U.S. Department of Health and Human Services
Assistant Secretary for Planning and Evaluation
Office of Disability, Aging and Long-Term Care Policy

THE EFFECT OF REDUCING FALLS ON LONG-TERM CARE EXPENSES:

Final Design Report

September 2004

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Abt Associates, Inc.
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1.0 BACKGROUND

Expenditures on health care in the United States are rising rapidly and in 2002, reached $1.6 trillion or $5,440 per person; spending rose 8.5 percent in 2001 and 9.3 percent in 2002, contributing to a spike of 1.6 percentage points in the health share of gross domestic product (GDP) since 2000.[1] Much of the increase in spending is fueled by growth in the use of hospital care but there is also significant use of long-term care (LTC) services such as nursing home and home health care. While accounting for roughly 12 percent of the United States population, elders account for more than 30 percent of all health care costs. Therefore, when thinking about strategies to reduce health care costs through preventive care programs, a focus on elderly populations is particularly warranted.

Although not commonly recognized, falls are the leading cause of injury deaths among individuals who are 65 years of age and older. In fact, falls among the elderly led to 1.8 million emergency room visits in 2000 and more than 10,000 deaths. Direct costs associated with those falls were estimated to be $16.4 billion.[2] Clearly, fall-related injuries are a major source of excess morbidity and mortality for elderly persons. Over one-third of the population aged 65 and older falls annually, although most falls do not lead to deaths.[3] As the population ages, cost-effective interventions that reduce the risk of falls can have important positive financial and quality of life implications for those who are at risk of falling, to their families, and to the American health care system.

As a leading cause of injury deaths, the subject of falls has received growing attention among clinicians and researchers who have identified many diverse risk factors for falls. Some risk factors may be totally beyond an individual's control to change, such as cognitive impairment or functional deficits resulting from chronic conditions. Others, like the acceptance and proper use of assistive devices to compensate for functional deficits, may be partially under an individual's control. Finally, other risk factors can be jointly influenced by the behavior of providers, caregivers and elderly individuals themselves. These include such things as environmental risk factors and polypharmacy. In its summary of the knowledge base on falls and interventions designed to reduce falls, the American Geriatrics Society (AGS) Falls Prevention Panel categorized risk factors as falling into two major categories: (1) "intrinsic" factors (balance problems, cognitive impairment) and (2) "extrinsic" factors (environmental

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[1] Levit K, Smith C, Cowan C, Sensenig A, and Catlin A. Health Spending Rebound Continues in 2002. Health Affairs, 2004; 23(1):147-159.

[2] Lewin Group; Corea J, Lutsky S, and Alecxih L. Estimated savings from falls prevented by targeted home modifications. Prepared for AARP Public Policy Institute, October 2000.

[3] Campbell AJ et al. Examination by logistic regression modeling of the variables which increase the relative risk of elderly women falling compared to elderly men. Journal of Clinical Epidemiology. 1990; 43:1415-1420.

factors, polypharmacy).[4] The panel also observed that while it may be the case that an intervention focused on one risk factor could theoretically be a cost-effective way to reduce falls, the literature provides no evidence to support this conclusion in practice. Thus, a focus on ways to reduce multiple risk factors appears to offer the best hope for a preventive strategy designed to reduce falls.

Most falls occur in the home. According to a study on risk factors for falls among the elderly, 77 percent of reported falls occur in the home.[5] The most frequently mentioned environmental hazards were objects tripped over and stairs, which accounted for 25 percent and 10 percent of the subjects' falls respectively. These types of hazards create danger for healthy elderly persons and pose a greater risk for those elderly already suffering from a functional or cognitive impairment.[6] Among individuals age 75 and over, those who fall are four to five times more likely to be admitted to a LTC facility for a year or longer.[7]

The RAND Corporation completed a meta-analysis of the literature on falls, which summarized research from more than 80 empirical studies. It concluded that a combination of risk assessment with tailored follow-up interventions holds the most promise of being a cost-effective approach to reducing falls among elders.[8] As mentioned, AGS guidelines also propose multifactorial interventions, which focus on a number of risk factors and intervention strategies designed to address them.[9]

To date, however, research provides no definitive guidance on the relative importance of different components of interventions and on whether the benefits of such programs justify the costs of an overall intervention. Studies focusing on intervention components such as exercise have provided conflicting evidence of effects on the incidence of

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[4] American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the Prevention of Falls in Older Persons. JAGS. 2001; 49:664-672. http://www.americangeriatrics.org/products/positionpapers/Falls.pdf.

[5] Gibson JF, Andres RO, and Isaac B. The prevention of falls in later life. Danish Medical Bulletin. 1987; 34(4):1-24.

[6] Ibid, 1987.

[7] Donald IP, and Bulpitt CJ. The prognosis of falls in elderly people living at home. Age and Aging. 1999; 28:121-125.

[8] RAND Evidence Report and Evidence-Based Recommendations. Falls Prevention Interventions in the Medicare Population. CMS (Health Aging Project) Contract Number 500-98-0281. http://cms.hhs.gov/healthyaging/FallsPI.asp.

[9] American Geriatrics Society, op cit.

falls.[10, 11, 12] Although there may be no consensus on the efficacy of specific intervention components, there is a growing body of research and programmatic experience suggesting that many falls are preventable; taking the necessary steps to "fall-proof" an individual and/or his environment can help elders remain independent and live in their own homes, thereby reducing the demand for both LTC and certain acute care services.

1.1   Purpose

The purpose of this document is to summarize the project and present a design for future phases of the project. It incorporates all suggestions from the Task Order Monitor (TOM) and the Technical Advisory Group (TAG). The full Literature Review was submitted to the Office of the Assistant Secretary for Planning and Evaluation (ASPE) as a separate document. However, presented throughout this document, relevant information that was drawn from the literature to synthesize common falls risk factors as well as the validated tools that form the basis of our proposed assessment and intervention strategies.

1.2   ASPE's Interest

ASPE commissioned this Task Order to build upon the wide body of literature on falls and fall prevention and to incorporate areas of interest that have not been thoroughly addressed in prior studies. Currently there is a research gap on the effects of falls prevention programs on long-term care expenses. For example, there have been few studies that have included a thorough assessment of fall prevention strategies on long-term or acute care costs or discussed various approaches to implementing recommended intervention(s). Also, in two of the more comprehensive studies done to date -- the RAND meta-analysis[13] and the AGS Guidelines[14] -- researchers have pointed to the need for further research to identify which intervention is effective for what population, as well as further study on the cost-effectiveness of recommended strategies.

