The Technologist's Guide to Setting up an Eldercare Field Study

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Abstract

One problem facing researchers trying to find technology solutions for eldercare is how to create a successful field study. Many interesting care solutions are being developed, but few have had successful field trials. In this paper, we describe some of the issues to consider when designing a field study so it will be *relevant* to the community and provide *valid* results. We discuss how to select a problem that will impact the community, how to ensure that the data you collect can be used, and how to select, recruit, and retain subjects.

1 Introduction

One problem facing researchers exploring technology solutions for eldercare is creating an effective field study. Few of the care solutions now under development have had successful field trials, e.g. [1; 4; 12; 16; 21]. While immaturity of the technology is a partial explanation for why more studies have not been executed, a more telling reason is that trials are poorly designed and executed. Field testing of new technology is rife with pitfalls that arise from aspects other than the technology itself, with the result that many otherwise promising ideas suffer defeat.

Since it is to everyone's benefit that field trials produce useful outcomes, this paper presents some of the elements that lead to a high quality, impactful field trial. We provide a checklist of questions to consider during the design process. Our goal is help every researcher answer the question:

"How do I avoid having my audience say 'so what'?"

Our thoughts are drawn from several perspectives, including our experiences with the Independent LifeStyle AssistantTM I.L.S.A. [4], geriatric nursing, and technology for large managed care settings. While our focus is on telehealth and remote telemonitoring systems, the guidance is more broadly applicable.

One common metric for evaluating the impact of health care studies is Patient-Oriented Evidence that Matters (POEM), e.g. [6; 17; 23]. POEMs extend evidence-based medicine by shifting the outcomes focus from the *disease* to the *patient*. Table 1 provides some examples. The concept has its origins in a formula developed by Slawson and Shaughnessy [19; 22]:

$$U = \frac{R \times V}{W}$$

where U=usefulness of the information, R=relevance of the information, V=validity of the information¹, and W=work to access the information and adopt the method. In other words, the most useful study is relevant, valid, and easy to understand and adopt. In this paper, we highlight how the POEM model can be used in the design of studies for the elder care setting.

The first step in designing a useful study is to ensure that you are studying a relevant problem. It is not enough to study a problem that may benefit *elders*, but it must be relevant to their *caregivers*. Determine how it benefits them, and why someone would want to use your findings. You must also present the outcomes results so that they are easy to understand.

Secondly, the data worth measuring and reporting is entirely dependent upon the *ability of the responder to use that report in a direct way*. It is impossible to determine what data to collect unless you understand the end user of that information, and their ability to take action on it. In this paper we extend the POEM model to evaluate the usefulness of the data reported by the system.

Finally, a study will only be useful if its results are valid; that is, if there are enough *well-selected* subjects to demonstrate the outcome.

2 Impactability

The first and most important question when designing a field study for elder care systems is *deciding what to study*. It is not enough to study a problem relevant to *elders*; you must also make the study relevant to *the other stakeholders*, tying back to the *relevance* factor of the POEM formula. You must also reduce the *work* involved in understanding the impact of your results. Determine who it benefits, how it benefits them, and why they would want to use your findings.

Health care professionals practicing in clinical or administrative health management positions look to the scientific literature to help them solve real-life, everyday problems. One of the most troubling issues in this search for answers is the ability (or lack thereof) to apply findings (negative or positive) from the literature toward practical, easy-to-

¹Validity here is usually defined by questions such as whether it was a controlled trial, the number and type of subjects, and the assessment tools.

Disease and intervention	Disease-oriented evidence	The actual patient-oriented evidence
Asymptomatic ventricular arrhythmia and treat-	Suppression of ventricular arrhythmia	Decreased survival with treatment using
ment with encainide and flecainide		these drugs
Lipid lowering with clofibrate	Lipid lowering	Increased noncardiac mortality
Blood pressure lowering with doxazosin	Lowered blood pressure	Increased heart failure
Postmenopausal osteoporosis treatment with fluo-	Increase bone mineral density	Increase in nonvertebral fractures
ride therapy		
Treatment of pain or inflammation with COX-	Decrease in endoscopically determined	No effect on the incidence of perfo-
2 inhibitors instead of older nonsteroidal anti-	gastric ulcers	rations, gastric outlet obstruction, or
inflammatory drugs		bleeding ulcers

