes. These approaches use unobtrusive wireless sensors placed in a subject's home (such as motion sensors, door sensors, and environmental sensors), or technologies that the subject wears or uses (such as medication adherence monitors, telemedicine boxes, personal computers, and body-worn location and activity sensors). Studies that use these technologies have found that even simple technologies can be valuable in assessing behavior in the home [13], and there are a growing number of researchers developing and evaluating emerging technologies for in-home assessment and health intervention. These technologies have the potential to transform the clinical research landscape by enabling the simultaneous assessment of an individual's activity, function, and physiologic status in a particular location across a wide array of time scales (for example, seconds to seasons), and by creating the potential to detect subtle changes in that status, by comparing this rich multidimensional data stream with baseline data from prior observations.

The general approach to this kind of study is to monitor a subject (or patient) over a period of time to establish a baseline, after which deviation from that baseline can be used to detect clinically-relevant change. Without this baseline, patients must instead be compared to a population norm–and what is normal for one individual may be a cause for alarm in someone else. Furthermore, by sampling infrequently, true trends may be masked, as a person has *good days* and *bad days*. Figure 1 illustrates how infrequent sampling can lead to substantial aliasing errors. In the figure, you will see that the top panel depicts test scores taken during a standard clinic visit, taken at six-month intervals, for two different patients. Then note that the bottom panel depicts how continuous assessment could reveal a very different picture. Thus, the continuous nature of the in-home sensor data collection allows many data points to be collected, providing better time resolution for looking at changes and for reducing the overall variance. This continuous collection also allows changes to be detected in a shorter period of time. The immediacy and frequency of the collection of these data form the basis for the transition to a true substantiation of personalized medicine and directly aligns with new healthcare delivery trends and mandates, including the wide-scale build-out of electronic medical or health records [19], the Medical Home [8], and comparative-effectiveness research (CER) [14].

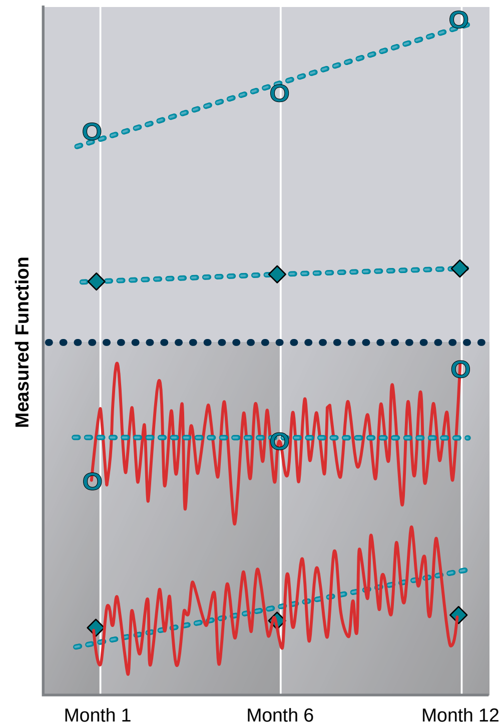

Figure 1: Problems with Infrequent Monitoring
Source: *Alzheimer's and Dementia*: Hayes TL, Abendroth F, Adami, A, Pavel, M, Zitzelberger TA, Kaye JA

The Role for In-Home Monitoring in Research

In-home monitoring has wide applicability in routine care and intervention. In particular, in-home monitoring allows tracking of conditions that evolve slowly over time or that have poor demarcation of onset; and it allows the tracking of conditions that transition to new clinical states, such as depression, frailty, and cognitive impairment. Suitable sensors placed in the home may also allow immediate detection of acute events that are rare or irregularly occurring, such as falls, naps, or transient neurological events.

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"The metrics of interest would become true rates of change and not simply binary 'present or absent' estimates."

Continuous monitoring would also greatly enhance clinical trials of both drug and behavioral therapies, by allowing the ongoing assessment of patient adherence to the trial or therapy regimen, and by providing those administering these trials the ability to assess side-effects and health changes throughout the day. Traditionally, both adherence and side-effects in clinical trials are measured through self-report, which at best corresponds modestly to actual medication taking and to true physiological changes [17, 20] (see Vignette 1 at the end of this article). The immediate identification of side-effects accurately aligned to the time of treatment would provide valuable insights into the efficacy of treatments. Data about patient behaviors would allow improved coaching of the patient to ensure better adherence to the treatment protocol. Furthermore, in studies of recovery (such as from a hip fracture or stroke), instead of assessing outcomes by using subjective measures, for example, arbitrary scale numbers at a fixed time point such as 3-6 months after the event, new measures could be generated from recovery curves that represent the rate of functional recovery (such as total activity or walking speed). One of the most interesting benefits of using the continuous home assessment platform is not only the opportunity to examine the trends in these objective measures, but equally importantly, to determine their variability over time. In many cases in aging research, the variance in a measure may be more informative than the absolute value [12, 16].

The ability to improve on self-report also has the potential to transform epidemiological studies. Currently, epidemiological survey and assessment methodologies tend to rely on sparsely spaced questionnaires that depend on recall of events. This approach makes it difficult to identify data or events with detailed temporal or spatial precision, and it limits their ecological validity. A way to improve this state is to bring the locus of assessment into the home or community by providing a means of recording continuously, in real-time, events as they occur and where they occur. If full sensor networks and on-line reporting capabilities were incorporated into thousands of households, there would be an opportunity to collect changing health outcomes at the point of occurrence. In this case the metrics of interest would become true rates of change and not simply binary "present or absent" estimates. Item-level data would be much less reliant on recall (e.g., "In the last six months how often did you wake at night?") and instead reflect actual events and more objective measures (e.g., the number of bathroom visits, hours in bed, and so on).