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[10] American Geriatrics Society, op cit.

[11] RAND Evidence Report and Evidence-Based Recommendations, op cit.

[12] Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, and Rowe BH. Interventions for preventing falls in elderly people (Cochrane Review). In: The Cochrane Library, Issue 4, 2003. Chichester, UK: John Wiley and Sons, Ltd.

[13] RAND Evidence Report and Evidence-Based Recommendations, op cit.

[14] American Geriatrics Society, op cit.

The goal is to contribute to the knowledge base of falls prevention, particularly in understanding the strategies that are cost effective. ASPE is interested in this topic from an aging and LTC policy perspective and from a prevention strategy perspective. Our goal is to obtain a consensus from the group of assembled experts regarding falls prevention assessment and intervention components that are most likely to be effective, replicable, adoptable and affordable.

Once the first phase of this project is complete, Phase 2 will involve the full development of all required assessment and intervention tools necessary to operationalize the design, as well as an evaluation strategy that builds upon those tools. We intend to draw our sample from individuals who have private LTC insurance policies. These individuals are a good "laboratory" for our work, since they can be easily recruited into the study, and we will be able to track their LTC expenditures, as well as acute care expenditures, over time. We acknowledge that LTC insurance holders may have different characteristics than the general population, and we are controlling for this through sample selection methods as well as the study of a "silent control group" of Medicare beneficiaries. This research will inform not only developments in the private LTC industry, but also Medicare policy toward preventive care financing.

1.3   Project Goals and Objectives

The goals of this project are to:

1.   Select a potentially effective falls prevention intervention;

2.   Develop a study design that will test a falls prevention intervention and its effect on acute and LTC use and cost.

As such, addressed are the issues related to the effectiveness of interventions in terms of reducing the incidence of falls and associated acute and LTC costs as well as the costs associated with implementing the intervention itself.

We focused our inquiry on addressing the three major research questions summarized below:

1.   What valid options exist for effective multifactorial falls prevention assessment and follow-up? What elements are the most important for inclusion? Is there a minimum- optimal mix that one could expect to be effective at preventing primary and secondary falls?

2.   What is the estimated average cost of a falls prevention intervention (e.g., initial assessment, actual intervention or program, and follow-up)?

3. What is the best methodological approach for determining the efficacy and cost-effectiveness of a selected comprehensive falls prevention intervention?

1.4   Synthesis of Literature Review

There has been a great deal of important descriptive and empirical research conducted on fall prevention. Some of that research focuses on specific components, such as a multifactorial assessment, or a specific strategy such as home modification. Other research, particularly the various meta-analyses, take a broader view of the literature and have distilled the larger body of work into comprehensive categories of actions that have an impact on reducing the probability of falling.

There remain limitations in the literature. These limitations suggest that a study that focused on a specific group, a set of homogeneous assessment and intervention strategies, outcomes measurement and tracking over time, as well as an analysis of the cost-effectiveness of the implemented strategies would make a significant contribution to the knowledge base. Based on our analysis of the literature, a carefully constructed fall prevention program designed exclusively for elders deemed to be at "high risk" would provide the greatest probability of producing a reduction in the incidence of falls, a reduction in related medical and LTC expenditures as well as justify in a cost-benefit calculation the expenditures related to operating such an intervention. Clearly, targeting strategies will be important in determining the best mix of cost-effective strategies for identified risk groups.

There is also a consensus in the literature regarding the intrinsic and extrinsic risk factors associated with a fall and these include muscle weakness, history of a fall or falls, gait deficit, balance deficit, use of assistive devices, medical conditions and health issues, medication use, functional impairment, cognitive impairment, environmental hazards and fear of falling. Table 1.1 lists the most common risk factors for falls in community-based seniors.

TABLE 1.1. Most Common Risk Factors for Falls in Community-Based Seniors[1,2,3,4]			
Risk Factor	**Intrinsic vs. Extrinsic**	**Risk Factors for Increasing Probability of Injurious Falls[5]***	**Factors Shown to have Maximum Predictive Accuracy for Falls[6]****
Muscle Weakness	Intrinsic	Not explicitly identified	XXX
History of Falls	Intrinsic	Yes -- Particularly if fracture occurred	
Gait Deficit	Intrinsic	Not explicitly identified	
Balance Deficit	Intrinsic	Yes	XXX
Use of assistive devices	Intrinsic and Extrinsic	Not explicitly identified	
Visual deficit	Intrinsic	Not explicitly identified	
Arthritis	Intrinsic	Not explicitly identified	
Impaired ADL	Intrinsic	Not explicitly identified	
Depression	Intrinsic	Not explicitly identified	
Cognitive impairment	Intrinsic	Yes	XXX
Age > 80 years	Intrinsic	Not explicitly identified	
Medication use	Intrinsic and Extrinsic	Yes -- Psychotropic medications	XXX
Environmental Hazards	Extrinsic	Not explicitly identified	
Fear of falling	Intrinsic	Not explicitly identified	

1. Leipzig RM, Cumming RG, Tinetti, ME. Drugs and falls in older people: a systematic review and meta-analysis: I. Psychotropic drugs. J AM Geriatr Soc. 1999; 47:30-39.
2. Rubenstein LZ, Josephson KR. Risk factors for falls: a central role in prevention. J Am Soc Aging. Winter 2002-3; 6(4):15-21.
3. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the Prevention of Falls in Older Persons. JAGS. 2001; 49:664-672. http://www.americangeriatrics.org/products/positionpapers/Falls.pdf.
4. Tinetti ME, Baker DI, McAvay G, Claus EB, Garrett P, Gottschalk M, Koch ML, Trainor K, Horwitz RI. A multifactorial intervention to reduce falling among elderly people living in the community. NEJM. 1994; 331:821-827.
5. Nevitt MC, Cummings SR, Hudes ES. Risk factors for injurious falls: a prospective study. J of Gerontology. 1991; 46:M164-170.
6. Robbins AS et al. Predictors of falls among elderly people. Results of two population based studies. Archives of Internal Medicine. 1989; 149:1628-1633.