Table 1: Example disease-oriented outcomes compared to patient-oriented outcomes. From Shaughnessy & Slawson [18].

implement and monitor solutions in a life where there is no time, no extra money, no extra staff and, sometimes, no administrative leadership support. Unfortunately, the words "obscure," "esoteric," "elegant, but not reality," "academic" or "ivory tower" are often associated with beautifully designed studies that lack applicability in the market place or in the lives of elders and their families. In fact, a strong evidence base for cost effectiveness and improved healthcare outcomes by using telemedicine is still not available [15]:

Of the more than 1000 articles surveyed, most were reports about the feasibility of various applications, and only a few of the studies reported a controlled comparison of a telemedicine application with conventional means of providing services.

Roine, Ohinmaa and Hailey [15]

These finding highlight that there is both a need and an opportunity to dramatically impact the caregiving community. The POEM model provides a framework for designing an impactful study. It highlights the need to understand the audience for your study, the relevance of the outcomes to that audience, and the effort to understand and apply the results. For the technology researcher, the key issues are to:

- make sure the audience cares about the problem you've identified,
- make sure you understand why they care, and
- make sure that your study addresses things they care about

The audience for your study is critical. Where is their interest? Their pain? Their financial risk? Their liability? Their quality issue? Their public image concern? Their willingness to act? Their fear? Their market scope? Their development goals? Their mission? Their budget capacity? Their ability to change? Their interest in acting on your results?

The reality is that most caregivers do not have the time to decipher a poor description of the impact of your study, adapt findings or approach to their meet their needs, or spend time learning how to change their caregiving practices. The POEM model was developed precisely to address the problem of studies that yield no useful results. To improve the chances of successfully transitioning to a caregiving setting, consider these kinds of issues:

1. How will you differentiate your geriatric assessment tool or process from what's already available? You can be confident that caregivers are aware of, and are trying to use,

- some kind of assessment tool already. How will yours be better? More useful? Easier to use? Require less time? Provide more effective documentation? Provide broader or more effective coverage? The more significantly different your tool is from the others, the more likely it will be adopted.
- 2. Why would a caregiver want to use your new and more effective tool or process? She has little or no time to read your paper or assess the content of your tool against what she's already using. What would compel her to make a change? The easier it is to assess the impact and value of your work, the more likely it will be adopted. It is also beneficial to highlight when not to use your tool.
- 3. What are the costs, real and perceived, for the caregivers to adopt or adapt your tool for their use? What other systems will it have to interface with? What are the incremental costs for installing individual systems (per patient)? The less effort needed to adapt your tools or techniques, the more likely it will be adopted.
- 4. How broad is the patient pool that your tool will be able to address? Across morbidities? Across capabilities? Across care settings? How broad is the caregiving pool that your tool will be useful for? Doctors? Nurses? Social workers? Family? The elder? The smaller the applicable audience, the less likely it will be used in large settings or by organizations with large populations.

The study *must* show the right kinds of results to show effectiveness (e.g. cost savings, improved outcomes, improved productivity, etc). While elder outcomes are the most important to consider, they may not be the determining factor for all stakeholders in all situations. There may be many consumers of your field study results, and certainly at least two: you and your funding source. Each stakeholder—current and future—will have different interests and concerns. Who are the possible interested parties? What criteria will they use to determine the effectiveness of your tools or techniques?

It is important to consider the entire context of the care environment when you design the system and the study so that you can build something that meets *all* of its users' expectations. A technology solution will not be adopted unless it meets the needs of *all* of its stakeholders: the caregivers, the funding sources, and the elder. You must show outcomes that convince the funding sources, features that serve the caregiver, and *also* meet the elder's requirements

for accepting the solution. Even better, provide a system whos outcomes and features serve the elder directly, creating an environment where elders enthusiastically adopt the solution.