Achieving Large-Scale Studies

Recent advances in ubiquitous computing and sensor network methodologies make large-scale, in-home research studies feasible. When coupled with other convergent technologies and methods, such as ecological momentary assessment and telemedicine, the potential to transform the practice of clinical research is staggering. However, in spite of the number of *smart homes* that are now being used to develop and evaluate in-home monitoring technologies, we are a long way from wide-scale deployment. Experience has shown that solutions that appear to work in a controlled laboratory environment, even when that environment is intended to simulate a home living situation, never work as expected in the field. For this reason, we have developed a staged approach to designing solutions for large-scale, in-home monitoring.

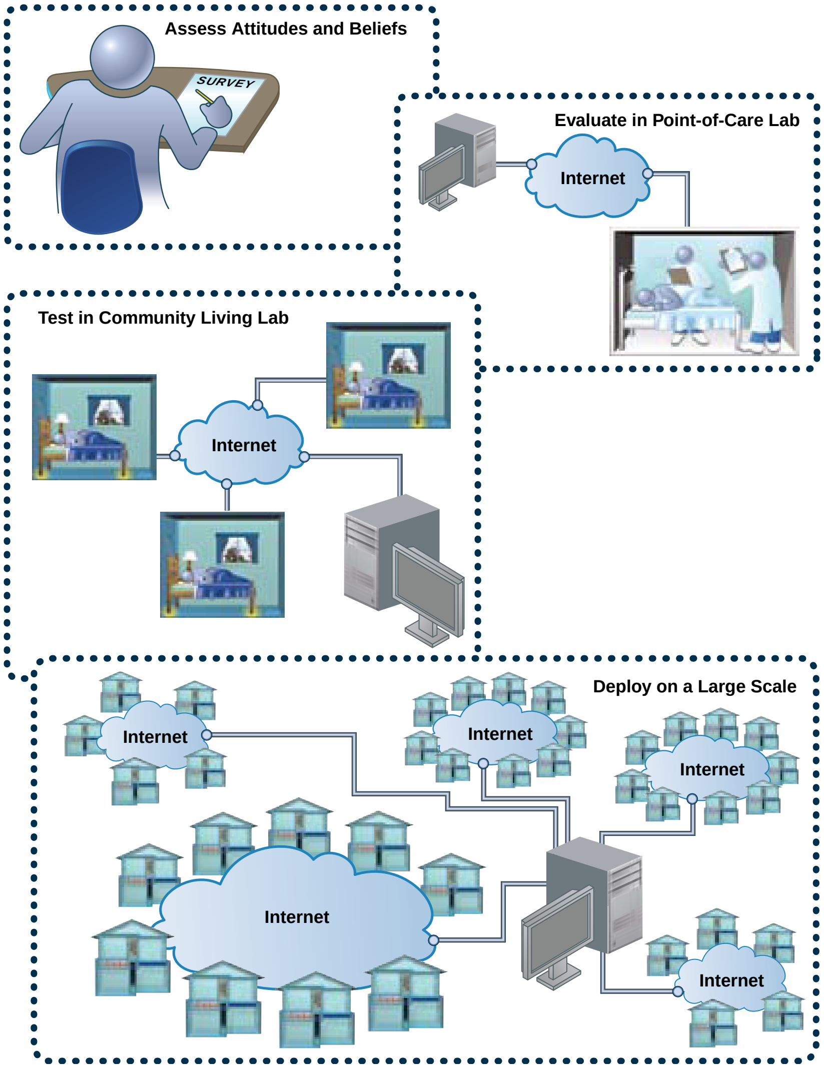

Figure 2: Scaling In-home Assessments from the Lab to Communities
Source: OHSU

Figure 2 illustrates the stages we use from technology inception to wide-scale deployment. First, we conduct focus groups and interviews to inform the technology design, and in particular to understand attitudes towards the technology and to identify key usability and acceptance issues. In the second stage, technologies are tested in a smart-home environment (the Point of Care Laboratory) by using convenience samples of participants. Data collection can be done quickly and easily, under controlled experimental conditions, and therefore this approach is appropriate for initial evaluations of technologies. However, these tests will not typically allow the collection of outcome measures that are representative of particular patient populations. Therefore, part of this

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stage includes bringing patients or subjects from the target cohort into the smart home, to collect additional data about how the population of interest will interact with the sensor systems. This is useful for improving our understanding of the limitations and capabilities of the sensor technologies. Clearly, subjects brought into a smart home will not behave as they would in their own home, and therefore data collected in such an environment has less ecological validity than those collected in the individual's home. Hence, the third stage entails taking the technology into the field — that is, instrumenting a small number (10-20) of patients' homes — to provide much better outcomes' data. We use the ORCATECH *Living Lab* for this deployment. The Living Lab is a group of senior volunteers who have agreed to allow technologies to be evaluated in their homes on an ongoing basis. A core set of technologies is continually maintained in the homes, and clinical and neurological assessments are conducted on this cohort on a semi-annual basis. This deployment helps to reveal problems that may arise when the technology is used with different home construction materials, infrastructure support, living arrangements, or patient populations. Once a technology has been *field-hardened* in the Living Lab, we are ready to begin to scale it to larger studies.