* It is important to note that many of these factors have not been specifically tested as risk factors for injurious falls. Thus, a finding of "Not Explicitly Identified" does not mean that the factor is not an important predictor of injurious falls, but rather, empirical evidence has not yet been collected to adequately test this factor.
** These were the factors found to have maximum predictive accuracy in the context of a multivariate study that took into account multiple risk factors.

2.0 METHOD

In this section we will discuss the method for drawing the sample, collecting the data and measuring the outcomes of the proposed assessment and intervention strategy.

2.1   Sample

For this project we propose the collection of data on four sample groups: (1) a silent control group (SCG), (2) an administrative control group (ADCG), (3) an active control group (ACG), and (4) an experimental group (EG). The silent control group will be comprised solely of Medicare beneficiaries, while the other three groups will be comprised of private LTC insurance policyholders.

We will draw a sample of at least 5,000 individuals aged 75 and over that have private LTC insurance policies and are not currently residing in nursing homes or assisted living facilities. These individuals will have had their policies for at least five years so that in terms of health status, they will resemble a general population of elders.[15] There are a number of reasons for drawing a sample of policyholders with LTC insurance policies. First, this enables us to employ an experimental design to test the impact of the intervention. Coordinating the sample with insurers will allow us to draw a random sample for the intervention as well a control sample. Thus, setting up the experimental design could be done in a very cost-effective manner. Second, we could easily track service utilization during the study period; the insurers' administrative systems would enable us to track the frequency, intensity, and duration of service use as well as the costs of services for both the experimental and control group. Claims cost data can easily be generated from the administrative systems of participating insurers. Third, we could leverage the fact that the participating companies have an established relationship with policyholders. This will enable us to cost-effectively identify the two samples, correspond with them, and implement the intervention. It will have the "backing" or seal-of-approval from their insurer. Already a number of major insurers have indicated their willingness to participate in such a demonstration project.

Once drawn, everyone in the sample will receive the same letter about the study. This letter will come from the insurance company in order to lend weight and credibility to the study and boost participation. The letter will include a description of the study, an informed consent and release of information form (for HIPAA purposes) and a proxy identification form along with a stamped addressed return envelope. Potential participants will be informed that they may be randomly assigned to an experimental or

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[15] The effects of underwriting typically wear off within a five-year period and projected service utilization for the insured group would resemble utilization for a similarly aged group of non-insured individuals.

control group. They will be instructed to return the signed forms if they want to participate in the study. To the extent it is necessary, follow-up telephone calls to those who do not return their forms will be made to secure participation.

The participating sample will then be randomized in to a screener group (those who will receive a telephone screen) and an ADCG who do not receive a telephone screen. Those in the screener group will then receive a comprehensive phone screen to classify their fall risk category and be further randomized into two groups: an active control group (ACG) and an EG.

Our ultimate goal is to have a final sample of at least 1,200 individuals in the ACG and EG. We realize that there will be people who do not want to participate in the study. Given our past experience with this population and the fact the participants' will know that the study has their insurance company's backing, we believe we will be able to achieve at least a 70 percent participation rate. We also want to ensure that the sample groups are large enough to detect statistical differences if analyses are done on sub-samples. For instance, if we are interested in determining if there is a difference in the effectiveness of the intervention strategy for males and females, we need to have enough observations in these groups.

2.2   Data Collection

In this section we outline the various data collection methods to be used for each of the four sample groups. For the purpose of determining the validity and effectiveness of a proposed fall prevention intervention, it may be necessary to limit data collection to certain geographic regions. This will allow for more adequate training of interviewers (ensuring inter-rater reliability) and tighter controls on the accuracy of data collection.

2.2.1 Silent Control Group (SCG)

The SCG will consist of Medicare beneficiaries matched on certain criteria (such as age and geography) for which we will obtain aggregate Medicare usage data for a period of three years beginning at the same time we draw and randomize the other groups.

2.2.2 Administrative Control Group (ADCG)

The ADCG consists of LTC insurance policyholders who agree to participate in the study and who receive no intervention, but for whom we obtain a release in order to get individual LTC claims and Medicare use data for a period of three years beginning at the time of randomization.

2.2.3. Active Control Group (ACG)

The ACG will consist of LTC insurance policyholders who have agreed to participate and have received the telephone screen. This ACG, when compared to the ADCG, will allow us to evaluate the "placebo effect" of the telephone screening process. The ACG will receive a falls calendar (to be returned monthly)[16] and we will obtain self-reported data in the form of quarterly telephone calls (beginning three months after the initial telephone screen) for two years beginning at the time of randomization. We will also collect LTC and Medicare claims data for three years beginning at the time of randomization.

2.2.4. Experimental Group (EG)

The EG will consist of LTC insurance policyholders who have agreed to participate and have received the telephone screen. Everyone in the EG will also receive a multi-factorial in-person assessment. Based on the findings of the assessment, some subset will receive further interventions and some will not. The EG will receive a falls calendar (to be returned monthly)[16] and we will obtain self-reported data in the form of quarterly telephone calls for two years beginning at the time of randomization. We will also collect LTC and Medicare claims data for three years beginning at the time of randomization.

Multi-factorial In-Person Assessment

A nurse trained in performing LTC risk and home safety assessments will visit with the participant in their home to perform an evaluation. The results of this evaluation will determine the intervention strategy used with each participant. Training of the nurses is of the utmost importance to both the accuracy of the data, as well as the effectiveness of the intervention. In addition, a re-assessment (containing the same data elements as the initial assessment for evaluative purposes) will be conducted in-person with each participant at the end of two years.

Confidentiality

All data will be collected in compliance with HIPAA regulations and be kept strictly confidential. A signed consent to participate in the study will be obtained from each participant, as well as signed authorizations in order to collect medical information, claims information and Medicare data. All participants will be randomly assigned a unique identifier so that when data is coded and analyzed it can be stripped of

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[16] If a fall is reported on the returned fall calendar, a call is made or questionnaire is sent to that participant to gather data related to the cause and outcome of the fall. If a participant falls more than three times in one month or for three consecutive months, a letter will be sent to the participant and/or three proxy recommending that they contact their primary doctor.

identifying information. All data file transfers will be encrypted and paper data will be kept in locked file cabinets until it is entered into a database and then the originals will be shredded.