Potential sources of this outcome data include:

- Sensor data: raw sensor events in the time series data (e.g., blood pressure)
- System data: how the system performed in processing the sensor evidence (e.g., timeliness, inferred conclusions)
- User behavior: what the users (elder and caregiver) did when interacting with the device or system
- User surveys: objective measurements of the users' (elder and caregiver) awareness of the elder's condition and subjective impressions of their experiences
- Tester's experience: what was learned beyond the evidence collected
- Outcomes: improved medical outcomes, improved productivity, cost savings, elder quality of life, elder and caregiver satisfaction

Several authors have presented additional guidance for performing assessments, e.g. [5; 7; 9; 10; 13; 20]; these guidelines focus predominantly on cost benefits, rather than quality of life or clinical outcomes. The Institute of Medicine strongly recommends broader studies of the effectiveness of technology:

Decision-makers exploring telemedicine are hampered by a lack of reliable information... Telemedicine should be subjected to the same rigorous review that should be accorded both new and established health care technologies to determine its effectiveness and cost-effectiveness compared with the alternatives, the committee said.

The committee recommended research that systematically compares telemedicine with the alternatives, examining several areas such as: the clinical process of care-giving; the patient's status or health outcome; access to care; costs for patients, payers, providers, and society; and the satisfaction of patients and clinicians.

Institute of Medicine [7]

Impactability Considerations

What question(s) are you trying to answer? Is your problem relevant? Have others tried to answer these questions, and how? What were their findings? Who is interested in the answers? What will those reading your study feel compelled to do about your results?

3 Selecting Data

The second key issue in designing an effective, valuable elder-care technology field study is *selecting actionable data*. The data worth measuring and reporting is entirely dependent on the *ability of the responder to use that report in a direct way*. It is impossible to determine what data to collect unless you understand who will use the information, why they are interested, and their ability to take action on it.

The first step is to consider who the real consumer of the *data* is.

 The elder? Information about their own habits may help them to make healthier choices.

- Their family? How close do they live to this person? How will they respond?
- A third-party responder? Which one? What is their business model? How will they respond?

Consider at least one real end user of the information you are producing, and interview as many of those people you can to discover how they make decisions, and what would convince them to use your proposed solution to assist that decision-making. If you are in business and intending to field-test a prototype product, you must conduct thorough market research because proofs may not transfer from one potential product channel to another. This step is imperative.

To ensure relevance to your audience, ask your intended end user "What information supports action or decision making?"

- How would you measure it?
- How often do you want to monitor it?
- What format will provide quick and accurate comprehension of the information?
- What action will you take based on this data?
- How will false negatives and false positives affect your decision making?

If the data is not valid, actionable, and timely, there is little point in collecting the information.

The POEM model was introduced to measure the impact and usefulness of the *results* of medical studies. It can also be extended to measure the usefulness of data collected *within* the study. Applying the POEM model, let's consider the aspects of data that might be important:

- Relevance: Can we collect actionable data? Can we measure the key outcomes that we want to measure? Was the data collection timely?
- Validity: Is the data valid? What peripheral data could we collect to illustrate validity? What important events did we miss (false negatives)?
- Work: Can we easily extract the data? Can we disseminate the data? Can we present findings effectively and appropriately to the audience? How much work is needed to filter false alarms (false positives)?

One problem that many systems face is that they present the information inappropriately the consumer. The information must provide feedback *consistently*, *clearly*, and *flexibly*, while supporting changing elder and caregiver needs. The physician does not want to see the raw sensor firings, and the Certified Nursing Assistant (CNA) may not have the skills to translate textual or graphed data into meaningful care plans. Some caregivers may not even be literate (English or otherwise). Consider also the elder's requirements. The raw data must be rendered to information at the right level of abstraction for each individual. Express the information simply, clearly and unambiguously.

Note that the raw data may need to be abstracted in different ways for different consumers. For example, a physical therapist may be interested in the number of stairs climbed or the number of metres the patient travelled. Meanwhile, a social worker may be interested in the number of different rooms occupied during a day or the number (and length)

of times the patient left the home. Each caregiver will have different information needs and interests. If the system generates one interface with *all* the information for *all* the caregivers, it will be very hard for individual caregivers to find the information that is valuable for them. Consider carefully what information to present to whom, and how to make it easy to understand and difficult to mis-interpret.

The problem also determines a number of other considerations for the data collection. Weight measurements, blood sugar readings, and fall detection each have different requirements on these axes:

- Timeliness: Must the data be available in real-time? hourly? daily? weekly? Make sure the architecture supports the timeliness requirements.
- Detail: How much detail is needed to reach the necessary conclusion? For example, does a location detector need to be accurate within a few centimetres? A metre? A room? The outer perimeter? Solve the problem to the detail needed to make actionable information; there is no "bonus" for providing more detail, and sometimes too much detail can overwhelm or mask the important conclusions.
- Accuracy: What rate of false alarms is acceptable? How
 important is it to catch all events? If the raw sensor data is
 inherently noisy, then filtering and evidence aggregation
 techniques need to be applied so that the data is reliable
 and valid. Redundant sensors may be an important component.