"The Living Lab is a group of senior volunteers who have agreed to allow technologies to be evaluated in their homes on an ongoing basis."

In spite of the challenges of scaling emerging technologies, there is a clear need to do so. The high inter-individual variability in behavior and health outcomes drives the need for large studies. For example, while small randomized clinical trials of cholinesterase inhibitors have shown modest improvements in cognitive function, trials with treatment and control groups of 200 – 300 people are typically necessary to have sufficient power to show improvements from baseline [18]. Population-based studies require a much larger sample size, since these studies typically control less for co-morbidities, and therefore the variance in those samples is much greater.

In the process of deploying various in-home monitoring and intervention technologies in more than 400 homes around the United States, we have learned a great deal about the challenges of scaling the technologies for research. These challenges relate in part to the complex, heterogeneous nature of the data that are collected, in part to the challenges of adding the use of technology into the already difficult problem of recruiting and retaining patient populations (who may be technophobic), and in part to the fact that the global infrastructure and sensors designed specifically for collecting behavioral health data do not yet exist. In the remainder of this article we review each of these challenges and propose possible solutions.

"The high, inter-individual variability in behavior and health outcomes drives the need for large studies."

The Nature of the Data

Continuous, in-home monitoring studies generate a vast amount of data pertaining to the daily activity of subjects. These datasets may contain mixtures of complex data, ranging from rare and random events to continuous signals. Uniquely, these data inherently describe multiple data domains simultaneously: space or location, time, activity, physiological function, neuropsychological function, etc. These data provide more accurate and detailed information than can be captured by traditional methods of self-report, and they hold information about patterns of activity in the home that could be used to examine a multitude of hypotheses about behaviors, such as restlessness at night, nocturia, patterns of use of the kitchen (and refrigerator), outings from the home, and acute events such as falls or stroke. However, the very strengths of these data — such as the high sampling frequency and the many different types of information gathered — make them challenging to manage, study, monitor, and interpret.

"These datasets may contain mixtures of complex data, ranging from rare and random events to continuous signals."

There are three key types of data that are needed to support large-scale research studies. The first type of data that is of interest is the raw data from the sensors themselves. These data reflect physical responses of the sensors to the behaviors of the research participants. For example, the instantaneous signal strength from a body-worn radio frequency identification (RFID) sensor as an individual walks through the home, the time at which a motion sensor fires when somebody passes by, and the force measured by a load cell under the support of a bed as a person breathes, are all signals that must be captured for subsequent processing and inference. Some of these (signal strength, load cell force) are sampled at regular intervals and form a time series sampled at a relatively high frequency. Others (sensor firing time) are event-driven, and the amount of data collected therefore depends upon the activity being sensed. Furthermore, these data may also be tied to location, and therefore they may require a spatio-temporal representation.

"These data may also be tied to location, and therefore they may require a spatio-temporal representation."

The second type of data is metadata about the sensors, the state of the sensors, and participants themselves. If one is relying on signal strength to estimate location, for example, then the battery level of the sensor becomes important to determining the likely variance and accuracy of the estimate. Similarly, if a motion sensor appears to have stopped firing, it is important to know if there is a hardware or communications problem or if the person being monitored has simply not passed near the sensor.

The third type of data is derived data, which come from inference algorithms that are used to extract information from the raw data. Often these derived data actually arise from sophisticated statistical models that fuse data from multiple sensors to make inferences about behaviors and health outcomes. Derived data could be as basic as an estimate of respiration or walking speed, or as complex as a determination of how well a person was performing a particular activity of daily living (ADL). The derivation of such measures and metrics from in-home sensors is an area of active research, and at this point, only a small number of measures have been developed and validated.

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"As purposed sensors become more common, what was once derived data will become raw data*."*

The applicability of each of these types of data typically relates to the maturity of the sensor technology. For example, a pulsed ultra-wideband location sensor could provide data in the form of the time-difference-of-arrival measures, or could provide an estimate of the individual's location, based on a sophisticated algorithm that integrates data from multiple nodes. If the sensor were well-tested and its behavior in home environments was well-understood, then the expense of storing the raw data might not be warranted. Instead, the location estimates would be sufficient. Thus, as purposed sensors become more common, what was once derived data will become *raw data*, which in turn will be used to develop more sophisticated and complex measures.

Managing Large-Scale Studies

"Unlike standard clinical trials, in-home studies require central tracking and remote systems management capabilities."

Conducting a large-scale, in-home trial differs from conducting a small pilot study as well as from conducting standard clinical trials. First, in large studies, the recruitment of subjects is often done across multiple sites in different cities or states, which raises issues of staff training, forming relationships with local infrastructure providers at each location, dealing with regional differences in attitudes towards the technologies, and cross-site coordination. Furthermore, unlike standard clinical trials, in-home studies require central tracking and remote systems management capabilities. Second, the innumerable possible variations on home configurations and environmental conditions means that in-home technology must be adaptable to many environments, which is not always straightforward. Third, short installation time and high equipment reliability become essential in a large study. Fourth, because in-home technologies can potentially produce a large amount of raw data, centralized data management and a means of visualizing and reviewing the data are essential as well.

"Short installation time and high equipment reliability become essential in a large study."