2.3   Outcomes

One of the goals of this project is to determine whether the proposed targeting and intervention strategy is effective, both in a clinical and a financial sense. In addition to consistently and accurately tracking the costs associated with the assessment and the intervention components, it is important to have clearly defined outcome measures and track them consistently and accurately as well. Another important aspect of measuring effectiveness for this project is the presence of a control and an experimental group. The fact that both of these groups are randomly assigned, we can assume that in the absence of any intervention, the outcomes of interest would be the same for both groups.

Table 2.1 outlines the specific outcomes we will track and the sources used to obtain the information.

TABLE 2.1. Proposed Outcome Measurement Strategy		
Outcome	**Measure**	**Data Source**
Falls Incidence	• Number of falls • Number of falls per level of activity	• Falls Diary • Quarterly follow-up • Physician records • Re-assessment

Long-term care service use
    Home care
    Nursing home
    Assisted living facility
    Alternate plan of care
    Assistive devices
	• Amount paid in long-term care claims over study period	• Insurer generated claims data
		• Quarterly follow-up (self-reported out-of-pocket expenditures)
		• Re-assessment

Acute care service use
    Doctor's visits
    Skilled nursing facility
    Skilled care at home
    In-patient hospitalization
    Out-patient hospital use
    Equipment
	• Amount paid for acute care services over study period	• CMS data
		• Quarterly follow-up (self-reported out-of-pocket expenditures)
		• Re-assessment (self-reported out-of-pocket expenditures)

Medication Use	• Compare number/type of medications at the start and end of the study	• Quarterly follow-up • Re-assessment
Costs (over time)	• Dollars spent on health care	• CMS data • Long-term care insurance data
Risk Profile	• Changes in risk factors and classification of falls risk	• Re-assessment
Fear of Falling	• Falls Efficacy Scale score	• Falls Efficacy Scale
Family caregiver burden	• Caregiving hours • Hours of work missed • Termination of employment	• Quarterly follow-up (self-reported data)

3.0 PROPOSED INTERVENTION DESIGN

At our two-day TAG meeting, the Assessment and Intervention strategies were discussed and agreed upon at a high level. During the next phase of the project, the mandate is to flesh out all of the specifics related to each. In this section, we summarize all of the points of discussion and lay out next steps for operationalizing the program.

3.1   Multifactorial Assessment Components

The literature shows (and experts at the TAG meeting reaffirmed) that assessment alone does not work in preventing falls. Effects are seen only when Interventions are implemented. The screening instruments (phone and in-person) should not be burdensome or overly detailed, but be sensitive enough to detect a person's fall risk level. Registered nurses (RNs) doing the assessments must be well trained. If possible, the RN who does the Telephonic Screen should be the same person that does quarterly follow-up, to assure continuity and to be able to pick up changes. ***The literature has not explicitly found that risk factors can be properly identified via phone***. This is why the TAG advocates seeing everyone In-person, unless there are budgetary restrictions. The TAG recommended that the triggers for accessing interventions be well defined so that each component is very clear along the way. This will be fleshed out in the next phase of the project.

Our proposed assessment and intervention strategies build upon the guidelines put forth by the AGS, with modifications to meet the goals of this project. In this section, we describe the two assessment components, with particular attention paid to how the elements work together. Our review of the literature, as well as the input from the TAG, leads us to propose the following components of the assessment strategy:

- •   Telephone Screen; and
- •   In-person Assessment.

Further research in the next project phase will flesh out and narrow down the different types of tests recommended by the TAG.

3.1.1 Telephone Screen

The use of a screening mechanism in a fall prevention intervention is prudent because it allows a more effective targeting of intervention resources. It allows one to relatively quickly and inexpensively identify the group most likely to benefit from an intervention. It also encourages buy-in from the potential target of the intervention, which can influence the likelihood of compliance once recommendations are made.

TABLE 3.1. Data Collection Components for Telephone Screen	
Demographics 1. Name 2. Address 3. Phone number 4. Age 5. Gender 6. Marital status 7. Living situation -- where living, lives with 8. Caregiver	**Medical History** 1. Visual deficit 2. Hearing deficit 3. Arthritis 4. Depression Screen -- using a scale such as the Geriatric Depression Scale 5. Other chronic diseases, including surgery -- dates, outcome 6. Symptom review 7. Medication review -- drug name, dosage, frequency -- OTC and prescription 8. ER or hospital visit in past year 9. Current long-term care services profile -- include both paid and family caregivers 10. Review of current assistive devices 11. Alcohol use
Cognitive Assessment 1. Mental Skills Test (MST) or 2. Delayed Word Recall Test (DWR) or 3. Telephone Interview of Cognitive Status (TICS)	**Falls History** 1. Define a "Fall" for the participant 2. Falls History -- Fallen in the past 6 months? If so, when, how many times, where/circumstances, outcome 3. Was there injury sustained during fall?
Functional Assessment 1. Activity Scale, for example Physical Activity Scale for the Elderly (PASE)[1] or Minnesota Inventory Scale 2. Brief review of Lawton's Instrumental Activities of Daily Living (IADLs) 3. Katz's Index of Activities of Daily Living (ADLs) 4. If functions are impaired, then ask Environmental questions 5. Describe all home safety devices 6. Describe any exercise -- type, frequency.	
1. Washburn, RA, Smith KW, Jette AM, Janney CA. The Physical Activity Scale for the Elderly (PASE): Development and evaluation. Journal of Clinical Epidemiology 1993, 46:153-162. **NOTE:** Although the TAG recommended that the Telephone Screen be comprehensive, it also recommended that it not be too burdensome. In our experience, the quality of information obtained via telephone degrades considerably after about 20-30 minutes. Elderly or disabled individuals are not interested in talking on the phone answering questions for more than this amount of time. Therefore it is our recommendation that if the budget permits us to see all individuals in-person, we move many of these questions to the In-person Interview.	

The TAG agreed that a telephonic screen was a cost-effective way to identify a person's risk for falling. Although there is conflicting evidence regarding the accuracy of information received over the telephone, they believe with the right questions and checks, we will be able to gather enough information to stratify people into broad risk categories that include our intervention targets. For example: environment, medical, functional or combinations. We should include questions to determine reliability of information (multiple questions about the same topic). The telephone screen must be sensitive enough to stratify the control and experimental groups into similar categories.

The group suggested doing a phone cognitive screen so that we may automatically contact a proxy if cognitive issues are detected.