To measure the criteria above, you need to monitor and document the results to each of the questions below. Moreover, it is vital to equip yourself with automated tools to assess each of these questions, or you will be buried in data that you cannot effectively analyze and validate.

- Did you get all the data you intended to collect?
- Did you process all the data you collected?
- Did you process that data correctly?
- Did you deliver that information to the right stakeholder?
- Did you deliver that information in a timely fashion?
- Did the responder understand that communication?
- Did they respond? How?
- Did they corroborate a valid concern or find a false alarm?

Recall the *work* aspect of POEM and do not spend resources to collect data that costs you more than it is worth. For example, being sloppy in designing surveys for field test subjects spends their time, spends down your good-will with them, and delivers little if any value in the end. On the other hand, look for every opportunity to collect evidence that is relatively free. If this is a software system, log as much as you can. You *will* think of new questions after your systems have been decommissioned.

The final critical step, assuming you've designed your system to answer all of these questions, is to run a small pilot study. (Using project engineers is appropriate, but elders are better.) Using the results of the pilot, go back and ask each of the above questions again, answering honestly and with no gloss. The pilot will help you calibrate your system, and possibly do some re-design before you dive into the big field test.

Case study. Let us consider one example field study. Best-Care Health Plan represents the group of health plans who are interested in serving the elderly population. Your study aims to determine whether or not nursing home placement can be avoided or delayed by using in-home monitoring with motion detectors. Your hypothesis is that, by using motion detectors, you could detect changes in activity patterns, which in turn would tell you when an elder's activity pattern is deteriorating. This deterioration is a precursor to placement in a nursing home. You can predict that, and by detecting these changes, you can get help to the elder and stop the progression to nursing home admission.

As you have clearly done your homework selecting which problem to study, BestCare Health Plan is willing to work with you on your idea. They have concerns about how well this will work, and are worried about alerts being generated that will be "false alarms." You assure them that you've done your homework and have found the most sensitive and specific monitors available. You obtain commercially available motion detectors, and rig up a system for them to signal alerts based on preconfigured patient-based activity norms. The alerts will come to a central website where case managers can view and act on them. The study is designed for a three month period.

You want 50 elders to participate. Many decisions need to be made: Which caregivers will monitor the alerts? Which elders to select? What if they have others living with them, or have large animals? What about weekends and holidays? What about vacations or trips out of town? Who will ask the elders for consent? How will you communicate the study opportunity to them? Are there any health plan committees to obtain permission from? Who will place the sensors? And on and on... Here's what happens:

With all the hoops addressed, you begin recruiting for the study. After 6 months, you finally get 30 elders to agree. Now, you have less power with the study, but you've run out of time, so you start up the monitors.

Interestingly, every patient has red alerts nearly every day. At first, you believe it's because the alert parameters were set too tightly, so you adjust them. Now, nearly 80% of elders are alerting every day, for a variety of reasons—in the bathroom for too long, not near the medication cabinet, too many trips up and about at night, etc. The case managers are complaining—they don't know when to act on alerts and when not to. The worst thing that happened is that an alert caused a worried family member to call EMS; the paramedics broke down the door only to find the elder peacefully snoozing away in his bed. Four of the elders were placed in nursing homes during the study, reducing your sample even further.

The system produced too much noise, and not enough (or perhaps no) actionable information. Why? Was it the design, the equipment, or the planning? It was probably some of all three. As the researcher, it's your job to assure that you've done your literature reviews and have identified success and failure paths for approaches similar to yours. In this case, the literature (technology literature, e.g. [4; 21];

not elder health literature) would have indicated that, while well-intended, technology based on raw motion-sensor data isn't yet sensitive and specific enough to enable decisions to be made from its outputs. Contacts with sensor scientists and manufacturers would have yielded similar information.

The lesson: *Make sure that decisions can be made from the data you gather.* When you know who your responder is, what they need to know, and what responses they are capable of, you are ready to consider recruiting and selecting subjects.