In our studies, the data and the remote installations are managed by using the ORCATECH Management Console (OMC), a multi-tiered remote monitoring application built from Open Source tools. This software tool was designed to support the activities of both clinical and technical research assistants. OMC provides a central view into the data and has the following capabilities:

- View subject and home information (floor plans, sensor placements, demographic info, etc.).
- Track recruitment and subject status, including generating alerts for upcoming scheduled visits for assessments or equipment installation.
- Track contact with subjects, for assessing *total cost* of installations (for example, time and frequency of support phone calls and visits).
- Roll up the *health* of the installed systems (and raise alerts if sensors fail to fire, or data fails to transfer).
- Provide summary views of the data to enable data validation on an ongoing basis. Figure 3 shows an example in which computer use is displayed for the two residents in a home. In this graph, we also plot in-home activity, since we should not expect any computer use if nobody is home.

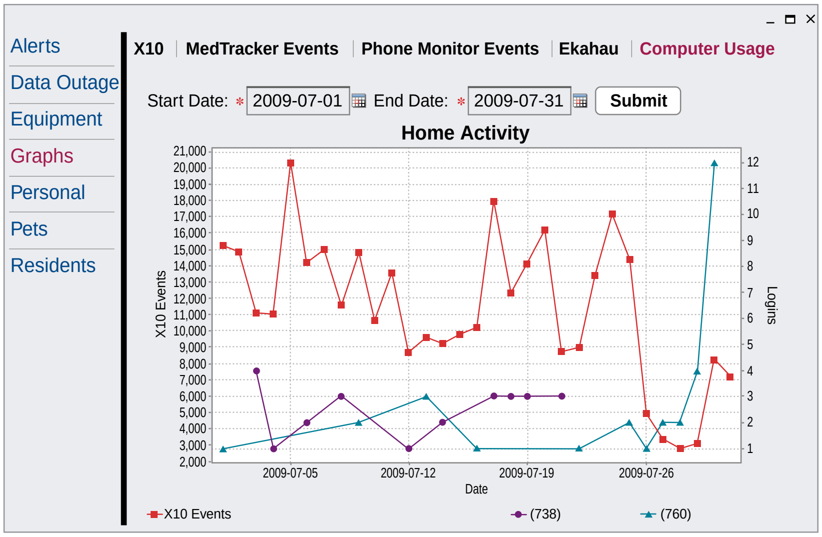

Figure 3: Checking Data Integrity with the ORCATECH Management Console
Source: OHSU

In the following sections we discuss the core issues this study management tool was designed to support — and those issues that still need to be addressed to make this tool ultimately scalable to studies that include thousands of subjects.

Cohort Management

One of the greatest challenges for any large-scale study is the recruitment and retention of the participant cohort. The challenges are exacerbated when the participant population is asked to use or interact with unfamiliar technology. In aging studies, many participants have never used a computer or cell phone and are highly intimidated by the thought of learning to do so. In one of our longitudinal studies, we require the participants to use a personal computer on a weekly basis. Approximately 32 percent of the participants we recruited already owned their own computer. The majority of the remainder, 169 subjects, were provided with a computer and trained to use it. A significant effort was spent in developing a training program that included skills ranging from the use of the mouse and how to double-click, to sending and receiving e-mail (a definition of computer literacy). The training program comprised six hour-long lessons that were taught to small groups. Clearly, this is not an approach that scales to tens of thousands of subjects. However, many computer classes for seniors are now available through libraries and senior centers, and through partnerships with such programs, it is possible that large-scale studies requiring frequent computer use may be viable even in studies of older adults, such as our studies (where the mean age is over 80 years old).

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Many of the technologies available commercially, such as cell phones and mice, are difficult to use for older adults. For an individual with a tremor, pressing a single key on a cell phone or moving a mouse to a target on a screen may be literally impossible to do with accuracy. For many elderly, the text on a cell phone is too small to see, even with glasses. Recent research has provided considerable insight into the usability needs of the aging population [2, 3, 15, 21], and large-scale studies must be prepared to adapt their technologies to accommodate the wide variety of needs in this population.

This difficulty with the technology translates into a retention problem for research studies: participants that become frustrated are more likely to drop out of the study. Therefore, in technology-based studies, even more than in traditional clinical studies, it is vital to maintain active personal relationships with the participants. In our own studies, this is done by maintaining continuity of contact as much as possible. Each participant has an assigned research assistant that they know well and with whom they are used to interacting. In addition, we maintain a help-line for the participants to call with any questions they may have about the technology. By knowing that they will receive a response about their problem within a day, and that somebody wants to help them through it, the participants are able to give voice to their frustrations, which is often all that is needed to defuse the situation. Of course, not all participants are frustrated by the technology.

"It is vital to maintain active personal relationships with the participants."

In aging studies, transitions are part of life. Many participants will move to smaller homes, to assisted living, or they will move in with family over the course of a study. Even more participants will become ill, have an exacerbation of a chronic disease, or undergo surgery. In a study of behaviors or health outcomes, these transitions will have a significant impact on the data. It is important to track these changes, and in some cases to collect additional data that will help in the interpretation of changes in the data that result from the life transition. For example, in our Intelligent Systems for Assessing Aging Changes (ISAAC) project, we are interested in changes in walking speed over time. In this project, 6.8 percent of our participants have moved in the last eight months. Often, their new homes are smaller, and therefore the participants do not need to move around as much to go from room to room. Alternatively (or in addition), the participants may have made the change because of changing health needs that themselves impact their daily activity. Therefore, in order to understand how the home move impacts our measurements of activity, it is important to study the time periods around these transitions carefully, and to understand what health changes may have happened at the same time. To help us understand these data, we ask our participants to complete weekly online questionnaires about any health changes, medication changes, or emergency room visits that may have occurred in the previous week.