The purpose of the Telephone Screen will be to: (1) introduce the participant to the falls prevention program, (2) secure their interest in participating, (3) gather background information, and (4) classify the participant into broad risk categories. Nurses experienced in LTC risk assessment will conduct the telephone interview. We expect that the telephone interview will take approximately one hour, to collect all of the information recommended by the TAG. Table 3.1 outlines the components of the Telephone Screen, as recommended by the TAG.

3.1.2 In-person Assessment

The In-person Assessment builds upon the data collected during the Telephone Screen. Observing a person in their home environment is very important, because it provides an opportunity to connect with the participant in a way that is not possible via phone. It also enables one to observe and test a number of intrinsic and extrinsic risk factors that cannot be ascertained over the telephone. We will not repeat questions where the answers were satisfactorily obtained during the Telephone Screen, except in those instances where information might have changed since the telephone interview. We would briefly review those answers and ask if there were changes, and document those accordingly.

Medication screening will be very important. The issue of medications was discussed in detail with the TAG. We will need to obtain a list of every medication the individual is taking, including OTC drugs. There are broad classifications of medications that, if noted on the Assessment, must be evaluated by the physician; this is because they do present a risk factor for falls. The TAG suggested that we review medications used by the participant against the Beers list or Lipsic's work. The Beers Criteria, updated in December 2003, identifies medications that are potentially inappropriate for use in patients over the age of 65 years. It is an extensive list, and includes over 68 drugs or drug categories. If the participant is identified as taking one or more of these high-risk drugs, then this needs to be brought to the attention of the physician. Findings from the physician will be incorporated into the profile of the participant to enable us to measure the effect of decreasing or eliminating these medications. It was agreed that the threshold of four or more medications as a risk factor for falls previously identified in the literature was no longer useful as almost everyone age 75 and over would be on at least four medications. They suggested using the above-mentioned lists and then categories of drugs (such as psychotropic, anti-depressants, etc.) as a risk factor. If we want to use a number as a criteria, we should probably bump it up to ten or more medications or any one of the medications on the lists we define.

Nurses experienced in LTC risk assessment will conduct the In-person Assessment. Note that some of the elements from the Telephone Screen are included in the In-person Assessment so that any possible changes or discrepancies from the phone

interview can be noted and important information validated. Table 3.2 outlines the components of the In-Person Assessment as recommended by the TAG.

TABLE 3.2. Data Collection Components for In-person Assessment	
Demographics 1. Name 2. Address 3. Phone number 4. Age 5. Gender 6. Marital status 7. Living situation -- where living, lives with, description of residence 8. Caregiver	**Medical History** 1. Physician information -- PCP Name and contact information 2. Visual deficit 3. Hearing deficit 4. Arthritis 5. Depression Screen -- using a scale such as the Geriatric Depression Scale 6. Other chronic diseases, including surgery -- dates, outcome 7. Symptom review 8. Medication review -- drug name, dosage, frequency -- OTC and prescription 9. ER or hHospital visit in past year 10. Current long-term care services profile -- include both paid and family caregivers 11. Review of current assistive devices 12. Alcohol use
Cognitive Assessment 1. Mental Skills Test (MST) or 2. Mini-Mental State Examination[1] (MMSE) 3. Assessor's evaluation of behavioral risks	**Functional Assessment** 1. Vital signs, including height, heart rate, weight and blood pressure (supine and standing, with a minimum of 3 minutes between each) 2. Brief review of Lawton'sInstrumental Activities of Daily Living (IADLs) 3. Katz's Index of Activities of Daily Living (ADLs) 4. Assessment of muscle weakness, using (1) Chair Stand and (2) Stand up on toes and (3) Guralnik Short Physical Performance Battery[2] 5. Activity Scale, for example Physical Activity Scale for the Elderly (PASE) or Minnesota Inventory Scale
Home Safety Evaluation Detailed assessment of the participant's home with emphasis on: 1. Entrances/exits 2. Stairs and hand rails 3. Living area 4. Kitchen 5. Bathroom 6. Bedroom	**General** 1. Assessor's clinical observations and concerns 2. Identification of any information not as yet disclosed in the assessment
1. Folstein MR, Folstein SE, McHugh, PR. Mini-mental state -- a practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975; 12:189-198. 2. Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, Scherr PA, Wallace RB: A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. J Gerontol 49:M85-M94, 1994.	

We expect the In-person Assessment to take between 90 minutes and two hours. This includes the actual assessment itself, as well as the time it will take for the assessor to

make any minor home modifications that can be done during the visit. These include, installing night-lights and bath mats, taping down loose scatter rugs, and installing extension cords in a safe manner.

3.1.3 Quality Assurance

The findings from the In-person Assessment will then be sent to a central location to be reviewed for Quality Assurance. Review of medications by the central office staff is part of the Quality Assurance process and will assure that this important risk factor is addressed. We expect that this Quality Assurance Review will take approximately one hour. These activities are summarized in Table 3.3.

TABLE 3.3. Summary of Quality Assurance Review
Review for completeness and internal consistency.
Review medications for interactions and number = 10.
Review for balance problems, gait problems, or muscle weakness.
Review Medical History for new or unstable concerns, including cognitive deficits, requiring primary Physician Assessment.
Review for recurrent falls.
Review for functional loss requiring supportive services or assistive devices in the home (or the suggestion of changing living environment).
Review for necessary home hazard modifications.
Make Intervention Recommendations.
Prepare findings of assessment to be delivered to participant.

3.2   Intervention Components

The Multifactorial Assessment outlined above is designed to identify the individual needs of the person at risk for a fall. In broad terms, the key components of the intervention strategies we will use include the following:

1.   Education packet;
2.   Exercise -- including gait and balance training;
3.   Primary physician assessment for disease management and medication monitoring;
4.   Supportive home care services;
5.   Home modifications and assistive devices for safety;
6.   Care Plan recommendations and delivery; and
7.   Initial Care Plan Follow-up.

Note that each individual will not need all of these components, although there may be some who do. The assessment process is designed to enable clinicians to specifically target the components of an intervention to best meet the needs of the individual at risk for falling. Each component of the intervention strategy is discussed in detail below.