Data Considerations

Who is the consumer of the data? What is the best way to present the data to that person? Is the data valid and timely? Can decisions be made based on the data you present?

4 Selecting and Recruiting Subjects

To answer the important questions with the greatest impact to obtain actionable data, you need to design studies that are *longitudinal*. People need to be followed over time in order to provide valid outcomes data. You need to see the long-term effects of the intervention, to understand the retention of what you have introduced, whether it involves technology or some other type of support to elderly clients. Panacek [14] presents a nice overview of the types of field studies that can be conducted.

Using the POEM model to guide selection of a group of people who will provide researchers with relevant, valid and useful outcomes, think carefully about the representativeness of the subject group in terms of the whole population. The *validity* factor in the POEM model is most strongly tied to the selection and number of appropriate subjects.

To meet the validity requirements for a good study, you need to ensure that you are carefully defining each step in the selection process.

- Are the inclusion and exclusion criteria clearly defined?
 Entry criteria must be reproducible and not too restrictive or too broad.
- Is the target population representative of the larger population of elders?
- Is the sample size adequate to detect the effect?
- Have you included a comparison group?
- Have you assessed the equivalency of the comparison group?
- Have you ensured that the contextual conditions are similar for all subjects (living situation, mobility, family support)? Will you be consistently tracking these environmental factors and confounding issues throughout the study?
- Have you planned to apply the proper metrics to assess outcomes? Do you know how to use the environmental factors to correctly *interpret* the outcomes?
- Have you taken care to protect the privacy of participants?
- Are you using a defined protocol for data collection and management?
- Have you sought advice and consent from participants, family members, and other caregivers?

- Have you taken steps to assure the safety of all participants?
- Are you monitoring who enrolls and who drops out, and tracking the reasons for this?

These considerations relate to the validity of the research design, a necessary component for the production of meaningful evidence. It is also important, however, to correctly interpret the results. When interpreting the outcomes results, carefully consider environmental effects and other confounding variables, as these issues may lead to over- or under-estimating your results. For example, consider trends, such as when the population is experiencing or participating in something outside the study that will effect outcomes. Perhaps their increased activity levels are not due to your system, but rather the fact that their health plan just started offering discounts for activity centers/gyms to seniors. Individual subjects may also have experiences that effect the interpretation of your outcomes results, for example consider when the elder experiences a dramatic family change, e.g. their spouse dies, leading to depression and lower activity.

Given a good design for the study, the next key issue is recruitment. If researchers do not attend to the issues that affect the decision by elders to *participate*, the study will fail and the whole idea of asking the right question will be irrelevant. Over the last two decades, healthcare researchers have explored the reasons why recruitment and retention of elders into research studies presents problems. Major barriers can be classified as relating to issues of trust, impact on the family, time, personal contact, provision of information, access to results, confidentiality and safety [2; 3; 8; 11; 24].

Trusting the researchers is key to participation. In order to gain trust with the potential participant, the researcher needs to approach each potential participant individually and have a face-to-face discussion about the study that includes presentation of a clear written explanation of the study to hand to the elder and his or her family. The information about the study needs to follow these guidelines:

- Consent forms need to be clear, simply worded and in large print so that they are easy to read.
- Elders and their families need to understand that their privacy will not be compromised, that their names will not be released.
- Elders *and their families* need to understand that they may withdraw from the study at any time.
- Elders need to understand why it is important for them to participate. Use words about how others will benefit from the new information learned through the study.
- Elders are more likely to participate if they have an opportunity to learn something new.
- Let participants know what their participation means; what will they will have to do, how much time it will take, how difficult it will be.
- Elders need information about whom to call if they or their family members have questions.
- Frankly address fears about being "guinea pigs" for something new. Be clear and honest about the risks involved in participation as well as the benefits.

 Offer rewards for participation. They need not be large, but should be a logical motivator. Money works, but so do things like gatherings of family and other participants, or describing results to them after the conclusion of the study.

In addition to providing a clear description of the study, the following suggestions will help develop a trusting relationship:

- The information should be in writing, but should also be delivered verbally.
- Allow a lot of time for questions.
- Elders are particularly interested in having a spouse and family members hear the information as well. If possible, visit the person at home and have him or her invite family members to be there.
- Plan for time for the family to discuss participation and offer to return after the decision is made. Note that many elders will not participate in a study if their family members are not in full agreement.
- Plan for more time than necessary to complete the measures. Many elders love to socialize and to treat you as a guest in their home.
- Make an effort to find common topics for conversation that go beyond the study measures. You will learn so much more than you imagined.