"In aging studies, transitions are part of life."

One final area of cohort management is important to consider. Many technology-based studies place expensive equipment into the homes of the participants. Depending on the neighborhood, this technology can make the participant a target for break-in and theft. Furthermore, in studies with cognitively impaired subjects, quite a few of the subjects will forget what the technology is for or even that it is in their home. In these cases, participants may pack up the equipment or even give it away. While these situations are rare, their resolution takes time and money.

"Many technology-based studies place expensive equipment into the homes of the participants."

Technology Management

There are three keys to successful technology management in a large-scale, in-home study: a stream-lined and well-supported installation process, continuous remote tracking of system status, and the ability to do remote management and maintenance of installed technologies. Our approach in each of these areas has changed over the years, as we have partnered with study sites around the country and have learned many lessons.

The installation of in-home technology often involves sensors and devices that are unfamiliar to many study assistants. Even setting up a computer may be outside the experience of the typical research assistant (RA). Therefore, the technology installation must be both orderly and as *idiot-proof* as possible. In addition, a live help line is essential to provide support for inexperienced RAs. For example, in one study in which medication tracking devices and computer kiosks for administering monthly or quarterly neuropsychological evaluations were to be installed in 200 homes in 25 cities around the country, we created a laminated step-by-step installation instruction sheet that was packed in the box with each technology set. All connectors between the equipment were color coded, and the instructions included photographs of how those color-coded connectors should be connected. A set of pre-install steps were clearly specified, including forming a working relationship with the local broadband provider for billing and technical support prior to commencing installs. Study coordinators from all sites converged locally for a one-day training session in which we attempted to cover possible problems with the installation. In spite of these preparations, the help line assistant received 55 calls during the first 57 installations. While the need for support tapered off sharply by the time each site had installed two systems, about two-thirds of sites still called for additional assistance at least once in the first year. Clearly, an effective help line with well-trained staff is one of the most essential components of ensuring a successful multi-site, large-scale, study deployment.

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The continuous monitoring of equipment status is another important component of ensuring good data collection in a large-scale study. In our studies we do this through the ORCATECH Management Console, which queries the status of numerous system variables in each home once per day. Figure 4 shows an example in which an alert screen provides visual indicators of the status of the sensors. The system checks for problem indicators daily and displays them as a red bar. Technicians can then reclassify the problems when they have determined the cause. Colors reflect the problem status. Multiple days can be displayed to assist in tracking problem status over time.

"The continuous monitoring of equipment status is another important component of ensuring good data collection in a large-scale study."

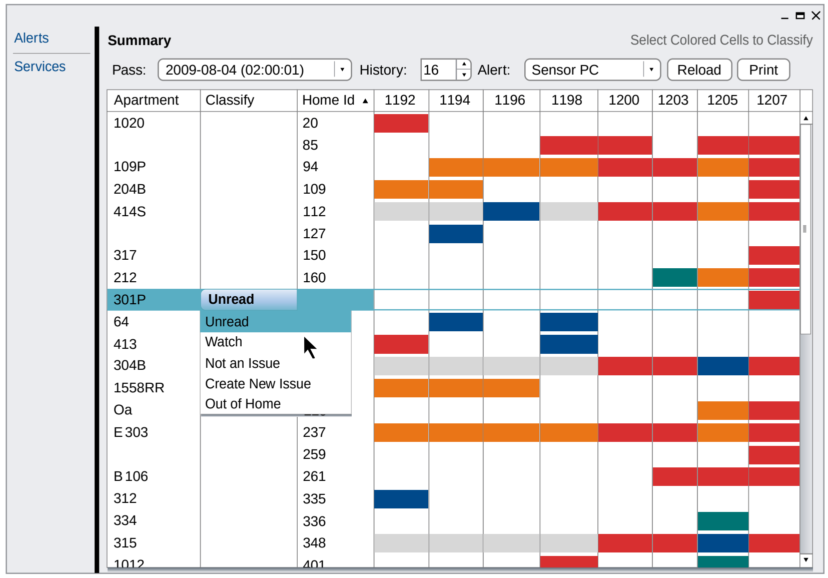

Figure 4: Screenshot of the ORCATECH Management Console Alert Screen
Source: OHSU

A great deal of system problem triaging can be done programmatically. Communication status between the routers and the in-home computers, the status of services running on the sensor computers in the home, remaining device battery life, failure to receive sensor heartbeats, sensor data values out of expected range, and even failure of the participant to complete a weekly form, can all be flagged as possible issues and brought to the attention of the study staff. Serious problems, which may result in the loss of data, can then be identified quickly and addressed immediately. By tracking the time taken to triage and fix problems, we are able to assess the overall quality of the study support.

"Scientifically, it is important to not visit with the participants more than necessary due to the study protocol."