3.2.1 Targeting Criteria

Gillespie et al. (2003) point out that interventions which target <u>known fallers</u> are likely to be more effective than those that target groups of individuals on the basis of fall risk factors or age alone. They also found that "standardized packages" of interventions, even when offered to individuals with varying levels of fall risk, are not as effective as interventions that are individually tailored to a specific individual's needs.[17]

When considering targeting strategies, the best use of financial resources would be to reserve the more costly interventions for those who have already had a fall. However, the problem with this approach is that the focus of the intervention moves away from preventing **primary falls** to preventing **repeat falls**. For this reason, we will actively intervene for all individuals who undergo the assessment and for whom specific risk factors are identified. With that said, the goal is to individually tailor the intervention strategies to meet the specific risk factors identified for each individual. There was some discussion of whether or not we would need to provide interventions to individuals in the control group identified as high falls risks during the Telephone Screen. TAG members felt that ethically, we need only intervene in cases where the current care shows evidence of egregious neglect.

3.2.2 Education Packet

The Education Packet will be provided to all participants in the active control group and experimental group. It will include the following necessary components: falls awareness and home safety information; wipe-off medication management planner; NIA exercise video; falls calendar; exercise diary, including functional goals; pedometer.

3.2.3 Exercise

The challenge is to implement exercise interventions that are practical, yet efficacious. The TAG agreed that we are concerned about four components of a person's gait and mobility profile: balance, strength, endurance and flexibility. If deficits are found during assessment, it was agreed that a Physical Therapy (PT) program tailored to ameliorate these deficits is the "first line" intervention, and would be brought to the attention of the physician. Every person found to have gait and mobility risk factors, if by phone will first be seen in-person, and when in-person, will be evaluated for the viability of referral to

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[17] Gillespie et al., op cit.

PT. The PT evaluation will dictate the content of the program and will be specific to the identified needs. It will be clearly documented as to type (balance, strength, endurance, flexibility), frequency and duration.

There was consensus that the key to motivating people to exercise is to set reasonable goals that can be achieved. If PT is not a reasonable option, either because the person is not impaired enough or because they decline to attend, then the NIA exercise video will be the "default" exercise program. In addition, people will be encouraged to walk and encouraged to accumulate as many as 10,000 steps every day. Pedometers will be part of the Education Packet, and can be worn to count steps and motivate people to do more walking.

3.2.4 Primary Physician Assessment for Disease Management and Medication Monitoring

A primary physician (or other primary health care provider) should know their patient, and provide medical assessment and diagnosis. While not always the case, the primary care physician should also direct the team of individuals that are involved in the care of the participant. If during the Assessment, a disease or condition is newly identified or unstable and in the judgment of the nurse assessor requires medical consideration, the findings should be sent to the participant's physician and a referral made to this physician. This not only preserves the patient-physician relationship, but also encourages "buy-in" from the physician for other fall prevention amelioration strategies that might be suggested. The intent is to provide the patient with the newly identified medical information and encourage him/her to make an appointment with their physician to address the issue.

The TAG feels that getting physician buy-in is very important, and the way we position this intervention component to physicians is critical in gaining their acceptance to do what we are recommending for the participant. We discussed a physician referral form, including a HIPAA-compliant authorization, which feeds information found during the assessment to the physician. The physician will be instructed to complete the form describing what actions were taken for the participant. This form is then sent back to the case manager for review and data collection. If we do not receive forms, or if the physician is resistant to consider our recommendations, then follow-up will be necessary to try to gain compliance. We may need to provide some education to physicians, particularly related to medications related to fall risks.

3.2.5 Supportive Home Care Services

At the time of the In-person Assessment, information is collected to inform the development of a care plan. This plan details the service recommendations, including the type of caregiver, frequency and duration of needed care. As part of the development of this plan, the assessor would also account for the availability and capabilities of the family caregivers to support the participant. These caregivers are

typically friends or family who provide assistance at no charge. Most individuals prefer family and friends to assist them because of the inconvenience and discomfort associated with having "strangers" come to their homes. Table 3.4 lists the types of supportive home care services that may be suggested to assist the person to remain safely and independently in their home.

TABLE 3.4. Supportive Home Care Services	
Home Health Aide/Personal Care Attendant	Medical Social Worker
Homemaker/Companion	Nutrition Services
Physical Therapist/Occupational Therapist/ Speech Therapist	Pharmaceutical Care
Nurse	Transportation
Family or Unpaid Caregiver	Home Delivered Meals

3.2.6 Home Modifications and Assistive Devices for Safety

Home safety interventions will be dictated by the current safety risk factors found during the In-person Assessment. Some of the general small modifications that the assessor can make while on-site include installing night-lights and bath mats, taping down loose scatter rugs, and installing extension cords in a safe manner. Many modifications are relatively simple to do and will be done by the assessor while at the home (as stated above). The items addressed in Table 3.5 would be ordered through a durable medical equipment (DME) vendor. Assistive devices such as a walker or other therapeutic device, will need to be ordered by a physician to assure reimbursement by Medicare or other insurance. If not qualified, the costs would need to be paid out-of-pocket. The DME vendor could place all of the items in Table 3.5, thereby bypassing installation concerns and additional cost.

TABLE 3.5. Safety Devices Included as Home Safety Modifications	
Pill Box	3 in 1 Toilet Assist
Bath Mat	Hand Held Shower
Bath Stool	Raised Toilet Seat
Shower Bench	Molded Raised Toilet Seat
Shower Bench with Back	Toilet Safety Frame
Bath Seat (up to 400 lbs)	Personal Emergency Response System
Bath Tub Rail	Extension Cord
Bath Tub Rail (multiple height gripping)	Carpet Tape

If additional items not previously mentioned are discovered during the home safety review (for example, broken stairs or missing stairway handrails), the participant would be provided with references for trade workers to repair or install them. If the participant agrees, the intervention team could assist in arranging for installation. The costs could potentially be paid through a combination of funding sources including Medicare, LTC insurance and out-of-pocket expenditures.

3.2.7 Care Plan Recommendations and Delivery

The results of the assessments and the recommended Interventions are delivered to the participant in the form of a Care Plan. The Care Plan includes a summary of the findings and recommended "action steps." The Care Plan will lay out for the participant all of the details of the recommended intervention tailored to meet the deficits identified in the assessment. It will be a written document, with specific "prescription" services for intervention, as described above. It will include goals, where appropriate, for the participant to achieve (for example, as with exercise), and will provide specific directions for how to implement the recommended interventions. We did not discuss this document in detail, and it will be developed as part of the next project phase. However, Table 3.6 details the Care Plan components as we envision them.