Recall that your study must have enough elders to adequately detect the effect; more elders means more power and a more valid result. Given the challenges of recruiting elders, a key consideration is whom to address first. It may be inappropriate and ineffective to start with the elders; instead, consider starting with a caregiver (formal or family). Some kinds of technology (monitoring in particular) can't do much for the elderly without a caregiver to respond to the information. If the primary user of the information is intended to be a caregiver, consider recruiting caregivers who are interested and motivated in being involved in the study. Use them as resources to suggest elder participants and to advocate your technology; the caregivers already have an established trust relationship with the elders, and therefore may lead to a more effective recruitment effort.

Finally, the value added in using a respectful approach to potential participants cannot be overstated. Working with elders presents many challenges, but it also offers many rewards.

Selection of Subjects Considerations

Are the inclusion criteria clear? Does your sample represent the population under study? Have you allocated enough time to build trust with the elders and their family? What rewards will you be providing?

5 Conclusion

There is nothing more useful than a carefully designed, well implemented study that can be replicated in elder care clinical and administrative practice. Your "customers," those in practice and managing health care, need your best thinking on the issues they're grappling with. In their world, research is wonderful and enables change, but only if:

- It applies to the patients they serve (i.e. your sample represents their population).
- It applies in their practice setting.
- It requires changes they can envision making, or actions they can envision taking, without too much effort, time or money.
- It will result in improvements for them and those they serve.
- The data presented by the system can be acted on without additional analysis, interpretation or evaluation.

Involve the user community: elders, professional caregivers and family caregivers. Begin with the end in mind. Who will use your system? Why? How much will it cost in dollars and effort (real and perceived)? Why wouldn't they use it? What are your users most interested in? Not interested in?

Two Key Questions

Will your study generate outcome results that will make a change in caregiving practice? Will your system generate reports of truly actionable information?

A good study needs to meet the criteria outlined in the POEM model for developing evidenc: it must be relevant, valid, and easy to understand and adopt. In this article, we highlight how POEM can be used in the setting of evaluating the *outcomes* of technological solutions for elder care. We also demonstrate how the POEM concepts can be applied for the *design of the technology solution itself*: relevance (is it actionable?), validity (how many false alarms or missed events), and work (how effectively the data was communicated).

Finally, conducting a field study is not an easy task. Questions to ask yourself as you design your field test (or better, before you begin):

- Are you prepared to provide adequate study support and oversight, daily if needed?
- Are you prepared to educate, re-educate and re-educate?
 - Have you developed and are you prepared to implement a robust and comprehensive communication and marketing program?
 - Have you planned for dissemination of information to several audiences, including healthcare professionals at all levels, elders and family members?
- Are you prepared for early and mid-course corrections? (They will definitely be needed.)
- Have you completed all necessary homework, literature reviews, expert interviews and user acceptance tests to assure your project has a solid chance for success?

A successful, well-designed field study will be worth the effort.

Biographies

Karen Haigh (Ph.D.) is a senior research scientist at the Honeywell Labs in Minneapolis, MN. Her research is in Machine Learning and data analysis. She was recently the technical lead on the Independent LifeStyle AssistantTM (I.L.S.A.) to aid elderly people to live longer in their homes and increase their independence.

- **Liana Kiff** (MSc) is a senior research scientist at the Honeywell Labs in Minneapolis, MN. Her expertise is the transfer of technology from research to practice. Liana was the development lead on the Independent LifeStyle AssistantTM (I.L.S.A.).
- Kathie Krichbaum (RN, Ph.D.) is an associate professor and division head at the School of Nursing at the University of Minnesota. Her research focuses on evaluating the quality of Long-term Care options for elderly clients, including interventions based on elders' response to computer assisted technology to support elder health and independence at home.
- **Jan Wuorenma** (RN, BSN, MBA) is the director for managed care development at Honeywell HomMed. She has worked in various managed care settings as a clinician, administrator and corporate health plan executive for over 20 years, where she oversaw several health technology trials and implementation efforts.

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