Finally, remote maintenance of installed technologies is an extremely important component of conducting in-home trials, both scientifically and financially. Scientifically, it is important to not visit with the participants more than necessary due to the study protocol, because that contact may itself influence the outcome of the study. For example, in one of our studies we are interested in changes in walking speed and motor activity over time. Each time we visit a participant's home to repair activity sensors, they become aware of their own activity and may subtly alter their behavior for a short period of time as a result. Furthermore, frequent visits to the participants can be an irritant to them, which puts study retention at risk. Financially, it is expensive to travel to participants' homes to make repairs. Clearly, some repairs require in-person visits (replacing batteries or broken equipment), but many things can be fixed remotely (restarting services, scheduling tasks, pushing new software versions, helping participants with computer programs, etc.). Wake-on-LAN capability has proven to be an extremely valuable feature of the in-home computer. In our studies, we used a laptop to collect sensor data that did not have wake-on-LAN capability in its wireless LAN card. As a result, in those homes in which we used 802.11g to connect to the router, we were unable to remotely boot many of the sensor computers that went off-line.

"Once the project reached steady state, the number of fixes trended down."

Figures 5 and 6 show the repair history for one of our studies, the ISAAC project [9]. In this project participants have passive infrared sensors distributed throughout their home to detect activity and walking speed and a personal computer that we use to track inter-keystroke intervals (a surrogate for finger tapping speed) and their interaction with a series of games. This study has two technical RAs who are responsible for supporting the 248 participants and 190 homes in the study. In Figure 5, you can see the clear pattern of install/bug fix that we engaged in during ramp-up of the study. Once the project reached steady state, the number of fixes trended down, reflecting the fact that issues that spanned multiple homes had been identified and addressed. At this point in the project, most fixes are maintenance issues, such as battery changes and issues with broadband.

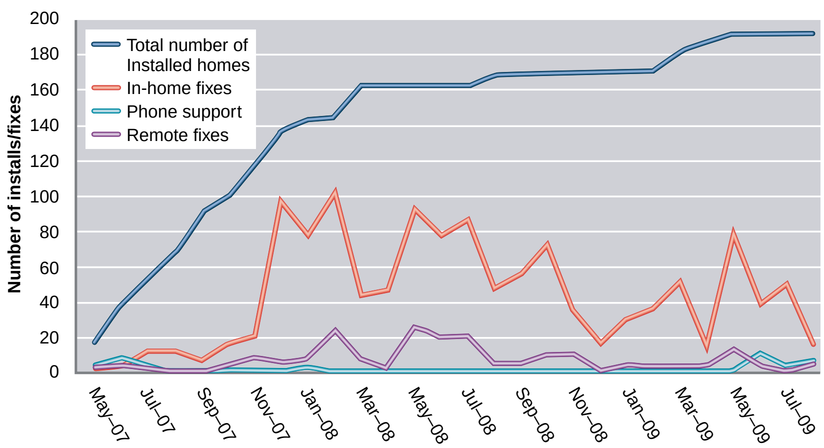

Figure 5: Patterns of Installation and Fixes on the ISAAC Project
Source: OHSU

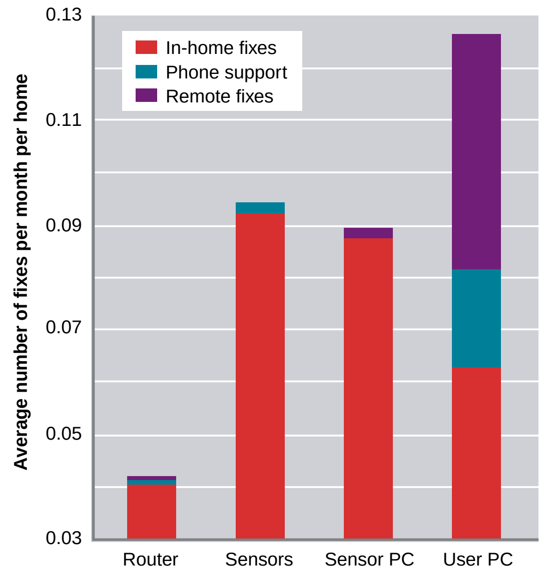

Figure 6: Types of Fixes for Each of the Four Major Technologies Installed in the ISAAC Project
Source: OHSU

Figure 6 shows the ratio of in-home visits to support calls with the participant, to remote fixes, for the main problem areas. Because participants in this study are required to use their computer weekly, we have put into place a help line (e-mail and phone) that they can call for support. This is reflected in the large number of remote fixes done on the PC, which often take the form of undeleting a subject's file that they cannot seem to locate, restoring e-mail settings that they have changed by mistake, or deleting spy ware that was inadvertently downloaded by their grandchildren. In spite of our best efforts to provide FAQs, handouts, and in-person training on basic computer use issues, many relatively simple tasks remain a challenge to the individuals who have never used computers prior to our studies.

"Surprisingly, most computer problems unrelated to participant use have required on-site visits."

Surprisingly, most computer problems unrelated to participant use have required on-site visits. This is a major barrier to scalability at this time. In part, this reflects the limited capabilities of the in-home systems used in this study. We chose inexpensive laptop computers running Windows* XP* for our study, in part because of the need to keep costs under control, and in part because some of the commercial sensor software we were using runs only under Windows. However, these laptops turned out to have unreliable network cards as well as some obscure device driver issues. Furthermore, at the time the study started, Intel® vPro™ technology was not yet available. Had we been able to use such technology, we would have been able to remotely diagnose a number of sensor computer issues rather than visit the home. Overall, our considered opinion at this time is that a Linux*-based system would perform more reliably, as well as require significantly less memory.