TABLE 3.6. Care Plan Components
Assessment Summary 1. Summary of Fall History (if any) 2. Summary outcome of all physical and functional testing

Action Steps -- as appropriate, tailored to each individual
1. Referral to Primary Physician -- including reason:
   a. Evaluate Medications
   b. Medical Management
      i. APS Provided for Physician, including salient results of :
         (1) Vital signs
         (2) Medication review
         (3) Assistive devices
         (4) Cognitive testing
         (5) IADL deficits
         (6) ADL deficits
         (7) Chair Stand and, Stand up on toes and Guralnik Short Physical Performance Battery
         (8) Physical Activity Scale for the Elderly (PASE)
2. Referral Recommendation for Home Health Care Services -- including reason and recommendation (may also need to involve physician)
3. Referral Recommendation for Physical Therapy -- including reason and recommendation (may also need to involve physician)
4. List of Equipment needed
5. List of Home Repairs needed
   a. Contacts for implementation of Repairs
6. Specific home exercise program given to participant

3.2.8 Initial Care Plan Follow-up

The TAG agreed that giving participants the names or places where they might be able to find services will not be effective, because individuals will not follow through on their own. Therefore, as part of the intervention, consensus was that there should be a phone call to the participant to review the Care Plan components, gain the participant's acceptance of the intervention and to "jump start" the implementation of the recommendations, by arranging for services wherever possible and accepted by the participant. The TAG feels strongly that the role of the case manager is to follow-up after the Care Plan is delivered to be sure that the recommendations are implemented. Without follow-through, there is no intervention.

Ability to assure implementation of suggested interventions was discussed. Specific concerns arose about the ability to assure compliance with exercise. How often will the case manager be able to contact the insured for "coaching" on exercise? The TAG suggested that we hire a "low level" individual (for example, a personal trainer or exercise physiologist) to call participants weekly at the beginning, then fading to monthly, as we know they are participating in exercise. Other ideas to encourage compliance include incentives. Some suggestions provided by the TAG include "punch card" for exercises completed, leading to "free things" or "certificates of award"; find each person an exercise partner; approach national chains to give coupons; Newsletters; pedometers. The TAG also suggested a stipend be provided, perhaps to a randomized group if budget allows, for home modifications.

3.3   Assessment and Intervention Cost Items

Table 3.7 shows the cost items necessary to implement the assessment and intervention strategy outlined above. The costs not addressed in this Table include all of the analysis work that will be performed at the completion of the study.

TABLE 3.7. Program Cost Items
Assessment and Intervention Components
1.   Telephone Screen
2.   In-person Assessment and QA Review
3.   Education Packet
4.   Exercise Tapes
5.   Home Health Care Services
6.   Physician Visit
7.   Home Modifications
8.   Durable Medical Equipment (Assistive Devices)
9.   Coordination of Implementation of Care Plan
10. Quarterly Follow-up for Two Year Period with Experimental and Control Group
11. Re-assessment

4.0 PROGRAM ANALYSIS

4.1   Testing Hypotheses

Under random assignment, we estimate the effects of the intervention simply by comparing averages of the outcome measures between the treatment and comparison groups. Properly implemented, random assignment of persons who are willing to join the study assures that the control group does not differ from the treatment group in any systematic way other than having access to the intervention. Thus any subsequent differences in outcomes between the two groups that exceed the bounds of sampling error can confidently be attributed to the intervention. With any non-random comparison group, there is always a chance that differences in outcomes are the result of pre-existing differences between the two groups, rather than the intervention itself.

We have also adopted an "assignment ratio" of equality in numbers between treatment and control group members. This ratio minimizes the standard errors of our estimates of intervention impacts for any given sample size.

Hypotheses of the evaluation (stated as "alternatives" to the null hypothesis of no effects) include:

- *By the end of the study, fewer treatment group members will be at high risk of falling, compared to control group members.* Measures of risk will come from the initial assessment and subsequent re-assessments.

- *Falls will be fewer among treatment group members.* Counts of all falls will come from the subjects' diary. We shall address effects of the intervention on the incidence of "serious" falls, using data from physician records. We also propose to scan diagnosis data from Medicare claims to identify a broader category of "accident and injury" outcomes that could capture spillover effects of the intervention on the incidence of injuries.

- *Use of physicians and other health professionals (Part B) services will be higher among treatment group members.* Since a core component of the intervention is risk assessment, we expect to see more ambulatory visits for screening and follow-up from treatment group members with identified risks.

- *Treatment group members will experience fewer hospitalizations and emergency department admissions than control group members.* If total hospital and ER incidents due to conditions other than falls are the same between treatment and control groups, fewer falls should mean less overall utilization.

- *By the end of the study, treatment group members will use fewer medications than control group members.* The risk of falls increases with multiple medications. If the medication review component of the initial assessment is effective, physicians for some treatment group members at risk will prescribe fewer medications.

- *By the end of the study, the use of psychotropic, anti-depressant and other medications that increase the risk of falls will be lower among treatment group members.* The hypothesis, and its rationale, is similar to the earlier hypothesis predicting fewer medications.

- *Admissions to nursing homes will be fewer among treatment group members.* If all other factors associated with nursing home admissions are the same in both groups, treatment group members should be less likely to be admitted for post-acute skilled nursing rehabilitation or for long-term placement due to fall-related injuries.

- *Total (acute and long-term) costs will be lower among treatment group members.* Reduced spending on "big ticket" items like hospital and nursing home admissions should outweigh increased spending for screening and prevention. Total costs will include out-of-pocket as well as third-party reimbursed expenditures.

- *Treatment group members will incur lower costs at home and in assisted living facilities.* Persons less likely to fall should also experience slower rates of physical and cognitive decline. They should require fewer formal medical and social support services. For some, fewer falls also delays their arrival at functional thresholds that trigger LTC coverage and payment.

- *Treatment group members will be less fearful of falling than control group members.* Raising consciousness could have the unintended consequence of making some treatment group members more fearful and apprehensive. However, if the intervention is to be successful, persons in the treatment group will have to have gained an increased sense of self-efficacy in falls prevention to accompany their increased awareness.