Data Management

The management of the data from in-home technology studies raises some unique issues. Of primary concern is the security of the data and the privacy of the participants. At all levels of data management (acquisition, transmission to a central site, ongoing storage, and retrieval for analysis), the data must be protected. Many organizations, such as the Veteran's Administration, have highly-regulated restrictions on where the data may be stored, when they need to be encrypted, and who may access them. However, even in research organizations with fewer regulations, the data must be appropriately anonymized to protect the subjects' privacy, and they must be stored securely. Data acquisition poses interesting challenges to maintaining this privacy, since often the data are not encrypted before being sent to a local receiving device.

"The data must be appropriately anonymized to protect the subjects' privacy, and they must be stored securely."

As described in the section on the Nature of the Data, raw data, metadata, and derived data all have different properties. As a result, they also have different storage needs. Large-scale, longitudinal studies that follow hundreds or thousands of subjects over years need to consider options for data compression, data storage, and data retrieval. As derived measures are developed, are the raw data still needed? Is it appropriate to archive these data, or does it make more sense to create a hierarchical storage model in which older data are down-sampled or summarized over longer time periods? Do meta-data need to be kept beyond the period in which they are used to address technology issues? If they are discarded, what historical data should be kept to allow for evaluation of the study's efficiency? As derived measures evolve over time, how should the versions be documented and stored? For large datasets, where processing the data to derive the measures may take hours or days, it may make the most sense to store all of the derived datasets. In other cases, where storage is at a premium, it may make more sense to store the algorithms used to derive the measures. While none of these issues are unsolvable, some choices may be irreversible. As a result, it is important to have a clear data management policy in place at the start of any large, in-home study.

"While none of these issues are unsolvable, some choices may be irreversible."

Scalability Issues

There are many issues that need to be addressed if large-scale deployments of in-home research studies are to be successful. One issue centers on the diversity of technology experience and acceptance in the aging population. A second issue is the lack of available tools for interpreting the complex data that result from such studies, and the need to enable data-sharing through visualization tools. However, the largest scalability issue is the lack of technology infrastructure, specifically focused on supporting large-scale research studies. We discuss these issues in more detail next.

"The largest scalability issue is the lack of technology infrastructure, specifically focused on supporting large-scale research studies."

Managing Diverse Populations

Differences in living environments, in attitudes towards technology, and even in the relative extent of in-home versus out-of-home activity across different groups may require modifications in the platform and approach for continuous in-home assessment. For example, a recent ORCATECH study [1] suggested that rural seniors may have several technological challenges. Of 128 seniors aged 80 or older that were surveyed, only 5 percent reported using a computer frequently, or sending or receiving e-mail daily. This cohort is a good example of the kind of research and environmental challenges that could be encountered during wider deployment in terms of subject training, and in terms of collecting and transferring of data. Another group that may provide unique challenges is low-socioeconomic status (SES) elderly. SES is a combined measure of an individual's economic and social position relative to others. SES is often assessed based on a method proposed by Hollingshead, which considers level of education and occupation. Krousel-Wood [11] found that level of education adversely affected patients' willingness to participate in a telemedicine study. In addition, due to economic constraints, this cohort is less likely to use a computer on a regular basis. Therefore, a particular challenge in this group could be recruiting and training on computer use. Finally, cognitively impaired elders are often less able to interact with technology.

"Another group that may provide unique challenges is low-socioeconomic status (SES) elderly."

The other interesting issue that arises when a study is scaled nationally is regional differences in home construction. For example, in our national studies using in-home technologies, we have found that the wiring in many of the older homes in New York City result in high data loss with DSL broadband. For commercial applications, such issues may mean loss of market opportunity and disappointment in some populations that the technologies do not work in their home. For a research study, such differences could result in loss of access to a key demographic or cohort. For example, participants with low socioeconomic status often live in older homes. This is a population notoriously underserved by the research community because they are less likely to volunteer for studies and must therefore be actively recruited. However, these individuals may benefit greatly from aging-in-place technologies, and therefore they are an important cohort for inclusion in research studies.

"We have found that the wiring in many of the older homes in New York City result in high data loss with DSL broadband."

The Need for Visual Analytics

"In the field of unobtrusive in-home monitoring, there has been no coordinated effort to share data from past and ongoing studies."

As mentioned previously, sensor-based, in-home studies generate large amounts of complex data. It is well accepted that sharing research data increases collaboration, increases research activity, and reduces the cost of research [10]. However, in the field of unobtrusive in-home monitoring, there has been no coordinated effort to share data from past and ongoing studies. Even if the data were available, analysis of those data requires significant domain knowledge and an understanding of the sensors, their deployment, and the clinical and sensor datasets that have been collected during the study. Therefore, there is a clear need for extensible, modular tools that allow researchers to focus on the data, without being mired in the details of the sensor technologies.

Specifically, new data analytic tools must be created. Data analytics is the use of visualization and descriptive statistical techniques for initial data exploration. Visualization is the display of multiple dimensions of a dataset graphically, grouped by some feature or category of interest. Visualization is meant to take advantage of the human capacity to process visual information quickly and efficiently. In the case of complex data such as in-home monitoring data, visualization tools must allow exploration of the spatial and temporal properties of the sensor data, as well as fuse information from multiple sensor types to examine interactions between different behavioral measures. These tools will enable collaboration between researchers already focused on this emerging paradigm, and they will facilitate entry into this area of research by investigators who may lack the resources to undertake the necessary data collection, the access to key patient populations, or both, thereby increasing the opportunities for discovery and formation of new hypotheses.

The Need for Global Technology Solutions

"More than 50 percent of technology issues were a result of failed broadband."

One of the primary barriers to wide-scale deployment of in-home, technology-based research studies is the lack of universally available and supported Internet infrastructure. In the one multi-state study in which we have used in-home technologies, more than 50 percent of technology issues were a result of failed broadband, ranging from a poor signal due to old wiring in the home, to difficulty on the part of the Internet service provider (ISP) in getting the broadband up and working in the home, and to the ISP discontinuing service inadvertently or because of billing errors on their part. There are no low-cost broadband options available universally across the country, and multi-site studies therefore require establishing a separate ISP relationship and billing agreement with each city, and sometimes each county, where the study is to be conducted. This is a significant administrative barrier to large-scale deployment for research.

"We have been forced to repurpose sensors developed for inventory tracking and security applications."

Another significant barrier to wide-scale, in-home research studies is the lack of a platform supporting purposed sensors designed for gathering behavioral and physiological data in the home. In our current studies, we have been forced to repurpose sensors developed for inventory tracking and security applications for our activity monitoring. In those cases where we have developed a new sensor (for example, with medication tracking [7]), it was done with a particular project in mind and did not grow out of a principled architecture intended to support the growing needs for different types of sensors. Ultimately, what is needed is the integration of sensors designed to optimize the collection of specific behavioral and physiological data with a platform built on an open, standards-based architecture. It is our hope that such an architecture may ultimately be derived from the combined efforts of organizations such as Continua Alliance, industry leaders promoting interoperable standards for personal health; Integrating the Healthcare Enterprise (IHE), an initiative sponsored by professional societies to provide a common framework for multi-vendor system integration; and the International Organization for Standardization (ISO), which has specified numerous standards for health devices and is one of the sponsoring organizations of Health Level 7 (HL7).

"What is needed is the integration of sensors designed to optimize the collection of specific behavioral and physiological data with a platform built on an open, standards-based architecture."

The research community has an additional need: standards-based data sharing and storage models, such as those developed by the Clinical Data Interchange Standards Consortium (CDISC) that have been endorsed by the FDA for use with clinical drug trial data. With the advent of large-scale, in-home studies that use technology to aid in the assessment and detection of health and behavior changes, there will be increasing amounts of temporal and spatial sensor data, as well as health outcome data, to be gathered, stored, analyzed, and archived for efficient later retrieval. Sharing of these research data would allow investigators to develop new algorithms for deriving health status and interpreting behavior from these data, without the considerable costs and resources that would be incurred if each investigator had to collect his or her own data. Data sharing is most effective when a standard data format and set of tools are available to facilitate data sharing. Unfortunately, current, continuous monitoring studies all use different methodologies, and thus far, none have made their data widely available to the research community for further analysis of health outcomes. No tools currently exist to facilitate the sharing of continuous monitoring data. Thus, the development of a common architecture for sharing and visualizing sensor-based study data is another key requirement for true scalability.

"Data sharing is most effective when a standard data format and set of tools are available to facilitate data sharing."

Conclusions

There is tremendous hope that independent living technologies may lead to a reduction in the cost of healthcare delivery in this country. These technologies have the potential not only to support aging-in-place, but to enhance our ability to assess and remediate health changes in the elderly. Although a number of mid-sized research studies using such technologies are underway, there are still significant barriers to their deployment in large-scale clinical trials. However, we are beginning to understand these barriers and to find solutions to overcoming them, which will lead some day soon to a significant evolution in the practice of clinical research.

Vignette

"I never miss a pill."

After taking care of herself for 23 years since her husband died, 85-year-old Ana is pretty sure she has things under control. Although she takes five medications each day, three in the morning and two at night, she maintains strict control of her medication regimen and is able to cheerfully confirm that she has taken her meds when she talks to her daughter in their nightly phone call. When she enrolled in our medication adherence study, we asked her to add a low-dose vitamin C to her regimen once in the morning and once at night when she took her regular meds. She put these into our Medtracker pillbox and agreed to take them twice a day. Ana scored very well on her cognitive test, achieving a score that was a little lower than some but still considered normal for her age.

After a couple of days, we noticed that she had stopped taking the vitamins and gave her a call to remind her to take them. She was adamant that she'd been taking them when she took her own meds, and so we went out to her house to replace the Medtracker, which clearly wasn't working properly. However, when we got there, we found that the pillbox was still full of pills. Ana was sure she had taken them, and thought that somebody else must have put more pills into her box. She wanted to continue in the study so we reviewed how to fill up the pillbox each week. After five weeks in the study, Ana's overall adherence was 38 percent. To this day she maintains that she "only missed a couple of pills."

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Jeffrey A. Kaye, M.D., is a Professor of Neurology and Biomedical Engineering and the Director of the Layton Aging and Alzheimer's Disease Center, as well as Director of the Oregon Center for Aging and Technology (ORCATECH) at Oregon Health and Sciences University. Dr. Kaye received his medical degree from New York Medical College and trained in neurology at Boston University. His Alzheimer's research is focused on understanding differing rates of progression and cognitive decline as compared to optimal cognitive health in the elderly. Through his work with ORCATECH, he seeks to facilitate successful aging and reduce the cost of healthcare through the use of in-home technologies for assessment and remediation.