- *Caregiver burden will be less in the treatment group.* For elderly persons living on their own, fewer falls should mean less need for both formal and informal support. We expect to find lower average weekly hours required of informal caregivers, and less likelihood of caregivers quitting their paying jobs.

There are certain challenges to the evaluation that merit discussion.

- *Precision.* Even though straight contrasts between treatment and control groups provide unbiased estimates of the intervention's effects, we measure these differences more precisely if we adjust for covariates like age, gender, race, and other relevant measures. Therefore, we propose to utilize available pre-intervention information that we have on both groups to adjust effects estimates in a multivariate context:

    $$y = \beta x + \theta d + \epsilon$$

    where y is an outcome measure, x stands for all the potential covariates we can measure and β measures the effect of the x's on the y's, d is a categorical measure of study status (= 1 for treatment, 0 for control), ϵ is a measure of error; θ is a measure of the intervention's effect on y, adjusted for all the x characteristics.

- *Internal validity.* Selective non-random attrition could threaten the experimental design. It seems reasonable to expect that controls will be more likely to stop participating in follow-up data collection than treatment group members. Attrition may also be higher among subjects with certain characteristics (for example, older individuals). We will compare persons who stop cooperating with the data collection effort between the groups, to suggest ways in which attrition might bias our estimates.

    Additionally, there could be a "halo effect" of data collection on behavior of the ACG. Even though control group members will not receive the intervention, ACG participation in the study through responding to requests for data could heighten awareness and generate behavior changes in that group similar to those hypothesized for the treatment group. As described earlier, we will assess the extent of this threat by sampling an ADCG from LTC insurance policy holders who (1) meet the general inclusion criteria for the study but who were not sampled for randomization and (2) who resemble the study sample in all measurable characteristics. If geographic strata are selected for the study sample, we will use these strata to sample the SCG. Only administrative data (LTC insurance claims and Medicare claims) will be collected for the ADCG.

- *External validity.* Persons who buy LTC insurance, a population from which we propose to recruit for the study, may be quite different from the average. At a minimum, we expect them to have higher incomes, and probably more assets.

    As described in Section 2.0, we propose to sample an external SCG of Medicare beneficiaries, matched to study subjects on age, gender, eligibility status and area of residence. We will compare these silent controls to controls in the study sample on utilization and expenditure outcomes for

which comparable data exist (from Medicare administrative eligibility and claims data). We have no way of knowing whether or not our external sample will include only Medicare beneficiaries who have no LTC insurance. However, we propose to draw a sample that explicitly excludes study sample members and is large enough (three or four times the size of the total study sample) to adequately represent a broad cross section of "similar" Medicare beneficiaries. If geographic strata are selected for the study sample, we will use these strata to sample the SCG.

- *Reporting bias.* Because the most important outcome variables (incidence of falls) rely on self-reported information, there will inevitably be some error due to poor memory or deliberate mis-statement. There also may be bias in reporting (over- or under-reporting the actual falls subjects experience) that will be associated with being a treatment or control group member, but we cannot predict the direction of bias. For example, the sense of external scrutiny and heightened awareness that treatment subjects may feel could lead to more scrupulous reporting of falls (compared to the controls), or it could lead subjects to under-report falls in an effort to show that the intervention worked for them. We cannot audit subjects' falls histories, but we can use claims data to compare variations among health services utilization associated with injury to variations in reported falls incidence.

4.2   Cost Benefit and Cost Effectiveness

The falls intervention generates new costs (of implementing the program), with some expectation that, in comparison to a world without the intervention, certain other costs (of care related to falls) may decrease. Therefore, it is appropriate to think in terms of the *net costs* of the intervention, taking into account both added costs and savings. The benefits of the intervention might include, among others, fewer falls and injuries, reduced mortality from falls, improved quality of life, and increased sense of self-efficacy. In order to compare this intervention to other proposals for reducing the incidence of falls, we will estimate various cost-effectiveness relationships (for example, the net costs of reducing the incidence of falls by one percentage point).

The net costs of the falls intervention include three major components:

- Direct costs of the intervention includes time for the nurse assessors in training, in conducting assessments and for staying in contact with study subjects, management and equipment costs, and costs incurred by subjects or third parties to implement the intervention (for example, home modifications).

- Net direct costs of health services utilization includes the costs of both acute and LTC. Net costs represent the difference between health services costs of treatment and control group members, and may be either positive or negative (net savings). We expect physician utilization to be higher initially among treatment subjects. However, hospital and nursing home admissions and costs should be lower.

- Net indirect costs associated with caregiver burden are estimates of the value of hours spent by family members or friends providing informal care. On the one hand, falls reduction may lower caregiver burden by increasing the time that seniors can live independently in their homes. On the other hand, the longer seniors remain at home, the more likely they are to need caregiver support.

We will collect data from various sources. We will compile data on the direct costs of the intervention from internal demonstration records and from self-reports of study subjects regarding their own out-of-pocket expenditures for home modifications, exercise programs and other activities related to the intervention. We will also acquire LTC claims from subjects' carriers. Subjects will be asked to report major utilization events (emergency department visit, hospital admission) as well as their own out-of-pocket expenditures on medical and LTC, and weekly hours of their principal informal caregiver(s).

To complete the health services cost estimates, we propose to acquire Medicare Enrollment Data Base (EDB) and National Claims History File data (Parts A, B and D) for study subjects, to provide information on covered acute care utilization and Medicare payments. However, for a minority of Medicare beneficiaries who belong to a Medicare Advantage plan, these claims will not be available. We could confine the full cost effectiveness analysis to those sample members not in Medicare Advantage plans. Alternatively, we could define the sampling frame in advance as persons in Traditional Medicare: this would require an initial merge of Medicare EDB data with data from the participating LTC insurance carriers to carry out sampling.

Assigning "imputed" pay rates to informal caregivers' time, in order to round out our estimates of net intervention costs, has always been a problematic exercise. Economists ask about the "opportunity cost" of a person's time. What is the value of an hour spent caring for one's mother, set by the value of alternative uses of that hour? For caregivers younger than 65, this value might be established by their current (or most recent) wage rate, or by the average wage of someone with their experience and credentials. For caregivers in retirement, alternative opportunities are more limited. We could assign an hourly rate based on fee schedules for formal homemaker assistance provided by home health agencies.